UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31 , 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-30739

INSMED INC ORPORATED

(Exact name of registrant as specified in its charter)

Virginia	**54-1972729**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. employer identification no.)**
700 US Highway 202/206 Bridgewater , New Jersey 08807 (Address of principal executive offices)	**(908) 977-9900 (Registrant's telephone number including area code)**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbols	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**INSM**	**Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company (See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act). Large accelerated filer X Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a Shell Company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant or June 30, 2024, was $ 11.0 billion (based on the closing price for shares of the registrant's common stock as reported on the Nasdaq Global Select Market on that date). In determining this figure, the registrant has assumed solely for this purpose that all of its directors, executive officers, persons beneficially owning 10% or more of the registrant's outstanding common stock and certain other stockholders of the registrant may be considered to be affiliates. This assumption shall not be deemed conclusive as to affiliate status for this or any other purpose.

On February 14, 2025, there were 180,999,350 shares of the registrant's common stock, $0.01 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2025 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission no later than April 30, 2025 and to be delivered to shareholders in connection with the 2025 Annual Meeting of Shareholders, are herein incorporated by reference in Part III of this Annual Report on Form 10-K.

INSMED INCORPORATED

INDEX

			PAGE
REPORT:	**FORM 10-K**		
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS			4
PART I			6
	ITEM 1	BUSINESS	6
	ITEM 1A	RISK FACTORS	35
	ITEM 1B	UNRESOLVED STAFF COMMENTS	62
	ITEM 1C	CYBERSECURITY	62
	ITEM 2	PROPERTIES	63
	ITEM 3	LEGAL PROCEEDINGS	63
	ITEM 4	MINE SAFETY DISCLOSURES	63
PART II			64
	ITEM 5	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	64
	ITEM 6	[RESERVED]	66
	ITEM 7	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	67
	ITEM 7A	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	77
	ITEM 8	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	77
	ITEM 9	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	77
	ITEM 9A	CONTROLS AND PROCEDURES	77
	ITEM 9B	OTHER INFORMATION	78
	ITEM 9C	DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS	78
PART III			79
	ITEM 10	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	79
	ITEM 11	EXECUTIVE COMPENSATION	79
	ITEM 12	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	79
	ITEM 13	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE	79
	ITEM 14	PRINCIPAL ACCOUNTANT FEES AND SERVICES	79
PART IV			80
	ITEM 15	EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	80
	ITEM 16	FORM 10-K SUMMARY	84
REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM			86
CONSOLIDATED FINANCIAL STATEMENTS			89

Unless the context otherwise indicates, references in this Annual Report on Form 10-K to “Insmed Incorporated” refer to Insmed Incorporated, a Virginia corporation, and the “Company,” “Insmed,” “we,” “us” and “our” refer to Insmed Incorporated together with its consolidated subsidiaries. INSMED, PULMOVANCE, and ARIKAYCE are trademarks of Insmed Incorporated. This Annual Report on Form 10-K also contains trademarks of third parties. Each trademark of another company appearing in this Annual Report on Form 10-K is the property of its owner.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. "Forward-looking statements," as that term is defined in the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the Exchange Act), are statements that are not historical facts and involve a number of risks and uncertainties. Words herein such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "intends," "potential," "continues," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) identify forward-looking statements.

Forward-looking statements are based on our current expectations and beliefs, and involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance and achievements and the timing of certain events to differ materially from the results, performance, achievements or timing discussed, projected, anticipated or indicated in any forward-looking statements. Such risks, uncertainties and other factors include, among others, the following:

- *failure to continue to successfully commercialize ARIKAYCE®, our only approved product, in the United States (US), Europe or Japan (amikacin liposome inhalation suspension, Liposomal 590 mg Nebuliser Dispersion, and amikacin sulfate inhalation drug product, respectively), or to maintain US, European or Japanese approval for ARIKAYCE;*
- *our inability to obtain full approval of ARIKAYCE from the US Food and Drug Administration (FDA), including the risk that we will not successfully or in a timely manner complete the confirmatory post-marketing clinical trial required for full approval of ARIKAYCE, or our failure to obtain regulatory approval to expand ARIKAYCE's indication to a broader patient population;*
- *failure to obtain, or delays in obtaining, regulatory approvals for brensocatib, treprostinil palmitil inhalation powder (TPIP) or our other product candidates in the US, Europe or Japan or for ARIKAYCE outside the US, Europe or Japan, including separate regulatory approval for the Lamira® Nebulizer System (Lamira) in each market and for each usage;*
- *failure to successfully commercialize brensocatib, TPIP or our other product candidates, if approved by applicable regulatory authorities, or to maintain applicable regulatory approvals for brensocatib, TPIP or our other product candidates, if approved;*
- *uncertainties or changes in the degree of market acceptance of ARIKAYCE or, if approved, brensocatib, TPIP, or our other product candidates, by physicians, patients, third-party payors and others in the healthcare community;*
- *our inability to obtain and maintain adequate reimbursement from government or third-party payors for ARIKAYCE or, if approved, brensocatib, TPIP, or our other product candidates, or acceptable prices for ARIKAYCE or, if approved, brensocatib, TPIP, or our other product candidates;*
- *inaccuracies in our estimates of the size of the potential markets for ARIKAYCE, brensocatib, TPIP, or our other product candidates or in data we have used to identify physicians, expected rates of patient uptake, duration of expected treatment, or expected patient adherence or discontinuation rates;*
- *failure of third parties on which the Company is dependent to manufacture sufficient quantities of ARIKAYCE, brensocatib, or TPIP for commercial or clinical needs, to conduct the Company's clinical trials, or to comply with the Company's agreements or laws and regulations that impact the Company's business;*
- *the risks and uncertainties associated with, and the perceived benefits of, our senior secured loan with certain funds managed by Pharmakon Advisors, LP (Pharmakon) and our royalty financing with OrbiMed Royalty & Credit Opportunities IV, LP (OrbiMed), including our ability to maintain compliance with the covenants in the agreements for the senior secured loan and royalty financing and the impact of the restrictions on our operations under these agreements;*
- *our inability to create or maintain an effective direct sales and marketing infrastructure or to partner with third parties that offer such an infrastructure for distribution of ARIKAYCE or any of our product candidates that are approved in the future;*
- *failure to successfully conduct future clinical trials for ARIKAYCE, brensocatib, TPIP, and our other product candidates and our potential inability to enroll or retain sufficient patients to conduct and complete the trials or generate data necessary for regulatory approval of our product candidates or to permit the use of ARIKAYCE in the broader population of patients with Mycobacterium avium complex (MAC) lung disease, among other things;*
- *development of unexpected safety or efficacy concerns related to ARIKAYCE, brensocatib, TPIP, or our other product candidates;*
- *risks that our clinical studies will be delayed, that serious side effects will be identified during drug development, or that any protocol amendments submitted will be rejected;*

- *failure to successfully predict the time and cost of development, regulatory approval and commercialization for novel gene therapy products;*
- *the risk that interim, topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or may be interpreted differently if additional data are disclosed, or that blinded data will not be predictive of unblinded data;*
- *risk that our competitors may obtain orphan drug exclusivity for a product that is essentially the same as a product we are developing for a particular indication;*
- *our inability to attract and retain key personnel or to effectively manage our growth;*
- *our inability to successfully integrate our acquisitions and appropriately manage the amount of management's time and attention devoted to integration activities;*
- *risks that our acquired technologies, products and product candidates will not be commercially successful;*
- *inability to adapt to our highly competitive and changing environment;*
- *inability to access, upgrade or expand our technology systems or difficulties in updating our existing technology or developing or implementing new technology;*
- *risk that we are unable to maintain our significant customers;*
- *risk that government healthcare reform materially increases our costs and damages our financial condition;*
- *business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises;*
- *risk that our current and potential future use of artificial intelligence (AI) and machine learning may not be successful;*
- *deterioration in general economic conditions in the US, Europe, Japan and globally, including the effect of prolonged periods of inflation, affecting us, our suppliers, third-party service providers and potential partners;*
- *the risk that we could become involved in costly intellectual property disputes, be unable to adequately protect our intellectual property rights or prevent disclosure of our trade secrets and other proprietary information, and incur costs associated with litigation or other proceedings related to such matters;*
- *restrictions or other obligations imposed on us by agreements related to ARIKAYCE, brensocatib or our other product candidates, including our license agreements with PARI Pharma GmbH (PARI) and AstraZeneca AB (AstraZeneca), and failure to comply with our obligations under such agreements;*
- *the cost and potential reputational damage resulting from litigation to which we are or may become a party, including product liability claims;*
- *risk that our operations are subject to a material disruption in the event of a cybersecurity attack or issue;*
- *our limited experience operating internationally;*
- *changes in laws and regulations applicable to our business, including any pricing reform and laws that impact our ability to utilize certain third parties in the research, development or manufacture of our product candidates, and failure to comply with such laws and regulations;*
- *our history of operating losses, and the possibility that we never achieve or maintain profitability;*
- *goodwill impairment charges affecting our results of operations and financial condition;*
- *inability to repay our existing indebtedness and uncertainties with respect to our ability to access future capital; and*
- *delays in the execution of plans to build out an additional third-party manufacturing facility approved by the appropriate regulatory authorities and unexpected expenses associated with those plans.*

We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. Any forward-looking statement is based on information current as of the date of this Annual Report on Form 10-K and speaks only as of the date on which such statement is made. Actual events or results may differ materially from the results, plans, intentions or expectations anticipated in these forward-looking statements as a result of a variety of factors, many of which are beyond our control. More information on factors that could cause actual results to differ materially from those anticipated is included from time to time in our reports filed with the Securities and Exchange Commission (SEC), including, but not limited to, those described in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in this Annual Report on Form 10-K. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

PART I

ITEM 1. BUSINESS

Business Overview

We are a people-first global biopharmaceutical company striving to deliver first- and best-in-class therapies to transform the lives of patients facing serious diseases. Our first commercial product, ARIKAYCE, is approved in the US as ARIKAYCE® (amikacin liposome inhalation suspension), in Europe as ARIKAYCE Liposomal 590 mg Nebuliser Dispersion and in Japan as ARIKAYCE inhalation 590mg (amikacin sulfate inhalation drug product). ARIKAYCE received accelerated approval in the US in September 2018 for the treatment of MAC lung disease as part of a combination antibacterial drug regimen for adult patients with limited or no alternative treatment options in a refractory setting. In October 2020, the European Commission (EC) approved ARIKAYCE for the treatment of nontuberculous mycobacterial (NTM) lung infections caused by MAC in adults with limited treatment options who do not have cystic fibrosis (CF). In March 2021, Japan's Ministry of Health, Labour and Welfare (MHLW) approved ARIKAYCE for the treatment of patients with NTM lung disease caused by MAC who did not sufficiently respond to prior treatment with a multidrug regimen. NTM lung disease caused by MAC (which we refer to as MAC lung disease) is a rare and often chronic infection that can cause irreversible lung damage and can be fatal.

Our pipeline includes clinical-stage programs, brensocatib, TPIP, and INS1201 as well as pre-clinical research programs. Brensocatib is a small molecule, oral, reversible inhibitor of dipeptidyl peptidase 1 (DPP1), which we are developing for the treatment of patients with bronchiectasis and other neutrophil-mediated diseases, including chronic rhinosinusitis without nasal polyps (CRSsNP) and hidradenitis suppurativa (HS). TPIP is an inhaled formulation of the treprostinil prodrug treprostinil palmitil which may offer a differentiated product profile for pulmonary hypertension associated with interstitial lung disease (PH-ILD) and pulmonary arterial hypertension (PAH). INS1201 is an intrathecally delivered gene therapy for patients with Duchenne muscular dystrophy (DMD). Our pre-clinical research programs encompass a wide range of technologies and modalities, including gene therapy, artificial intelligence-driven protein engineering, protein manufacturing, RNA end-joining, and synthetic rescue. A summary of our commercial and pipeline products is shown below:

The information below summarizes our updates and anticipated near-term milestones for ARIKAYCE and our product candidates.

ARIKAYCE

- Following the announcement of positive topline results from the ARISE trial, in June 2024, we met and al igned with the FDA on the primary endpoint for the ENCORE trial. If the data are positive, ENCORE may support a label expansion to include all MAC lung patients as well as support full approval for the current refractory indication.
- We completed enrollment in the ENCORE trial with 425 patients in the fourth quarter of 2024.
- We anticipate reporting topline data from the ENCORE trial in the first quarter of 202 6, with the submission of a US supplementary new drug application for ARIKAYCE in all patients with MAC lung disease projected for late 2026.

Brensocatib

- We announced positive topline results from the ASPEN trial in May 2024. The study met its primary endpoint, with both dosage strengths of brensocatib demonstrating statistically significant reductions in the annualized rate of adjudicated pulmonary exacerbations (PEs) versus placebo.
- Our new drug application (NDA) for brensocatib in patients with bronchiectasis was accepted and granted priority review by the FDA in February 2025. Under the Prescription Drug User Fee Act (PDUFA), the FDA set a target action date of August 12, 2025. We are advancing commercial readiness activities in preparation for a launch of brensocatib for patients with bronchiectasis and, if approved, we anticipate a US launch in the third quarter of 2025. Launches in Europe and Japan are expected in 2026, pending approvals.
- We initiated a Phase 2b study of brensocatib in patients with CRSsNP, which we refer to as the BiRCh trial, in the fourth quarter of 2023. We anticipate reporting topline data from the BiRCh trial before the end of 2025.
- We initiated a Phase 2b study of brensocatib in patients with HS, which we refer to as the CEDAR trial, in December 2024.

TPIP

- In May 2024, we reported topline safety data and certain exploratory efficacy endpoints from the Phase 2a study of TPIP in patients with PH-ILD. We anticipate initiating a Phase 3 study of TPIP in patients with PH-ILD in the second half of 2025.
- Enrollment of the Phase 2b study of TPIP in patients with PAH was completed in the fourth quarter of 2024, with 102 patients enrolled in the study. We anticipate topline results for this study in mid-2025.

Gene Therapy

- In the fourth quarter of 2024, we received clearance from the FDA for our investigational new drug (IND) application for INS1201, an intrathecally delivered gene therapy for patients with DMD. We anticipate initiating a clinical trial in patients with DMD in the first half of 2025.

Pre-Clinical Programs

- We continue to progress our pre-clinical research programs across a wide range of technologies and modalities, including gene therapy, artificial intelligence-driven protein engineering, protein manufacturing, RNA end-joining, and synthetic rescue.

To complement our internal research and development, we also actively evaluate in-licensing and acquisition opportunities for products, product candidates and technologies, including those that address serious diseases with significant unmet need.

Our Strategy

We strive to develop and commercialize first- and best-in-class therapies that serve patient communities where the need is greatest. Our first product, ARIKAYCE, is approved in the US as ARIKAYCE® (amikacin liposome inhalation suspension), in Europe as ARIKAYCE Liposomal 590 mg Nebuliser Dispersion and in Japan as ARIKAYCE inhalation 590mg (amikacin sulfate inhalation drug product). We are not aware of any other approved inhaled therapies specifically indicated to treat MAC lung disease in North America, Europe or Japan. We believe that ARIKAYCE has the potential to prove beneficial in other patients with refractory MAC. Our product candidates are brensocatib, our Phase 3 product candidate that we are developing for patients with bronchiectasis and other neutrophil-mediated diseases, TPIP, our Phase 2 product candidate that may offer a differentiated product profile for patients with PH-ILD and PAH, and INS1201, our intrathecally delivered gene therapy product candidate for patients with DMD. We announced positive topline results from our Phase 3 ASPEN trial of brensocatib in May 2024 and the acceptance by the FDA of our NDA, with priority review granted, for brensocatib in patients with bronchiectasis in February 2025, which we anticipate will be followed by filings with the European and Japanese regulatory authorities. We are also advancing our pre-clinical research programs encompassing a wide range of technologies and modalities, including gene therapy, AI-driven protein engineering, protein manufacturing, RNA end-joining, and synthetic rescue.

Our key priorities are as follows:

- Continue to provide ARIKAYCE to appropriate patients and expand our reliable revenue stream;
- Advance commercial readiness activities to serve significantly more patients facing serious diseases;
- Produce topline clinical data readouts in the near and long term; and
- Control spending, prudently deploying capital to support the best return-generating opportunities.

ARIKAYCE for Patients with MAC Lung Disease

ARIKAYCE is our first approved product. ARIKAYCE received accelerated approval in the US in September 2018 for the treatment of refractory MAC lung disease as part of a combination antibacterial drug regimen for adult patients with limited or no alternative treatment options. In October 2020, ARIKAYCE received approval in Europe for the treatment of NTM lung infections caused by MAC in adults with limited treatment options who do not have CF. In March 2021, ARIKAYCE received approval in Japan for the treatment of patients with NTM lung disease caused by MAC who did not sufficiently respond to prior treatment with a multidrug regimen. MAC lung disease is a rare and often chronic infection that can cause irreversible lung damage and can be fatal. Amikacin solution for parenteral administration is an established drug that has activity against a variety of NTM; however, its use is limited by the need to administer it intravenously and by toxicity to hearing, balance, and kidney function. Unlike amikacin solution for intravenous administration, our proprietary Pulmovance™ technology uses charge-neutral liposomes to deliver amikacin directly to the lungs where liposomal amikacin is taken up by the lung macrophages where the MAC infection resides. This technology also prolongs the release of amikacin in the lungs, while minimizing systemic exposure, thereby offering the potential for decreased systemic toxicities. ARIKAYCE's ability to deliver high levels of amikacin directly to the lung and sites of MAC infection via the use of our Pulmovance technology distinguishes it from intravenous amikacin. ARIKAYCE is administered once-daily using Lamira, an inhalation device developed and manufactured by PARI. Lamira is a portable nebulizer that enables aerosolization of liquid medications via a vibrating, perforated membrane, and was designed specifically for ARIKAYCE delivery.

The FDA has designated ARIKAYCE as an orphan drug and a Qualified Infectious Disease Product (QIDP) for the treatment of NTM lung disease. Orphan designated drugs are eligible for seven years of exclusivity for the orphan indication. QIDP designation provides an additional five years of exclusivity for the designated indication. The FDA granted a total of 12 years of exclusivity in the indication for which ARIKAYCE was approved.

ARIKAYCE also has been included in the international treatment guidelines for NTM lung disease treatment. The evidence-based guidelines, issued by the American Thoracic Society (ATS), European Respiratory Society (ERS), European Society of Clinical Microbiology and Infectious Diseases (ESCMID), and Infectious Diseases Society of America (IDSA), strongly recommend the use of ARIKAYCE for MAC lung disease as part of a combination antibacterial drug regimen for adult patients with limited or no alternative treatment options who have failed to convert to a negative sputum culture after at least six months of treatment.

In October 2020, the FDA approved a supplemental new drug application for ARIKAYCE, adding important efficacy data regarding the durability and sustainability of culture conversion to the ARIKAYCE label. The data, which are from the Phase 3 CONVERT study of ARIKAYCE, demonstrate that the addition of ARIKAYCE to guideline-based therapy (GBT) was associated with sustained culture conversion through the end of treatment as well as durable culture conversion three months post-treatment compared with GBT alone.

Accelerated Approval

In March 2018, we submitted an NDA for ARIKAYCE to the FDA to request accelerated approval. Accelerated approval allows drugs that (i) are being developed to treat a serious or life-threatening disease or condition and (ii) provide a meaningful therapeutic benefit over existing treatments to be approved substantially based on an intermediate endpoint or a surrogate endpoint that is reasonably likely to predict clinical benefit, rather than a clinical endpoint such as survival or irreversible morbidity. In September 2018, the FDA granted accelerated approval for ARIKAYCE under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) for the treatment of refractory MAC lung disease as part of a combination antibacterial drug regimen for adult patients with limited or no alternative treatment options. LPAD, which was enacted as part of the 21st Century Cures Act, serves to advance the development of new antibacterial drugs to treat serious or life-threatening infections in limited populations of patients with unmet needs. As required for drugs approved under the LPAD pathway, labeling for ARIKAYCE includes certain statements to convey that the drug has been shown to be safe and effective only for use in a limited population.

As a condition of accelerated approval, we must conduct a post-marketing confirmatory clinical trial. In December 2020, we commenced the post-marketing confirmatory clinical trial program for ARIKAYCE in patients with MAC lung disease consisting of the ARISE trial, an interventional study designed to validate cross-sectional and longitudinal characteristics of a PRO tool in MAC lung disease, and the ENCORE trial, designed to establish the clinical benefits and evaluate the safety of ARIKAYCE in patients with newly diagnosed or recurrent MAC lung infection who have not started antibiotics using the PRO tool validated in the ARISE trial. In September 2023, we announced positive topline results from the ARISE trial. The study met its primary objective of demonstrating that the QOL-B respiratory domain works effectively as a PRO tool in patients with MAC lung disease. In June 2024, we met and aligned with the FDA on the primary endpoint for the ENCORE study. If the data are positive, ENCORE may support a label expansion to include all MAC lung patients as well as support full approval for the current refractory indication. Based on feedback and in alignment with the FDA, we have determined that the primary endpoint for the ENCORE study will include eight questions from the QOL-B respiratory domain PRO. We completed enrollment of the ENCORE study in the fourth quarter of 2024, with 425 patients enrolled. We anticipate reporting topline data in the first quarter of 2026.

Reimbursement Outside of the US

In October 2020, the EC granted marketing authorization for ARIKAYCE for the treatment of NTM lung infections caused by MAC in adults with limited treatment options who do not have CF. ARIKAYCE can now be prescribed for appropriate patients across the European Union (EU) countries as well as in the United Kingdom (UK). ARIKAYCE is reimbursed nationally in France, Belgium, the Netherlands, the UK and Ireland. We have worked with the German National Association of Statutory Health Insurance Funds towards an agreement on the reimbursement price of ARIKAYCE that would allow us to better serve the needs of patients in Germany; however, since we have been unable to reach an agreement, patient supply of ARIKAYCE in Germany was enabled by import from other EU countries in September 2022. To date, we have been unable to reach an acceptable agreement of a nationally reimbursed price with the Italian Medicines Agency; however, ARIKAYCE remains commercially available for physicians to prescribe in Italy under Class C, where we set the price and funding is agreed locally.

In March 2021, Japan's MHLW approved ARIKAYCE for the treatment of patients with NTM lung disease caused by MAC who did not sufficiently respond to prior treatment with a multidrug regimen. In July 2021, we launched ARIKAYCE in Japan.

The CONVERT Study and 312 Study

Accelerated approval of ARIKAYCE was supported by preliminary data from the CONVERT study, a global Phase 3 study evaluating the safety and efficacy of ARIKAYCE in adult patients with refractory MAC lung disease, using achievement of sputum culture conversion (defined as three consecutive negative monthly sputum cultures) by Month 6 as the primary endpoint. Patients who achieved sputum culture conversion by Month 6 continued in the CONVERT study for an additional 12 months of treatment following the first monthly negative sputum culture in order to assess the durability of culture conversion, as defined by patients that have completed treatment and continued in the CONVERT study off all therapy for three months. In May 2019, we presented at the American Thoracic Society meeting that 41/65 (63.1%) of patients on ARIKAYCE plus GBT who had achieved culture conversion by Month 6 had maintained durable culture conversion for three months off all therapy compared to 0/10 (0%) on GBT only ($p<0.0002$). Safety data for these patients were consistent with safety data previously reported for patients by Month 6 of the CONVERT study.

Patients who did not culture convert by Month 6 may have been eligible to enroll in the 312 study, an open-label extension study for these non-converting patients who completed six months of treatment in the CONVERT study. The primary objective of the 312 study was to evaluate the long-term safety and tolerability of ARIKAYCE in combination with a standard multi-drug regimen. The secondary objectives of the 312 study included evaluating the proportion of subjects achieving culture conversion (defined in the same way as the CONVERT study) by Month 6 and the proportion of subjects achieving culture

conversion by Month 12, which was the end of treatment. We previously reported interim data as of December 2017 for patients in the 312 study, with 28.4% of patients who received GBT only in the CONVERT study (19/67) and 12.3% of patients who had received ARIKAYCE plus GBT in the CONVERT study (7/57) achieving culture conversion by Month 6 of receiving ARIKAYCE plus GBT as part of the 312 study. The 312 study has concluded and final efficacy data regarding culture conversion were consistent with these interim data. We have analyzed the safety and efficacy data from the 312 study, and we did not observe any new safety signals.

The ARISE Study

The ARISE trial was a global, randomized, double-blind, placebo-controlled Phase 3b study in adult patients with newly diagnosed or recurrent MAC infections that aimed to generate evidence demonstrating the domain specification, reliability, validity, and responsiveness of PRO-based scores, including a respiratory symptom score. The ARISE study met its primary objective of demonstrating that the QOL-B respiratory domain works effectively as a PRO tool in patients with MAC lung disease. Based on feedback and in alignment with the FDA, we have determined that the primary endpoint for the ENCORE study will include eight questions from the QOL-B respiratory domain PRO.

Patients in ARISE (N=99) were randomized 1:1 to treatment with ARIKAYCE plus macrolide-based background regimen (ARIKAYCE arm) or placebo plus macrolide-based background regimen (comparator arm) once daily for six months, followed by one month off treatment. ARIKAYCE-treated patients performed better than those in the comparator arm as measured by the QOL-B instrument, with 43.8% of patients achieving an improvement in QOL-B respiratory score above the estimated meaningful within-subject score difference of 14.8, compared with 33.3% of patients in the comparator arm. While the study was not powered to show a statistically significant difference between treatment arms, a strong trend toward significance was observed for improvement from baseline at Month 7 (12.24 vs. 7.76, p=0.1073). Patients in the ARIKAYCE arm also achieved nominally statistically significantly higher culture conversion rates at Month 7 versus patients in the comparator arm (78.8% vs. 47.1%, p=0.0010), and culture conversion was faster and more likely to persist through Month 7 for the ARIKAYCE arm.

Consistent with our expectations, the FDA and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan confirmed that they would not consider a label expansion for ARIKAYCE based on data from the ARISE study alone.

ARISE Culture Conversion

Consistent with prior clinical studies, a higher proportion of patients in the ARIKAYCE arm achieved culture conversion by Month 6 (defined as negative cultures at Months 5 and 6) compared to patients in the comparator arm (80.6% vs. 63.9%, p=0.0712). Among patients who achieved culture conversion by Month 6, more patients in the ARIKAYCE arm achieved the first of their two required monthly negative cultures for clinical conversion at Month 1 versus the comparator arm (74.3% vs. 46.7%). As reported above, at Month 7 (one month following the cessation of treatment), 78.8% of patients in the ARIKAYCE arm vs. 47.1% of patients in the comparator arm were culture-converted, suggesting that ARIKAYCE-treated patients are more likely to remain negative.

Correlation Between ARISE Culture Conversion and QOL-B Performance

Patients in the ARIKAYCE arm who achieved culture conversion at both Month 6 and Month 7 had nominally statistically significantly greater improvements in QOL-B respiratory domain scores at Month 7 compared to patients in the ARIKAYCE arm who did not achieve culture conversion (15.74 vs. 3.53, p=0.0167 at Month 6 and 14.89 vs. 4.50, p=0.0416 at Month 7).

ARISE Safety and Tolerability

The discontinuation rate of ARIKAYCE or the placebo used in the comparator arm was 22.9% in the ARIKAYCE arm and 7.8% in the comparator arm. Study completion rates were 91.7% in the ARIKAYCE arm and 94.1% in the comparator arm. No new safety events were observed in the ARIKAYCE arm, and the safety profile in general was as expected in both treatment arms. Treatment-emergent adverse events (TEAEs) were reported by 91.7% of patients in the ARIKAYCE arm and 80.4% of patients in the comparator arm. The most common TEAEs were dysphonia (41.7% for the ARIKAYCE arm vs. 3.9% for the comparator arm), cough (27.1% vs. 7.8%), diarrhea (27.1% vs. 25.5%), and COVID-19 (12.5% vs. 9.8%). Of the treatment-emergent serious adverse events observed in the trial, none were determined to be related to ARIKAYCE by investigators.

Further Research and Lifecycle Management

We are currently exploring and supporting research and lifecycle management programs for ARIKAYCE beyond treatment of refractory MAC lung disease as part of a combination antibacterial regimen for adult patients who have limited or no treatment options. As noted above, we will continue to advance the post-marketing confirmatory MAC lung disease clinical trial program for ARIKAYCE, through the completed ARISE and ongoing ENCORE trials, which are intended to fulfill the FDA's post-marketing requirement to allow for the full approval of ARIKAYCE in the US, as well as to support the use of ARIKAYCE as a treatment for patients with MAC lung disease.

The ENCORE trial is a randomized, double-blind, placebo-controlled Phase 3b study to evaluate the efficacy and safety of an ARIKAYCE-based regimen in patients with newly diagnosed or recurrent MAC infection who have not started antibiotics. Patients are randomized 1:1 to receive ARIKAYCE plus background regimen or placebo plus background regimen once daily for 12 months. Patients will then discontinue all study treatments and remain in the trial for three months for the assessment of durability of culture conversion. The primary endpoint is change from baseline to Month 13 in respiratory symptom score. The key secondary endpoint is the proportion of subjects achieving durable culture conversion at Month 15. In June 2024, we met and aligned with the FDA on the primary endpoint for the ENCORE study. If the data are positive, ENCORE may support a label expansion to include all MAC lung patients as well as support full approval for the current refractory indication. Based on feedback and in alignment with the FDA, we have determined that the primary endpoint for the ENCORE study will include eight questions from the QOL-B respiratory domain PRO. We completed enrollment of the ENCORE study in the fourth quarter of 2024, with 425 patients enrolled. We anticipate reporting topline data in the first quarter of 2026.

Subsequent lifecycle management studies could also potentially enable us to reach more patients. These initiatives may include new clinical studies sponsored by us and may also include investigator-initiated studies, which are independent clinical studies initiated and sponsored by physicians or research institutions, with funding from us.

Market Opportunity for ARIKAYCE in MAC Lung Disease

NTM lung disease is associated with increased rates of morbidity and mortality, and MAC is the predominant pathogenic species in NTM lung disease in the US, Europe and Japan. The prevalence of NTM lung disease has increased over the past two decades, and we believe it is an emerging public health concern worldwide. Based on an analysis using information from external sources, including market research funded by us and third parties, and internal analyses and calculations, we estimate the potential patient populations in the US, the European 5 (comprised of France, Germany, Italy, Spain and the UK) and Japan are as follows:

Potential Market	Estimated Number of Patients with Diagnosed MAC Lung Disease	Estimated Number of Patients with Refractory MAC Lung Disease
United States	95,000-115,000	12,000-17,000
European 5	14,000	1,400
Japan	125,000-145,000	15,000-18,000

We are not aware of any other approved inhaled therapies specifically indicated for NTM lung disease in North America, Europe or Japan. Based on a burden of illness study that we conducted in the US with a major medical benefits provider, we previously concluded that patients with NTM lung disease are costly to healthcare plans, while a claims-based study in the US has shown that patients with NTM lung disease have higher resource utilization and costs than their age and gender-matched controls. Accordingly, we believe that a significant market opportunity for ARIKAYCE in NTM lung disease exists in the US and internationally.

Product Pipeline

Brensocatib

Brensocatib is a small molecule, oral, reversible inhibitor of DPP1, which we licensed from AstraZeneca in October 2016. DPP1 is an enzyme responsible for activating neutrophil serine proteases (NSPs) in neutrophils when they are formed in the bone marrow. Neutrophils are the most common type of white blood cell and play an essential role in pathogen destruction and inflammatory mediation. Neutrophils contain the NSPs (including neutrophil elastase, proteinase 3, and cathepsin G) that have been implicated in a variety of inflammatory diseases. In chronic inflammatory lung diseases, neutrophils accumulate in the airways and result in excessive active NSPs that cause lung destruction and inflammation. Brensocatib may decrease the damaging effects of inflammatory diseases such as bronchiectasis by inhibiting DPP1 and its activation of NSPs.

In June 2020, the FDA granted breakthrough therapy designation for brensocatib for the treatment of adult patients with non-cystic fibrosis bronchiectasis (NCFBE) for reducing exacerbations. The FDA's breakthrough therapy designation is designed to expedite the development and review of therapies that are intended to treat serious or life-threatening diseases and for which preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy. The benefits of breakthrough therapy designation include more frequent communication and meetings with the FDA, eligibility for rolling and priority review, intensive guidance on an efficient drug development program, and organizational commitment from the FDA involving senior managers. In November 2020, brensocatib was granted access to the PRIME scheme from the European Medicines Agency (EMA) for patients with NCFBE.

In October 2021, the EMA’s Paediatric Committee approved the brensocatib Pediatric Investigational Plan for the treatment of patients with NCFBE. Subsequently, the ASPEN trial included 41 adolescent patients between ages 12 to 17,

which will fulfill the pediatric study requirements to support marketing applications in this patient population in the US, Europe and Japan.

The WILLOW Study

The WILLOW study was a randomized, double-blind, placebo-controlled, parallel-group, multi-center, multi-national, Phase 2b study to assess the efficacy, safety and tolerability, and pharmacokinetics of brensocatib administered once daily for 24 weeks in patients with NCFBE. The WILLOW study was conducted at 116 sites and enrolled 256 adult patients diagnosed with NCFBE who had at least two documented pulmonary exacerbations in the 12 months prior to screening. Patients were randomized 1:1:1 to receive either 10 mg or 25 mg of brensocatib or matching placebo. The primary efficacy endpoint was the time to first pulmonary exacerbation over the 24-week treatment period in the brensocatib arms compared to the placebo arm.

WILLOW Efficacy Data

We announced topline data for the WILLOW study in February 2020 and full data for the WILLOW study in June 2020. In September 2020, final results from the WILLOW study were published online in the New England Journal of Medicine. The data demonstrate that the WILLOW study met its primary endpoint of time to first pulmonary exacerbation over the 24-week treatment period for both the 10 mg and 25 mg dosage groups of brensocatib compared to placebo (p=0.027, p=0.044, respectively). The risk of exacerbation at any time during the trial was reduced by 42% for the 10 mg group versus placebo (HR 0.58, p=0.029) and by 38% for the 25 mg group versus placebo (HR 0.62, p=0.046). In addition, treatment with brensocatib 10 mg resulted in a significant reduction in the rate of pulmonary exacerbations, a key secondary endpoint, versus placebo. Specifically, patients treated with brensocatib experienced a 36% reduction in the 10 mg arm (p=0.041) and a 25% reduction in the 25 mg arm (p=0.167) versus placebo. Change in concentration of active neutrophil elastase in sputum versus placebo from baseline to the end of the treatment period was also statistically significant (p=0.034 for 10 mg, p=0.021 for 25 mg).

WILLOW Safety and Tolerability Data

Brensocatib was generally well-tolerated in the study. Rates of AEs leading to discontinuation in patients treated with placebo, brensocatib 10 mg, and brensocatib 25 mg were 10.6%, 7.4%, and 6.7%, respectively. The most common AEs in patients treated with brensocatib were cough, headache, sputum increase, dyspnea, fatigue, and upper respiratory tract infection. Rates of adverse events of special interest (AESIs) in patients treated with placebo, brensocatib 10 mg, and brensocatib 25 mg, respectively, were as follows: rates of skin events (including hyperkeratosis) were 11.8%, 14.8%, and 23.6%; rates of dental events were 3.5%, 16.0%, and 10.1%; and rates of infections that were considered AESIs were 17.6%, 13.6%, and 16.9%.

The ASPEN Study

Based on the positive results of the WILLOW study, in December 2020 we commenced the ASPEN study, a global, randomized, double-blind, placebo-controlled Phase 3 study to assess the efficacy, safety, and tolerability of brensocatib in adult patients with bronchiectasis. Patients with bronchiectasis due to CF were not enrolled in the study. The primary endpoint was the rate of adjudicated PEs over the 52-week treatment period. Secondary endpoints included the time to first adjudicated PE, the proportion of subjects free of adjudicated PE by 52 weeks, the absolute change from baseline in post-bronchodilator FEV1, the reduction in annualized rate of severe adjudicated PE, and the change from baseline in the Bronchiectasis QOL-B Respiratory Symptoms Domain Score.

The total number of active sites in ASPEN was 391 sites in 35 countries. A dult patients (ages 18 to 85 years) were randomized 1:1:1 and adolescent patients (ages 12 to <18 years) were randomized 2:2:1 for treatment with brensocatib 10 mg, brensocatib 25 mg, or placebo once daily for 52 weeks, followed by 4 weeks off treatment.

ASPEN Safety and Efficacy Data

We announced positive topline results from the ASPEN trial in May 2024. The primary efficacy analysis included data from 1,680 adult patients and 41 adolescent patients. Brensocatib was well-tolerated in the study. In addition, the study met its primary endpoint, with both dosage strengths of brensocatib demonstrating statistically significant reductions in the annualized rate of adjudicated PEs versus placebo. The study also met several of its prespecified secondary endpoints with statistical significance. In February 2025, the FDA accepted our NDA, with priority review granted, for brensocatib in patients with bronchiectasis.

Topline efficacy results from the ASPEN study were as follows:

	Brensocatib 10 mg compared to placebo		Brensocatib 25 mg compared to placebo	
Primary Endpoint				
Reduction in annualized rate of PEs	21.1%	p=0.0019*	19.4%	p=0.00
Secondary Endpoints				
Prolongation of time to first PE	18.7%	p=0.0100*	17.5%	p=0.01
Increase in odds of remaining exacerbation free over 52 weeks	41.2%	p=0.0059*	40.0%	p=0.00
Change from baseline in post-bronchodilator forced expiratory volume in 1 second (FEV1) at week 52	11 mL	p=0.3841	38 mL	p=0.00
Reduction in annualized rate of severe PEs	25.8%	p=0.1277	26.0%	p=0.1(
Change from baseline in the Quality of Life – Bronchiectasis (QOL-B) Respiratory Score at week 52	2.0 points	p=0.0594	3.8 points	p=0.00

* - Statistically significant

^ - Nominally significant p-value

Further Research and Development

In August 2019, we received notice from the FDA that we were awarded a development grant of $1.8 million for specific work to be performed on a PRO tool. The grant funding was for the development of a novel PRO tool for use in clinical trials to measure symptoms in patients with NCFBE with and without NTM lung infection. The grant has come to the end of the funding period and met the objectives with grant deliverables submitted to the FDA's Drug Development Tool Qualification Program for evaluation by the FDA.

In January 2023, we reported topline data from the Phase 2a, multiple-dose, pharmacokinetic/pharmacodynamic study of brensocatib in patients with CF. This Phase 2a study included both patients who were on background CFTR modulator drugs and patients who were not on CFTR modulator drugs. The study duration was approximately one month and dosed CF patients to placebo, 10 mg, 25 mg, and 40 mg of brensocatib. A clear dose-dependent and exposure-dependent inhibition of blood NSPs was observed in patients treated with brensocatib across all doses in this study, consistent with the mechanism of action of brensocatib. Safety and tolerability were consistent with what was observed during the Phase 2b WILLOW study, with no significant drug-related findings. We concluded that an additional cohort evaluating a 65 mg dose of brensocatib is not needed in this patient population.

We are conducting further studies to explore the potential of brensocatib in additional neutrophil-mediated diseases, including CRSsNP and HS. CRSsNP currently has one approved pharmacological therapy (corticosteriod nasal spray); however, many patients do not respond to corticosteroids or endoscopic sinus surgery. The Phase 2b BiRCh trial of brensocatib in patients with CRSsNP is underway. In the fourth quarter of 2024, we initiated a Phase 2b study of brensocatib in patients with HS.

Market Opportunity for Brensocatib in Bronchiectasis

Bronchiectasis is a severe, chronic pulmonary disorder in which the bronchi become permanently dilated due to a cycle of infection, inflammation, and lung tissue damage. The condition is marked by frequent pulmonary exacerbations requiring antibiotic therapy and/or hospitalizations. Symptoms include chronic cough, excessive sputum production, shortness of breath, and repeated respiratory infections, which can worsen the underlying condition. Based on information from external sources, including market research funded by us and third parties, and internal analyses and calculations, we estimate the potential addressable market in bronchiectasis at launch in the US, the European 5 and Japan will be as follows (approximately):

Potential Market	Estimated Number of Patients Diagnosed with Bronchiectasis
United States	500,000
European 5	600,000
Japan	150,000

Today, there are no approved therapies in the US, Europe, or Japan for the treatment of patients with bronchiectasis.

Treprostinil Palmitil Inhalation Powder

TPIP is an investigational inhaled formulation of a treprostinil prodrug that has the potential to address certain of the current limitations of existing prostanoid therapies. We believe that TPIP prolongs duration of effect and may provide patients

with greater consistency in pulmonary arterial pressure reduction over time. Current inhaled prostanoid therapies must be dosed four to nine times per day. Reducing dose frequency has the potential to ease treatment burden for patients and improve compliance. Additionally, we believe that TPIP may be associated with fewer side effects, including severity and/or frequency of cough, headache, throat irritation, nausea, flushing and dizziness that are associated with high initial drug levels and local upper airway exposure when using current inhaled prostanoid therapies. We believe TPIP may offer a differentiated product profile for PH-ILD and PAH.

In February 2021, we announced topline results from the Phase 1 study of TPIP in healthy volunteers. The objective of this first-in-human single ascending dose and multiple ascending dose study was to assess the pharmacokinetics and tolerability profile of TPIP. Data from the study demonstrated that TPIP was generally well tolerated, with a pharmacokinetic profile that supports continued development with once-daily dosing. The most common AEs across all cohorts in the study were cough, dizziness, headache, and nausea. Most AEs were mild in severity and consistent in nature with those typically seen with other inhaled prostanoid therapies. There were few moderate AEs and no severe or serious AEs. Subjects in the multiple dose panel that incorporated an up-titration approach beginning at 112.5 µg once-daily and progressing to 225 µg once-daily reported fewer AEs compared to the panel dosed with 225 µg once-daily from the first dose.

Overall pharmacokinetic results demonstrated that treprostinil exposure (AUC and Cmax) was dose-proportional, with low to moderate inter-subject variability. Treprostinil was detected in the plasma at 24 hours at all doses and throughout the 48-hour sampling period for the two highest doses. Compared with currently available inhaled treprostinil therapy, TPIP showed substantially lower Cmax and longer half-life. Data from this study were presented in an oral session at the European Society of Cardiology Congress in August 2021.

In May 2024, we reported topline safety data and certain exploratory efficacy endpoints from the Phase 2a study of TPIP in patients with PH-ILD. We anticipate initiating a Phase 3 registration program in PH-ILD in the second half of 2025. We also have an ongoing Phase 2b study designed to investigate the effect of TPIP in patients with PAH. Enrollment in the Phase 2b study of TPIP in PAH completed in the fourth quarter of 2024 and we anticipate topline results in mid-2025.

Market Opportunity for TPIP in PH-ILD and PAH

We believe TPIP may be a highly effective therapy that has the potential to ease the treatment burden for patients with PH-ILD and PAH, improve compliance and be associated with fewer side effects compared to current therapies. Based on our assessment of information from external sources, including market research conducted by third parties, we estimate the potential addressable market for TPIP at launch in the US, the European 5 and Japan will be as follows (approximately):

Potential Market	Estimated Number of Patients Diagnosed with PH-ILD	Estimated Number of Patients Diagnosed with PAH
United States	50,000	35,000
European 5	65,000	40,000
Japan	20,000	15,000

Gene Therapy

In the fourth quarter of 2024, we received clearance from the FDA for our IND application for INS1201, a microdystrophin adeno-associated virus gene replacement therapy for patients with DMD. Administered intrathecally, this approach has the potential to target both skeletal and cardiac muscles at lower doses. We anticipate initiating a clinical trial in patients with DMD in the first half of 2025.

Pre-Clinical Development

Our early-stage research efforts are comprised of our preclinical programs, advanced through internal research and development and augmented through business development activities. In March 2021, we acquired a proprietary protein deimmunization platform, called Deimmunized by Design, focused on the reengineering of therapeutic proteins to evade immune recognition and reaction. In August 2021, we acquired Motus Biosciences, Inc. (Motus) and AlgaeneX, Inc. (AlgaeneX), preclinical stage companies engaged in the research, development and manufacturing of gene therapies for rare genetic disorders. In January 2023, we acquired Vertuis Bio, Inc. (Vertuis), a privately held, preclinical stage company engaged in the research and development of gene therapies for rare genetic disorders. In June 2023, we acquired Adrestia Therapeutics Ltd. (Adrestia), a privately held, preclinical stage company using precision genetic models to search for therapeutic targets, precision diagnostics, novel drug compounds and new applications for existing drugs.

We continue to progress our pre-clinical research programs across a wide range of technologies and modalities, including gene therapy, AI-driven protein engineering, protein manufacturing, RNA end-joining, and synthetic rescue.

Corporate Development

We plan to continue to develop, acquire, in-license or co-promote other products, product candidates and technologies, including those that address serious diseases that currently have significant unmet needs. We are focused broadly on serious disease therapeutics and prioritizing those areas that best align with our core competencies.

Manufacturing

We do not have any in-house manufacturing capability other than for small-scale preclinical development programs and we depend completely on a small number of third-party manufacturers and suppliers for the manufacture of our product candidates for use in clinical trials. We plan to rely primarily on third-party manufacturers and suppliers for the commercial manufacture and supply of most product candidates that we commercialize. ARIKAYCE is manufactured currently by Resilience Biotechnologies Inc. (Resilience) (formerly Therapure Biopharma Inc.) in Canada at a 200 kilogram (kg) scale. For additional information about our agreement with Resilience, see *License and Other Agreements—ARIKAYCE-related Agreements*.

In October 2017, we entered into certain agreements with Patheon UK Limited (Patheon), a wholly-owned subsidiary of Thermo Fisher Scientific, Inc. (Thermo Fisher), related to increasing our long-term production capacity for ARIKAYCE commercial inventory. The agreements provide for Patheon to manufacture and supply ARIKAYCE for our anticipated long-term commercial needs. Under these agreements, we are required to deliver to Patheon the required raw materials, including active pharmaceutical ingredients, and certain fixed assets needed to manufacture ARIKAYCE. The aggregate investment to increase the long-term production capacity, including under these agreements, and related agreements or purchase orders with third parties for raw materials and fixed assets, is estimated to be approximately $116.0 million. In addition, we have a commercialization agreement with PARI, the manufacturer of our drug delivery nebulizer for ARIKAYCE, to address our commercial supply needs (the Commercialization Agreement).

In January 2024, we entered into certain agreements with Patheon Inc., a wholly-owned subsidiary of Thermo Fisher, related to the manufacture and supply of brensocatib by Patheon Inc. for our anticipated long-term commercial needs. In addition, in September 2024, we entered into a commercial manufacturing and supply agreement with Esteve Química, S.A. (Esteve) for the manufacture and supply of brensocatib's active pharmaceutical ingredient. We are required to deliver to Patheon Inc. the active pharmaceutical ingredient needed to manufacture brensocatib.

We expect to utilize contract manufacturing organizations (CMOs) to fulfill our future manufacturing requirements for TPIP. Certain product candidates will be manufactured using future in-house manufacturing capabilities.

Intellectual Property

We own or license rights to more than 850 issued patents and pending patent applications in the US and in foreign countries, including more than 300 issued patents and pending patent applications related to ARIKAYCE. Our success depends in large part on our ability to maintain proprietary protection surrounding our product candidates, technology and know-how; to operate without infringing the proprietary rights of others; and to prevent others from infringing our proprietary rights. We actively seek patent protection by filing patent applications, including on inventions that are important to the development of our business in the US, Europe, Japan, Canada, and selected other foreign markets that we consider key for our product candidates. These international markets generally include Australia, China, India, Israel and Mexico.

Our patent strategy includes obtaining patent protection, where possible, on compositions of matter, methods of manufacture, methods of use, dosing and administration regimens and formulations. We also rely on trade secrets, know-how, continuing technological innovation, in-licensing and partnership opportunities to develop and maintain our proprietary position.

We monitor for activities that may infringe our proprietary rights, as well as the progression of third-party patent applications that may have the potential to create blocks to our products or otherwise interfere with the development of our business. We are aware, for example, of US patents, and corresponding international counterparts, owned by third parties that contain claims related to treating lung infections using inhaled antibiotics. If any of these patents were to be asserted against us, we do not believe that our marketed product or development candidates would be found to infringe any valid claim of these patents.

Reflecting our commitment to safeguarding proprietary information, we require our employees, consultants, advisors, collaborators and other third-party partners to sign confidentiality agreements to protect the exchange of proprietary materials and information. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

ARIKAYCE Patents

Of the patents and applications related to ARIKAYCE, there are 13 in force issued US patents that cover the ARIKAYCE composition and its use in treating NTM that are listed in the FDA Orange Book. These patents and their expiration dates, based on filing dates, are as follows:

- US Patent No. 7,718,189 (expires June 6, 2025)
- US Patent No. 8,226,975 (expires August 15, 2028)
- US Patent No. 8,632,804 (expires December 5, 2026)
- US Patent No. 8,679,532 (expires December 5, 2026)
- US Patent No. 8,642,075 (expires December 5, 2026)
- US Patent No. 9,566,234 (expires January 18, 2034)
- US Patent No. 9,895,385 (expires May 15, 2035)
- US Patent No. 10,251,900 (expires May 15, 2035)
- US Patent No. 10,751,355 (expires May 15, 2035)
- US Patent No. 11,446,318 (expires May 15, 2035)
- US Patent No. 12,016,873 (expires May 15, 2035)
- US Patent No. 12,168,021 (expires May 15, 2035)
- US Patent No. 12,168,022 (expires May 15, 2035)

In addition, we own four pending US patent applications that cover the ARIKAYCE composition and/or its use in treating NTM lung disease, including those caused by MAC infections. One or more of the patent applications, if issued as patents in their current form, may be eligible for listing in the FDA Orange Book for ARIKAYCE. We also own a pending US application that covers methods for making ARIKAYCE. We anticipate that in the US, we will have patent coverage for ARIKAYCE and its use in treating NTM lung disease, including NTM lung disease caused by MAC, through at least May 15, 2035.

Ten patents have been granted by the European Patent Office (EPO) (European Patent Nos. 1909759, 1962805, 2823820, 2852391, 3067046, 3142643, 3466432, 3766501, 4005576 and 4122470) that relate to ARIKAYCE and its use in treating NTM lung disease, including those caused by MAC infections. In addition, we have additional patent applications pending before the EPO that relate to ARIKAYCE and its use in treating NTM lung disease. European Patent No. 1909759 (the ’759 patent), owned by us, was previously opposed by Generics (UK) Ltd. A hearing was held on October 19, 2015, during which we submitted amended claims. The European Patent Office Opposition Division (EPOOD) maintained the patent as amended and Generics (UK) Ltd appealed the decision. The EPO Technical Board of Appeals heard arguments related to the appeal on January 8, 2019 and the product claims of the patent were held invalid. The method of manufacture claims was remitted to the EPOOD for further consideration, and the EPO has since maintained the validity of these claims. European Patent Nos. 1962805 and 3067046, both of which expire approximately five months after the ‘759 patent (December 5, 2026 vs. July 19, 2026), also include claims related to ARIKAYCE and its use in treating NTM lung disease. European Patent Nos. 2852391 and 4005576 each expires May 21, 2033 and include claims related ARIKAYCE together with a vibrating mesh nebulizer having certain properties. European Patent Nos. 3142643, 3466432, 3766501 and 4122470 each expire May 15, 2035 and include claims related to ARIKAYCE and its use for treating MAC lung infections.

More than 50 patents have also been issued and are in force in other major foreign markets, e.g., Japan, China, Korea, Australia, and India, that relate to ARIKAYCE and/or methods of using ARIKAYCE for treating various pulmonary disorders, including NTM lung disease. More than 30 foreign patent applications are pending that relate to the ARIKAYCE composition and/or its use in treating various pulmonary disorders, including NTM lung disease.

Through our agreements with PARI, we have license rights to US and foreign patents and applications that cover the Lamira medical device through January 18, 2034. We have entered into a commercial supply agreement with PARI and we also have rights to use the nebulizers in expanded access programs and clinical trials.

Brensocatib Patents

Through our agreement with AstraZeneca, we have licensed US Patent Nos. 9,522,894, 9,815,805, 10,287,258, 10,669,245, 11,655,221, 11,655,222, 11,655,223, 11,655,224, 11,673,871, 11,773,069, 11,814,359, and 12,054,465, which have claims related to brensocatib and methods for using brensocatib in certain treatment methods, including the treatment of obstructive diseases of the airway such as bronchiectasis. US Patent No. 9,522,894 expires March 12, 2035 while the remaining US patents expire January 21, 2035 (not taking into account any potential patent term extension). Counterpart patents of the aforementioned US patents have issued in Australia, Canada, Europe, China, Japan, South Korea, India, Israel, and Mexico and expire January 21, 2035, not accounting for any potential patent term extension. We have also licensed US Patent No. 12,059,424 from AstraZeneca, and this patent expires February 21, 2040. The claims in US Patent No. 12,059,424 relate to certain components of the brensocatib oral tablet. Counterpart patents have issued in China, Europe and Japan and expire March 1, 2039. In addition, patent applications related to brensocatib and methods of using the same to treat indications of interest such as bronchiectasis, HS and chronic rhinosinusitis are pending in the US and throughout the world, including in Europe, China, and Japan.

TPIP Patents

We own US Patent Nos. 9,255,064, 9,469,600, 10,010,518, 10,526,274, 10,995,055 and 11,795,135, each expiring October 24, 2034 (not taking into account any potential patent term extensions or adjustments), each with claims covering treprostinil palmitil, the treprostinil prodrug component of TPIP, compositions comprising the same, and/or its use. US Patent No. 9,255,064 has claims reciting hexadecyl-treprostinil, and other treprostinil prodrugs. US Patent No. 9,469,600 has claims related to TPIP and other treprostinil prodrug formulations. US Patent No. 10,010,518 has claims directed to methods of treating pulmonary hypertension, including PAH, using compositions related to TPIP such as treprostinil prodrug formulations. US Patent No. 10,526,274 has claims directed to methods for treating pulmonary fibrosis with treprostinil palmitil. US Patent No. 10,995,055 has claims directed to compositions comprising treprostinil palmitil in the form of a dry powder, and methods for treating pulmonary hypertension with the same. US Patent No. 11,795,135 has claims directed to methods for treating PH-ILD, with treprostinil palmitil. Counterpart patent applications to these US Patents have issued in Europe, Japan and other foreign jurisdictions. Counterpart patent applications to these US Patents are also pending in select jurisdictions, including the US, Europe and Japan.

We own pending patent applications that relate to methods for using treprostinil prodrugs and formulations comprising the same, including TPIP in treating patients with PAH and other diseases, as well as methods for manufacturing such treprostinil prodrugs and formulations. Should the patent applications related to TPIP formulations and methods of using TPIP in pulmonary hypertension treatment methods issue, these patents would expire in October 2041.

Trademarks

In addition to our patents and trade secrets, we have filed applications to register certain trademarks in the US and/or abroad, including INSMED and ARIKAYCE. At present, we have received two registrations for the INSMED mark and one registration for the ARIKAYCE mark from the US Patent and Trademark Office (USPTO). We have also received notices of allowance or registrations in a number of countries abroad for the INSMED and ARIKAYCE marks, among others. The EMA has authorized the use of the name ARIKAYCE liposomal, and the FDA has approved our use of the name ARIKAYCE, as the trade name for amikacin liposome inhalation suspension. Our ability to obtain and maintain trademark registrations will in certain geographical locations depend on making use of the mark in commerce on or in connection with our products and approval of the trademarks for our products by regulatory authorities in each country.

License and Other Agreements

Multi-program Agreements

PPD Development, L.P. (a wholly-owned subsidiary of Thermo Fisher)

In April 2020, we entered into a master services agreement with PPD Development, L.P. (PPD) pursuant to which we retained PPD to perform clinical development services in connection with certain of our clinical research programs. The master services agreement has an initial term of five years. Either party may terminate (i) any project addendum under the master services agreement for any reason and without cause upon 30 days' written notice, (ii) any project addendum in the event of the other party's breach of the master services agreement or such project addendum upon 30 days' written notice, provided that such breach is not cured within such 30-day period, (iii) the master services agreement or any project addendum immediately upon the occurrence of an insolvency event with respect to the other party or (iv) any project addendum upon 30 days' written notice if (a) the continuation of the services under such project addendum would post material ethical or safety risks to study participants, (b) any approval from a regulatory authority necessary to perform the applicable study is revoked, suspended or expires without renewal or (c) in the reasonable opinion of such party, continuation of the services provided under such project addendum would be in violation of applicable law. We have entered into project addenda with PPD to perform clinical development services over several years for, but not limited to, our ARISE, ENCORE and ASPEN studies and other trials involving brensocatib and TPIP. The total cost of these project addenda is $498.9 million.

ARIKAYCE-related Agreements

We currently rely, and will continue to rely, on agreements with a number of third parties in connection with the development and manufacture of ARIKAYCE.

PARI

We have a licensing agreement with PARI for use of the optimized Lamira Nebulizer System for delivery of ARIKAYCE in treating patients with NTM lung infections, CF and bronchiectasis. Under the licensing agreement, we have rights under several US and foreign issued patents and patent applications involving improvements to the optimized Lamira Nebulizer System, to exploit the system with ARIKAYCE for the treatment of such indications, but we cannot manufacture the nebulizers except as permitted under our Commercialization Agreement with PARI, which is described in further detail below. Lamira has been approved for use in the US (in combination with ARIKAYCE) and EU and is authorized for use in Japan. We also currently have rights to use the nebulizers in expanded access programs and clinical trials. Lamira must receive regulatory approval before we can market ARIKAYCE outside the US, EU and Japan, and it is labeled as investigational for use in our clinical trials outside of these regions.

We have certain obligations under this licensing agreement in relation to specified licensed indications. With respect to NTM, we met all obligations to achieve certain commercial, developmental and regulatory milestones by the required deadlines. With respect to bronchiectasis, we have satisfied our obligation to use commercially reasonable efforts to initiate a Phase 3 trial for bronchiectasis. With respect to CF, we are obligated to use commercially reasonable efforts to develop, obtain regulatory and reimbursement approval, market and sell ARIKAYCE in two or more major European countries, as well as to achieve certain milestones specified in the licensing agreement. Termination of the licensing agreement or loss of exclusive rights may occur if we fail to meet our obligations, including payment of royalties to PARI.

Under the licensing agreement, we paid PARI an upfront license fee and milestone payments. Upon FDA acceptance of our NDA and the subsequent FDA and EMA approvals of ARIKAYCE, we made additional milestone payments of €1.0 million, €1.5 million and €0.5 million, respectively, to PARI. In October 2017, we exercised an option to buy-down the royalties payable to PARI. PARI is entitled to receive royalty payments in the mid-single digits on annual global net sales of ARIKAYCE pursuant to the licensing agreement, subject to certain specified annual minimum royalties.

This licensing agreement will remain in effect on a country-by-country basis until the final royalty payments have been made with respect to the last country in which ARIKAYCE is sold, or until the agreement is otherwise terminated by either party. We have the right to terminate this licensing agreement upon written notice for PARI's uncured material breach, if PARI is the subject of specified bankruptcy or liquidation events, or if PARI fails to reach certain specified obligations. PARI has the right to terminate this licensing agreement upon written notice for our uncured material breach, if we are the subject of specified bankruptcy or liquidation events, if we assign or otherwise transfer the agreement to a third-party that does not agree to assume all of our rights and obligations set forth in the agreement, or if we fail to reach certain specified milestones.

In July 2014, we entered into a Commercialization Agreement with PARI for the manufacture and supply of the Lamira® Nebulizer Systems and related accessories (the Device), which is an e-Flow® nebulizer modified and optimized for use with ARIKAYCE. Under the Commercialization Agreement, PARI manufactures the Device except in the case of certain defined supply failures, when we will have the right to make the Device and have it made by third parties (but not certain third parties deemed under the Commercialization Agreement to compete with PARI). The Commercialization Agreement has an initial term of 15 years that began to run in October 2018 (the Initial Term). The term of the Commercialization Agreement may be extended by us for an additional five years by providing written notice to PARI at least one year prior to the expiration of the Initial Term.

Resilience

In February 2014, we entered into a contract manufacturing agreement with Therapure Biopharma Inc., which has been assumed by Resilience, for the manufacture of ARIKAYCE, on a non-exclusive basis, at a 200 kg scale. Pursuant to the agreement, we collaborated with Resilience to construct a production area for the manufacture of ARIKAYCE in Resilience's existing manufacturing facility in Mississauga, Ontario, Canada. The agreement had an initial term of five years, which began in October 2018, and renews automatically for successive periods of two years each, unless terminated by either party by providing the required two years' prior written notice to the other party. Under the agreement, we are obligated to pay a minimum of $6.0 million, subject to inflation, for commercial ARIKAYCE batches produced and certain manufacturing activities each calendar year. The agreement allows for termination by either party upon the occurrence of certain events, including (i) the material breach by the other party of any provision of the agreement or the quality agreement expected to be entered into between the parties, and (ii) the default or bankruptcy of the other party. In addition, we may terminate the agreement for any reason upon no fewer than 180 days' advance notice.

Patheon (a wholly-owned subsidiary of Thermo Fisher) and related agreements

In October 2017, we entered into certain agreements with Patheon related to the increase of our long-term production capacity for ARIKAYCE. The agreements provide for Patheon to manufacture and supply ARIKAYCE for our anticipated commercial needs. Under these agreements, we are required to deliver to Patheon the required raw materials, including active pharmaceutical ingredients, and certain fixed assets needed to manufacture ARIKAYCE. Patheon's supply obligations will

commence once certain technology transfer and construction services are completed. Our manufacturing and supply agreement with Patheon will remain in effect for a fixed initial term, after which it will continue for successive renewal terms unless either we or Patheon have given written notice of termination. The technology transfer agreement will expire when the parties agree that the technology transfer services have been completed. The agreements may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or the other party's insolvency. These early termination clauses may reduce the amounts due to the relevant parties. The aggregate investment to increase our long-term production capacity, including under the Patheon agreements and related agreements or purchase orders with third parties for raw materials and fixed assets, is estimated to be approximately $116.0 million.

Cystic Fibrosis Foundation Therapeutics, Inc.

In 2004 and 2009, we entered into research funding agreements with Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT) whereby we received $1.7 million and $2.2 million in research funding for the development of ARIKAYCE. As a result of the US approval of ARIKAYCE and in accordance with the CFFT agreements, as amended, we owe milestone payments to CFFT of $13.4 million in the aggregate payable through 2025, of which $10.4 million has been paid as of December 31, 2024. Furthermore, if certain global sales milestones were met within five years of the commercialization of ARIKAYCE, we would have owed up to an additional $3.9 million. We met and paid $1.7 million of these additional global sales milestone payments.

Brensocatib-related Agreements

AstraZeneca

In October 2016, we entered into a license agreement with AstraZeneca (the AZ License Agreement), pursuant to which AstraZeneca granted us exclusive global rights for the purpose of developing and commercializing AZD7986 (renamed brensocatib). In consideration of the licenses and other rights granted by AstraZeneca, we made an upfront payment of $30.0 million in late October 2016. In December 2020, we incurred a $12.5 million milestone payment obligation upon the first dosing in a Phase 3 clinical trial of brensocatib. In May 2024, upon our release of an official public statement that we intended to file an NDA, we incurred an additional $12.5 million milestone payment obligation. Upon regulatory approval by the FDA of an NDA, we will owe AstraZeneca an additional $30.0 million. Subsequent to this milestone, we are also obligated to make a series of additional contingent milestone payments totaling up to an additional $30.0 million upon the achievement of regulatory filing milestones. If we elect to develop brensocatib for a second indication, we will be obligated to make an additional series of contingent milestone payments totaling up to $42.5 million, the first of which occurs at the initiation of a Phase 3 trial in the additional indication. We are not obligated to make any additional milestone payments for additional indications. In addition, we have agreed to pay AstraZeneca tiered royalties ranging from a high single-digit to mid-teens on net sales of any approved product based on brensocatib and one additional payment of $35.0 million upon the first achievement of $1.0 billion in annual net sales. The AZ License Agreement provides AstraZeneca with the option to negotiate a future agreement with us for commercialization of brensocatib in chronic obstructive pulmonary disease or asthma. If we fail to comply with our obligations under our agreements with AstraZeneca (including, among other things, if we fail to use commercially reasonable efforts to develop and commercialize a product based on brensocatib, or we are subject to a bankruptcy or insolvency), AstraZeneca would have the right to terminate the license.

In March 2020, AstraZeneca exercised its first option pursuant to our October 2016 license agreement under which AstraZeneca can advance clinical development of brensocatib in the indications of chronic obstructive pulmonary disease (COPD) or asthma. Under the terms of the agreement, upon exercise of this option, AstraZeneca became solely responsible for all aspects of the development of brensocatib up to and including Phase 2b clinical trials in COPD or asthma. In March 2024, AstraZeneca exercised its second and final option under the agreement to further develop brensocatib beyond Phase 2b clinical trials and, if approved, commercialize brensocatib in the indications of COPD or asthma, upon reaching agreement after good faith negotiations resulting in terms, including financial terms, satisfactory to us and to AstraZeneca for such further development and commercialization. In June 2024, the negotiation period following such exercise of the final option expired. No agreement was reached between us and AstraZeneca to permit AstraZeneca to further develop and, if approved, commercialize brensocatib in the indications of COPD or asthma. As a result, we retain full worldwide development and commercialization rights for brensocatib in all indications other than COPD or asthma and AstraZeneca has no further development or commercialization rights for brensocatib in COPD, asthma or any other indication.

Patheon Inc. (a wholly-owned subsidiary of Thermo Fisher) and related agreements

In January 2024, we entered into certain agreements with Patheon Inc. related to the manufacture and supply of brensocatib by Patheon Inc. for our anticipated long-term commercial needs. Under these agreements, we are required to deliver to Patheon Inc. the active pharmaceutical ingredients needed to manufacture brensocatib. Our master commercial manufacturing services agreement with Patheon Inc. will remain in effect for a fixed initial term, after which it will continue for successive renewal terms unless either we or Patheon Inc. have given written notice of termination. The agreements may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or the other party's insolvency. Patheon Inc.'s supply obligations are governed by individual product agreements entered into from

time to time under the master commercial manufacturing services agreement. The product agreements specify, among other things, the term and pricing for Patheon Inc.'s supply obligations.

Esteve Química, S.A.

In September 2024, we entered into a commercial manufacturing and supply agreement with Esteve for the manufacture and supply of brensocatib's active pharmaceutical ingredient. The commercial manufacturing and supply agreement has an initial term of three years, after which it will continue for successive 12-month renewal terms unless either we or Esteve have given written notice of termination. The agreement may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or the other party's insolvency, the discontinue of specified dosages or changes in the regulatory landscape. Esteve's supply obligations are based on rolling forecasts of our anticipated demand for brensocatib.

Competition

The biotechnology and pharmaceutical industries are highly competitive. We face potential competitors from many different areas including commercial pharmaceutical, biotechnology and device companies, academic institutions and scientists, other smaller or earlier stage companies and non-profit organizations developing anti-infective drugs and drugs for respiratory, inflammatory, immunology, oncology, and rare diseases. Many of these companies have greater human and financial resources and may have product candidates in more advanced stages of development and may reach the market before our product candidates. Competitors may develop products that are more effective, safer or less expensive or that have better tolerability or convenience. We also may face generic competitors where third-party payors will encourage use of the generic products. Although we believe that our formulation delivery technology, respiratory and anti-infective expertise, experience and knowledge in our specific areas of focus provide us with competitive advantages, these potential competitors could reduce our commercial opportunity. Additionally, there currently are, and in the future there may be, already-approved products for certain of the indications for which we are developing, or in the future may choose to develop, product candidates. For instance, PAH is a competitive indication with established marketed products, including other formulations of treprostinil.

In the lung disease market, our major competitors include pharmaceutical and biotechnology companies that have approved therapies or therapies in development for the treatment of chronic lung infections. There are other companies that are currently conducting clinical trials for the treatment of lung disease. While there are currently no approved treatments for bronchiectasis, clinical studies in this disease state and specific endotypes (for instance, bronchiectasis with eosinophilic inflammation) have been initiated. Certain entities have expressed interest in studying other DPP1 inhibitors for the treatment of bronchiectasis and we are aware of at least two entities currently conducting clinical trials for the treatment of bronchiectasis with a DPP1 inhibitor. Products developed by certain of our competitors may potentially be used in combination with brensocatib, if approved.

With regard to ARIKAYCE, we are not aware of any approved inhaled therapies specifically indicated for refractory NTM lung infections in North America, Europe or Japan, but there is a recommended treatment regimen that is utilized. The international treatment guidelines, which are issued by the ATS, ERS, ESCMID and IDSA, strongly recommend the use of ARIKAYCE for the treatment of patients with refractory NTM lung disease caused by MAC as a part of a combination antibacterial drug regiment for adult patients with limited or no alternative treatment options who have failed to convert to a negative sputum culture after at least six months of treatment.

The fields of gene therapy and protein engineering are rapidly advancing and highly competitive. While we believe our internal expertise provides a competitive advantage, we expect competition to intensify, including from other pharmaceutical companies, government agencies and public and private research institutions. If any of our gene therapy or protein engineering programs are approved for their indications, we expect to compete with other gene therapy products, protein engineering technologies and any other existing or new therapies or technologies that may become available in the future.

Government Regulation

Orphan Drug Designation

United States

Under the Orphan Drug Act (ODA), the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, defined as a disease or condition for which the drug is intended affects fewer than 200,000 people in the US or for which there is no reasonable expectation that the cost of developing and making available in the US a drug for such disease or condition will be recovered from US sales of such drug, if it meets certain criteria specified by the ODA and FDA. After the FDA grants orphan drug designation, the drug and the specific intended use(s) for which it has obtained designation are listed by the FDA in a publicly accessible database. The FDA designated ARIKAYCE as an orphan drug for treatment of NTM infections, bronchiectasis in patients with *Pseudomonas* aeruginosa or other susceptible microbial pathogens, and bronchopulmonary *Pseudomonas* aeruginosa infections in CF patients. However, the orphan drug designations for

bronchiectasis in patients with *Pseudomonas* aeruginosa or other susceptible microbial pathogens and bronchopulmonary *Pseudomonas* aeruginosa infections in CF patients were withdrawn at our request in August 2023.

Orphan drug designation qualifies the sponsor for various development incentives of the ODA, including tax credits for qualified clinical testing, and a waiver of the PDUFA application fee (unless the application seeks approval for an indication not included in the orphan drug designation). Orphan drug designation also may afford the company a period of exclusivity for the orphan indication upon approval of the drug. Specifically, the first NDA or biologics license application (BLA) applicant with an FDA orphan drug designation for a particular drug to receive FDA approval of the drug for an indication covered by the orphan designation is entitled to a seven-year exclusive marketing period, often referred to as orphan drug exclusivity, in the US for that drug in that indication. A product that has several separate orphan designations may have several separate exclusivities for separate orphan indications. During the orphan drug exclusivity period, the FDA may not approve any other applications to market the same drug for the same indication for use, except in limited circumstances, such as a showing of clinical superiority to the product that has orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition or the same drug for a different disease or condition, and it does not alter the timing or scope of the regulatory review and approval process; the sponsor must still submit evidence from clinical and non-clinical studies sufficient to demonstrate the safety and effectiveness of the drug.

In a decision issued in September 2021 (*Catalyst Pharmaceuticals, Inc. v. Becerra*), the US Court of Appeals for the Eleventh Circuit held that the FDA had erred by limiting the scope of orphan drug exclusivity for FIRDAPSE® (amifampridine) to the product's approved indication, an action that the FDA taken in accordance with its regulations interpreting the ODA. The court held that under the ODA, FIRDAPSE's orphan drug exclusivity instead protected the broader rare disease or condition that received orphan drug designation. Notwithstanding the Eleventh Circuit's decision in *Catalyst*, the FDA announced in January 2023 that it would continue to apply the FDA's regulations tying the scope of orphan drug exclusivity to a product's approved uses or indications. In light of the FDA's announcement, the scope of orphan drug exclusivity and other issues relating to the FDA's implementation of the ODA with respect to previously approved and future products may be the subject of further litigation or legislative action.

European Union

The EMA grants orphan drug designation to promote the development of drugs or biologics (1) for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU, or (2) for life threatening, seriously debilitating or serious and chronic condition in the EU where, without incentives, sales of the drug in the European Economic Area (the EU plus Iceland, Lichtenstein and Norway) (EEA) are unlikely to be sufficient to justify its development. Orphan drug designation is available either if no other satisfactory method of diagnosing, preventing or treating the condition is approved in the EEA or if such a method does exist but the proposed orphan drug will be of significant benefit to patients.

If a drug with an orphan drug designation subsequently receives an orphan drug marketing authorization from the EC for a therapeutic indication which is covered by such designation, the drug is entitled to orphan exclusivity. The EC has granted an orphan drug marketing authorization for ARIKAYCE for the treatment of NTM lung infections caused by MAC in adults with limited treatment options who do not have CF. Orphan exclusivity means that the EMA or a national medicines agency may not accept another application for authorization, or grant an authorization, for a same or similar drug for the same therapeutic indication. Competitors may receive such a marketing authorization despite orphan exclusivity, provided that they demonstrate that the existing orphan product is not supplied in sufficient quantities or that the 'second' drug or biologic is clinically superior to the existing orphan product. The 'second' drug may but need not have an orphan designation as well. The period of orphan exclusivity is 10 years, which can be extended by two years where an agreed pediatric investigation plan has been implemented. The exclusivity period may also be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Each orphan designated marketing authorization carries the potential for one market exclusivity for all the therapeutic indications that are covered by the designation. Market exclusivity is an orphan incentive awarded by the EC to a specific clinical indication with an orphan designation. Each indication with an orphan designation confers ten years of market exclusivity for the particular indication. A medicine that has multiple orphan designations for different conditions may benefit from separate market exclusivity periods pertaining to its different orphan designations.

Orphan drug designation also provides opportunities for free protocol assistance and fee reductions for access to the centralized regulatory procedure or fee exemptions for companies with a small and medium enterprises status. In addition, EU Member States may provide national benefits to orphan drugs, such as early access to the reimbursement procedure or exemption from any turnover tax imposed on pharmaceutical companies.

The orphan designation may be applied for at any time during the development of the drug but before the application for marketing authorization. At the time of marketing authorization, the criteria for orphan designation are examined again, and the EC decides on the maintenance of the orphan designation in granting an orphan drug marketing authorization. The non-maintenance of the orphan designation means that the drug loses its orphan status and thus no longer benefits from orphan exclusivity, fee reductions or exemptions, and national benefits.

Japan

The MHLW may, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council, grant orphan drug designation to a drug intended to treat a rare disease or condition if the drug meets the following conditions: (i) the number of target patients is less than 50,000 in Japan; (ii) the necessity of orphan drug designation is high from a medical point of view; and (iii) the plan for development of the drug is appropriate. Even if a drug is granted orphan drug designation, however, it does not always receive the manufacturing and marketing approval that is necessary for the drug to be sold or marketed in Japan. ARIKAYCE did not qualify for orphan drug designation in Japan due to the estimated number of NTM patients in Japan exceeding 50,000.

Drug Approval

United States

In the US, pharmaceutical products are subject to extensive regulation by the FDA and other government bodies. The US Federal Food, Drug, and Cosmetic Act (FDCA), the Public Health Services Act (PHSA) (in the case of biological products), and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable US requirements at any time during product development, approval, or after approval may subject a company to a variety of administrative or judicial sanctions, such as imposition of clinical holds, FDA refusal to file or approve NDAs or BLAs, warning letters, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, civil penalties, and criminal prosecution. The description below summarizes the current approval process in the US for our product and product candidates.

Preclinical Studies

Preclinical studies may include laboratory evaluation of product chemistry, formulation and toxicity, and pharmacology, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including the FDA's good laboratory practice (GLP) regulations and the US Department of Agriculture's regulations implementing the Animal Welfare Act. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature, and a proposed clinical trial protocol, among other things, to the FDA as part of an IND. Certain non-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND might not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects (healthy volunteers or patients) under the supervision of a qualified investigator. Clinical trials must be conducted (i) in compliance with all applicable federal regulations and guidance, including those pertaining to good clinical practice (GCP) standards that are meant to protect the rights, safety, and welfare of human subjects and to define the roles of clinical trial sponsors, investigators, and monitors as well as (ii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing of a new drug in the US (whether in patients or healthy volunteers) must be included as a submission to the IND, and the FDA must be notified of subsequent protocol amendments, including new protocols. In addition, the protocol must be reviewed and approved by an institutional review board (IRB), and all study subjects must provide informed consent. Typically, before any clinical trial, each institution participating in the trial will require review of the protocol before the trial commences at that institution. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and there are additional, more frequent reporting requirements for certain AEs.

A study sponsor might choose to discontinue a clinical trial or a clinical development program for a variety of reasons. The FDA may impose a temporary or permanent clinical hold, or other sanctions, if it believes that the clinical trial either is not being conducted in accordance with the FDA requirements or presents an unacceptable risk to the clinical trial subjects. An IRB also may require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential pre-approval phases, but the phases may overlap or be combined. In Phase 1, short term (typically less than a few months) testing is conducted in a small group of subjects (typically 20-100), who may be patients with the target disease or condition or healthy volunteers, to evaluate its safety, determine a safe dosage range, and identify side effects. In Phase 2, the drug is given to a

larger group of subjects (typically up to several hundred) with the target condition to further evaluate its safety and gather preliminary evidence of efficacy. Phase 3 studies typically last between several months and two years. In Phase 3, the drug is given to a large group of subjects with the target disease or condition (typically several hundred to several thousand), often at multiple geographical sites, to confirm its effectiveness, monitor side effects, and collect data to support drug approval. Only a small percentage of investigational drugs complete all three phases of development and obtain marketing approval.

NDAs and BLAs

After completion of the required clinical testing, an NDA or BLA can be prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the US. The NDA or BLA is a large submission that must include, among other things, the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The application also includes representative samples, copies of the proposed product labeling, patent information, and a financial certification or disclosure statement. The cost of preparing and submitting an NDA or BLA is substantial. Additionally, under federal law (as amended by the most recent reauthorization of the Prescription Drug User Fee Act (PDUFA VII) in the FDA User Fee Reauthorization Act of 2022), most NDAs and BLAs are subject to a substantial application fee and, upon approval, the applicant will be assessed an annual prescription drug program fee, both of which are adjusted annually. NDAs and BLAs for orphan drugs are not subject to an application fee, unless the application includes an indication other than an orphan-designated indication. The FDA also has the authority to grant waivers of certain user fees, pursuant to the FDCA.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application is accepted for filing based on the FDA's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins a substantive review. The FDA may refer applications for novel drug or biological products or drug or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes outside clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will typically inspect the facility or the facilities at which the drug or biological product is manufactured. The FDA will not approve the product unless, among other requirements, compliance with current good manufacturing practice (cGMP) is satisfactory and the NDA or BLA contains data that provide substantial evidence of effectiveness for the proposed indication, generally consisting of adequate and well-controlled clinical investigations, and that the drug is safe for use under the conditions of use in the proposed labeling. The FDA also reviews the proposed labeling submitted with the NDA or BLA and typically requires changes in the labeling text.

After the FDA evaluates the NDA or BLA and the manufacturing and testing facilities, it issues either an approval letter or a complete response letter. Complete response letters generally outline the deficiencies in the submission and delineate the additional testing or information needed in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. An approval letter, which may specify post approval requirements, authorizes commercial marketing of the drug or biological product for the approved indication or indications and the other conditions of use set out in the approved prescribing information. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. The FDA sets a goal date by which the FDA expects to issue either an approval letter or a complete response letter, unless the review period is adjusted by mutual agreement between the FDA and the applicant or as a result of the applicant submitting a major amendment. The FDA's current performance goals call for the FDA to complete review of 90 percent of standard (non-priority) NDAs and BLAs within 10 months of the end of the 60-day filing review period and priority NDAs and BLAs within six months of the end of the 60-day filing review period (in the case of new molecular entity (NME) NDA and original BLA submissions). For non-NME NDA/BLAs the FDA's current performance goals call for the FDA to complete review of 90 percent of standard (non-priority) NDAs and BLAs within 10 months of receipt and priority NDAs and BLAs within 6 months of receipt.

As a condition of NDA or BLA approval, the FDA may require substantial post-approval testing, known as Phase 4 studies, to be conducted in order to gather additional information on the drug's effect in various populations and any side effects. Beyond routine post marketing safety surveillance, the FDA may require specific additional surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions that can materially affect the potential market and profitability of the drug. As a condition of approval, or after approval, the FDA also may require submission of a risk evaluation and mitigation strategy (REMS) or a REMS with elements to assure safe use to mitigate any identified or suspected serious risks. The REMS may include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. Further post-approval requirements are discussed below.

Expedited Review and Approval of Eligible Drugs

Under the FDA's accelerated approval program, the FDA may approve certain drugs for serious or life-threatening conditions on the basis of a surrogate or intermediate endpoint that is reasonably likely to predict clinical benefit, which can substantially reduce time to approval. A surrogate endpoint used for accelerated approval is a marker—a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than irreversible morbidity and mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit. The FDA bases its decision on whether to accept the proposed surrogate or intermediate clinical endpoint on the scientific support for that endpoint.

As a condition of accelerated approval, the FDA typically requires certain post-marketing clinical studies to verify and describe clinical benefit of the product, and may impose restrictions on distribution to assure safe use. Under the Consolidated Appropriations Act, 2023, Congress gave FDA the authority to require, as appropriate, that a confirmatory trial be underway prior to accelerated approval or within a specified time period after the date of accelerated approval. In addition, promotional materials for an accelerated approval drug to be used in the first 120 days post-approval must be submitted to the FDA prior to approval, and materials to be used after that 120-day period must be submitted 30 days prior to first use. If the required post-marketing studies fail to verify the clinical benefit of the drug, or if the applicant fails to perform the required post-marketing studies with due diligence, the FDA may withdraw approval of the drug under streamlined procedures in accordance with the FDCA, as amended by the Consolidated Appropriations Act, 2023. The agency may also withdraw approval of a drug if, among other things, the promotional materials for the product are false or misleading, or other evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use.

The FDA also has various programs—fast track designation, priority review and breakthrough designation—that are intended to expedite or streamline the process for the development and FDA review of drugs that meet certain qualifications. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. The programs each have different eligibility criteria and provide different benefits, and can be applied either alone or in combination depending on an applicant's circumstances.

Fast track designation applies to a drug that is intended to treat a serious condition and for which nonclinical or clinical data demonstrate the potential to address unmet medical need. It should be requested at the time of IND submission or ideally no later than the pre-NDA or pre-BLA meeting. The FDA must respond to requests for fast track designation within 60 days of receipt of the request. If granted, the applicant is eligible for actions to expedite development and review, such as frequent interaction with the review team, as well as rolling review, meaning that the applicant may submit sections of the application as they are available. The timing of the FDA's review of these sections depends on a number of factors, and the review clock does not start running until the agency has received a complete NDA or BLA submission. The FDA may withdraw fast track designation if the agency determines that the designation is no longer supported by data emerging in the drug development process.

Priority review applies to an application (both original and efficacy supplement) for a drug that treats a serious condition and that, if approved, would provide a significant improvement in safety or effectiveness. It also applies to any supplement that proposes a labeling change pursuant to a report on a pediatric study conducted pursuant to section 505A of the FDCA. A request for priority review is submitted at the time of submission of an NDA or BLA, or supplemental NDA or BLA. The FDA must respond within 60 days of receipt of the request. If granted, the review time is shortened from the standard 10 months to 6 months, beginning either after the 60-day filing review period (in the case of NME NDA and original BLA submissions) or the date of receipt (in the case of non-NME original NDA submissions).

Breakthrough therapy designation applies to a drug that is intended to treat a serious condition and for which preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. It can be requested with the IND submission and ideally no later than the end-of-Phase 2 meeting. The FDA must respond within 60 days of receipt of the request. If granted, the applicant receives intensive guidance on efficient drug development, intensive involvement of senior managers and experienced review and regulatory health project management staff in a proactive, collaborative, cross-disciplinary review, rolling review, and other actions to expedite review. Designation may be rescinded if the product no longer meets the criteria for breakthrough therapy designation.

Drugs that are designated as QIDPs may be eligible for priority review and will receive fast track designation upon the request of the sponsor, and also may be eligible for market exclusivity. A product is eligible for QIDP designation if it is an antibacterial or anti-fungal drug for human use that is intended to treat serious or life-threatening infections, including: those caused by an anti-bacterial or anti-fungal resistant pathogen, including novel or emerging infectious pathogens; or caused by qualifying pathogens listed by the FDA. A drug sponsor may request that the FDA designate its product as a QIDP at any time prior to NDA submission.

Additionally, the FDA may approve eligible drugs under the LPAD. A product is eligible if it is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs, the drug otherwise meets the standards of approval, and the FDA receives a written request from the sponsor to approve the drug under this pathway. An antibacterial or anti-fungal drug approved through this pathway may follow a streamlined clinical development program involving smaller, shorter, or fewer clinical trials. Approval is based on a benefit-risk assessment in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment for the patient population. Such drugs might not have favorable benefit-risk profiles in a broader population. Drugs approved under LPAD are subject to additional regulatory requirements, including labeling and advertising statements regarding the limited population and submission of promotional materials to the FDA at least 30 days prior to dissemination. The FDA may remove these additional requirements if the agency approves the drug for a broader population.

Exclusivities

In the US, after NDA or BLA approval of a drug not previously approved, owners of relevant drug patents may obtain up to a five-year patent term extension on a single patent. The allowable patent term extension is generally calculated as half of the drug's testing phase (the time between the date the IND becomes effective and the NDA or BLA submission date) and all of the review phase (the time between the NDA or BLA submission date and the approval date) up to a maximum of five years, to the extent such testing phase and approval phase occur after the issue date of the patent. The total post-NDA or BLA approval patent term including the extension may not exceed 14 years. The extension also can be shortened if the FDA determines that the NDA/BLA applicant did not pursue approval with due diligence. For patents that might expire while a patent term extension application is pending, the patent owner may request an interim patent term extension. The Director of the USPTO shall extend, until a final determination is made, the term of the patent for periods of up to one year if the Director determines that the patent is eligible for extension. An interim patent term extension may be renewed up to four times until a final determination is made, and up to the amount of time for which the patent might be eligible for extension. For each interim patent term extension granted, the final patent term extension is reduced by a corresponding amount. Interim patent extensions may also be available for a patent that will expire before a drug is expected to be approved, but the NDA or BLA for the drug must have been submitted.

A variety of non-patent exclusivity periods are available under the FDCA that can delay the submission or approval of certain applications for competing products.

A five-year period of non-patent exclusivity within the US is granted to the first applicant to gain approval of an NDA for a new chemical entity (NCE). An NCE is a drug that contains no active moiety (the molecule or ion responsible for the action of the drug substance) that has been approved by the FDA in any other application submitted under section 505(b) of the FDCA. During the exclusivity period for an NCE, the FDA may not accept for review an abbreviated NDA (ANDA) or a 505(b)(2) NDA submitted by another company that references (i.e., relies on the FDA's prior approval of) the NCE drug. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement with respect to a patent listed with the FDA for the NCE drug.

A three-year period of non-patent exclusivity is granted for a drug product that contains an active moiety that has been previously approved, when the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application, for example, for new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations, which means that the FDA may approve ANDAs and 505(b)(2) NDAs for other versions of the original, unmodified drug product. Where this form of exclusivity applies, it prevents FDA approval of an ANDA or 505(b)(2) NDA that is subject to the exclusivity for the three-year period; however, the FDA may accept and review ANDAs or 505(b)(2) NDAs during the three-year period.

These exclusivities also do not preclude FDA approval of a 505(b)(1) NDA for a duplicate version of the approved drug during the period of exclusivity, provided that the follow-on applicant conducts or obtains a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Products with QIDP designation may receive a five-year extension of other non-patent exclusivities for which the drug is also eligible, subject to certain limitations. Depending upon the scope of the non-patent exclusivity that is extended, the five-year extension might not prevent the FDA from approving a subsequent application for a change to the QIDP-designated drug that results in, for example, a new indication, route of administration, dosing, schedule, dosage form, delivery system, delivery device, or strength. A drug that has been designated as both an orphan drug and a QIDP for the same indication, like ARIKAYCE, might be eligible for a combined 12 years of exclusivity for that indication.

Under the PHSA, the FDA recognizes reference product exclusivity starting from the first licensure of a biological product. Reference product exclusivity affects the timing of submission and approval of a BLA for a biosimilar product. Under section 351(k) of the PHSA, a BLA for a biosimilar product may be approved based upon a showing that the proposed product is highly similar to a previously licensed product, known as the reference product, notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the proposed biosimilar product and

the reference product in terms of safety, purity, and potency. Reference product exclusivity prevents the FDA from accepting a BLA submitted under section 351(k) of the PHSA for a proposed biosimilar product for 4 years after the date of first licensure of the reference product, and prevents the FDA from approving such BLA for a proposed biosimilar product for 12 years after such date of first licensure. An additional period of reference product exclusivity is not available upon approval of a supplemental BLA. Moreover, the PHSA limits the availability of reference product exclusivity for a subsequent BLA filed by the same sponsor or manufacturer of a biological product (or a licensor, predecessor in interest, or other related entity).

Medical Device Regulation

Medical devices, such as Lamira, may be marketed as stand-alone devices, or in some cases, as constituent parts of a combination product. In either case, the product will need to satisfy and comply with FDA requirements. Unless an exemption applies, each medical device commercially distributed in the US requires either FDA clearance of a 510(k) premarket notification, approval of a premarket approval application (PMA), or issuance of a de novo classification order. Medical devices are classified into one of three classes -- Class I, Class II or Class III -- depending on the degree of risk and the level of control necessary to assure the safety and effectiveness of each medical device. Medical devices deemed to pose lower risks are generally placed in either Class I or II.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a pre-market notification. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting, or many implantable devices, or devices that have been found not substantially equivalent to a legally marketed Class I or Class II predicate device, are placed in Class III, requiring approval of a PMA. De novo classification is a risk-based classification process to classify novel medical devices into Class I or Class II.

Medical devices are also subject to certain postmarket requirements. Those requirements include, for example, establishment registration and device listing; compliance with the requirements of the Quality System Regulation (QSR); medical device reporting regulations; correction and removal reporting regulations; compliance with requirements for Unique Device Identification; and post-market surveillance activities and obligations. Device manufacturers must also comply with FDA requirements regarding promotion, which require that promotion is truthful, not misleading, fairly balanced, and that all claims are substantiated, and prohibit the promotion of products for unapproved or "off-label" uses.

Medical device manufacturers must demonstrate and maintain compliance with the FDA's QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of medical devices. The FDA enforces the QSR through periodic inspections and unannounced "for cause" inspections. In January 2024, the FDA issued a final rule amending the QSR to align more closely with the international consensus standard for Quality Management Systems for medical devices used by many other regulatory authorities around the world, ISO 13485:2016. The revised regulation is referred to as the Quality Management System Regulation (QMSR) and becomes effective on January 2, 2026. The FDA made conforming edits to the combination product regulation to clarify the device Quality Management System (QMS) requirements for combination products.

The FDCA permits medical devices intended for investigational use to be shipped to clinical sites if such devices comply with prescribed procedures and conditions. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of study review and approval, informed consent, recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators.

Failure to comply with applicable regulations could result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; inability to distribute products; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; FDA refusal to grant, or delay in obtaining, marketing authorizations; and in the most serious cases, criminal penalties.

Combination Products

A combination product is a product comprising two or more regulated components (e.g., a drug and device) that are combined into a single product, co-packaged, or sold separately but intended for co-administration, as evidenced by the labeling for the products. Drugs that are administered using a nebulizer or another device, such as ARIKAYCE or TPIP, are examples of drug/device combination products.

The FDA is divided into various Centers, which each have authority over a specific type of product. NDAs are reviewed by personnel within the Center for Drug Evaluation and Research, while device applications, premarket notifications, and de novo authorization requests are reviewed by the Center for Devices and Radiological Health. Combination products, such as drug/device combinations, are typically reviewed through a marketing submission that corresponds to the constituent part which provides the product's primary mode of action (PMOA), i.e., is the single mode of action that provides the most important therapeutic action of the combination product. If the PMOA is unclear or in dispute, a sponsor may file a Request for

Designation with the FDA's Office of Combination Products (OCP), which will render a determination and assign a lead Center. OCP generally assigns jurisdiction based on PMOA. If it is not possible to determine which one mode of action will provide a greater contribution than any other mode of action to the overall therapeutic effects of the combination product, the FDA makes a determination as to which Center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions. When there are no other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole, the agency will assign the combination product to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product.

When evaluating an application or other marketing submission for a combination product, a lead Center may consult other Centers, or it may assign review of a specific section of the application to another Center, delegating its review authority for that section. Depending on the type of combination product, approval or clearance could be obtained through submission of a single marketing application or through separate applications for the individual constituent parts (e.g., an NDA for the drug and a premarket notification for the device). The FDCA directs the FDA to conduct a review of a combination product under a single marketing application whenever appropriate. Applicants may choose to submit separate applications for constituent parts of a combination product (unless the FDA determines one application is necessary), and in limited situations, the FDA may determine an application for each constituent part is warranted. One reason to submit multiple applications is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product exclusivity. If multiple applications are submitted, each application is generally reviewed by the Center with authority over each application type. For combination products that contain an approved constituent part (such as a drug-device combination product in which the device has previously received clearance), the FDA may require that the application(s) include only such information as is necessary to meet the standard for clearance or approval, using a risk-based approach and taking into account any prior finding of safety or effectiveness for the approved constituent part.

Like their constituent products—e.g., drugs and devices—combination products are highly regulated and subject to a broad range of post marketing requirements including cGMP, adverse event reporting, periodic reports, labeling and advertising and promotion requirements and restrictions. Failure to comply with applicable requirements could result in enforcement actions.

Disclosure of Clinical Trial Information

Under US and certain foreign laws intended to improve clinical trial transparency, sponsors of clinical trials may be required to register and disclose certain information about their clinical trials. This can include information related to the investigational drug, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial. This information is then made publicly available. Under US regulations, sponsors are obligated to disclose the results of these trials after completion. In the US, disclosure of the results of these trials can be delayed for up to two years if the sponsor is seeking initial approval of the product or approval of a new indication. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Other Post-approval Regulatory Requirements

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements, including those relating to advertising, promotion, adverse event reporting, recordkeeping, and cGMP, as well as registration, listing, and inspection. There also are continuing, annual user fee requirements.

The FDA regulates the content and format of prescription drug labeling, advertising, and promotion, including direct-to-consumer advertising and promotional Internet communications. The FDA also establishes parameters for permissible non-promotional communications between industry and the medical community, including industry-supported scientific and educational activities. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion for uses not consistent with the approved labeling, and a company that is found to have improperly promoted off-label uses or otherwise not to have met applicable promotion rules may be subject to significant liability under the FDCA, the PHSA, and other statutes, including the False Claims Act.

Manufacturers are subject to requirements for adverse event reporting and submission of periodic reports following FDA approval of an NDA or BLA.

All aspects of pharmaceutical manufacture must conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the FDA inspects manufacturing facilities to assess compliance with cGMP. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use.

Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, product formulation, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA or NDA or BLA supplement, in some cases before the change may be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs or BLAs.

As previously mentioned, the FDA also may require Phase 4 studies and may require a REMS, which could restrict the distribution or use of the product.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (PDMA), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

European Union

Marketing Authorization Application

To obtain approval of a drug under the EU regulatory system, an application for a marketing authorization may be submitted under a centralized, a decentralized or a national procedure. The centralized procedure, which is compulsory for medicines produced by certain biotechnological processes or for orphan drugs, provides for the grant of a single marketing authorization that is valid for all EU member states, which grants the same rights and obligations in each member state as a national marketing authorization. As a general rule, only one marketing authorization may be granted for drugs approved through the centralized procedure and the marketing authorization is also relevant for the EEA countries.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (CHMP) is required to adopt an opinion on a valid application within 210 days, excluding clock stops when additional information is to be provided by the applicant in response to questions. More specifically, on day 80 of the procedure, the Rapporteur and Co-Rapporteur generate their draft assessment report. This is followed at day 120 by issuing to the applicant their formal report and a list questions. Applicants then have up to three months to respond to the questions (and can request a three-month extension). The Rapporteur, Co-Rapporteur and CHMP assess the applicant's replies and at day 150 generate their Joint Assessment Report. At day 180, the Joint Assessment Report along with a list of outstanding issues for unresolved matters (as needed) is provided to the applicant. Applicants then have one month to respond to the CHMP (and can request a one or two-month extension). At day 180 the CHMP can also request the involvement of a Scientific Advisory Group (SAG), where the applicant is given the opportunity to present data supporting the application and addressing the specific questions addressed by the CHMP to the SAG. If the outstanding issues remain, an oral explanation may be requested by the EMA, where the applicant must attend the CHMP plenary session and address the Major Objections related to approval of the marketing authorization application (MAA). The CHMP members can then question the applicant on the key issues. At day 210, once its scientific evaluation is completed, the CHMP gives a favorable or unfavorable opinion as to whether to grant the marketing authorization. After the adoption of the CHMP opinion, a decision must be adopted by the EC, after consulting the Standing Committee of the Member States. The EC prepares a draft decision and circulates it to the member states; if the draft decision differs from the CHMP opinion, the Commission must provide detailed explanations. The EC adopts a decision within 15 days of the end of the consultation procedure.

Accelerated Procedure, Conditional Approval and Approval Under Exceptional Circumstances

Various programs, including accelerated assessment, conditional approval and approval under exceptional circumstances, are intended to expedite or simplify the approval of drugs that meet certain qualifications. The purpose of these programs is to provide important new drugs to patients earlier than under standard approval procedures.

For drugs which are of major interest from the point of view of public health, in particular from the viewpoint of therapeutic innovation, applicants may submit a substantiated request for accelerated assessment. If the CHMP accepts the request, the review time is reduced from 210 to 150 days.

Furthermore, for certain categories of medicinal products, marketing authorizations may be granted on the basis of less complete data than is normally required in order to meet unmet medical needs of patients or in the interest of public health. In such cases, the company may request, or the CHMP may recommend, the granting of a marketing authorization, subject to certain specific obligations; such marketing authorization may be conditional or under exceptional circumstances. The timelines for the centralized procedure described above also apply with respect to applications for a conditional marketing authorization or marketing authorization under exceptional circumstances.

Conditional marketing authorizations may be granted for products designated as orphan medicinal products, if all of the following conditions are met: (1) the risk-benefit balance of the product is positive, (2) the applicant will likely be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs, and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

Conditional marketing authorizations are valid for one year, on a renewable basis until the holder provides a comprehensive data package. The granting of conditional marketing authorization depends on the applicant's ability to fulfill the conditions imposed within the agreed upon deadline. They are subject to "conditions", i.e., the holder is required to complete ongoing studies or to conduct new studies with a view to confirming that the benefit-risk balance is positive or to fulfill specific obligations in relation to pharmacovigilance. Once the holder has provided a comprehensive data package, the conditional marketing authorization is replaced by a 'regular' marketing authorization.

Marketing authorizations under exceptional circumstances may be granted where the applicant demonstrates that, for objective and verifiable reasons, they are unable to provide comprehensive data on the efficacy and safety of the drug under normal conditions of use. Such marketing authorizations are subject to certain conditions, in particular relating to safety of the drug, notification of incidents relating to its use or actions to be taken. They are valid for an indefinite period of time, but the conditions upon which they are based are subject to an annual reassessment in order to ensure that the risk-benefit balance remains positive.

Exclusivities

If an approved drug contains a new active substance, it is protected by data exclusivity for eight years from the notification of the Commission decision granting the marketing authorization and then by marketing protection for an additional two or three years. Overall, the drug is protected for ten or eleven years against generic competition, and no additional exclusivity protection is granted for any new development of the active substance it contains.

During the eight-year period of data exclusivity, competitors may not refer to the marketing authorization dossier of the approved drug for regulatory purposes. During the period of marketing protection, competitors may not market their generic drugs. The period of marketing protection is normally two years but may become three years if, during the eight-year data exclusivity period, a new therapeutic indication is approved that is considered as bringing a significant clinical benefit over existing therapies.

Medical Devices Regulations

In May 2017, the EU adopted a new Medical Devices Regulation (EU) 2017/745 (MDR), which repealed and replaced Directive 93/42/EEC on Medical Devices (Directive 93/42) on May 26, 2021. The MDR and its associated guidance documents and harmonized standards, govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance.

As of May 26, 2021, before a device can be placed on the market in the EU, compliance with the MDR requirements (i.e., the General Safety and Performance Requirements, or GSPRs, set out in Annex I of the MDR) must be demonstrated in order to affix the Conformité Européene mark, or CE Mark, to the product. The MDR provides recourse to harmonized European standards in order to facilitate compliance with the GSPRs. Harmonized standards provide a presumption of conformity with the GSPRs (although there are a limited number of standards harmonized currently). However, under transitional provisions provided for in the MDR, medical devices with Notified Body certificates issued under Directive 93/42 prior to May 26, 2021 may continue to be placed on the market for the remaining validity of the certificate, until December 31, 2027 at the latest for higher risk medical devices and until December 31, 2028 for other medical devices, in each case, so long as there is no significant changes in the design or intended purpose. After the expiry of any applicable transitional period, only devices that have been CE marked under the MDR may be placed on the market in the EU.

To demonstrate compliance with these requirements, a conformity assessment procedure is required. The MDR provides for several conformity assessment procedures, which depends on the type of medical device and the risks involved. Devices are divided in four groups based on risk: Class I, Class IIa, Class IIb, and Class III. Class I devices present the lowest level of risk so that, for most of these devices (other than those that are sterile and/or have measuring functionality) the manufacturer can self-certify the product plus affix the CE mark. For the other classes, the conformity assessment is carried out by an organization designated and supervised by a member state of the EEA to conduct conformity assessments, known as a Notified Body. The manufacturer initially classifies every device. However, when a device undergoes a conformity assessment with a Notified Body, the Notified Body may dispute the classification and assert that the device should be included in a class requiring stricter conformity assessment procedures. Specific rules apply to custom-made medical devices, medical devices that are used in clinical trials, and medical devices that incorporate a medicinal ingredient.

For classes of devices other than Class I, the Notified Body carries out the conformity assessment and issues a certificate of conformity, which entitles the manufacturer to affix the CE mark to its devices after having prepared and signed a related EU Declaration of Conformity. Affixing a CE mark allows the product to move freely within the EU and thus prevents EU Member States from restricting sales and marketing of the devices, unless such measure is justified on the basis of evidence of non-compliance. Ultimately, the manufacturer is responsible for the conformity of the device with the GSPRs and for the affixing of the CE mark. Lamira is CE marked by PARI, i.e., its manufacturer, in the EU.

Clinical evidence is required for most medium and high risk devices. In some cases, a clinical study may be required to support a CE marking application. A manufacturer that wishes to conduct a clinical study involving the device is subject to the clinical investigation requirements of the MDR, EU member state requirements, and current good clinical practices defined in harmonized standards and guidance documents.

After a device is placed on the market, it remains subject to significant regulatory requirements. The MDR prohibits misleading claims about devices and so devices may be marketed only for the uses and indications for which they are approved (although more detailed rules on marketing may be contained in national legislation). For CE marked devices, certain modifications to the device or quality system depending on the conformity assessment procedure used must be submitted to and approved by the Notified Body before placing the modified device on the market.

Economic Operators, include device manufactures, must register their establishments and devices in the EUDAMED database once available. Manufacturers of medical devices are subject to vigilance obligations that require reporting of incidents and are required to implement a post-marketing surveillance system (for monitoring data about the device and confirming the benefits of the device outweigh the risks). The vigilance obligations require that manufacturers must report serious incidents involving the device made available in the EU and any field safety corrective actions in respect of the device made available in the EU (including actions taken outside the EU) to relevant competent authorities. In addition, Notified Bodies regularly reassess the conformity of a medical device to the GSPRs and may from time to time audit the manufacturer and may, where needed, suspend or withdraw the manufacturer's certificate of conformity.

Japan

Under the Japanese regulatory system administered by the MHLW and the PMDA (which is responsible for product review and evaluations under the supervision of the MHLW), in principle, pre-marketing approval and clinical studies are required for all pharmaceutical products. The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960) requires a license for marketing authorization when importing to Japan and selling pharmaceutical products manufactured in other countries, a holder of such license is referred to as a marketing authorization holder. It also requires a foreign manufacturer to get each of its manufacturing sites certified as a manufacturing site of pharmaceutical products to be marketed in Japan. To receive a license for marketing authorization, the manufacturer or seller must, at the very least, employ certain manufacturing marketing, quality and safety personnel. A license for marketing authorization may not be granted if the quality management methods and post marketing safety management methods applied with respect to the pharmaceutical product fail to conform to the standards stipulated in the ordinances promulgated by the MHLW. To obtain manufacturing/marketing approval for a new product, a Company must submit an application for approval to the MHLW with results of CMC, nonclinical and clinical studies to show the quality, efficacy and safety of the product candidate. A data compliance review, on-site inspection for good clinical practice, audit and detailed data review for compliance with current good manufacturing practices are undertaken by the PMDA. The application is then discussed by the committees of the Pharmaceutical Affairs and Food Sanitation Council. Based on the results of these reviews, the final decision on approval is made by the MHLW. The time required for the approval process varies depending on the product. PMDA's target review period (submission to approval) is twelve months (standard review) and nine months (priority review), although this is not a commitment. The product also needs approval for pricing in order to be eligible for reimbursement under Japan's National Health Insurance system. The medical products which, once they are approved and marketed, are subject to the continuing standards of Good Manufacturing Practice and Good Quality Practice and are also subject to regular post-marketing vigilance of safety and quality under the standards of Good Vigilance Practice and Good Post-marketing Study Practice. In Japan, the National Health Insurance system maintains a Drug Price List specifying which pharmaceutical products are eligible for reimbursement, and the MHLW sets the prices of the products on this list. After receipt of marketing approval, negotiations regarding the reimbursement price with the MHLW would begin. Price would be determined within 60 to 90 days following receipt of marketing approval unless the applicant disagrees, which may result in extended pricing negotiations. The government is currently introducing price cut rounds every year and mandates price decreases for specific products. New products judged innovative or useful, that are indicated for pediatric use, or that target orphan or small population diseases, however, may be eligible for a pricing premium. Price revisions after product launch based on Health Technology Assessment (HTA) and Cost-Effectiveness Analysis (CEA) were introduced in 2019. Products meeting the relevant criteria may have their prices adjusted according to the outcomes of the HTA/CEA evaluation. Additionally, certain rules for post-launch price reductions, such as Repricing for Market Expansion, are also applied. The government has also promoted the use of generics, where available.

Pediatric Information

United States

Under the Pediatric Research Equity Act of 2003 (PREA), as amended, certain NDAs, BLAs, and supplements must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may, on its own initiative or at the request of an applicant, grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, and subject to an exception for certain oncology drugs, PREA does not apply to any drug for an indication for which orphan designation has been granted. Under the Best Pharmaceuticals for Children Act (BPCA), pediatric research is incentivized by the possibility of six months of pediatric exclusivity, which if granted, is added to existing statutory and patent-based exclusivity periods listed for the applicable drug in the FDA's Orange Book at the time the FDA determines that the sponsor has satisfied the FDA's "written request" for pediatric research, provided that the FDA makes such determination at least nine months before the expiration of such exclusivity period. Sponsors may seek to negotiate the terms of a written request during drug development. While the sponsor of an orphan-designated drug may not be required to perform pediatric studies under PREA unless one of the above exceptions applies, they are eligible to participate in the incentives under the BPCA if the FDA issues a written request.

European Union

In the EU, new drugs (i.e., drugs containing a new active substance) for adults must also be tested in children.
This can also include pediatric pharmaceutical forms, in all subsets of the pediatric population. The mandatory pediatric testing is carried out through the implementation of a pediatric investigation plan (PIP), which is proposed by the applicant and approved by the EMA. A PIP contains all the studies to be conducted and measures to be taken in order to support the approval of the new drug, including pediatric pharmaceutical forms, in all subsets of the pediatric population. Implementation of a PIP is a prerequisite to validation of an MAA. Following granting of the marketing authorization, post approval compliance is also reviewed through the life cycle of the product until the PIP is completed. A PIP may allow for one or more waivers or deferral for one or more of the studies or measures included therein in order not to delay the approval of the drug in adults, and, on another hand, the EMA may grant either a product-specific waiver for the (adult) disease/condition or one or more pediatric subsets or a class waiver for the disease/condition. PIPs are subject to potential modifications from time to time, when they no longer are workable, if approved by EMA. Any new indication as a variation to an existing marketing authorization requires a new PIP for that indication. In the case of orphan medicinal products, completion of an approved PIP can result in an extension of the market exclusivity period from ten to twelve years. To benefit from the additional exclusivity the PIP must be completed and content from the PIP must be included in the approved summary of product characteristics.

Japan

In Japan, there is no statutory rule which imposes any different obligation on pharmaceutical manufacturers engaging in pediatric drug development than on other pharmaceutical manufacturers. However, the guidelines of the MHLW (Handling of Pharmaceuticals during the Reexamination Interval Period (Issue No. 107, February 1, 1999) and Enforcement of the Ministerial Ordinance Partially Revising the Ministerial Ordinance on Standards for Post-marketing Surveillance of Pharmaceutical Products and Review of Post-marketing Surveillance for the Reexamination of Pharmaceutical Products (No. 1324, December 27, 2000)) state as follows: (i) since information on pediatric patients obtained in clinical trials may be limited, the MHLW recommends that pharmaceutical manufacturers conduct adequate post-marketing surveillance during the reexamination interval period and collect as much information as possible for proper use of drugs for pediatric patients; and (ii) if a pharmaceutical manufacturer plans to conduct a clinical trial to set the dose of a pediatric drug to prepare application for manufacturing/marketing approval or after receiving the same approval, the reexamination interval period may be extended up to ten years. The notification of MHLW (Partial Revision of Handling of Reexamination Period (Issue No. 0116/3, January 16, 2024)) states that ten years will be applied as the reexamination period for the “addition of clearly different dosage such as pediatric doses.” In addition, since February 2010 the MHLW has convened a study group composed of physicians on a regular basis to discuss and promote the development of children’s drugs that have been approved for use in Europe and the US but are not yet approved in Japan, so that they can be used as early as possible in Japan as well.

Regulation Outside the US, Europe and Japan

In addition to regulations in the US, Europe and Japan, we will be subject to a variety of regulations in other jurisdictions governing clinical studies of our candidate products, including medical devices. Regardless of whether we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of countries outside the US before we can commence clinical studies or marketing of the product candidate in those countries. The requirements for approval and the approval process vary from country to country, and the time may be longer or shorter than that required for FDA approval. Under certain harmonized medical device approval/clearance regulations outside the US, reference to US clearance permits fast-tracking of market clearance. Other regions are harmonized with EU standards, and therefore recognize the CE mark as a declaration of conformity to applicable standards. Furthermore, we must obtain any required pricing approvals in addition to regulatory approval prior to launching a product candidate in the approving country. Although the UK is no longer part of the EU, its medicinal product and medical device regulations remain broadly aligned with the EU requirements.

Early Access Programs (EAPs)

Certain countries allow the supply or use of non-authorized medicinal products within strictly regulated EAPs. Some may also provide reimbursement for drugs provided in the context of EAPs. Under EU law, member states are authorized to adopt national legal regimes for the supply or use of non-authorized drugs in case of therapeutic needs. The most common national legal regimes are compassionate use programs and named-patient sales, but other national regimes for early access may be available, depending on the member state. For drugs that must be approved through the centralized procedure, such as orphan drugs, compassionate use programs are also regulated at the European level. ARIKAYCE is available in certain countries under these early access programs.

Special programs can be set up to make available to patients with an unmet medical need a promising drug which has not yet been authorized for their condition (compassionate use). As a general rule, compassionate use programs can only be put in place for drugs or biologics that are expected to help patients with life-threatening, long-lasting or seriously disabling illnesses who currently cannot be treated satisfactorily with authorized medicines, or who have a disease for which no medicine has yet been authorized. The compassionate use route may be a way for patients who cannot enroll in an ongoing clinical trial to obtain treatment with a potentially life-saving medicine. Compassionate use programs are coordinated and implemented by the EU member states, which decide independently how and when to open such programs according to national rules and legislation. These programs are mainly used to treat a group or cohort of patients. Generally, doctors who wish to obtain a promising drug for their seriously ill patients will need to contact the relevant national authority in their respective country and follow the procedure that has been set up. Typically, the national authority keeps a register of the patients treated with the drug within the compassionate use program, and a system is in place to record any side effects reported by the patients or their doctors. Orphan drugs very often are subject to compassionate use programs due to their very nature (rare diseases are life-threatening, long-lasting or seriously disabling diseases) and the long time required for both their approval and effective marketing.

Doctors can also obtain certain drugs for their patients by requesting a supply of a drug from the manufacturer or a pharmacist located in another country, to be used for an individual patient under their direct responsibility. This is often called treatment on a 'named-patient basis' and is distinct from compassionate use programs. For access via named-patient such medicine should, or must (depending on legislation) be authorized in at least one country, from which it can be imported into the patient’s country under a named-patient access program. In this case, the doctor responsible for the treatment will either contact the manufacturer directly or issue a prescription to be fulfilled by a pharmacist. While manufacturers or pharmacists do record what they supply, there is no central register of the patients that are being treated in this way.

Reimbursement of Pharmaceutical Products

In the US, many independent third-party payors, as well as the Medicare and state Medicaid programs, reimburse dispensers of pharmaceutical products. Medicare is the federal program that provides healthcare benefits to senior citizens and certain disabled and chronically ill persons. Medicaid is the need-based federal and state program administered by the states to provide healthcare benefits to certain persons.

As one of the conditions for obtaining Medicaid and, if applicable, Medicare Part B coverage for our marketed pharmaceutical products, we will need to agree to pay a rebate to state Medicaid agencies that provide reimbursement for those products. We will also have to agree to sell our commercial products under contracts with the Department of Veterans Affairs, Department of Defense, Public Health Service, and numerous other federal agencies as well as certain hospitals that are designated by federal statutes to receive drugs at prices that are significantly below the price we charge to commercial pharmaceutical distributors. These programs and contracts are highly regulated and will impose restrictions on our business. Failure to comply with these regulations and restrictions could result in adverse consequences such as civil money penalties, imposition of a Corporate Integrity Agreement and/or a loss of Medicare and Medicaid reimbursement for our drugs.

Private healthcare payors also attempt to control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered.

In August 2022, President Biden signed the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) into law. This law will, for the first time, allow Medicare to negotiate the price of certain high expenditure, single source Medicare Part B or Part D drugs. The Centers for Medicare & Medicaid Services has implemented a Medicare Drug Price Negotiation Program, and this program may affect future Medicare reimbursement for our drugs. The IRA also requires manufacturers of certain Part B and Part D drugs to issue to the US Department of Health and Human Services (HHS) rebates based on certain calculations and triggers (i.e., when drug prices increase and outpace the rate of inflation) which may influence the pricing of current and future products. Drug pricing is an active area for regulatory reform at both the federal and state levels, and additional significant changes to current drug pricing and reimbursement structures in the US could be forthcoming.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of drugs through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to patients. Some jurisdictions operate positive and negative list systems under which drugs may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for drugs, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new drugs. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drugs will allow favorable reimbursement and pricing arrangements for any of our products.

In Japan, drugs can be sold on the market if they undergo the PMDA's review of quality, efficacy and safety and receive manufacturing/marketing approval. However, in order for drugs to be covered by the National Health Insurance, they must be included in a Drug Price List. The "Drug Pricing Organization," which is a division of the Central Social Insurance Medical Council (CSIMC), calculates the price of drugs, the general meeting of the CSIMC approves the calculated price, and the MHLW includes the drugs and the calculated price in the Drug Price List. After receiving manufacturing/marketing approval, drugs are included in the Drug Price List within 60 to 90 days unless the applicant disagrees, which may result in extended pricing negotiations. The MHLW updates the Drug Price List annually after taking into account the survey result of the actual sales price of drugs and hearing the opinion of the CSIMC.

Fraud and Abuse and Other Laws

Physicians and other healthcare providers and third-party payors (government or private) often play a primary role in the recommendation and prescription of healthcare products. In the US and most other jurisdictions, numerous detailed requirements apply to government and private healthcare programs, and a broad range of fraud and abuse laws, transparency laws, and other laws are relevant to pharmaceutical companies. US federal and state healthcare laws and regulations in these areas include the following:

- The federal Anti-kickback Statute;
- The federal civil False Claims Act;
- The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act;
- The federal criminal false statements statute;
- The price reporting requirements under the Medicaid Drug Rebate Program and the Veterans Health Care Act of 1992;
- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program; and
- Analogous and similar state laws and regulations.

Similar restrictions apply in the member states of the EU and Japan, which have been set out by laws or industry codes of conduct.

Employees

As of December 31, 2024, we had a total of 1,271 full-time employees: 579 in research, clinical, regulatory, medical affairs and quality assurance; 89 in technical operations, manufacturing and quality control; 210 in general and administrative functions; and 393 in commercial activities. We had 1,007 full-time employees in the US, 153 employees in Europe and 111 employees in Japan. We anticipate increasing our headcount in 2025.

None of our employees are represented by a labor union and we believe that our relations with our employees are generally good. Generally, our US employees are at-will employees; however, we have entered into employment agreements with certain of our executive officers.

Human Capital

Employee Attraction, Retention and Development

We are dedicated to attracting and retaining the best possible talent. Our compensation program, including short- and long-term incentives and benefits, is designed to allow us to attract and retain individuals whose skills are critical to our current and long-term success. Total compensation is generally positioned within a competitive range of the peer market median, with differentiation based on market benchmarks, experience, skills, proficiency, and performance to attract and retain key talent. With our compensation program, we also aim to align the interests of our employees with those of our stockholders.

We believe that continued growth and development are essential to the professional well-being of our team. We seek to develop our employee talent within the organization through access to internal and external training, continuous learning programs and other development initiatives. As our organization and capabilities grow, we aim to ensure we have provided our team members with the guidance and resources they need to develop as professionals and to support our business.

Our Values

Five core values—collaboration, accountability, passion, respect, and integrity—set the tone for our culture and guide the actions we take each day. We strive to ensure that these values drive all of our human capital endeavors, including hiring, our annual employee feedback process, our Global Core Competencies, our Recognition Program, and our employee onboarding initiatives.

We are focused on maintaining an inclusive work environment that best supports the varied needs of the patient communities we serve. W e continue to grow our list of employee resource groups, adding two in 2024, and expand our sourcing for new talent to enhance our talent pipeline. We are also committed to equitable pay for all employees. We use industry benchmarks and annual internal equity reviews to make salary adjustments as needed in efforts to ensure a fair and bias-free compensation system. As we grow, we are continuing to implement initiatives to advance the development of our talent and ensure comprehensive succession plans both in our employee workforce and our board of directors.

As part of our effort to further the integration of our values across our business, in 2024, we hired a director of sustainability, with centralized responsibility for our Responsibility Report and sustainability efforts. This individual, together with members of our executive leadership, updates our Nominations and Governance Committee and Board of Directors on sustainability considerations and strategy. We are cognizant of our environmental impact, currently support several green measures and community service programs, and continue to explore options to improve and build upon our sustainability efforts. We are committed to ensuring the health and well-being of our employees and promoting patient advocacy and safety. Finally, we are driven by integrity and believe good corporate governance is important and necessary to maintain ethical and compliant business practices. In 2024, we published our second Responsibility Report.

Available Information

We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (Exchange Act). We make available on our website at http://www.insmed.com, free of charge, copies of these reports as soon as reasonably practicable after filing, or furnishing them to, the SEC. The public can also obtain materials that we file with the SEC through the SEC's website at http://www.sec.gov.

Also available through our website's "Investors-Corporate Governance" page are charters for the Audit, Compensation, Nominations and Governance and Science and Technology Committees of our board of directors, our Corporate Governance Guidelines, and our Code of Business Conduct and Ethics. We intend to satisfy the disclosure requirements regarding any amendment to, or waiver from, a provision of the Code of Business Conduct and Ethics by making disclosures concerning such matters available on our website.

The references to our website and the SEC's website are intended to be inactive textual references only. Neither the information in or that can be accessed through our website, nor the contents of the SEC's website, are incorporated by reference in this Annual Report on Form 10-K.

Financial Information

The financial information required under this Item 1 is incorporated herein by reference to Item 8 of this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

Our business is subject to substantial risks and uncertainties. Any of the risks and uncertainties described below, either alone or taken together, could materially and adversely affect our business, financial condition, results of operations, prospects for growth, and the value of an investment in our common stock. In addition, these risks and uncertainties could cause actual results to differ materially from those expressed or implied by forward-looking statements contained in this Annual Report on Form 10-K (please read the Cautionary Note Regarding Forward-Looking Statements appearing at the beginning of this Annual Report on Form 10-K).

Risk Factor Summary

An investment in our securities is subject to various risks, the most significant of which are summarized below.

- Our prospects are highly dependent on the success of our only approved product, ARIKAYCE. If we are unable to continue to successfully market and commercialize or maintain approval for ARIKAYCE, our business, financial condition, results of operations and prospects and the value of our common stock will be materially adversely affected.
- We may not be able to obtain regulatory approvals for brensocatib, TPIP, or for our other product candidates and we may not be able to receive approval for ARIKAYCE in front-line NTM lung disease or in new markets. Any such failure to obtain regulatory approvals, particularly for brensocatib in the US, may materially adversely affect us.
- The commercial success of ARIKAYCE depends on continued market acceptance by physicians, patients, third-party payors and others in the healthcare community, and the commercial success of brensocatib, TPIP, or our other product candidates, if approved, will similarly depend on such market acceptance.
- We obtained regulatory approval of ARIKAYCE in the US through an accelerated approval process, and full approval will be contingent on successful and timely completion of a confirmatory post-marketing clinical trial.
- We remain subject to substantial, ongoing regulatory requirements related to ARIKAYCE, and failure to comply with these requirements could lead to enforcement action or otherwise materially harm our business.
- If we are unable to obtain or maintain adequate reimbursement from government or third-party payors for ARIKAYCE or, if approved, brensocatib, TPIP, or our other product candidates, or if we are unable to obtain or maintain acceptable prices for ARIKAYCE, or, if approved, brensocatib, TPIP, or our other product candidates, our prospects for generating revenue and achieving profitability will be materially adversely affected.
- ARIKAYCE, brensocatib, TPIP, or our other product candidates could develop unexpected safety or efficacy concerns, which could have a material adverse effect on us.
- If estimates of the size of the potential markets for ARIKAYCE, brensocatib, TPIP, or our other product candidates are overstated or data we have used to identify physicians is inaccurate, our ability to earn revenue to support our business could be materially adversely affected.
- We may not be successful in clinical trials or in obtaining regulatory approvals required to expand the indications for ARIKAYCE, which may materially adversely affect our prospects and the value of our common stock.
- Pharmaceutical research and development is very costly and highly uncertain, and we may not succeed in developing product candidates in the future.
- Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, may be interpreted differently if additional data are disclosed, and are subject to audit and verification procedures that could result in material changes in the final data.
- Failure to obtain or maintain regulatory approval or clearance of our product devices, including Lamira, as a delivery system for ARIKAYCE, and the dry powder delivery system for TPIP, could materially harm our business.
- If our clinical studies do not produce positive results or our clinical trials are delayed, or if serious side effects are identified during drug development, we may experience delays, incur additional costs and ultimately be unable to obtain regulatory approval for and commercialize our product candidates in the US, Europe, Japan or other markets.
- We may not be able to enroll enough patients to conduct and complete our clinical trials or retain a sufficient number of patients in our clinical trials to generate the data necessary for regulatory approval of our product candidates or to permit the use of ARIKAYCE in the broader population of patients with MAC lung disease.
- If another party obtains orphan drug exclusivity for a product that is considered the same or essentially the same as a product we are developing for a particular indication, we may be precluded or delayed from commercializing the product in that indication.
- Our pre-clinical research activities include the research and development of novel gene therapy product candidates. It will be difficult to predict the time and cost of development and of subsequently obtaining regulatory approval for any such product candidates, or how long it will take to commercialize any gene therapy product candidates.
- If we are unable to form and sustain relationships with third-party service providers that are critical to our business, or if any third-party arrangements that we may enter into are unsuccessful, our ability to develop and commercialize our products may be materially adversely affected.
- We may not have, or may be unable to obtain, sufficient quantities of ARIKAYCE, Lamira or our product candidates to meet our required supply for commercialization or clinical studies, which would materially harm our business.

- Adverse consequences to our business could result if we and our manufacturing partners fail to comply with applicable regulations or maintain required approvals.
- We are dependent upon retaining and attracting key personnel, the loss of whose services could materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.
- We expect to continue to expand our development, regulatory and sales and marketing capabilities, and as a result, may encounter difficulties in managing our growth, which could disrupt our operations.
- Any acquisitions we make, or collaborative relationships we enter into, may not be clinically or commercially successful, and may require financing or a significant amount of cash, which could adversely affect our business.
- Our business and operations, including our drug development and commercialization programs, could be materially disrupted and/or subject to reputational harm in the event of system failures, security breaches, cyber-attacks, deficiencies in our cybersecurity, violations of data protection laws or data loss or damage by us or third parties.
- We are subject to data privacy laws and regulations that govern how we can collect, process, store and transfer personal data, and violations can result in meaningful penalties, enforcement, and/or reputational harm and have a significant impact on our operations.
- We have limited experience operating internationally, are subject to a number of risks associated with our international activities and operations and may not be successful in any efforts to further expand internationally.
- We have a limited number of significant customers and losing any of them could have an adverse effect on our financial condition and results of operations.
- Deterioration in general economic conditions in the US, Europe, Japan and globally, including the effect of prolonged periods of inflation on our suppliers, third-party service providers and potential partners, could harm our business and results of operations.
- If we are unable to adequately protect our intellectual property rights, the value of ARIKAYCE and our product candidates could be materially diminished.
- If we fail to comply with obligations in our third-party agreements, our business could be adversely affected, including as a result of the loss of license rights that are important to our business.
- Government healthcare reform could materially increase our costs, which could materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.
- If we fail to comply with applicable laws, including "fraud and abuse" laws, anti-corruption laws and trade control laws, we could be subject to negative publicity, civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.
- We have a history of operating losses, expect to incur operating losses for the foreseeable future and may never achieve or maintain profitability.
- We may need to raise additional funds to continue our operations, and any failure to obtain capital when needed on acceptable terms, or at all, could force us to delay, reduce or eliminate our development programs, commercialization efforts, or other operations.
- We have outstanding indebtedness in the form of convertible senior notes, a term loan and a royalty financing arrangement and may incur additional indebtedness in the future, which could adversely affect our financial position, prevent us from implementing our strategy, and dilute the ownership interest of our existing shareholders.
- We may be unable to use certain of our net operating losses and other tax assets.
- Goodwill impairment charges in the future could have a material adverse effect on our business, results of operations and financial condition.
- Our shareholders may experience dilution of their ownership interests because of the future issuance of additional shares of our common stock for general corporate purposes and upon the conversion of the 2028 Convertible Notes.
- Certain provisions of Virginia law, our articles of incorporation and amended and restated bylaws and arrangements between us and our employees could hamper a third party’s acquisition of us or discourage a third party from attempting to acquire control of us.

Risks Related to the Commercialization and Continued Approval of ARIKAYCE, and the Potential Approval and Commercialization of Brensocatib and TPIP

Our prospects are highly dependent on the continued success of our only approved product, ARIKAYCE, which was approved in the United States as ARIKAYCE (amikacin liposome inhalation suspension), in Europe as ARIKAYCE Liposomal 590 mg Nebuliser Dispersion and in Japan as ARIKAYCE inhalation 590mg (amikacin sulfate inhalation drug product). If we are unable to continue to successfully market and commercialize or maintain approval for ARIKAYCE, our business, financial condition, results of operations and prospects and the value of our common stock will be materially adversely affected.

Our long-term viability and growth depend on the continued successful commercialization of ARIKAYCE, our only approved product. ARIKAYCE was approved in the US for the treatment of MAC lung disease as part of a combination

antibacterial drug regimen for adult patients with limited or no alternative treatment options in a refractory setting, as defined by patients who do not achieve negative sputum cultures after a minimum of six consecutive months of a multidrug background regimen therapy. Subsequently, ARIKAYCE was approved in Europe for the treatment of NTM lung infections caused by MAC in adults with limited treatment options who do not have CF, and in Japan for the treatment of patients with NTM lung disease caused by MAC who did not sufficiently respond to prior treatments with a multidrug regimen. We refer to NTM lung disease caused by MAC as MAC lung disease. We have invested and continue to invest significant efforts and financial resources in the commercialization of ARIKAYCE, and our ability to continue to generate revenue from ARIKAYCE will depend heavily on successfully commercializing and obtaining full regulatory approval for ARIKAYCE from the FDA by conducting an appropriate confirmatory post-marketing study. ARIKAYCE was our first commercial launch, and its continued successful commercialization and our receipt of full regulatory approval for ARIKAYCE in the US are subject to many risks.

In order to continue to commercialize ARIKAYCE, we must continue to establish and maintain marketing, market access, sales and distribution capabilities on our own or make arrangements with third parties for its marketing, sale and distribution. We are commercializing ARIKAYCE in the US, Europe and Japan using our sales force, but we may not continue to be successful in these efforts. The establishment, development and maintenance of our own sales force is and will continue to be expensive and time-consuming. As a result, we may seek one or more partners to handle some or all of the sales and marketing of ARIKAYCE in certain markets following approval by the relevant regulatory authority in those markets. In that case, we will be reliant on third parties to successfully commercialize ARIKAYCE and will have less control over commercialization efforts than if we handled commercialization with our own sales force. However, we may not be able to enter into arrangements with third parties to sell ARIKAYCE on favorable terms or at all. In the event that either our own marketing, market access, sales force or third-party marketing, and sales organizations are not effective, our ability to generate revenue would be adversely affected.

We may not be able to obtain regulatory approvals for brensocatib, or for our other product candidates and we may not be able to receive approval for ARIKAYCE in front-line NTM lung disease or in new markets. Any such failure to obtain regulatory approvals, particularly for brensocatib, may materially adversely affect us.

We are required to obtain various regulatory approvals prior to studying our products in humans and then again before we market and distribute our products, and the failure to obtain such approvals will prevent us from commercializing our products, which would materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock. While we have obtained accelerated approval for ARIKAYCE in the US and approval in the EU and Japan, seeking regulatory approvals for brensocatib and any future regulatory approvals for our other product candidates as well as approval for ARIKAYCE in front-line NTM lung disease or in other jurisdictions presents significant obstacles. Approval processes in the US, Europe, Japan and other markets require the submission of extensive preclinical and clinical data, manufacturing and quality information regarding the process and facility, scientific data characterizing our product and other supporting data in order to establish safety and effectiveness. These processes are complex, lengthy, expensive, resource intensive and uncertain. Regulators will also conduct a rigorous review of any trade name we intend to use for our products. Even after they approve a trade name, these regulators may request that we adopt an alternative name for the product if adverse event reports indicate a potential for confusion with other trade names and medication error. If we are required to adopt an alternative name, potential commercialization of brensocatib or our other product candidates could be delayed or continued commercialization of ARIKAYCE could be delayed or interrupted. We have limited experience in submitting and pursuing applications necessary to obtain these regulatory approvals.

Data submitted to regulators are subject to varying interpretations that could delay, limit or prevent regulatory agency approval. Even if we believe our clinical trial results are promising, regulators may disagree with our interpretation of data, study design or execution and may refuse to accept our application for review or decline to grant approval.

In addition, the grant of a designation by the FDA or EMA or approval by the FDA, EC or MHLW does not ensure a similar decision by the regulatory authorities of other countries, and a decision by one foreign regulatory authority does not ensure regulatory authorities in other foreign countries or the FDA will agree with the decision. For instance, although ARIKAYCE received orphan drug designation in the US, ARIKAYCE did not qualify for orphan drug designation in Japan due to the estimated number of NTM patients in Japan exceeding 50,000. Similarly, clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval procedures vary among countries and can involve additional product testing, including additional preclinical studies or clinical trials, and administrative review periods. The time required to obtain approval in these other territories might differ from that required to obtain FDA approval. We may never obtain approval for brensocatib or for our other product candidates in the US or other jurisdictions, or for ARIKAYCE outside of the US, Europe and Japan, which would limit our market opportunities and materially adversely affect our business. Even if brensocatib or another product candidate is approved, or if ARIKAYCE is approved outside of the US, Europe and Japan, regulators may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval.

We may also encounter delays or rejections based on changes in regulatory agency policies during the period in which we develop a product and the period required for review of any application for regulatory agency approval of a particular

product. Resolving such delays could force us or third parties to incur significant costs, limit our allowed activities or the allowed activities of third parties, diminish any competitive advantages that we or our third parties may attain or adversely affect our ability to receive royalties, any of which could materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

The commercial success of ARIKAYCE depends on continued market acceptance by physicians, patients, third-party payors and others in the healthcare community and the commercial success of brensocatib, TPIP, or our other product candidates, if approved, will similarly depend on market acceptance.

Despite receiving FDA, EC and Japan's MHLW approval of ARIKAYCE, market acceptance may vary among physicians, patients, third-party payors or others in the healthcare community. ARIKAYCE was the first product approved in the US via the LPAD pathway, and its approval under this pathway may impact market acceptance of the product. The degree of market acceptance of ARIKAYCE, which we launched in the US early in the fourth quarter of 2018, in Europe in the fourth quarter of 2020, and in Japan in the second quarter of 2021, is also dependent on a number of additional factors, including the following:

- The willingness of the target patient populations to use, and of physicians to prescribe, ARIKAYCE;
- The efficacy and potential advantages of ARIKAYCE over alternative treatments;
- The risk and safety profile of ARIKAYCE, including, among other things, physician and patient concern regarding the US boxed warning and other safety precautions resulting from its association with an increased risk of respiratory adverse reactions, and any adverse safety information that becomes available as a result of longer-term use of ARIKAYCE;
- Relative convenience and ease of administration, including any requirements for hospital administration of ARIKAYCE;
- The ability of the patient to tolerate ARIKAYCE;
- The pricing of ARIKAYCE;
- The ability and willingness of the patient to pay out of pocket costs for ARIKAYCE (for example co-payments);
- Sufficient third-party insurance coverage and reimbursement;
- The strength of marketing and distribution support and timing of market introduction of competitive products and treatments; and
- Publicity concerning ARIKAYCE or any potential competitive products and treatments.

Our efforts to educate physicians, patients, third-party payors and others in the healthcare community on the benefits of ARIKAYCE have required and will continue to require significant resources, which may be greater than those required to commercialize more established technologies and these efforts may never be successful. If approved, the market acceptance of brensocatib, TPIP, or our other product candidates may vary among physicians, patients, third-party payors or others in the healthcare community and will depend on substantially similar factors.

We obtained regulatory approval of ARIKAYCE in the US through an accelerated approval process, and full approval will be contingent on successful and timely completion of a confirmatory post-marketing clinical trial. Failure to obtain full approval or otherwise meet our post-marketing requirements and commitments would have a material adverse effect on our business.

The FDA approved ARIKAYCE under the LPAD and accelerated approval pathways, and full approval will be based on results from a post-marketing confirmatory clinical trial. Accelerated approval allows drugs that (i) are being developed to treat a serious or life-threatening disease or condition and (ii) provide a meaningful therapeutic benefit over existing treatments to be approved substantially based on an intermediate endpoint or a surrogate endpoint that is reasonably likely to predict clinical benefit, rather than a clinical endpoint such as survival or irreversible morbidity. Accelerated approval of ARIKAYCE was supported by preliminary data from the Phase 3 CONVERT study, which evaluated the safety and efficacy of ARIKAYCE in adult patients with refractory MAC lung disease, using achievement of sputum culture conversion (defined as three consecutive negative monthly sputum cultures) by Month 6 as the primary endpoint.

As a condition of accelerated approval, we must conduct a post-marketing confirmatory clinical trial. Additionally, we are required to submit periodic reports on the progress of this clinical trial. In the fourth quarter of 2020, we commenced the post-marketing confirmatory clinical trial program for ARIKAYCE in patients with MAC lung disease. The confirmatory clinical trial program consists of the ARISE trial, an interventional study designed to validate cross-sectional and longitudinal characteristics of a PRO tool in MAC lung disease, and the ENCORE trial, designed to establish the clinical benefits and evaluate the safety of ARIKAYCE in patients with newly diagnosed or recurrent MAC lung disease using the PRO tool validated in the ARISE trial. The confirmatory clinical program is intended to fulfill the FDA’s post-marketing requirement to allow for full approval of ARIKAYCE by the FDA, and verification and description of clinical benefit in the ENCORE trial will be necessary for full approval of ARIKAYCE. The trial completion timetable agreed upon with the FDA when the

approval letter for ARIKAYCE was received has been delayed. We remain engaged with the FDA regarding the timeline, status and execution of the post-marketing confirmatory clinical trials. There is little precedent for clinical development and regulatory expectations for agents to treat MAC lung disease. In September 2023, we announced positive topline results from the ARISE trial. The study met its primary objective of demonstrating that the QOL-B respiratory domain works effectively as a PRO tool in patients with MAC lung disease. Based on feedback and in alignment with the FDA, we have determined that the primary endpoint for the ENCORE trial will include eight questions from the QOL-B respiratory domain PRO. We completed enrollment of the ENCORE trial in the fourth quarter of 2024, with 425 patients enrolled. However, we may encounter substantial delays in conducting the ENCORE trial, and we may not be able to conduct the trial in a manner satisfactory to the FDA or within the time period required by the FDA. The FDA could, among other things, withdraw its approval of ARIKAYCE using expedited procedures if the ENCORE trial is not successful or if the FDA concludes that we failed to conduct the ENCORE trial with due diligence, that other evidence demonstrates that ARIKAYCE is not shown to be safe and effective, or that we disseminated false or misleading promotional materials with respect to ARIKAYCE. Additionally, under the amendments to the FDCA made by the Consolidated Appropriations Act, 2023, the FDA could pursue administrative and judicial remedies for a violation of the FDCA if we were to fail to conduct the ENCORE trial with due diligence or not timely submit the required reports on the progress of the ENCORE trial. Separate from the confirmatory trial, additional results from ongoing and recently completed studies may affect the FDA's benefit-risk analysis for the product. Failure to meet all post-marketing commitments may raise additional regulatory challenges.

We remain subject to substantial, ongoing regulatory requirements, and failure to comply with these requirements could lead to enforcement action or otherwise materially harm our business.

We are subject to a variety of manufacturing, packaging, storage, labeling, advertising, promotion, and record-keeping requirements in the US, Europe, and Japan including requirements to:

- Conduct sales, marketing and promotion, scientific exchange, speaker programs, charitable donations and educational grant programs in compliance with federal and state laws;
- Disclose clinical trial information and payments to healthcare professionals and healthcare organizations on publicly available databases;
- Monitor and report complaints, AEs and instances of failure to meet product specifications;
- Comply with cGMP and quality systems requirements for devices;
- Acquire licenses for marketing authorization and certifications for our third-party manufacturers when importing and selling pharmaceutical products manufactured in other countries into Japan;
- Negotiate with national governments and other counterparties on pricing and reimbursement status;
- Carry out post-approval confirmatory clinical trials;
- Comply with ongoing pharmacovigilance requirements; and
- Disclose payments to healthcare professionals and healthcare organizations to national regulatory authorities and/or on publicly available websites.

If we ultimately receive approval for ARIKAYCE or any of our product candidates in jurisdictions other than the US, Europe, and Japan, we expect to be subject to similar ongoing regulatory oversight by the relevant foreign regulatory authorities, including the requirement to negotiate with national governments and other counterparties on pricing and reimbursement prices for each new jurisdiction.

Failure to comply with these ongoing regulatory obligations could have significant negative consequences, including:

- Issuance of warning letters or untitled letters by the FDA asserting that we are in violation of the law;
- Imposition of injunctions or civil monetary penalties or pursuit by regulators of civil or criminal prosecutions and fines against us or our responsible officers;
- Suspension or withdrawal of regulatory approval;
- Suspension or termination of ongoing clinical trials or refusal by regulators to approve pending marketing applications or supplements to approved applications;
- Seizure of products, required product recalls or refusal to allow us to enter into supply contracts, including government contracts, or to import or export products;
- Enforcement actions, such as a product recalls, or product shortages due to failure to meet certain manufacturing or regulatory requirements, including the successful completion and results of quality control or release testing;
- Suspension of, or imposition of restrictions on, our operations, including costly new manufacturing requirements with respect to ARIKAYCE, brensocatib, TPIP, INS1201, or any of our other product candidates; and

- Negative publicity, including communications issued by regulatory authorities, which could negatively impact the perception of us or ARIKAYCE, brensocatib, TPIP, INS1201, or any of our other product candidates by patients, physicians, third-party payors or the healthcare community.

We provide financial assistance with out-of-pocket costs to patients enrolled in commercial health insurance plans. In addition, independent foundations may assist with out-of-pocket financial obligations. The ability of these organizations to provide assistance to patients is dependent on funding from external sources, and we cannot guarantee that such funding will be available at adequate levels, if at all. Patient assistance programs, whether provided directly by manufacturers or charitable foundations, have come under recent government scrutiny. If we are deemed to fail to comply with relevant laws, regulations or government guidance with respect to these programs, we could be subject to significant fines or penalties.

If we are unable to obtain adequate reimbursement from government or third-party payors for ARIKAYCE or, if approved, brensocatib, TPIP, or our other product candidates, or if we are unable to obtain acceptable prices for ARIKAYCE, or, if approved, brensocatib or TPIP, our prospects for generating revenue and achieving profitability will be materially adversely affected.

Our prospects for generating revenue and achieving profitability depend heavily upon the availability of adequate reimbursement for the use of ARIKAYCE or, if approved, brensocatib, TPIP, or our other product candidates from governmental and other third-party payors, both in the US and in other markets. A portion of our current ARIKAYCE revenue in the US comes from Medicare reimbursement, and we expect that trend to continue. Reimbursement by a third-party payor depends upon a number of factors, including the third-party payor's determination that use of a product is:

- A covered benefit under its health plan;
- Safe, effective and medically necessary;
- Appropriate for the specific patient;
- Cost-effective; and
- Neither experimental nor investigational.

Obtaining a determination of coverage and reimbursement for a product from each relevant governmental or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. Payors in the US have evaluated ARIKAYCE for inclusion on formularies. Going forward, we may not be able to provide data sufficient to gain positive coverage and reimbursement determinations or we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of ARIKAYCE to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources.

Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or non-US regulatory authorities and/or may set a reimbursement rate that is too low to support a profitable sales price for the product. For example, in France we agreed with the French authorities to a reimbursed price which was lower than the price in our temporary authorization for use (Autorisation Temporaire d'Utilisation or ATU) and are required to refund the difference. As a result, we recorded a revenue reversal in the fourth quarter of 2022, related to revenue recorded in prior periods. In addition, in 2023, we experienced a one-time, prospective price decrease for ARIKAYCE in Japan of 9.4%. In the US, payors have restricted and continue to restrict coverage of ARIKAYCE by using a variable co-payment structure that imposes higher costs on patients for drugs that are not preferred by the payor and by imposing requirements for prior authorization or step edits. Subsequent approvals of competitive products could result in a detrimental change to the reimbursement of our products. The occurrence of any of these events likely would adversely impact market acceptance and demand for ARIKAYCE, which, in turn, could affect our ability to successfully commercialize ARIKAYCE and adversely impact our business, financial condition, results of operations and prospects and the value of our common stock.

There is a significant focus in the US healthcare industry and elsewhere on drug prices and value, and public and private payors are taking increasingly aggressive steps to control their expenditures for pharmaceuticals by, among other things, negotiating manufacturer discounts and placing restrictions on reimbursement for, and patient access to, medications. These pressures could negatively affect our business. We expect changes in the Medicare program and state Medicaid programs, as well as managed care organizations and other third-party payors, to continue to put pressure on pharmaceutical product pricing. One significant example of recent legislative action is the IRA, which was signed into law on August 16, 2022. The IRA gives the HHS the ability and authority to directly negotiate with manufacturers the price that Medicare will pay for certain high-priced drugs and set caps on the negotiated price of such drugs, among other changes. The IRA also requires manufacturers of certain Part B and Part D drugs to issue to HHS rebates based on certain calculations and triggers (i.e., when drug prices increase and outpace the rate of inflation), which may influence the pricing of current and future products. At this time, while we believe that ARIKAYCE will be excluded from negotiation due to its orphan drug designation, we cannot predict other potential implications the IRA provisions will have on our business or the pricing of brensocatib or TPIP, if approved, or any

future products. These types of laws may have a significant impact on our ability to set a product price we believe is fair and may adversely affect our ability to generate revenue and achieve or maintain profitability. We expect further federal and state proposals and healthcare reforms to continue to be proposed, which could limit the prices that can be charged for the products we develop or may otherwise limit our commercial opportunity. See Reimbursement of Pharmaceutical Products in Item 1 of Part I of this Annual Report on Form 10-K for more information. In addition, in connection with various government programs, we are required to report certain pricing information to the government, and the failure to do so may subject us to penalties.

In markets outside the US, including countries in Europe, Japan and Canada, pricing of pharmaceutical products is subject to governmental control. Evaluation criteria used by many government agencies in European countries for the purposes of pricing and reimbursement typically focus on a product's degree of innovation and its ability to meet a clinical need unfulfilled by currently available therapies. The Patient Protection and Affordable Care Act (ACA) created a similar entity, the Patient-Centered Outcomes Research Institute, designed to review the effectiveness of treatments and medications in federally-funded healthcare programs. An adverse result could lead to a treatment or product being removed from Medicare or Medicare coverage. The decisions of such governmental agencies could affect our ability to sell our products profitably.

We continue to have discussions with third-party payors regarding our price for ARIKAYCE, and our pricing may meet resistance from them and the public generally. If we are unable to maintain adequate reimbursement for ARIKAYCE in the US, Europe and Japan, the adoption of ARIKAYCE by physicians and patients may be limited. If we are unable to negotiate acceptable prices for ARIKAYCE, we may be unable to generate sufficient revenue to achieve profitability. Both of these risks, in turn, could affect our ability to successfully commercialize ARIKAYCE and adversely impact our business, financial condition, results of operations and prospects and the value of our common stock.

ARIKAYCE, brensocatib, TPIP, or our other product candidates could develop unexpected safety or efficacy concerns, which would likely have a material adverse effect on us.

ARIKAYCE is now being used by larger numbers of patients, for longer periods of time than during our clinical trials (including in the CONVERT study), and we and others (including regulatory agencies and private payors) are collecting extensive information on the efficacy and safety of ARIKAYCE by monitoring its use in the marketplace. In addition, we are conducting a confirmatory trial to assess and describe the clinical benefit of ARIKAYCE in patients with MAC lung disease. We may also conduct additional trials in connection with lifecycle management programs for ARIKAYCE and, if approved, brensocatib or TPIP. New safety or efficacy data from both market surveillance and our clinical trials may result in negative consequences including the following:

- Modification to product labeling or promotional statements, such as additional boxed or other warnings or contraindications, or the issuance of additional "Dear Doctor Letters" or similar communications to healthcare professionals;
- Required changes in the administration of ARIKAYCE, brensocatib, or TPIP;
- Imposition of additional post-marketing surveillance, post-marketing clinical trial requirements, distribution restrictions or other risk management measures, such as a risk evaluation and mitigation strategy (REMS) or a REMS with elements to assure safe use;
- Suspension or withdrawal of regulatory approval;
- Suspension or termination of ongoing clinical trials or refusal by regulators to approve pending marketing applications or supplements to approved applications;
- Suspension of, or imposition of restrictions on, our operations, including costly new manufacturing requirements with respect to ARIKAYCE, brensocatib, or TPIP; and
- Voluntary or mandatory product recalls or withdrawals from the market and costly product liability claims.

Any of these circumstances could reduce ARIKAYCE's market acceptance or, if approved, the market acceptance of brensocatib or TPIP and would be likely to materially adversely affect our business.

If estimates of the size of the potential markets for ARIKAYCE, brensocatib, TPIP, or our other product candidates are overstated or data we have used to identify physicians is inaccurate, our ability to earn revenue to support our business could be materially adversely affected.

We have relied on external sources, including market research funded by us and third parties, and internal analyses and calculations to estimate the potential market opportunities for ARIKAYCE, brensocatib, TPIP, or any of our other product candidates. The externally sourced information used to develop these estimates has been obtained from sources we believe to be reliable, but we have not verified the data from such sources, and their accuracy and completeness cannot be assured. With respect to ARIKAYCE, our internal analyses and calculations are based upon management's understanding and assessment of numerous inputs and market conditions, including, but not limited to, the projected increase in prevalence of MAC lung disease, Medicare patient population growth and ongoing population shifts to geographies with increased rates of MAC lung disease. These understandings and assessments necessarily require assumptions subject to significant judgment and may prove to be

inaccurate. As a result, our estimates of the size of these potential markets for ARIKAYCE could prove to be overstated, perhaps materially.

In addition, we are relying on third-party data to identify the physicians who treat the majority of MAC lung disease patients in the US and to determine how to deploy our resources to market to those physicians; however, we may not be marketing to the appropriate physicians and may therefore be limiting our market opportunity.

With regard to brensocatib, our estimated number of total diagnosed bronchiectasis patients in the US was derived from an external source. A similar per capita prevalence was used to calculate the estimated prevalence in the European 5. Our potential addressable market for TPIP in the US, the European 5 and Japan was also derived from external sources. However, studies indicate a lack of consensus on prevalence rates.

In the future, we may develop additional estimates with respect to market opportunities for our other product candidates, and such estimates are subject to similar risks. In addition, a potential market opportunity could be reduced if a regulator limits the proposed treatment population for one of our product candidates, similar to the limited population for which ARIKAYCE was approved. In either circumstance, even if we obtain regulatory approval, we may be unable to commercialize the product on a scale sufficient to generate significant revenue from such product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects and the value of our common stock.

We may not be successful in clinical trials or in obtaining regulatory approvals required to expand the indication for ARIKAYCE, which may materially adversely affect our prospects and the value of our common stock.

The FDA granted accelerated approval of ARIKAYCE for the treatment of MAC lung disease as part of a combination antibacterial drug regimen for adult patients with limited or no alternative treatment options in a refractory setting, as defined by patients who do not achieve negative sputum culture after a minimum of six consecutive months of a multidrug background regimen therapy. Our CONVERT study and 312 study focused on this refractory population, and we do not anticipate obtaining an indication for a broader population of patients with MAC lung disease or any other illnesses or infections without additional clinical data. Additional clinical trials will require additional time and expense. While we reported positive topline results from our ARISE trial, we are continuing to conduct our confirmatory clinical trial program for full approval of ARIKAYCE in the broader population of patients with MAC lung disease through our ENCORE trial, but this trial program, along with any other clinical trials of ARIKAYCE, may not be successful. Additional results from ongoing and recently completed studies may affect the FDA's benefit-risk analysis for the product. If we are unable to expand the indication for use of ARIKAYCE, our prospects and the value of our common stock may be materially adversely affected.

Risks Related to the Development and Regulatory Approval of Our Product Candidates Generally

Pharmaceutical research and development is very costly and highly uncertain, and we may not succeed in developing product candidates in the future.

Product development in the pharmaceutical industry is an expensive, high-risk, lengthy, complicated, resource intensive process. In order to develop a product successfully, we must, among other things:

- Identify potential product candidates;
- Submit for and receive regulatory approval to perform clinical trials;
- Design and conduct appropriate preclinical and clinical trials, including confirmatory clinical trials, according to good laboratory practices and good clinical practices and disease-specific expectations of the FDA and other regulatory bodies;
- Select and recruit clinical investigators and subjects for our clinical trials;
- Obtain and correctly interpret data establishing adequate safety of our product candidates and demonstrating with statistical significance that our product candidates are effective for their proposed indications, as indicated by satisfaction of pre-established endpoints;
- Submit for and receive regulatory approvals for marketing; and
- Manufacture the product candidates and device constituent parts according to cGMP and other applicable standards and regulations.

There is a high rate of failure inherent in this process, and potential products that appear promising at early stages of development may fail for a number of reasons. Importantly, positive results from preclinical studies of a product candidate may not be predictive of similar results in human clinical trials, promising results from earlier clinical trials of a product candidate may not be replicated in later clinical trials, and observations from ongoing trials, including observations based on interim, preliminary, or blinded data, may not be representative of results after the trials are completed and all data is collected and analyzed. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving positive results in earlier stages of development and have abandoned development efforts or sought partnerships in order to continue development.

In addition, there are many other difficulties and uncertainties inherent in pharmaceutical research and development that could significantly delay or otherwise materially impair our ability to develop future product candidates, including the following:

- Conditions imposed by regulators, ethics committees or institutional review boards for preclinical testing and clinical trials relating to the scope or design of our clinical trials, including selection of endpoints and number of required patients or clinical sites;
- Challenges in designing our clinical trials to support potential claims of superiority over current standard of care or future competitive therapies;
- Restrictions placed upon, or other difficulties with respect to, clinical trials and clinical trial sites, including with respect to potential clinical holds or suspension or termination of clinical trials due to, among other things, potential safety or ethical concerns or noncompliance with regulatory requirements;
- Delayed or reduced enrollment in clinical trials, high discontinuation rates or overly concentrated patient enrollment in specific geographic regions;
- Failure by third-party contractors, contract research organizations (CROs), clinical investigators, clinical laboratories, or suppliers to comply with regulatory requirements or meet their contractual obligations in a timely manner;
- Greater than anticipated cost of our clinical trials; and
- Insufficient product supply or inadequate product quality.

We cannot state with certainty when or whether our product candidates now under development will be approved or launched; whether, if initially granted, such approval will be maintained; whether we will be able to develop, license, or otherwise acquire additional products or product candidates; or whether our products, once launched, will be commercially successful. Failure to successfully develop future product candidates for any of these reasons may materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, may be interpreted differently if additional data are disclosed, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical trials, which may be based on a preliminary analysis of then-available data in a summary or topline format, and the results and related findings may change as more patient data become available, may be interpreted differently if additional data are disclosed at a later time and are subject to audit and verification procedures that could result in material changes in the final data. For example, in May 2024, we announced topline data for the ASPEN trial. If additional results from our clinical trials are not consistent with this topline data or other previously released data or are not viewed favorably, our ability to obtain approval for and commercialize our approved drug and drug candidates, our business, operating results, prospects, or financial condition may be harmed and our stock price may decrease.

We also make assumptions, estimates, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary or topline results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been disclosed and/or are received and fully evaluated. Such data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary and topline data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Differences between preliminary or interim data and final data could significantly harm our business prospects. In addition, blinded data may not be predictive of unblinded data.

Further, other parties, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product, and our business in general. In addition, in regards to the information we publicly disclose regarding a particular study or clinical trial, such as topline data, you or others may not agree with what we determine is the material or otherwise appropriate information to include in such disclosure, and any information we determine not to disclose, or to disclose at a later date, such as at a medical meeting may ultimately be deemed significant with respect to future decisions, conclusions, views, activities, or otherwise regarding a particular drug, drug candidate, or our business. If the topline data that we report differ from actual results or are interpreted differently once additional data are disclosed at a later date, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our drug candidates, our business, operating results, prospects, or financial condition may be harmed or our stock price may decline.

We will need to secure regulatory approval in each market for Lamira as a delivery system for ARIKAYCE. Any failures to secure separate regulatory approvals for Lamira as a delivery system will limit our ability to successfully commercialize ARIKAYCE. Additionally, we plan to submit an NDA for TPIP as a drug/device combination product or as a stand-alone marketing application, as dictated by local regulations, with Lamira as the dry powder delivery system for TPIP. Failure to obtain or maintain regulatory approval or clearance of our devices or drug-device combination products could materially harm our business.

Lamira must receive separate regulatory approval or clearance in connection with each approved product or product candidate it will be used to administer. The FDA granted accelerated approval of Lamira with ARIKAYCE as part of the approval of the drug/device combination product, and Lamira is CE marked by PARI in Europe and authorized for use by MHLW in Japan. However, outside the US, Europe and Japan, Lamira is labeled as investigational for use in our clinical trials, including in Canada and Australia, and is not approved for commercial use in Canada or certain other markets in which we may seek to commercialize ARIKAYCE in the future.

In addition, we plan to submit a marketing application for TPIP as a drug/device combination product or as a stand-alone application, as dictated by local regulations, with Lamira as the dry powder delivery system for TPIP. We will need to seek additional approvals in connection with the delivery device for TPIP in certain markets before we can market and commercialize TPIP in them.

We will continue to work closely with PARI to coordinate efforts regarding regulatory requirements, including our proposed filings. If we and PARI are not successful in obtaining approval for each usage of Lamira in each market, our ability to commercialize ARIKAYCE in those markets would be materially impaired. In addition, failure to maintain regulatory approval or clearance of Lamira could result in increased development costs, withdrawal of regulatory approval, delays or other material harm our business. Finally, failure to obtain regulatory approval or clearance of the delivery device for TPIP would affect our ability to develop and commercialize TPIP.

If our clinical studies do not produce positive results or our clinical trials are delayed, or if serious side effects are identified during drug development, we may experience delays, incur additional costs and ultimately be unable to obtain regulatory approval for and successfully commercialize our product candidates in the US, Europe, Japan or other markets.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct, at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals, and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. If we experience delays in our clinical trials or other testing or the results of these trials or tests are not positive or are only modestly positive, including with respect to safety, we may:

- Experience increased product development costs;
- Be delayed in obtaining, or be unable to obtain, regulatory approval for one or more of our product candidates;
- Obtain approval for indications or patient populations that are not as broad as intended or entirely different than those indications for which we sought approval or with labeling with boxed warnings or other warnings or contraindications;
- Need to change the way the product is administered;
- Be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- Have regulatory authorities withdraw, or suspend, their approval of the product or impose risk mitigation strategies such as restrictions on distribution or other REMS;
- Face a shortened patent protection period during which we may have the exclusive right to commercialize our products;
- Have competitors that are able to bring similar products to market before us;
- Be sued for alleged injuries caused to patients using our products; or
- Suffer reputational damage.

Such circumstances would impair our ability to commercialize our products and harm our business and results of operations.

The risk of finding adverse side effects may be particularly heightened in the case of gene therapies. For instance, new gene copies may produce too much or too little of the desired protein or RNA, or the production of the desired protein or RNA may change over time. Because the treatment is irreversible, there may be challenges in managing side effects. Some adverse effects would not be able to be reversed or relieved and might require us to develop additional clinical safety procedures. Furthermore, new gene copies may disrupt other normal biological molecules and processes which could also result in undesirable adverse effects. Adverse side effects may also be experienced by patients as a result of the process for administering the therapy or related procedures.

There have been several significant adverse side effects in gene therapy treatments in the past, including reported cases of leukemia, immune-mediated responses, and death seen in other trials. Gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. For instance, possible adverse side effects that could occur include immunologic-mediated reactions early after administration, which could substantially limit the effectiveness of the treatment, and could lead to further adverse side effects, possibly including organ failure or death. Additional manufacturing, clinical, and preclinical testing may be required, as well as additional analyses, assessments, and potential long-term patient and clinical study subject monitoring, beyond what is currently required, and sample testing and associated regulatory reporting. Serious adverse events in our clinical trials, or other clinical trials involving gene therapy products or our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could further adversely impact our product candidates in the form of increased government regulation, unfavorable public perception, the need for additional testing or monitoring, potential regulatory delays, stricter labeling requirements, and a decrease in demand.

We may not be able to enroll enough patients to conduct and complete our clinical trials or retain a sufficient number of patients in our clinical trials to generate the data necessary for regulatory approval of our product candidates or to permit the use of ARIKAYCE in the broader population of patients with MAC lung disease.

The completion rate of our clinical trials is dependent on, among other factors, the patient enrollment rate. Patient enrollment is a function of many factors, including:

- Investigator identification and recruitment;
- Regulatory approvals to initiate study sites;
- Patient population size;
- The nature of the protocol to be used in the trial;
- Patient proximity to clinical sites;
- Eligibility criteria for the trial;
- Patient willingness to participate in the trial;
- Discontinuation rates; and
- Competition from other companies' potential clinical trials for the same patient population.

Delays in patient enrollment for our clinical trials could increase costs and delay commercialization and sales, if any, of our products. Once enrolled, patients may elect to discontinue participation in a clinical trial at any time. If patients elect to discontinue participation in our clinical trials at a higher rate than expected, including with respect to our ENCORE trial, we may be unable to generate the data required by regulators for approval of our product candidates.

If another party obtains orphan drug exclusivity for a product that is considered the same or essentially the same as a product we are developing for a particular indication, we may be precluded or delayed from commercializing the product in that indication.

Under the ODA, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition. In the EU, the EMA Committee for Orphan Medicinal Products grants orphan drug designation to products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating disease or condition affecting not more than five in 10,000 people in the EU. The company that obtains the first regulatory approval from the FDA for a designated orphan drug for an indication within the designated rare disease or condition generally receives marketing exclusivity for use of that drug for that indication for a period of seven years. Similar laws exist in the EU with a term of 10 years. See Business — Government Regulation — Orphan Drug Designation in Item 1 of Part I of this Annual Report on Form 10-K for additional information. If a competitor obtains approval of the same drug for the same indication before us, and the FDA grants such orphan drug exclusivity, we would be prohibited from obtaining approval for our product for seven years (or longer if the seven-year exclusivity period is extended for a QIDP or due to pediatric exclusivity), unless our product can be shown to be clinically superior. In addition, even if we obtain orphan exclusivity, the FDA may approve another product during our orphan exclusivity period for the same indication under certain circumstances.

Our pre-clinical research activities include the research and development of novel gene therapy product candidates. It will be difficult to predict the time and cost of development and of subsequently obtaining regulatory approval for any such product candidates, or how long it will take to commercialize any gene therapy product candidates.

We intend to identify and develop novel gene therapy product candidates as part of our pre-clinical research efforts. We have limited experience in developing gene therapy programs and cannot be certain that any gene therapy product candidates that we develop will successfully complete preclinical studies and clinical trials, or that they will not cause significant adverse events or toxicities. Any such results could impact our ability to develop a product candidate, including our ability to enroll patients in our clinical trials. Furthermore, there is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products

used to carry the genetic material, which could adversely affect our ability to obtain and maintain regulatory approvals for and commercialize any gene therapy products we may develop.

In addition, to date, only a small number of gene therapy products have been approved in the US, Europe or elsewhere, and regulatory requirements governing gene therapy products have changed frequently and may continue to change in the future. We may seek regulatory approval in territories outside the US and Europe, which may have their own regulatory authorities along with frequently changing requirements or guidelines. The regulatory review committees and advisory groups in the US, Europe and elsewhere, and any new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Within the FDA, the Center for Biologics Evaluation and Research (CBER) regulates gene therapy products. Within CBER, the review of gene therapy and related products is consolidated in the Office of Therapeutic Products, and the FDA has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its reviews. CBER works closely with the National Institutes of Health (the NIH) in connection with the development of gene therapy. The FDA has published specific guidance documents with respect to the development and approval of gene therapy products. For example, in January 2020, the FDA issued final guidance documents that updated draft guidance documents that were originally released in July 2018 to reflect recent advances in the field, and to set forth the framework for the development, review and approval of gene therapies. Amongst these guidance documents are final guidance documents that pertain to the development of gene therapies for the treatment of specific disease categories, including rare diseases of interest to Insmed, and to manufacturing and long-term follow-up issues relevant to gene therapy, among other topics. The FDA also issued a final guidance document in September 2021 describing the FDA's approach for determining whether two gene therapy products are the same or are different for the purpose of orphan-drug designation and orphan-drug exclusivity. The FDA has continued to issue additional draft and final guidance documents on the development and manufacture of gene therapy products. In addition, the FDA can put an IND for a gene therapy study on clinical hold for several reasons, including, but not limited to, if the information in an IND is not sufficient to assess the potential risks in study subjects.

As we advance gene therapy product candidates, we will be required to consult with these regulatory authorities and advisory groups, and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of certain of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate product revenue.

Due to these factors, it is more difficult for us to predict the time and cost of gene therapy product candidate development, and we cannot predict whether the application of our approach to gene therapy, or any similar or competitive programs, will result in the identification, development and regulatory approval of any product candidates, or that the gene therapy programs of our competitors will not be considered better or more attractive or available in the market prior to ours. There can be no assurance that any development problems we experience in the future related to gene therapy product candidates will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays and challenges in achieving sustainable, reproducible and scalable production. Additionally, if a safety concern arises in connection with a gene therapy product from any sponsor, regulatory authorities might apply greater scrutiny to our gene therapy product candidates and any approved gene therapy products, and it might become more challenging to enroll patients in clinical trials and commercialize approved gene therapy products. Any of these factors may prevent us from completing our pre-clinical studies or clinical trials or commercializing any gene therapy product candidates we may develop on a timely or profitable basis, if at all.

Risks Related to Our Reliance on Third Parties

We rely on third parties including collaborators, CROs, clinical and analytical laboratories, CMOs and other providers for many services that are critical to our business. If we are unable to form and sustain these relationships, or if any third-party arrangements that we may enter into are unsuccessful, including due to non-compliance by such third parties with our agreements or applicable law, our ability to develop and commercialize our products may be materially adversely affected.

We currently rely, and expect to continue to rely, on third parties for significant research, analytical services, pre-clinical development, clinical development and manufacturing of our product candidates and commercial scale manufacturing of ARIKAYCE and Lamira. For example, we do not own facilities for clinical-scale or commercial manufacturing of our product candidates, and we expect that our future supply requirements for brensocatib and TPIP will be manufactured by CMOs. We currently rely on Resilience and Patheon to provide our clinical and commercial supply of ARIKAYCE. We currently primarily rely on Esteve and Thermo Fisher to provide our clinical supply for brensocatib. Additionally, almost all of our clinical trial work is done by CROs, such as PPD, our CRO for the ENCORE, BiRCh, and TPIP trials, and clinical laboratories. In addition, we rely on third parties to manufacture clinical materials for our pre-clinical research programs. Reliance on these third parties poses a number of risks, including the following:

- The diversion of management time and cost of third-party advisers associated with the negotiation, documentation and implementation of agreements with third parties in the pharmaceutical industry;
- The inability to control whether third parties devote sufficient resources to our programs or products, including with respect to meeting contractual deadlines;
- The inability to control the regulatory and contractual compliance of third parties, including their quality systems, processes and procedures, systems utilized to collect and analyze data, and equipment used to test drug product and/or clinical supplies;
- The inability to establish and implement collaborations or other alternative arrangements on favorable terms;
- Disputes with third parties, including CROs, leading to loss of intellectual property rights, delay or termination of research, development, or commercialization of product candidates or litigation or arbitration;
- Contracts with our collaborators fail to provide sufficient protection of our intellectual property; and
- Difficulty enforcing our contractual rights if one of these third parties fails to perform.

We also rely on third parties to select and enter into agreements with clinical investigators to conduct clinical trials to support approval of our product candidates, and the failure of these third parties to appropriately carry out such evaluation and selection can adversely affect the quality of the data from these studies and, potentially, the approval of our products. In particular, as part of future drug approval submissions to the FDA, we must disclose certain financial interests of investigators who participated in any of the clinical studies being submitted in support of approval, or must certify to the absence of such financial interests. The FDA evaluates the information contained in such disclosures to determine whether disclosed interests may have an impact on the reliability of a study. If the FDA determines that financial interests of any clinical investigator raise serious questions of data integrity, the FDA can institute a data audit, request that we submit further data analyses, conduct additional independent studies to confirm the results of the questioned study, or refuse to use the data from the questioned study as a basis for approval. A finding by the FDA that a financial relationship of an investigator raises serious questions of data integrity could delay or otherwise adversely affect approval of our products.

In January 2024, the US House of Representatives introduced the BIOSECURE Act (H.R. 7085) and the Senate advanced a substantially similar bill (S.3558), which legislation, if passed and enacted into law, would potentially restrict our ability to utilize certain products and services from, or otherwise collaborate with, any "biotechnology company of concern," in the performance of a government contract or subcontract. Although the House version of the bill passed on September 9, 2024, the legislation ultimately did not pass before the end of the last session of Congress. It is possible that the BIOSECURE Act could be raised again in some form in this new and current session of Congress, either as a standalone bill or as part of broader legislation, and focus on these issues is expected to continue. We do business with companies in China and it is possible some of our contractual counterparties could be impacted by this legislation.

These risks could materially harm our business, financial condition, results of operations and prospects and the value of our common stock.

We may not have, or may be unable to obtain, sufficient quantities of ARIKAYCE, Lamira or our product candidates to meet our required supply for commercialization or clinical studies, which would materially harm our business.

We do not have any in-house manufacturing capability other than for small-scale preclinical development programs and depend completely on a small number of third-party manufacturers and suppliers for the manufacture of our product candidates on a clinical or commercial scale. For instance, we are and expect to remain dependent upon Resilience and Patheon to supply ARIKAYCE both for our clinical trials and commercial sale. Resilience manufactures placebo for our clinical trials and our current supply of ARIKAYCE for commercial sale. However, we may not be able to maintain adequate quantities to meet future demand, including as a result of manufacturing and/or quality issues experienced by our third-party manufacturers or higher customer demand than expected. If we encounter delays or difficulties in the manufacturing process that disrupt our ability to supply our distributors and others with ARIKAYCE or our product candidates, we may experience product stock-outs, which would likely have a material adverse effect on our business and reputation.

In addition, we have entered into certain agreements with Patheon related to increasing our long-term production capacity for ARIKAYCE commercial inventory, although Patheon’s supply obligations will commence only after certain technology transfer and construction services are completed. Any delay in the commencement of Patheon’s supply obligations, whether due to delays in technology transfer and construction or from adding Patheon to our NDA as a CMO, would increase the risks associated with Resilience being unable to provide us with an adequate supply of ARIKAYCE.

We are also dependent upon PARI being able to provide an adequate supply of nebulizers for commercial sale of ARIKAYCE, any ongoing clinical trials, and future commercial sales of our product candidates that use Lamira as their delivery mechanism, as PARI is the sole manufacturer of Lamira. We have no alternative supplier for the nebulizer, and because significant effort and time were expended in the optimization of the nebulizer for use with ARIKAYCE, we do not intend to seek an alternative or secondary supplier. In the event PARI cannot provide us with sufficient quantities of the

nebulizer, replication of the optimized device by another party would likely require considerable time and additional regulatory approval. In the case of certain specified supply failures, we have the right under our commercialization agreement with PARI to make the nebulizer and have it made by certain third parties, but not those deemed under the commercialization agreement to compete with PARI.

We will be reliant on CMOs to manufacture supply of brensocatib and TPIP for our future requirements. Esteve manufactures the active pharmaceutical ingredient for brensocatib and Patheon manufactures our current supply of brensocatib. We plan to enter into commercial agreements with CMOs for TPIP, and cannot guarantee that we will be able to locate adequate partners or enter into favorable agreements with them.

We are in the process of developing in-house clinical manufacturing capability for our gene therapy product candidates, but we expect to rely on third-party CMOs for manufacturing of all testing materials for the foreseeable future. Products intended for use in gene therapies are novel, complex and difficult to manufacture. As we shift towards in-house clinical manufacturing capability for our gene therapy product candidates, we may encounter delays in obtaining regulatory approval of our manufacturing processes or in complying with ongoing manufacturing regulatory requirements and applicable cGMP, including challenges related to producing adequate quantities of clinical grade materials that meet FDA, EMA, MHLW or other applicable standards or specifications with consistent and acceptable production yields and costs.

We do not have long-term commercial agreements with all of our suppliers and if any of our suppliers are unable or unwilling to perform for any reason, we may not be able to locate suppliers or enter into favorable agreements with them.

An inadequate supply of ARIKAYCE, Lamira, brensocatib, TPIP, or our other product candidates would likely harm our commercial efforts or delay or impair clinical trials of ARIKAYCE or our product candidates and adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

The manufacturing facilities of our third-party manufacturers are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we and our manufacturing partners fail to comply with the regulations or maintain the approvals.

Manufacturers of ARIKAYCE, Lamira and our product candidates are subject to cGMP, Quality System Regulations and similar standards. While we have policies and procedures in place to select third-party manufacturers for our product and product candidates that adhere, and monitor their adherence to, such standards, they may nonetheless fail to do so. Similarly, while we have entered into a Commercialization Agreement with PARI for the manufacture of Lamira for use with ARIKAYCE, PARI and its affiliates involved in manufacturing may fail to adhere to applicable standards. These manufacturers and their facilities will be subject to periodic review and inspections by the FDA and other regulatory authorities following regulatory approval of our products, as with ARIKAYCE. For instance, to monitor compliance with applicable regulations, the FDA routinely conducts inspections of facilities and may identify potential deficiencies. The FDA issues what are referred to as “Form 483s” that set forth observations and concerns identified during its inspections. Failure to satisfactorily address the concerns or potential deficiencies identified in a Form 483 could result in the issuance of a warning letter, which is a notice of the issues that the FDA believes to be significant regulatory violations requiring prompt corrective actions. Failure to respond adequately to a warning letter, or to otherwise fail to comply with applicable regulatory requirements could result in enforcement, remedial and/or punitive actions by the FDA or other regulatory authorities.

If one of these manufacturers fails to maintain compliance with regulatory requirements or experiences supply problems, including in the scale-up of commercial production, the production of ARIKAYCE, Lamira, brensocatib and our other product candidates could be interrupted, resulting in delays, additional costs or restrictions on the marketing or sale of our products. An alternative manufacturer would need to be qualified, through regulatory filings, which could result in further delay. The regulatory authorities may also require additional testing if a new manufacturer is relied upon for commercial production. In addition, with respect to our product candidates, our manufacturers and their facilities are subject to pre-approval cGMP inspection by the FDA and other regulatory authorities, and the findings of the cGMP inspection could result in a failure to obtain, or a delay in obtaining, regulatory approval for future product candidates.

Risks Related to the Operation of our Business

We are dependent upon retaining and attracting key personnel, the loss of whose services could materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

We depend heavily on our management team and our principal clinical and commercial personnel, the loss of whose services might significantly delay or prevent the achievement of our research, development or commercialization objectives. Our success depends, in large part, on our ability to attract and retain qualified management, clinical and commercial personnel, including those who join us through our business development activities. Our inability to retain and attract personnel could also negatively impact our ability to develop and maintain important relationships with commercial partners, leading research institutions and key distributors.

Competition for skilled personnel in our industry and market is intense because of the numerous pharmaceutical and biotechnology companies that seek similar personnel. These companies may have greater financial and other resources, offer a greater opportunity for career advancement and have a longer history in the industry than we do. We also experience competition for the hiring of our clinical and commercial personnel from universities, research institutions, and other third parties. We cannot assure that we will attract and retain such people or maintain such relationships. Our inability to retain and attract qualified employees would materially harm our business, financial condition, results of operations and prospects and the value of our common stock.

We expect to continue to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

In connection with our commercialization of ARIKAYCE in the US, Europe and Japan, our continued international expansion efforts, and our ongoing development and planned commercialization of brensocatib, TPIP, INS1201, and other product candidates, we expect to continue to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, quality, commercial compliance, medical affairs, and sales and marketing. For example, we plan to continue to hire additional personnel to support ARIKAYCE, the continued development and anticipated commercialization of brensocatib and the advancement of our other pipeline programs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel, all while continuing to maintain our culture. Due to the limited experience of our management team in managing a company with this anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. We may not be able to effectively manage the expansion of our operations, which could delay the execution of our business plans or disrupt our operations.

Any acquisitions we make, or collaborative relationships we enter into, may not be clinically or commercially successful, and may require financing or a significant amount of cash, which could adversely affect our business.

As part of our business strategy, we may effect acquisitions to obtain additional businesses, products, technologies, capabilities and personnel. For example, we acquired Motus and AlgaeneX in August 2021 (the Business Acquisition), Vertuis in January 2023, and Adrestia in June 2023, each a privately-held, pre-clinical stage company. Acquisitions involve a number of operational risks, including:

- Failure to achieve expected synergies;
- The possibility that our acquired technologies, products and product candidates may not be commercially successful;
- Difficulty and expense of assimilating the operations, technology and personnel of any acquired business;
- The inability to retain the management, key personnel and other employees of any acquired business;
- The inability to maintain any acquired company’s relationship with key third parties, such as alliance partners;
- Exposure to legal claims or other liabilities for activities of any acquired business prior to acquisition;
- Diversion of our management’s attention from our core business; and
- Potential impairment of intangible assets, adversely affecting our reported results of operations and financial condition.

We also may enter into collaborative relationships that would involve our collaborators conducting proprietary development programs. Disagreements with collaborators may develop over the rights to our intellectual property, and any conflict with our collaborators could limit our ability to obtain future collaboration agreements and negatively influence our relationship with existing collaborators.

If we make one or more significant acquisitions or enter into a significant collaboration in which the consideration includes cash, we may be required to use a substantial portion of our available cash and/or need to raise additional capital, which could adversely affect our financial condition.

We may be subject to product liability claims, and we have only limited product liability insurance.

The manufacture and sale of human therapeutic products involve an inherent risk of product liability claims, particularly as we continue to commercialize ARIKAYCE in the US, Europe and Japan, and look to commercialize brensocatib, if approved. Regardless of merit or eventual outcome, liability claims may result in:

- Decreased demand for ARIKAYCE and any other products that we may commercialize, and a corresponding loss of revenue;
- Substantial monetary awards to patients or trial participants;
- Significant time and costs to defend the related litigation;

- Withdrawal or reduced enrollment of clinical trial participants; and
- Reputational harm and significant negative media attention.

We have limited product liability insurance for our products. We do not know if we will be able to maintain existing, or obtain additional, product liability insurance on acceptable terms or with adequate coverage against potential liabilities. This type of insurance is expensive and may not be available on acceptable terms. If we are unable to obtain or maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to commercialize our products. A successful product liability claim brought against us in excess of our insurance coverage, if any, may require us to pay substantial amounts and may materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

Our business and operations, including our drug development and commercialization programs, could be materially disrupted and/or subject to reputational harm in the event of system failures, security breaches, cyber-attacks, deficiencies in cybersecurity, violations of data protection laws or data loss or damage by us or third parties.

We are dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable information, including protected health information, of clinical trial participants, patients and employees. Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such an event could have a material adverse effect on our business operations, including a material disruption of our drug development and commercialization programs.

It is critical that we maintain such confidential information in a manner that preserves its confidentiality and integrity. Unauthorized disclosure of or access to sensitive or confidential patient or employee data, including personally identifiable information, whether through breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. In addition, the loss of clinical trial data for our product candidates could result in delays in our regulatory submission and approval efforts and significantly increase our costs to recover or reproduce the data, if possible. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. For example, the loss of or damage to clinical trial data, such as from completed or ongoing clinical trials, for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our drug candidates or any future drug candidates and to conduct clinical trials, and similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions.

We have previously been, and expect to remain, the target of cyber-attacks. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. Notifications and follow-up actions related to a security incident could impact our reputation or cause us to incur substantial costs, including legal and remediation costs, in connection with these measures and otherwise in connection with any actual or suspected security breach. Although we have general liability insurance coverage, including coverage for errors and omissions and potential cyber security breaches, our insurance may not cover all claims, continue to be available on reasonable terms or be sufficient in amount to cover one or more large claims; additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, financial condition, results of operations and prospects and the value of our common stock.

We are subject to data privacy laws and regulations that govern how we can collect, process, store, and transfer personal data, and violations can result in meaningful penalties, enforcement, and/or reputational harm and have a significant impact on our operations.

Laws and regulations governing personal data continue to develop at a rapid pace, and jurisdictions around the world continue to propose new legislation and rules. For example, a number of US states have passed consumer privacy laws or consumer health data laws. Other jurisdictions outside of the US either have data protection laws in place or continue to advance proposals for similar legislation and regulation. These laws place restrictions on how we collect, use, and transfer personal data, and they result in increased compliance and operational costs. Noncompliance with data protection laws and

regulations can result in meaningful penalties, enforcement, and/or reputational harm and have a significant impact on our operations.

Our inability to access, upgrade or expand our technology systems or difficulties in updating our existing technology or developing or implementing new technology could have a material adverse effect on our business or results of operations.

We have and will continue to expand, upgrade and develop our information technology capabilities, including our enterprise resource planning system, which was implemented through Oracle software in 2022, and a new enterprise-wide human capital management system, Workday, implemented in 2024. If we are unable to successfully continue upgrading or expanding our technological capabilities to support our growth or if there are deficiencies in the design or implementation of such capabilities, we may not be able to take advantage of market opportunities, manage our costs effectively, manage our inventory, maintain a secure data environment, file timely reports with the SEC, or otherwise efficiently manage our internal controls. In addition, costs, potential problems and interruptions associated with the implementation of new or upgraded systems and technology, or with maintenance or adequate support of existing systems, could also disrupt or reduce the efficiency of our operations. Moreover, many of our vendors provide their services to us via a cloud-based model instead of software that is installed on our premises. As a result, we depend upon our vendors to provide us with services that are always available and are free of errors or defects that could cause disruptions in our business processes. Any failure by such vendors to do so, or any disruption in our ability to access the Internet, could materially and adversely affect our ability to manage our operations.

We have limited experience operating internationally, are subject to a number of risks associated with our international activities and operations and may not be successful in our efforts to expand internationally.

We currently have limited operations outside of the US. As of December 31, 2024, we had 153 employees located in Europe and 111 employees located in Japan, although we have clinical trial sites and suppliers located around the world. In order to meet our long-term goals, we expect to grow our international operations over the next several years, including in Europe and Japan, and continue to source material used in the manufacture of our product candidates from abroad. Additionally, a substantial portion of our commercial supply of ARIKAYCE is currently manufactured in Canada and, if approved, we expect that commercial supply of brensocatib will also be manufactured in Canada. Consequently, we are and will continue to be subject to risks related to operating in foreign countries, including:

- Limited experience with international regulatory requirements;
- An inability to achieve optimal pricing and reimbursement for ARIKAYCE, if approved in another jurisdiction, or subsequent changes in reimbursement, pricing and other regulatory requirements;
- Any implementation of, or changes to, tariffs, trade barriers and other import-export regulations in the US or other countries in which we, or our third-party partners, operate;
- Unexpected AEs related to ARIKAYCE or our product candidates occurring in foreign markets that we have not experienced in the US, Europe or Japan;
- Scrutiny from customers, regulators, investors and other stakeholders related to environmental, health and safety, diversity, labor conditions, human rights and other concerns in the countries in which we, or our third-party partners, operate;
- Economic and political conditions, including foreign currency fluctuations and inflation, could result in reduced revenue, increased or unpredictable operating expenses and other obligations incident to doing business in, or with a company located in, another country;
- Geopolitical events, such as conflicts, war and terrorism, could cause disruptions in our international operations, including planned or ongoing clinical studies; and
- Compliance with foreign or US laws, rules and regulations, including data privacy requirements, labor relations laws, tax laws, anti-competition regulations, import, export and trade restrictions, anti-bribery/anti-corruption laws, regulations or rules, which could lead to actions by us or our distributors, manufacturers, other third parties who act on our behalf or with whom we do business in foreign countries or our employees who are working abroad that could subject us to investigation or prosecution under such foreign or US laws.

These and other risks associated with our international operations may materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

We operate in a highly competitive and changing environment, and if we are unable to adapt to our environment, we may be unable to compete successfully.

Biotechnology and related pharmaceutical technology have undergone and are likely to continue to experience rapid and significant change. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies and to obtain and maintain protection for our intellectual property. Compounds, products or

processes that we develop or that are developed on our behalf may become obsolete before we recover any expenses incurred in connection with their development. We face substantial competition from pharmaceutical, biotechnology and other companies, universities and research institutions with respect to NTM lung disease, bronchiectasis, PAH and PH-ILD, and our gene therapy indications, and will face substantial competition with respect to future product candidates we may develop in these and other disease areas. Relative to us, most of these entities have substantially greater capital resources, research and development staffs, facilities and experience in conducting clinical studies, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. Many of our competitors may achieve product commercialization or obtain patent protection earlier than us. Furthermore, we believe that our competitors have used, and may continue to use, litigation and patent office challenges to gain a competitive advantage. Our competitors may also use different technologies or approaches to develop products similar to ARIKAYCE, brensocatib, TPIP, INS1201, and our pre-clinical product candidates.

We expect that competing successfully will depend on, among other things, the relative speed with which we can develop products, complete the clinical testing and regulatory approval processes and supply commercial quantities of the product to the market, as well as product efficacy, safety, reliability, availability, timing and scope of regulatory approval and price. We expect competition to increase as technological advances are made and commercial applications broaden. There are potential competitive products, both approved and in development, which include oral, systemic, or inhaled antibiotic products to treat chronic respiratory infections. For instance, certain entities have expressed interest in studying their products for lung disease and are seeking to advance studies in lung disease, including NTM lung disease caused by mycobacterial species other than MAC. We are not aware of any entities currently conducting clinical trials for the treatment of refractory MAC lung disease or of any other approved inhaled therapies specifically indicated for NTM lung disease in North America, Europe or Japan. If any of our competitors develops a product that is more effective, safe, tolerable or convenient, or less expensive than ARIKAYCE or our product candidates, it would likely materially adversely affect our ability to generate revenue. We also may face lower priced generic competitors if third-party payors encourage use of generic or lower-priced versions of our product or if competing products are imported into the US or other countries where we may sell ARIKAYCE. In addition, in an effort to put downward pressure on drug pricing, Congress and the FDA are working to facilitate generic competition, which could result in our experiencing competition earlier than otherwise would be the case.

There are also other amikacin products that have been approved by the FDA, MHLW and other regulatory agencies for use in other indications, and physicians may elect to prescribe those products rather than ARIKAYCE to treat the indications for which ARIKAYCE has received approval, which is commonly referred to as off-label use. Although regulations prohibit a drug company from promoting off-label use of its product, the FDA and other regulatory agencies do not regulate the practice of medicine and cannot direct physicians as to what product to prescribe to their patients. As a result, we would have limited ability to prevent any off-label use of a competitor's product to treat diseases for which we have received FDA or other regulatory agency approval, even if this use violates our patents or any statutory exclusivities that the FDA may grant for the use of amikacin to treat such diseases.

In addition, based in part on our successful phase 2b Willow trial in bronchiectasis, certain entities have expressed interest in studying other DPP1 inhibitors for the treatment of bronchiectasis. We are aware of at least two entities currently conducting clinical trials for the treatment of bronchiectasis with a DPP1 inhibitor. If any of these competitors develops a DPP1 inhibitor product that is more effective, safe, tolerable or convenient, it would likely materially adversely affect our ability to generate revenue, should brensocatib ultimately be approved. If we are unable to compete successfully, it will materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

We have a limited number of significant customers and losing any of them could have an adverse effect on our financial condition and results of operations.

Our three largest customers as of December 31, 2024 accounted for 85% and 88% of our total gross product revenue for the years ended December 31, 2024 and 2023, respectively. The degree to which a limited number of customers make up a significant portion of our gross product revenue may change as we continue to commercialize ARIKAYCE and, if approved, our product candidates in additional markets. There can be no guarantee that we will be able to sustain our accounts receivable or gross sales levels from our key customers. If, for any reason, we were to lose, or experience a decrease in the amount of business with our largest customers, whether directly or through our distributor relationships, our financial condition and results of operations could be negatively affected.

Deterioration in general economic conditions in the United States, Europe, Japan and globally, including the effect of prolonged periods of inflation on our suppliers, third-party service providers and potential partners, could harm our business and results of operations.

Our business and results of operations could be adversely affected by changes in national or global economic conditions. These conditions include but are not limited to inflation, rising interest rates, limited availability of financing, energy availability and costs, the negative impacts caused by public health crises, negative impacts resulting from the military conflict between Russia and the Ukraine or the ongoing conflict in the Middle East, relations between the US and China, and the effects of governmental initiatives to manage economic conditions. Impacts of such conditions could be passed on to our

business in the form of higher costs for labor and materials, possible reductions in pharmaceutical industry-wide spending on research and development and acquisitions and higher costs of capital.

The emergence of a pandemic, and efforts to reduce its spread, could negatively impact our business and operations.

Our global operations expose us to risks associated with public health crises and pandemics, particularly as the patients we seek to treat suffer from serious diseases that may make them especially vulnerable. A pandemic, including a resurgence of COVID-19, may also have an adverse impac t on our operations and supply chain as a result of (i) our or our third-party manufacturers' employees or other key personnel becoming infected, (ii) preventive and precautionary measures that governments and we and other businesses, including our third-party manufacturers, are taking, such as border closures, prolonged quarantines and other travel restrictions, (iii) shortages of supplies necessary for the manufacture of ARIKAYCE, including as a result of government orders providing for the requisition of personal protective equipment and other medical supplies and equipment, and (iv) cold-chain storage and shipping limitations resulting from the need to prioritize delivery of vaccines, which could cause disruptions or delays in our ability to distribute ARIKAYCE due to lack of sufficient cold-chain storage and shipping capacity. Any of these circumstances could impact the ability of third parties on which we rely to manufacture ARIKAYCE or its components and our ability to perform critical functions, which could significantly hamper our ability to supply ARIKAYCE to patients. While we have experienced no disruption to date in our supply chain due to a pandemic, if we encounter delays or difficulties in the manufacturing process that disrupt our ability to supply ARIKAYCE, we may not be able to satisfy patient demand or we may experience a product stock-out, which would likely have a material adverse effect on our business.

The emergence of a pandemic could also require us to delay the start of new clinical trials or otherwise impair our ability to complete those trials. For instance, our ability to enroll patients and retain principal investigators and site staff could be impaired due to an outbreak in their geography or prioritization of hospital resources toward the outbreak, or as a result of quarantines and other travel restrictions that interrupt healthcare services. Furthermore, patients, investigators, or site staff may be unwilling or unable to comply with clinical trial protocols due to illness, concerns about a pandemic, or quarantines or other travel restrictions that impede their movement. Additionally, any interruption in the supply of the study drug might delay our ability to start or complete clinical trials. Significant delays in the timing and completion of our clinical trials are costly and could adversely affect our ability to satisfy our post-marketing requirements for ARIKAYCE and to obtain regulatory approval for and to commercialize our product candidates.

Our current and potential future use of artificial intelligence (AI) and machine learning may not be successful and presents new risks and challenges to our business.

We currently integrate AI and machine learning in certain of our research and development activities, including identification of potential product candidates, and are seeking to further integrate AI and machine learning throughout our business. We are exploring additional opportunities to incorporate AI and machine learning into our processes for drug discovery, drug development, drug commercialization, and in connection with our enabling functions. For example, we are currently evaluating the use of AI to produce initial drafts of documents like clinical study reports. Such efforts may not be successful. Issues relating to the use of new and evolving technologies such as AI and machine learning may cause us to experience brand or reputational harm, competitive harm, legal liability, and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues.

As with many innovations, AI presents risks and challenges that could undermine or slow its adoption, and therefore harm our business. Developing, testing and deploying AI systems may also increase our operating costs due to the nature of the computing costs involved in such systems, which could adversely affect our business, financial condition and results of operation. The use of AI by us and our business partners may lead to novel and urgent cybersecurity risks, which could have a material adverse effect on our operations and reputation as well as the operations of any of our business partners. We may also face increased competition from other companies that are using AI, some of whom may develop more effective methods than we and any of our business partners have, which could have a material adverse effect on our business, results of operations, or financial condition. In addition, our efforts to develop, acquire or integrate these technologies will involve significant time, costs, and other resources, and may divert our management team's attention and focus from executing on other elements of our strategy. Furthermore, uncertainties regarding developing legal and regulatory requirements and standards may require significant resources to modify and maintain business practices to comply with US and non-US laws concerning the use of AI, the nature of which cannot be determined at this time.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights adequately, the value of ARIKAYCE and our product candidates could be materially diminished.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal, technical, scientific and factual questions, and our success depends in large part on our ability to protect our

proprietary technology and to obtain and maintain patent protection for our products, prevent third parties from infringing our patents, both domestically and internationally. We have sought to protect our proprietary position by filing patent applications in the US and abroad related to our novel technologies and products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection or otherwise provide us with any competitive advantage. Any conclusions we may reach regarding non-infringement, inapplicability or invalidity of a third party's intellectual property vis-à-vis our proprietary rights, or those of a licensor, are based in significant part on a review of publicly available databases and other information. There may be information not available to us or otherwise not reviewed by us that could render these conclusions inaccurate. Our competitors may also be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

Additionally, patents issued to us or our licensors may be challenged, narrowed, invalidated, held to be unenforceable or circumvented through litigation, either in district court, the US international trade commission (ITC) or US patent office (USPTO), or in analogous foreign courts and patent offices, which could limit our ability to stop competitors from marketing similar products or reduce the term of patent protection for ARIKAYCE or our product candidates. US patents and patent applications may also be subject to interference or derivation proceedings, and US patents may be subject to re-examination proceedings, reissue, post-grant review and/or *inter partes* review in the USPTO. Our foreign patents have been and may be in the future subject to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. See *Intellectual Property—ARIKAYCE Patents* in Item 1 of Part I of this Annual Report on Form 10-K for more information on our European patents that have been previously opposed.

Changes in either patent laws or in interpretations of patent laws in the US and other countries may also diminish the value of our intellectual property or narrow the scope of our patent protection, including making it easier for competitors to challenge our patents. For example, the America Invents Act included a number of changes to established practices, including the transition to a first-inventor-to-file system and new procedures for challenging patents and implementation of different methods for invalidating patents.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of ARIKAYCE and our product candidates could be materially diminished.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality and restrictive covenant agreements with our employees, consultants, advisors, collaborators, and other third parties and partners to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information or may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, third parties may independently develop or discover our trade secrets and proprietary information. Regulators also may disclose information we consider to be proprietary to third parties under certain circumstances, including in response to third-party requests for such disclosure under the Freedom of Information Act or comparable laws. Additionally, the FDA, as part of its Transparency Initiative, continues to consider whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time whether and how the FDA's disclosure policies may change in the future. Further, several states have limited or prohibited the use of post-employment non-compete agreements and the Federal Trade Commission is evaluating a federal-level prohibition on such agreements, which could increase the difficulty of protecting trade secrets and other proprietary information. There are similar risks outside the US, such as the risk that a foreign regulatory agency would make available information we consider to be proprietary to third parties or the public, and the risks arising from other factors making it difficult to protect trade secrets, such as prohibitions or restrictions on post-employment non-compete agreements and other rules and regulations.

We may not be able to enforce our intellectual property rights throughout the world, which could harm our business.

The legal systems of some foreign countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. Many companies have encountered significant problems in protecting and defending intellectual property rights in such foreign jurisdictions. For example, certain foreign countries have compulsory licensing laws under which a patent owner may be required to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. This legal environment could make it

difficult for us to stop the infringement of our patents or in-licensed patents or the misappropriation of our other intellectual property rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, and our efforts to protect our intellectual property rights in such countries may be inadequate.

The drug research and development industry has a history of intellectual property litigation, and we could become involved in costly intellectual property disputes, which could delay or impair our product development efforts or prevent us from, or increase the cost of, commercializing ARIKAYCE or any other approved product candidate.

Third parties may claim that we have infringed upon or misappropriated their proprietary rights. Any existing third-party patents, or patents that may later issue to third parties, could negatively affect our commercialization of ARIKAYCE, brensocatib, TPIP, INS1201, or any other product candidate that receives regulatory approval. For instance, PAH is a competitive indication with established products, including other formulations of treprostinil. Our supply of treprostinil palmitil, the treprostinil prodrug present in TPIP, is dependent upon a single supplier. The supplier owns patents on its manufacturing process and crystalline drug product, and we have filed patent applications for TPIP; however, a competitor in the PAH or PH-ILD indication may claim that we or our supplier have infringed upon or misappropriated its proprietary rights. Moreover, in the event that we pursue approval of TPIP, or any other product candidate, via the 505(b)(2) regulatory pathway, we will be required to file a certification of non-infringement or invalidity against any unexpired patents listed in the Orange Book for the third-party drug we reference as part of our regulatory submission. This certification process may lead to litigation and could also delay launch of a product candidate, if approved by regulators.

In the event of successful litigation or settlement of claims against us for infringement or misappropriation of a third party's proprietary rights, we may be required to take actions including but not limited to the following:

- Paying damages, including up to treble damages, royalties, and the other party's attorneys' fees, which may be substantial;
- Ceasing development, manufacture, marketing and sale of products or use of processes that infringe the proprietary rights of others;
- Expending significant resources to redesign our products or our processes so that they do not infringe the proprietary rights of others, which may not be possible, or may result in significant regulatory delays associated with conducting additional clinical trials or other steps to obtain regulatory approval; and/or
- Acquiring one or more licenses from third parties, which may not be available to us on acceptable terms or at all.

We may also have to undertake costly litigation or engage in other proceedings, such as interference or *inter partes* review, to enforce or defend the validity of any patents issued or licensed to us, to confirm the scope and validity of our or a licensor's proprietary rights or to defend against allegations that we have infringed a third party's intellectual property rights. Any proceedings regarding our intellectual property rights are likely to be time consuming and may divert management attention from operation of our business, and could have a material adverse effect on our business, financial condition, results of operations and prospects and the value of our common stock.

Certain of the agreements to which we are, or may become, a party relating to ARIKAYCE and our product candidates impose, or may in the future impose, restrictions on our business or other material obligations on us. If we fail to comply with these obligations, our business could be adversely affected, including as a result of the loss of license rights that are important to our business.

We are a party to various agreements related to ARIKAYCE and our product candidates, including licensing agreements with PARI and AstraZeneca, which we view as material to our business. For additional information regarding the terms of these agreements, see *Business—License and Other Agreements* in Item 1 of Part I of this Annual Report on Form 10-K. These agreements impose a number of obligations on us and our business, including restrictions on our ability to freely develop or commercialize our product candidates and requirements to make milestone and royalty payments to our counterparties upon certain events. For example, under our license agreement with AstraZeneca, AstraZeneca retains a right of first negotiation pursuant to which it may exclusively negotiate with us before we can negotiate with a third party regarding any transaction to develop or commercialize brensocatib, subject to certain exceptions. While this right of first negotiation is not triggered by a change of control, it may impede or delay our ability to consummate certain other transactions involving brensocatib.

If we fail to comply with our obligations under these agreements, our counterparties may have the right to take action against us, up to and including termination of a relevant license. For instance, under our license agreement with AstraZeneca, AstraZeneca may terminate our license to brensocatib if we fail to use commercially reasonable efforts to develop and commercialize a product based on brensocatib, or we are subject to a bankruptcy or insolvency. Reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms and may materially harm our business.

Risks Related to Government Regulation

Government healthcare reform could materially increase our costs, which could materially adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

Our industry is highly regulated and changes in or revisions to laws and regulations that make gaining regulatory approval, reimbursement and pricing more difficult or subject to different criteria and standards may adversely impact our business, operations or financial results.

There have been a number of legal challenges and certain changes to the ACA since it was enacted. On January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, on February 10, 2021, the Biden Administration withdrew the federal government's support for overturning the ACA. Changes to the ACA, to the Medicare or Medicaid programs, or to the ability of the federal government to negotiate or otherwise affect drug prices, or other federal legislation regarding healthcare access, financing or legislation in individual states, could affect our business, financial condition, results of operations and prospects and the value of our common stock. We may face similar challenges to gaining regulatory approval and sufficient reimbursement and pricing due to government healthcare reform in the EU, Japan and other jurisdictions where ARIKAYCE or any of our other product candidates are approved. The Trump Administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. Drug pricing is an active area for regulatory reform at both the federal and state levels, and additional significant changes to current drug pricing and reimbursement structures in the US could be forthcoming. It remains unclear how any new legislation or regulation might affect the prices we may obtain for ARIKAYCE or any of our product candidates for which regulatory approval is obtained.

If we are found in violation of federal or state "fraud and abuse" laws, we may be required to pay a penalty or may be suspended from participation in federal or state healthcare programs, which may adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

In the US, we are subject to various federal and state healthcare "fraud and abuse" laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse in federal and state healthcare programs. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the US government, and our business, financial condition, results of operations and prospects and the value of our common stock may be adversely affected. Our reputation could also suffer. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Under the ACA and certain state laws, we are required to report information on payments or transfers of value to any US physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, or certified nurse-midwives (in each case who are not bona fide employees of the applicable manufacturer that is reporting the payment) and teaching hospitals, which is posted in searchable form on a public website. Failure to submit required information may result in civil monetary penalties.

Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. In addition to the federal government, some states, as well as other countries, including France, require the disclosure of certain payments to healthcare professionals. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), state, and foreign privacy laws may limit access to information identifying those individuals who may be prospective users or limit the ability to market to them. Some of these laws are new or ambiguous as to what is required to comply with their requirements, and we could be subject to penalties if it is determined that we have failed to comply with an applicable legal requirement.

We are subject to anti-corruption laws and trade control laws, as well as other laws governing our operations. If we fail to comply with these laws, we could be subject to negative publicity, civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition, results of operations and prospects and the value of our common stock.

Our operations are subject to anti-corruption laws, including the US Foreign Corrupt Practices Act (FCPA), the UK Bribery Act and other anti-corruption laws that apply in countries where we do business. The FCPA, UK Bribery Act and these other laws generally prohibit us, our employees and our intermediaries from making prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We have conducted various studies at a broad range of trial sites around the world. Certain of these jurisdictions pose a risk of potential FCPA violations, and we have relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the US Department of Commerce's Bureau of Industry and Security, the US Department of Treasury's Office of Foreign Assets Control, and various non-US government entities, including applicable export control regulations, economic sanctions on countries and persons, customs requirements, currency exchange regulations and transfer pricing regulations (collectively, Trade Control laws).

We may not be effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and prospects and the value of our common stock. Likewise, even an investigation by US or foreign authorities of potential violations of the FCPA other anti-corruption laws or Trade Control laws could have an adverse impact on our reputation, business, financial condition, results of operations and prospects and the value of our common stock.

Our research, development and manufacturing activities used in the production of ARIKAYCE and our product candidates involve the use of hazardous materials, which could expose us to damages, fines, penalties and sanctions and materially adversely affect our results of operations and financial condition.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development program and manufacturing activities for ARIKAYCE and our product candidates involve the controlled use of hazardous materials and chemicals. We generally contract with third parties for the disposal of these materials and wastes.

Although we strive to comply with all pertinent regulations, the risk of environmental contamination, damage to facilities or injury to personnel from the accidental or improper use or control of these materials remains. In addition to any liability we could have for any misuse by us of hazardous materials and chemicals, we could also potentially be liable for activities of our CMOs or other third parties. Any such liability, or even allegations of such liability, could materially adversely affect our results of operations and financial condition. We also could incur significant costs as a result of civil or criminal fines and penalties.

In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Inadequate funding for the FDA and other government agencies and/or potentially shifting priorities under the new administration could hinder the FDA's and/or those other government agencies' ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products, provide feedback on clinical trials and development programs, meet with sponsors and otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels; ability to hire and retain key personnel and accept the payment of user fees; and statutory, regulatory, and policy changes, among other factors. Average review times at the agency may fluctuate as a result. In addition, government funding of other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also increase the time necessary for new drugs to be reviewed and/or approved by necessary government agencies or to otherwise respond to regulatory submissions, such as our NDA submission for brensocatib, which would adversely affect our business. For example the Trump Administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. Additionally, over the last several years, the US government has shut down multiple times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If funding for the FDA is reduced, FDA priorities

change, or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, including our NDA submission for brensocatib, which could have a material adverse effect on our business.

Risks Related to Our Financial Condition and Need for Additional Capital

We have a history of operating losses, expect to incur operating losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred losses each previous year of our operation, except in 2009, when we sold our manufacturing facility and certain other assets to Merck & Co, Inc. As of December 31, 2024, our accumulated deficit was $4.4 billion. For the years ended December 31, 2024, 2023 and 2022, our consolidated net loss was $913.8 million, $749.6 million and $481.5 million, respectively. Our ability to generate revenue depends on the success of commercial sales of ARIKAYCE; however, we do not anticipate our revenue from the sale of ARIKAYCE will be sufficient for us to become profitable without reductions in our operating expenses. Despite commercialization of ARIKAYCE in the US, Europe and Japan, we expect to continue to incur substantial operating expenses, and resulting operating losses, for the foreseeable future as we:

- Initiate or continue clinical studies of our product candidates;
- Complete a post-marketing clinical trial of ARIKAYCE, consisting of the completed ARISE and ongoing ENCORE trials, as required by the FDA;
- Seek to discover or in-license additional product candidates;
- Support the sales and marketing efforts necessary for the continued commercialization of ARIKAYCE;
- Scale-up manufacturing capabilities for future ARIKAYCE production, including the increase of production capacity at Patheon and process improvements in order to manufacture at a larger commercial scale;
- Seek the approval of brensocatib in the US and other markets and, if approved, support the commercial launch of brensocatib and scale-up manufacturing capabilities for brensocatib;
- Seek the approval of TPIP and other product candidates in various markets and, if approved, support the commercial launch of TPIP;
- File, prosecute, defend, and enforce patent claims related to ARIKAYCE, brensocatib, TPIP, INS1201 and our other product candidates; and
- Enhance operational, compliance, financial, quality and information management systems and hire more personnel, including personnel to support our commercialization efforts and development of our product candidates.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We may need to raise additional funds to continue our operations, and any failure to obtain capital when needed on acceptable terms, or at all, could force us to delay, reduce, or eliminate our development programs, commercialization efforts or other operations.

Our operations have consumed substantial amounts of cash since our inception. We expect to expend substantial financial resources on pre-commercialization activities and the regulatory approval process for brensocatib, to continue to commercialize ARIKAYCE and conduct the confirmatory post-marketing ENCORE trial, seek full regulatory approval for ARIKAYCE, as well as continue research and development of brensocatib, TPIP, and INS1201, as well as our other current and future product candidates. We may need to raise additional capital to fund these activities, including due to changes in our product development plans or misjudgment of expected costs, to fund corporate development, to maintain our intellectual property portfolio or for other purposes, including to resolve litigation. Our operating expenses and long-term investments were significantly higher in 2024 than in 2023, reflecting our continued investment in the build-out of our commercial organization to support global expansion activities for ARIKAYCE, preparation for the commercial launch of brensocatib if approved for the treatment of bronchiectasis, the manufacture of commercial inventory, which includes capital and long-term investments, and continued investment in research and development as well as selling, general and administrative expenses. We do not know whether additional financing will be available when needed, or, if available, whether the terms will be favorable. If adequate funds are not available to us when needed, we may be forced to delay, restrict or eliminate all or a portion of our development programs or commercialization efforts.

We have outstanding indebtedness in the form of convertible senior notes, a term loan and a royalty financing arrangement and may incur additional indebtedness in the future, which could adversely affect our financial position, prevent us from implementing our strategy, and dilute the ownership interest of our existing shareholders.

In October 2022, we entered into a loan agreement (the Loan Agreement) with certain funds managed by Pharmakon and a revenue interest purchase agreement (the Royalty Financing Agreement) with OrbiMed. In October 2024, we entered into an Amended and Restated Loan Agreement (the A&R Loan Agreement) and amended the Royalty Financing Agreement.

The A&R Loan Agreement provides for a senior secured term loan of $350.0 million (in addition to the accrual and capitalization of $46.8 million of paid-in-kind interest under the Loan Agreement), which we drew in full in connection with our entry into the Loan Agreement (the Tranche A Term Loan). The A&R Loan Agreement amends the Loan Agreement to, among other items, add a new $150.0 million senior secured term loan tranche (the Tranche B Term Loan and, together with the Tranche A Term Loan, the Term Loans). The Term Loans bear interest at a fixed rate of 9.60% per annum. The A&R Loan Agreement extends the maturity date of the Term Loans to September 30, 2029, subject to acceleration to February 1, 2028 on the occurrence of certain prespecified events. As consideration for the provision of the Tranche B Term Loan, we agreed to pay Pharmakon a fee equal to 2.00% of the Tranche B Term Loan at the closing date of the Tranche B Term Loan and an additional exit fee of 2.00% of the amount of each prepayment or repayment of the Term Loans. The Term Loans will be repaid in eight equal quarterly payments starting on January 3, 2028.

Under the Royalty Financing Agreement, OrbiMed paid us $150.0 million in exchange for the right to receive, on a quarterly basis, royalties (the Royalty Financing) in an amount equal to 4.0% of ARIKAYCE global net sales prior to September 1, 2025 and 4.5% of ARIKAYCE global net sales on or after September 1, 2025, as well as 0.75% of brensocatib global net sales, if approved (the Revenue Interest Payments). In the event that OrbiMed has not received aggregate Revenue Interest Payments equal to or greater than $150.0 million on or prior to March 31, 2028, the royalty rate for ARIKAYCE will be increased for all subsequent fiscal quarters to a rate that, if applied retroactively, would have resulted in aggregate Revenue Interest Payments to OrbiMed for all fiscal quarters ended on or prior to March 31, 2028 equal to $150.0 million. In addition, we must make a one-time payment to OrbiMed in an amount that, when added to the aggregate amount of Revenue Interest Payments received by OrbiMed as of March 31, 2028, would equal $150.0 million. The total Revenue Interest Payments payable by us to OrbiMed are capped at 1.8x of the purchase price or up to a maximum of 1.9x of the purchase price under certain conditions.

In May 2021, we completed an underwritten offering of 0.75% convertible senior notes due in 2028 (the 2028 Convertible Notes). The 2028 Convertible Notes may be convertible into common stock at an initial conversion rate of 30.7692 shares of common stock per $1,000 principal amount of 2028 Convertible Notes. We sold $575.0 million aggregate principal amount of the 2028 Convertible Notes, including the exercise in full of the underwriters' option to purchase additional 2028 Convertible Notes, resulting in net proceeds of approximately $559.3 million. Holders of the 2028 Convertible Notes may convert their 2028 Convertible Notes at their option at any time prior to the close of business on the business day immediately preceding March 1, 2028, only under certain circumstances, which circumstances have existed each quarter since the third quarter of 2024. On or after March 1, 2028, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2028 Convertible Notes at any time. Upon conversion of the 2028 Convertible Notes, we may deliver cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

Our debt service obligations and the degree to which we are leveraged could have negative consequences on our business, such as the following:

- We may be more vulnerable to economic downturns, less able to withstand competitive pressures, and less flexible in responding to changing economic conditions;
- Our ability to obtain financing in the future may be limited;
- We may be required to sell debt or equity securities or to sell some of our core assets, possibly on unfavorable terms, to meet payment obligations;
- We may be placed at a possible competitive disadvantage with less leveraged competitors and competitors that may have better access to capital resources;
- A substantial portion of our cash flows from operations in the future may be required for the payment of our interest or principal payments under the A&R Loan Agreement, Revenue Interest Payments under the Royalty Financing Agreement and the principal amounts of the 2028 Convertible Notes when they or any additional indebtedness become due, thereby reducing the amount of our cash flow available for other purposes, including funds for clinical development or to pursue future business opportunities; and
- We may elect to make cash payments upon conversion of the 2028 Convertible Notes, which would reduce our available cash.

Our ability to pay principal or interest on or, if desired, to refinance our indebtedness, including the A&R Loan Agreement, the Royalty Financing Agreement and the 2028 Convertible Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors, some of which are beyond our control. Our business may not generate cash flow from operations in the future sufficient to satisfy any obligations under the A&R Loan Agreement, the Royalty Financing Agreement or the 2028 Convertible Notes or our obligations under any future indebtedness we may incur. If we are unable to generate such cash flow, we may be required to delay, restrict or eliminate all or a portion of our development programs or commercialization efforts or refinance or obtain additional equity capital on terms that may be onerous or highly dilutive. If we do not meet our debt obligations, it could materially adversely affect our results of operations, financial condition and the value of our common stock.

The A&R Loan Agreement and the Royalty Financing Agreement each contain customary affirmative and negative covenants that restrict our operations, including, among other things, restrictions on our ability to incur liens, incur additional indebtedness, make investments, engage in certain mergers and acquisitions or asset sales, and declare dividends or redeem or repurchase capital stock. The A&R Loan Agreement includes certain customary events of default. If a default occurs and is continuing, we may be required to repay all amounts outstanding under the A&R Loan Agreement. The Royalty Financing Agreement gives OrbiMed the option (the Put Option) to terminate the Royalty Financing Agreement and to require us to repurchase future Revenue Interest Payments upon enumerated events such as a bankruptcy event, a payment default, an uncured material breach or a change of control. The triggering of the Put Option, including by our failure to comply with these covenants, could permit OrbiMed to declare certain amounts to be immediately due and payable. Further, if we are liquidated, Pharmakon's and OrbiMed's rights to repayment would be senior to the rights of the holders of our common stock. Any triggering of the Put Option or other event of default under the A&R Loan Agreement or Royalty Financing Agreement could significantly harm our financial condition, business and prospects and could cause the price of our common stock to decline.

We may also incur additional indebtedness in the future which would result in increased fixed payment obligations and could also result in additional restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license assets or intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

We may be unable to use certain of our net operating losses and other tax assets.

We have substantial tax loss carry forwards in the US (both federal and state), Ireland, the United Kingdom and Switzerland. In general, our net operating losses and tax credits have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. In particular, our ability to fully use certain US tax loss carry forwards and general business tax credit carry forwards recorded prior to December 2010 to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended. Changes in the ownership of our stock, including those resulting from the issuance of shares of our common stock offerings or upon exercise of outstanding options, may limit or eliminate our ability to use certain net operating losses and tax credit carry forwards in the future.

Changes in our effective income tax rate and future changes to US and non-US tax laws could adversely affect our results of operations.

We are subject to income taxes in the US and various ex-US jurisdictions in which we operate globally. Various factors may have favorable or unfavorable impacts on our effective tax rate, including changes in tax rates and laws, interpretations of existing laws, changes in accounting standards, changes in the jurisdiction of our pre-tax earnings and examinations of our tax filings.

Goodwill impairment charges in the future could have a material adverse effect on our business, results of operations and financial condition.

We have recorded a significant amount of goodwill on our consolidated balance sheet as a result of acquisitions. We review the recoverability of goodwill annually and whenever events or circumstances indicate that the carrying value of a reporting unit may not be recoverable.

The impairment tests require us to make an estimate of the fair value of our reporting units. An impairment could be recorded as a result of changes in assumptions, estimates or circumstances, some of which are beyond our control. Since a number of factors may influence determinations of fair value of goodwill, we are unable to predict whether impairments of goodwill will occur in the future, and there can be no assurance that continued conditions will not result in future impairments of goodwill. The future occurrence of a potential indicator of impairment could include matters such as (i) a decrease in expected net earnings, (ii) adverse equity market conditions, (iii) a decline in current market multiples, (iv) a decline in our common stock price, (v) a significant adverse change in legal factors or the general business climate, and (vi) an adverse action or assessment by a regulator. Any such impairment would result in us recognizing a non-cash charge in our consolidated financial statements, which could adversely affect our business, results of operations and financial condition.

Risks Related to Ownership of Our Common Stock

Our shareholders may experience dilution of their ownership interests because of the future issuance of additional shares of our common stock for general corporate purposes and upon the conversion of the 2028 Convertible Notes.

In the future, we may issue additional equity securities for capital raising purposes, in connection with hiring or retaining employees, to fund acquisitions, or for other business purposes. We have previously funded, and expect to continue to fund, acquisitions using shares of our common stock as consideration. In addition, we may issue shares of our common stock upon the conversion of our 2028 Convertible Notes. The conversion of some or all of the 2028 Convertible Notes will dilute the ownership interests of our existing shareholders to the extent we deliver shares upon their conversion. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the 2028 Convertible Notes may encourage short selling by market participants because the

conversion of the 2028 Convertible Notes could be used to satisfy short positions, or the anticipated conversion of the 2028 Convertible Notes into shares of our common stock could depress the price of our common stock. The future issuance of any additional shares of common stock will dilute our current shareholders and may create downward pressure on the value of our shares. The potential for the issuance of a significant amount of our common stock pursuant to the 2028 Convertible Notes could create a circumstance commonly referred to as an “overhang” and in anticipation of which the market price of our stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, could also hinder our ability to raise additional equity capital at a time and price that we deem reasonable or appropriate.

The market price of our stock has been and may continue to be highly volatile, which could lead to shareholder litigation against us.

Our common stock is listed on the Nasdaq Global Select Market under the ticker symbol “INSM”. The market price of our stock has been and may continue to be highly volatile and could be subject to wide fluctuations in price in response to various factors, including those discussed herein, many of which are beyond our control. In addition, the stock market has from time to time experienced extreme price and volume fluctuations, which have particularly affected the market prices for emerging biotechnology and pharmaceutical companies like us, and which have often been unrelated to their operating performance.

Historically, when the market price of a stock has been volatile, shareholders are more likely to institute securities and derivative class action litigation against the issuer of such stock. We previously faced a shareholder suit following a decline in our stock price. If any of our shareholders bring a lawsuit against us in the future, it could have a material adverse effect on our business. We have insurance policies related to some of the risks associated with our business, including directors’ and officers’ liability insurance policies; however, our insurance coverage may not be sufficient and our insurance carriers may not cover all claims in a given litigation. If we are not successful in our defense of claims asserted in shareholder litigation, those claims are not covered by insurance or they exceed our insurance coverage, we may have to pay damage awards, indemnify our executive officers, directors and third parties from damage awards that may be entered against them and pay our and their costs and expenses incurred in defense of, or in any settlement of, such claims. In addition, such shareholder suits could divert the time and attention of management from our business.

Certain provisions of Virginia law, our articles of incorporation and amended and restated bylaws and arrangements between us and our employees could hamper a third party’s acquisition of us or discourage a third party from attempting to acquire control of us.

Certain provisions of Virginia law, our articles of incorporation and amended and restated bylaws and arrangements with our employees could hamper a third party’s acquisition of us or discourage a third party from attempting to acquire control of us, or limit the price that investors might be willing to pay for shares of our common stock. These provisions or arrangements include:

- The ability to issue preferred stock with rights senior to those of our common stock without any further vote or action by the holders of our common stock. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of the holders of our common stock. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock.
- The existence of a staggered board of directors in which there are three classes of directors serving staggered three-year terms, thus expanding the time required to change the composition of a majority of directors.
- The requirement that shareholders provide advance notice when nominating director candidates to serve on our board of directors.
- The inability of shareholders to convene a shareholders’ meeting without the chairman of the board, the president or a majority of the board of directors first calling the meeting.
- The prohibition against entering into a business combination with the beneficial owner of 10% or more of our outstanding voting stock for a period of three years after the 10% or greater owner first reached that level of stock ownership, unless certain criteria are met.
- In addition to severance agreements with our officers and provisions in our incentive plans that permit acceleration of equity awards upon a change in control, a severance plan for eligible full-time employees that provides such employees with severance equal to six months of their then-current base salaries in connection with a termination of employment without cause upon, or within 18 months following, a change in control.

Under Virginia law, our board of directors may implement a shareholders’ rights plan or "poison pill" without shareholder approval. Our board of directors regularly considers this matter, even in the absence of specific circumstances or takeover proposals, to facilitate its future ability to quickly and effectively protect shareholder value.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We incorporate assessment of our cybersecurity initiatives into our Enterprise Risk Management program. The Enterprise Risk Management program evaluates risk areas including, but not limited to, operational risk, intellectual property theft, fraud, harm to employees, patients, or third parties, and violation of privacy or security-related laws or regulations. As part of our efforts to mitigate cyber risk, we have implemented cybersecurity processes, technologies, and controls designed to identify and manage potential material cyber risks and have obtained cyber-specific insurance coverage.

We employ a range of tools and services, including regular network and endpoint monitoring, managed detection and response, system patching, managed security services, server and endpoint scheduled backups, awareness training and testing, periodic vulnerability assessment and penetration testing, to update our ongoing risk identification and mitigation efforts. We have a cybersecurity assessment process, which helps identify our cybersecurity risks by comparing our processes to standards set by the Center for Internet Security. Our processes also assess cybersecurity risks associated with our use of third-party service providers. We proactively engage with key vendors, industry participants, and law enforcement/cyber threat intelligence communities as part of our continuing efforts to evaluate and enhance the effectiveness of our information security policies and procedures.

Our information security program is managed by a senior director who reports to the Chief Information Officer (CIO), providing routine security program updates and briefings. The current senior director has more than 25 years of experience in cybersecurity, federal law enforcement, and cyber investigations, while possessing the required subject matter expertise, skills, experience, and industry certifications expected of an individual assigned to these duties. Our information security team, which includes the CIO and senior director, as well as additional professionals , is responsible for leading enterprise-wide cybersecurity strategy, policy, standards, and processes. Our CIO provides regular updates to our Chief Executive Officer and other members of management. The Audit Committee of the Board of Directors is responsible for oversight of the Company’s cybersecurity risk exposure and the CIO provides reports to the Audit Committee, as well as the full Board of Directors, at least annually. The reports to management and our Board include updates on the Company’s cyber risks and threats, the status of projects to strengthen our information security systems, assessments of the information security program, and the emerging threat landscape.

For the year ended December 31, 2024, we are not aware of any material cybersecurity incidents.

ITEM 2. PROPERTIES

We currently lease 117,022 square feet of office space for our corporate headquarters in Bridgewater, New Jersey. The initial lease, which commenced in the fourth quarter of 2019, provided us a one-time option to expand the leased premises by up to 50,000 square feet prior to the fifth anniversary of the initial lease commencement. We did not exercise the one-time option. The initial term of this lease will expire in 2030.

We lease laboratory space located in Bridgewater for which we exercised the renewal option to extend the lease term until December 2026. In July 2023, we expanded this lease to a total of 46,671 square feet and further extended the lease term until April 2027. We also lease facilities in California totaling 54,478 square feet and a facility in New Hampshire. In addition, we lease space outside of the US in France, Ireland, the Netherlands, Switzerland, the UK, and Japan.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are a party to various lawsuits, claims and other legal proceedings that arise in the ordinary course of business. While the outcomes of these matters are uncertain, management does not expect that the ultimate costs to resolve these matters will have a material adverse effect on our consolidated financial position, results of operations or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

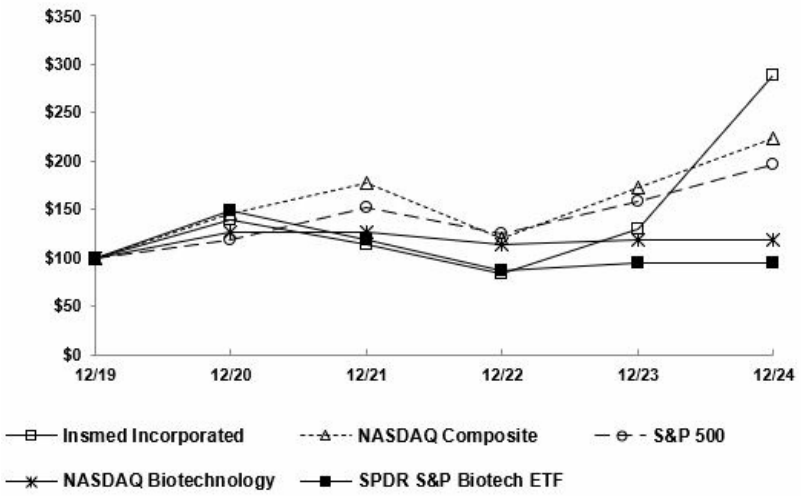
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our trading symbol is "INSM." Our common stock currently trades on the Nasdaq Global Select Market. As of February 14, 2025, there were approximately 148 holders of record of our common stock.

We have never declared or paid cash dividends on our common stock. We anticipate that we will retain all earnings, if any, to support operations and to finance the growth and development of our business for the foreseeable future. Any future determination as to the payment of dividends will be dependent upon these and any contractual or other restrictions to which we may be subject and, to the extent permissible thereunder, will be at the sole discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements and other factors our board of directors deems relevant at that time.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Insmed Incorporated, the NASDAQ Composite Index,
the S&P 500 Index, the NASDAQ Biotechnology Index and the SPDR S&P Biotech ETF Index



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* $100 invested on 12/31/19 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

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ITEM 6. [RESERVED]

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion also should be read in conjunction with our consolidated financial statements and the notes thereto contained elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the section entitled Risk Factors, Cautionary Note Regarding Forward-Looking Statements and elsewhere herein, our actual results may differ materially from those anticipated in these forward-looking statements.

EXECUTIVE OVERVIEW

We are a people-first global biopharmaceutical company striving to deliver first- and best-in-class therapies to transform the lives of patients facing serious diseases. Our first commercial product, ARIKAYCE, was approved in the US in September 2018, in the EU in October 2020 and in Japan in March 2021. Our pipeline includes clinical-stage programs brensocatib, TPIP, and INS1201, as well as pre-clinical research programs. Brensocatib is a small molecule, oral, reversible inhibitor of DPP1, which we are developing for the treatment of patients with bronchiectasis and other neutrophil-mediated diseases, including CRSsNP and HS. TPIP is an inhaled formulation of the treprostinil prodrug treprostinil palmitil which may offer a differentiated product profile for PH-ILD and PAH. INS1201 is an intrathecally delivered gene therapy for patients with DMD. Our pre-clinical research programs encompass a wide range of technologies and modalities, including gene therapy, AI-driven protein engineering, protein manufacturing, RNA end-joining, and synthetic rescue.

Refer to Part I, Item 1. "Business" for a summary of our ongoing commercial and clinical programs for ARIKAYCE and our ongoing clinical activities for brensocatib, TPIP, INS1201, and pre-clinical research programs.

Prior to 2019, we had not generated significant revenue and through December 31, 2024, we had an accumulated deficit of $4.4 billion. We have financed our operations primarily through the public offerings of our equity securities, debt financings and revenue interest financings. Although it is difficult to predict our future funding requirements, based upon our current operating plan, we anticipate that our cash and cash equivalents and marketable securities as of December 31, 2024 will enable us to fund our operations for at least the next 12 months.

Our ability to reduce our operating loss and begin to generate positive cash flow from operations depends on the continued success in commercializing ARIKAYCE and achieving positive results from the ARIKAYCE confirmatory clinical trial program in order to obtain full approval of ARIKAYCE in the US and potentially reach more patients. Our continued success also depends on commercializing brensocatib, if approved, as well as bringing additional clinical stage products to market, such as TPIP and INS1201, and advancement of our pre-clinical research programs. We expect to continue to incur substantial expenses related to our research and development activities as we continue the ARIKAYCE confirmatory clinical program, conduct studies to explore the potential of brensocatib in additional neutrophil-mediated diseases, inc luding CRSsNP and HS, continue the trials for TPIP, and fund development of our pre-clinical research programs. We also expect to continue to incur significant costs related to the commercialization of ARIKAYCE and our commercial readiness activities, and if approved, commercial activities in preparation for a launch of brensocatib for patients with bronchiectasis. Our financial results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of ARIKAYCE; the scope and progress of our research and development efforts; and the timing of certain expenses. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such products and whether or when they may become profitable.

KEY COMPONENTS OF OUR RESULTS OF OPERATIONS

Product Revenues, Net

Product revenues, net consist of net sales of ARIKAYCE. In October 2018, we began shipping ARIKAYCE to our customers in the US, which include specialty pharmacies and specialty distributors. In December 2020, we began commercial sales of ARIKAYCE in Europe. In July 2021, we began recognizing product revenue from commercial sales of ARIKAYCE in Japan. We recognize revenue for product received by our customers net of allowances for customer credits, including prompt pay discounts, service fees, estimated rebates, including government rebates, such as Medicaid rebates and Medicare Part D coverage gap reimbursements in the US, and chargebacks.

Cost of Product Revenues (Excluding Amortization of Intangible Assets)

Cost of product revenues (excluding amortization of intangible assets) consist primarily of direct and indirect costs related to the manufacturing of ARIKAYCE sold, including third-party manufacturing costs, packaging services, freight, and allocation of overhead costs, in addition to royalty expenses. We began capitalizing ARIKAYCE related inventory upon FDA approval of ARIKAYCE in September 2018.

Research and Development (R&D) Expenses

R&D expenses consist of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our research and development functions. R&D expenses also include other internal operating expenses, the cost of manufacturing product candidates, including the medical devices for drug delivery, for clinical study, the cost of conducting clinical studies, and the cost of conducting preclinical and research activities. In addition, R&D expenses include payments to third parties for the license rights to products in development (prior to marketing approval), such as brensocatib, and may include the cost of asset acquisitions. Our R&D expenses related to manufacturing our product candidates and medical devices for clinical study are primarily related to activities at CMOs that manufacture brensocatib, TPIP, INS1201, and pre-clinical research activities. Our R&D expenses related to clinical trials are primarily related to activities at CROs that conduct and manage clinical trials on our behalf. These contracts with CROs set forth the scope of work to be completed at a fixed fee or amount per patient enrolled. Payments under these contracts with CROs primarily depend on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones as well as time-based fees. Expenses are accrued based on contracted amounts applied to the level of patient enrollment and to activity according to the clinical trial protocol. Deposits for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are then recognized as an expense as the related goods are delivered or the services are performed.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses consist of salaries, benefits and other related costs, including stock-based compensation, for our non-employee directors and personnel serving in our executive, finance and accounting, legal and compliance, commercial and pre-commercial, corporate development, field sales, information technology and human resource functions. SG&A expenses also include professional fees for legal services, consulting services, including commercial activities, insurance, board of director fees, tax and accounting services and certain milestones related to ARIKAYCE.

Amortization of Intangible Assets

Upon commercialization of ARIKAYCE, our intangible assets began to be amortized over their estimated useful lives. The fair values assigned to our intangible assets are based on estimates and assumptions we believe are reasonable based on available facts and circumstances. Unanticipated events or circumstances may occur that require us to review the assets for impairment.

Change in Fair Value of Deferred and Contingent Consideration Liabilities

In connection with the Business Acquisition, we recorded deferred and contingent consideration liabilities related to potential future milestone payments. Adjustments to the fair value are due to changes in the probability of achieving milestones, our stock price, or certain other estimated assumptions. The change in fair value of deferred and contingent consideration liabilities is calculated quarterly with gains and losses recorded in the consolidated statements of comprehensive loss. Our deferred consideration liabilities were fully settled in the third quarter of 2024. As of December 31, 2024, only contingent consideration liabilities exist.

Investment Income and Interest Expense

Investment income consists of interest and dividend income earned on our cash and cash equivalents and marketable securities. Interest expense consists primarily of contractual interest costs, Royalty Financing Agreement non-cash interest expense and the amortization of debt issuance costs related to our debt. Debt issuance costs are amortized to interest expense using the effective interest rate method over the term of the debt. Our consolidated balance sheets reflect debt, net of the debt issuance costs paid to the lender, and other third-party costs.

Change in Fair Value of Interest Rate Swap

We record derivative and hedge transactions in accordance with generally accepted accounting principles in the US (GAAP). In the fourth quarter of 2022, we entered into an interest rate swap contract (the Swap Contract) with a notional value of $350.0 million to economically hedge our variable rate-based term debt for three years, effectively changing the variable rate under the term debt to a fixed interest rate. Our interest rate swap was not designated as a hedging instrument for accounting purposes. We settled and terminated the Swap Contract in October 2024. All changes in the fair value of the Swap Contract were reported as change in fair value of interest rate swap in the consolidated statements of comprehensive loss.

RESULTS OF OPERATIONS

Comparison of the Years Ended December 31, 2024 and 2023

Overview - Operating Results

Our operating results for the year ended December 31, 2024, included the following:

- Product revenues, net, increased $58.5 million, or 19.2%, as compared to the prior year as a result of the growth in ARIKAYCE sales;

- The cost of product revenues (excluding amortization of intangibles) increased $20.2 million, or 30.8%, as compared to the prior year primarily as a result of the growth in ARIKAYCE sales;
- R&D expenses increased $27.4 million, or 4.8%, as compared to the prior year primarily as a result of the increase in compensation and benefit-related expenses and stock-based compensation costs;
- SG&A expenses increased $116.6 million, or 33.9%, as compared to the prior year primarily as a result of the increase in compensation and benefit-related expenses and stock-based compensation costs;
- Amortization of intangible assets was consistent with the prior year;
- The change in fair value of deferred and contingent consideration liabilities increased $63.0 million as compared to the prior year primarily as a result of the increase in our share price;
- Investment income increased $11.2 million, or 26.5%, as compared to the prior year primarily as a result of an increase in our average cash and cash equivalents and marketable securities balances; and
- Interest expense increased $3.2 million, or 3.9%, as compared to the prior year primarily as a result of the $150.0 million Tranche B Term Loan borrowing in October 2024.

Product Revenues, Net

Product revenues, net, consist of net sales of ARIKAYCE. The following table summarizes revenue by geography for the years ended December 31, 2024 and 2023 (in thousands):

	Years Ended December 31,		Increase (decrease)	
	2024	2023	$	%
US	$ 254,800	$ 224,195	$ 30,605	13.7%
Japan	87,699	65,733	21,966	33.4%
Europe and rest of world	21,208	15,280	5,928	38.8%
Total product revenues, net	$ 363,707	$ 305,208	$ 58,499	19.2%

Product revenues, net for the year ended December 31, 2024 were $363.7 million as compared to $305.2 million for the year ended December 31, 2023, an increase of $58.5 million, or 19.2%. This increase was a result of the growth in sales of ARIKAYCE in the US, Japan, and Europe and the rest of the world.

Cost of Product Revenues (Excluding Amortization of Intangibles)

Cost of product revenues (excluding amortization of intangibles) for the years ended December 31, 2024 and 2023 were comprised of the following (in thousands):

	Years Ended December 31,		Increase (decrease)	
	2024	2023	$	%
Cost of product revenues (excluding amortization of intangibles)	$ 85,742	$ 65,573	$ 20,169	30.8%
Cost of product revenues, as % of revenues	*23.6 %*	*21.5 %*		

Cost of product revenues (excluding amortization of intangibles) were $85.7 million for the year ended December 31, 2024 as compared to $65.6 million for the year ended December 31, 2023, an increase of $20.2 million, or 30.8%. This increase was primarily attributable to the growth in total revenues discussed above.

R&D Expenses

R&D expenses for the years ended December 31, 2024 and 2023 were comprised of the following (in thousands):

	Years Ended December 31,		Increase (decrease)	
	2024	2023	$	%
External Expenses				
Clinical development and research	$ 171,635	$ 166,448	$ 5,187	3.1%
AstraZeneca milestone	12,500	—	12,500	NA
Manufacturing	94,766	73,614	21,152	28.7%
Regulatory, quality assurance, and medical affairs	36,476	27,002	9,474	35.1%
Non-cash asset acquisitions	—	86,747	(86,747)	(100.0)%
Subtotal—external expenses	$ 315,377	$ 353,811	$ (38,434)	(10.9)%
Internal Expenses				
Compensation and benefit-related expenses	$ 194,907	$ 140,861	$ 54,046	38.4%
Stock-based compensation	47,674	35,880	11,794	32.9%
Other internal operating expenses	40,409	40,459	(50)	(0.1)%
Subtotal—internal expenses	$ 282,990	$ 217,200	$ 65,790	30.3%
Total R&D expenses	$ 598,367	$ 571,011	$ 27,356	4.8%

R&D expenses were $598.4 million for the year ended December 31, 2024 as compared to $571.0 million for the year ended December 31, 2023, an increase of $27.4 million, or 4.8%. This increase was primarily due to the $65.8 million increase in compensation and benefit-related expenses and stock-based compensation costs due to an increase in headcount, a $21.2 million increase in manufacturing expense, the $12.5 million AstraZeneca milestone upon our release of an official public statement that we intended to file an NDA for brensocatib, and a $9.5 million increase in regulatory, quality assurance, and medical affairs expense, partially offset by the $86.7 million non-cash asset acquisition cost of Adrestia and Vertuis in 2023.

External R&D expenses by product for the years ended December 31, 2024 and 2023 were comprised of the following (in thousands):

	Years Ended December 31,		Increase (decrease)	
	2024	2023	$	%
ARIKAYCE external R&D expenses	$ 60,269	$ 62,418	$ (2,149)	(3.4)%
Brensocatib external R&D expenses	98,569	108,556	(9,987)	(9.2)%
TPIP external R&D expenses	65,935	50,185	15,750	31.4%
Non-cash asset acquisitions	—	86,747	(86,747)	(100.0)%
AstraZeneca milestone	12,500	—	12,500	NA
Other external R&D expenses	78,104	45,905	32,199	70.1%
Total external R&D expenses	$ 315,377	$ 353,811	$ (38,434)	(10.9)%

We expect R&D expenses to increase in 2025 relative to 2024 primarily d ue to our clinical trial activities and related spend including our confirmatory clinical trial of ARIKAYCE in a treatment setting for patients with MAC lung disease, our TPIP and brensocatib clinical trials, and other research efforts for our product candidates.

SG&A Expenses

SG&A expenses for the years ended December 31, 2024 and 2023 were comprised of the following (in thousands):

	Years Ended December 31,		Increase (decrease)	
	2024	2023	$	%
Compensation and benefit-related expenses	$ 168,498	$ 117,926	$ 50,572	42.9%
Stock-based compensation	49,161	38,898	10,263	26.4%
Professional fees and other external expenses	173,631	138,151	35,480	25.7%
Facility related and other internal expenses	69,826	49,526	20,300	41.0%
Total SG&A expenses	$ 461,116	$ 344,501	$ 116,615	33.9%

SG&A expenses were $461.1 million during the year ended December 31, 2024 as compared to $344.5 million for the year ended December 31, 2023, an increase of $116.6 million, or 33.9%. This increase was primarily due to a $60.8 million

increase in compensation and benefit-related expenses and stock-based compensation costs due to an increase in headcount as part of commercial readiness activities for brensocatib, a $35.5 million increase in professional fees and other external expenses driven by commercial readiness activities for brensocatib, and a $20.3 million increase in facility-related and other internal expenses. We expect SG&A expenses to continue to increase in 2025 relative to 2024 due, in part, to commercial readiness activities, and commercial activities for brensocatib, if approved.

Amortization of Intangible Assets

Amortization of intangible assets for both the years ended December 31, 2024 and 2023 was $5.1 million. Amortization of intangible assets is comprised of amortization of acquired ARIKAYCE R&D and amortization of the milestones paid to PARI for the FDA and EMA approvals of ARIKAYCE.

Change in Fair Value of Deferred and Contingent Consideration Liabilities

The change in fair value of deferred and contingent consideration liabilities for the year ended December 31, 2024 was $91.7 million and was primarily due to the increase in our share price. The change is related to the fair value of the potential future consideration to be paid to former equityholders of the businesses we have acquired.

Investment Income

Investment income was $53.3 million for the year ended December 31, 2024 as compared to $42.1 million for the year ended December 31, 2023. The increase was primarily due to an increase in our average cash and cash equivalents and marketable securities balances in 2024 relative to 2023.

Interest Expense

Interest expense was $84.9 million for the year ended December 31, 2024 as compared to $81.7 million for the year ended December 31, 2023. The increase was primarily due to the $150.0 million Tranche B Term Loan borrowing in October 2024 and the increase in the Term Loan principal balance due to the capitalization of paid-in-kind interest partially offset by the interest reduction on the Tranche A Term Loan. See *Note 10 - Debt* and *Note 11 - Royalty Financing Agreement* for further details.

Change in Fair Value of Interest Rate Swap

The change in fair value of interest rate swap for the year ended December 31, 2024 was $0.2 million. Prior to settlement and termination of the Swap Contract in October 2024, adjustments to the fair value were due to changes in interest rates during 2024 relative to the interest rate of the Swap Contract as of December 31, 2023.

Provision for Income Taxes

The income tax provision was $3.7 million for the year ended December 31, 2024 as compared to $2.6 million for the year ended December 31, 2023. The income tax provision for the years ended December 31, 2024 and 2023 reflects the income tax expense recorded as a result of taxable income in certain of our subsidiaries in Europe and Japan, as well as a liability for certain state income taxes.

Comparison of the Years Ended December 31, 2023 and 2022

Please refer to the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 for a comparative discussion of our fiscal years ended December 31, 2023 and December 31, 2022.

LIQUIDITY AND CAPITAL RESOURCES

Overview

There is considerable time and cost associated with developing potential pharmaceutical products to the point of regulatory approval and commercialization. We commenced commercial shipments of ARIKAYCE in October 2018. We expect to continue to incur consolidated operating losses, including losses at our US and certain international entities, as we plan to fund R&D for ARIKAYCE, brensocatib, TPIP and our other pipeline programs, continue commercialization and regulatory activities for ARIKAYCE, fund commercial readiness activities for brensocatib, and engage in other general and administrative activities.

In May 2024, we completed an underwritten offering of 14,514,562 shares of our common stock at a public offering price of $51.50 per share. 1,893,203 of the shares of common stock were issued pursuant to the exercise in full of the underwriters' option to purchase additional shares. Our net proceeds from the sale of the shares, after deducting underwriting discounts and estimated offering expenses of $34.3 million, were $713.2 million.

In October 2022, we entered into a $350.0 million Tranche A Term Loan with Pharmakon that would have matured on October 19, 2027. The Tranche A Term Loan originally bore interest at a rate based upon the Secured Overnight Financing Rate (SOFR), subject to a SOFR floor of 2.5%, in addition to a margin of 7.75% per annum. Net proceeds from the Tranche A Term Loan, after deducting the lenders fees and deal expenses of $15.1 million, were $334.9 million. In October 2024, we entered into the A&R Loan Agreement with BioPharma Credit PLC, BPCR Limited Partnership and BioPharma Credit Investments V (Master) LP, which are funds managed by Pharmakon, and the guarantors party to such agreement. The A&R Loan Agreement amends and restates the Loan Agreement, dated as of October 19, 2022, pursuant to which the Tranche A Term Loan was provided. The A&R Loan Agreement, among other items, provides an additional $150.0 million senior secured Tranche B Term Loan. The A&R Loan Agreement extends the maturity of the Term Loans to September 30, 2029, subject to acceleration to February 1, 2028 on the occurrence of certain prespecified events, and amends the interest rate on the Term Loans to a fixed rate of 9.6% per annum. As consideration for the provision of the Tranche B Term Loan, we agreed to pay Pharmakon a fee equal to 2.0% of the Tranche B Term Loan at the closing date of the Tranche B Term Loan and an additional exit fee of 2.0% of the amount of each prepayment or repayment of the Term Loans. The Term Loans will be repaid in eight equal quarterly payments starting on January 3, 2028. Net proceeds from the Tranche B Term Loan, after deducting the lenders fees and administrative expenses of $3.7 million, were $146.3 million.

In October 2022, we entered into the Royalty Financing Agreement with OrbiMed, whereby OrbiMed paid us $150.0 million in exchange for the right to receive, on a quarterly basis, royalties in an amount equal to 4.0% of ARIKAYCE global net sales prior to September 1, 2025 and 4.5% of ARIKAYCE global net sales on or after September 1, 2025, as well as 0.75% of brensocatib global net sales, if approved. In the event that OrbiMed has not received aggregate Revenue Interest Payments equal to or greater than $150.0 million on or prior to March 31, 2028, the royalty rate for ARIKAYCE will be increased for all subsequent fiscal quarters to a rate which, if applied retroactively, would have resulted in aggregate Revenue Interest Payments to OrbiMed for all fiscal quarters ended on or prior to March 31, 2028 equal to $150.0 million. In addition, we must make a one-time payment to OrbiMed in an amount that, when added to the aggregate amount of Revenue Interest Payments received by OrbiMed as of March 31, 2028, would equal $150.0 million. The total Revenue Interest Payments payable by us to OrbiMed are capped at 1.8x of the purchase price or up to a maximum of 1.9x of the purchase price under certain conditions. Net proceeds from the Royalty Financing Agreement, after deducting the lenders fees and deal expenses of $3.6 million, were $146.4 million. The Royalty Financing Agreement was amended in October 2024 to, among other things, amend certain restrictions on the Company’s ability to incur indebtedness.

In the first quarter of 2021, we entered into a sales agreement with SVB Leerink LLC (now known as Leerink Partners LLC) (Leerink Partners), to sell shares of our common stock, with aggregate gross sales proceeds of up to $250.0 million, from time to time, through an “at the market” equity offering program (the ATM program), under which Leerink Partners acted as sales agent. During the year ended December 31, 2023, we issued and sold an aggregate of 6,503,041 shares of common stock through the ATM program at a weighted-average public offering price of $24.12 per share and received net proceeds of $152.2 million. In the first quarter of 2024, we entered into a new sales agreement (the new sales agreement) with Leerink Partners to sell shares of our common stock, with aggregate gross sales proceeds of up to $500.0 million, from time to time, through a new "at the market" equity offering program (the new ATM program), under which Leerink Partners acted as sales agent. In connection with entering into the new ATM program, we terminated the ATM program. During the year ended December 31, 2024, we issued and sold an aggregate of 5,022,295 shares of common stock through the new ATM program at a weighted-average public offering price of $75.64 per share and received net proceeds of $371.3 million. On November 18, 2024, we terminated the new sales agreement.

We may need to raise additional capital to fund our operations, the continued commercialization of ARIKAYCE, commercial readiness activities for the launch of brensocatib for the treatment of patients with bronchiectasis, if approved, clinical trials for brensocatib, TPIP, INS1201, and our future product candidates, and to develop, acquire, in-license or co-promote other products or product candidates, including those that address serious diseases. While we believe we currently have sufficient funds to meet our financial needs for at least the next 12 months, we may opportunistically raise additional capital and may do so through equity or debt financing(s), strategic transactions or otherwise. Our cash requirements for the next 12 months will be impacted by a number of factors, the most significant of which we expect to be expenses related to our commercialization efforts and our ARISE and ENCORE clinical trials for ARIKAYCE, and other development activities for brensocatib, and to a lesser extent, expenses related to the clinical development of TPIP and INS1201, and our pre-clinical research programs.

Cash Flows

We had cash and cash equivalents of $555.0 million as of December 31, 2024 as compared with $482.4 million as of December 31, 2023, an increase of $72.7 million. This increase was primarily due to our underwritten offering of common stock in May 2024, proceeds from the new ATM program, and maturities of marketable securities, partially offset by our cash used in operating activities. In addition, we had marketable securities of $878.8 million as of December 31, 2024 as compared to $298.1 million as of December 31, 2023, an increase of $580.7 million. This increase is due to our use of cash proceeds to purchase investments. Our working capital was $1.3 billion as of December 31, 2024 as compared to $703.4 million as of December 31, 2023.

Net cash used in operating activities was $683.9 million and $536.2 million for the years ended December 31, 2024 and 2023, respectively. The net cash used in operating activities during the years ended December 31, 2024 and 2023 was primarily for the commercial, clinical, and manufacturing activities related to ARIKAYCE, as well as other SG&A expenses and clinical trial expenses related to brensocatib and TPIP. The increase in cash used in operating activities for the year ended December 31, 2024 as compared to 2023 was primarily due to the increase in net loss, excluding the adjustments to reconcile net loss to net cash used in operating activities.

Net cash used in investing activities was $583.2 million and $223.6 million for the years ended December 31, 2024 and 2023, respectively. The increase in cash used for investing activities for the year ended December 31, 2024 as compared to 2023 is due to the purchases of marketable securities, partially offset by maturity of certain marketable securities.

Net cash provided by financing activities was $1.3 billion and $168.4 million for the years ended December 31, 2024 and 2023, respectively. The increase in cash provided by financing activities for the year ended December 31, 2024 as compared to 2023 is due to net cash proceeds received from the issuance of common stock in our underwritten offering in May 2024, proceeds from our terminated new ATM program, proceeds from the Tranche B Term Loan, and proceeds from stock options and our Employee Stock Purchase Program (ESPP).

Contractual Obligations

In October 2022, we entered into financings resulting in aggregate gross proceeds of $500.0 million, comprised of the $350.0 million Tranche A Term Loan with funds managed by Pharmakon and the $150.0 million Royalty Financing Agreement with OrbiMed, which was subsequently amended in October 2024. Under the Royalty Financing Agreement, OrbiMed will be entitled to receive royalties of 4.0% on ARIKAYCE global net sales until September 1, 2025, and royalties of 4.5% on ARIKAYCE global net sales on or after September 1, 2025, as well as royalties of 0.75% on brensocatib global net sales, if approved. The total royalty payable to OrbiMed is capped at 1.8x of the $150.0 million purchase price or up to a maximum of 1.9x of the $150.0 million purchase price under certain conditions. For more information, see *Note 10 - Debt* and *Note 11 - Royalty Financing Agreement* in our notes to the consolidated financial statements.

In October 2024, we entered into the A&R Loan Agreement with BioPharma Credit PLC, BPCR Limited Partnership and BioPharma Credit Investments V (Master) LP, which are funds managed by Pharmakon, and the guarantors party to such agreement. The A&R Loan Agreement amends and restates the Loan Agreement, dated as of October 19, 2022, pursuant to which the Tranche A Term Loan was provided. The A&R Loan Agreement, among other items, provides the Tranche B Term Loan. The A&R Loan Agreement extends the maturity of the Term Loans to September 30, 2029, subject to acceleration to February 1, 2028 on the occurrence of certain prespecified events, and amends the interest rate on the Term Loans to a fixed rate of 9.6% per annum. For more information, see *Note 10 - Debt* in our notes to the consolidated financial statements.

In May 2021, we completed an underwritten public offering of $575.0 million aggregate principal amount of the 2028 Convertible Notes pursuant to an indenture between the Company and Wells Fargo Bank, National Association, as trustee (the Indenture). Net proceeds from the offering, after deducting underwriting discounts and offering expenses of $15.7 million, were $559.3 million. The 2028 Convertible Notes bear interest payable semiannually in arrears on June 1 and December 1 of each year, beginning on December 1, 2021. The 2028 Convertible Notes mature on June 1, 2028, unless earlier converted, redeemed, or repurchased. The 2028 Convertible Notes are convertible into common stock of the Company under certain circumstances described in the Indenture. On July 1, 2024 and October 1, 2024, the 2028 Convertible Notes became convertible, through the end of the third quarter of 2024 and fourth quarter of 2024, respectively, by the holders of such notes due to the satisfaction of the Stock Price Convertibility Trigger applicable to such notes. The current conversion rate for the 2028 Convertible Notes is 30.7692 shares of common stock per $1,000 principal amount of notes (equivalent to an initial conversion price of approximately $32.50 per share of common stock). We have elected to settle any conversions of the 2028 Convertible Notes in shares of common stock. For more information, see *Note 10 - Debt* in our notes to the consolidated financial statements.

In January 2024, we entered into certain agreements with Patheon Inc., a wholly-owned subsidiary of Thermo Fisher, related to the manufacture and supply of brensocatib by Patheon Inc. for our anticipated long-term commercial needs. Under these agreements, we are required to deliver to Patheon Inc. the active pharmaceutical ingredients needed to manufacture brensocatib. In addition, in September 2024, we entered into a commercial manufacturing and supply agreement with Esteve for the manufacture and supply of brensocatib's active pharmaceutical ingredient.

In April 2020, we entered into a master services agreement with PPD pursuant to which we retained PPD to perform clinical development services in connection with certain of our clinical research programs. The master services agreement has an initial term of five years. Either party may terminate (i) any project addendum under the master services agreement for any reason and without cause upon 30 days' written notice, (ii) any project addendum in the event of the other party's breach of the master services agreement or such project addendum upon 30 days' written notice, provided that such breach is not cured within such 30-day period, (iii) the master services agreement or any project addendum immediately upon the occurrence of an insolvency event with respect to the other party or (iv) any project addendum upon 30 days' written notice if (a) the continuation of the services under such project addendum would post material ethical or safety risks to study participants, (b) any approval from a regulatory authority necessary to perform the applicable study is revoked, suspended or expires without renewal or (c) in the reasonable opinion of such party, continuation of the services provided under such project addendum would be in violation of applicable law. We have entered into project addenda with PPD to perform clinical development services over several years for, but not limited to, our ARISE, ENCORE and ASPEN studies and other trials involving brensocatib and TPIP. The total cost of these project addenda is $498.9 million.

In September 2018, we entered into an agreement (the Lease) with Bridgewater Biotech Center LLC (assumed from Exeter 700 Route 202/206, LLC) to lease 117,022 square feet of office space located in Bridgewater, New Jersey for our corporate headquarters. Subject to certain conditions, we had the one-time option to expand the leased premises by up to 50,000 rentable square feet, exercisable prior to the fifth anniversary of the Commencement Date, which was October 1, 2019. We did not exercise this one-time option. The initial Lease term runs 130 months from the Commencement Date and we have the option to extend that term for up to three additional five-year periods. In addition, we are responsible for operating expenses and taxes pursuant to the Lease. Future minimum payments under the Lease during the initial Lease term are approximately $15.3 million. The Lease contains customary default provisions, including those relating to payment defaults, performance defaults and events of bankruptcy.

In October 2017, we entered into certain agreements with Patheon related to the increase of our long-term production capacity for ARIKAYCE. The agreements provide for Patheon to manufacture and supply ARIKAYCE for our anticipated commercial needs. Under these agreements, we are required to deliver to Patheon the required raw materials, including active pharmaceutical ingredients, and certain fixed assets needed to manufacture ARIKAYCE. Patheon's supply obligations will commence once certain technology transfer and construction services are completed. Our manufacturing and supply agreement with Patheon will remain in effect for a fixed initial term, after which it will continue for successive renewal terms unless either we or Patheon have given written notice of termination. The technology transfer agreement will expire when the parties agree that the technology transfer services have been completed. The agreements may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or the other party's insolvency. These early termination clauses may reduce the amounts due to the relevant parties. The aggregate investment to increase our long-term production capacity, including under the Patheon agreements and related agreements or purchase orders with third parties for raw materials and fixed assets, is estimated to be approximately $116.0 million.

In October 2016, we entered into the AZ License Agreement, pursuant to which AstraZeneca granted us exclusive global rights for the purpose of developing and commercializing AZD7986 (which we renamed brensocatib). In consideration of the licenses and other rights granted by AstraZeneca, we made an upfront payment of $30.0 million, which was included as research and development expense in the fourth quarter of 2016. In December 2020, we incurred a $12.5 million milestone payment obligation upon first dosing in a Phase 3 clinical trial of brensocatib. In May 2024, upon our release of an official public statement that we intended to file an NDA, we incurred an additional $12.5 million milestone payment obligation. Upon regulatory approval by the FDA of an NDA, we will owe AstraZeneca an additional $30.0 million. Subsequent to this milestone, we are also obligated to make a series of additional contingent milestone payments totaling up to an additional $30.0 million upon the achievement of regulatory filing milestones. If we elect to develop brensocatib for a second indication, we will be obligated to make an additional series of contingent milestone payments totaling up to $42.5 million, the first of which occurs at the initiation of a Phase 3 trial in the additional indication. We are not obligated to make any additional milestone payments for any additional indications. In addition, we have agreed to pay AstraZeneca tiered royalties ranging from a high single-digit to mid-teens on net sales of any approved product based on brensocatib and one additional payment of $35.0 million upon the first achievement of $1 billion in annual net sales. The AZ License Agreement provides AstraZeneca with the option to negotiate a future agreement with us for commercialization of brensocatib in chronic obstructive pulmonary disease or asthma.

We have a licensing agreement with PARI for the use of optimized Lamira for delivery of ARIKAYCE in treating patients with NTM lung infections, CF and bronchiectasis. Under the licensing agreement, we have rights under several US and

foreign issued patents, and patent applications involving improvements to optimized Lamira, to exploit the system with ARIKAYCE for the treatment of such indications, but we cannot manufacture the nebulizers except as permitted under our Commercialization Agreement with PARI, as described below. Lamira has been approved for use in the US (in combination with ARIKAYCE), the EU and Japan. Under the licensing agreement, we made an upfront license fee and milestone payments to PARI. Upon the FDA acceptance of our NDA and the subsequent FDA and EMA approvals of ARIKAYCE, we made additional milestone payments of €1.0 million, €1.5 million, and €0.5 million, respectively, to PARI. In October 2017, we exercised an option to buy-down the royalties payable to PARI, which was included within selling, general and administrative expenses in the fourth quarter of 2017. PARI is entitled to receive royalty payments in the mid-single digits on the annual global net sales of ARIKAYCE, pursuant to the licensing agreement, subject to certain specified annual minimum royalties.

In July 2014, we entered into a Commercialization Agreement with PARI for the manufacture and supply of Lamira, which is an e-Flow ® nebulizer modified and optimized for use with ARIKAYCE. Under the Commercialization Agreement, PARI manufactures Lamira except in the case of certain defined supply failures, when the Company will have the right to make Lamira and have it made by third parties (but not certain third parties deemed under the Commercialization Agreement to compete with PARI). The Commercialization Agreement has an initial term of 15 years that began in October 2018. The term of the Commercialization Agreement may be extended by us for an additional five years by providing written notice to PARI at least one year prior to the expiration of the Initial Term.

In February 2014, we entered into a contract manufacturing agreement with Therapure Biopharma Inc., which has been assumed by Resilience, for the manufacture of ARIKAYCE, on a non-exclusive basis, at a 200 kg scale. Pursuant to the agreement, we collaborated with Resilience to construct a production area for the manufacture of ARIKAYCE in Resilience's existing manufacturing facility in Canada. The agreement has an initial term of five years, which began in October 2018, and renews automatically for successive periods of two years each, unless terminated by either party by providing the required two years' prior written notice to the other party. Under the agreement, we are obligated to pay certain minimum amounts for the batches of ARIKAYCE produced each calendar year.

In 2004 and 2009, we entered into research funding agreements with CFFT whereby we received $1.7 million and $2.2 million, respectively, in research funding for the development of ARIKAYCE. As a result of the US approval of ARIKAYCE and in accordance with the agreements, as amended, we owe milestone payments to CFFT of $13.4 million in the aggregate payable through 2025, of which $10.4 million has been paid as of December 31, 2024. Furthermore, if certain global sales milestones were met within five years of the commercialization of ARIKAYCE, we would have owed up to an additional $3.9 million. Through December 31, 2024, we have met and paid $1.7 million of these additional global sales milestone payments.

Future Funding Requirements

We may need to raise additional capital to fund our operations, including the development and potential commercialization of brensocatib, continued commercialization of ARIKAYCE, current and future clinical trials related to ARIKAYCE, development of TPIP, and the potential development, acquisition, in-license or co-promotion of other products or product candidates, including those that address orphan or serious diseases. We expect that our future capital requirements may be substantial and will depend on many factors, including:

- The timing, outcome, and cost of our ongoing and anticipated clinical trials for our product candidates;
- The timing and cost of our current and future clinical trials of ARIKAYCE for the treatment of patients with NTM lung infections, including the ENCORE trial;
- The cost of discovering or in-licensing additional product candidates;
- The costs of activities related to the regulatory approval process and the timing of approvals, if received;
- The cost of supporting the sales and marketing efforts necessary to support the continued commercial efforts of ARIKAYCE;
- The timing and costs of supporting the commercial launch activities of brensocatib, if approved;
- The cost of eventually supporting the commercial launches of TPIP and our other product candidates;
- The cost of filing, prosecuting, defending, and enforcing patent claims;
- The costs of our manufacturing-related activities;
- The cost of hiring more personnel to support our ongoing development and commercialization efforts; and
- The levels, timing and collection of revenue earned from sales of ARIKAYCE and other products approved in the future, if any.

We have raised $2.2 billion in net proceeds from securities offerings and other financing transactions since January 1, 2022. We believe we currently have sufficient funds to meet our financial needs for at least the next 12 months. However, our business strategy may require us to raise additional capital at any time through equity or debt financing(s), strategic transactions or otherwise.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. We do not have any interest in special purpose entities, structured finance entities or other variable interest entities.

CRITICAL ACCOUNTING ESTIMATES

Preparation of financial statements in accordance with GAAP requires us to make estimates and assumptions affecting the reported amounts of assets, liabilities, revenues and expenses and the disclosures of contingent assets and liabilities. We use our historical experience and other relevant factors when developing our estimates and assumptions and we regularly evaluate these estimates and assumptions. The amounts of assets and liabilities reported in our consolidated balance sheets and the amounts reported in our consolidated statements of comprehensive loss are affected by estimates and assumptions, which are used for, but not limited to, the accounting for revenue recognition and indefinite-lived intangible assets. The accounting estimates discussed below involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition or results of operations. Actual results could differ materially from our estimates. For additional accounting policies, see *Note 2 - Summary of Significant Accounting Policies* in our notes to the consolidated financial statements.

Revenue Recognition

In accordance with Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers, we recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration we expect to receive in exchange for the goods or services provided. To determine revenue recognition for arrangements within the scope of ASC 606, we perform the following five steps: (1) identify the contracts with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when or as the entity satisfies a performance obligation. At contract inception, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied. For all contracts that fall into the scope of ASC 606, we have identified one performance obligation: the sale of ARIKAYCE to our customers. We have not incurred or capitalized any incremental costs associated with obtaining contracts with customers.

Product revenues, net, consist of net sales of ARIKAYCE. Our customers in the US include specialty pharmacies and specialty distributors. In December 2020, we began recognizing product revenue from commercial sales of ARIKAYCE in Europe. In July 2021, we began recognizing product revenue from commercial sales of ARIKAYCE in Japan. Globally, product revenues are recognized once we perform and satisfy all five steps of the revenue recognition criteria mentioned above.

Revenue is recorded at net selling price (transaction price), which includes estimates of variable consideration for which reserves are established for estimated government rebates, such as Medicaid and Medicare Part D reimbursements, and estimated managed care rebates. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as a current liability. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the applicable contract. The amount of variable consideration included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, we adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Rebates: We contract with certain government agencies and managed care organizations, or collectively, third-party payors, so that ARIKAYCE will be eligible for purchase by, or partial or full reimbursement from, such third-party payors. We estimate the rebates we will provide to third-party payors and deduct these estimated amounts from total gross product revenues at the time the revenues are recognized. These reserves are recorded in the same period in which the revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. The current liability is included in accounts payable and accrued liabilities on the consolidated balance sheets. We estimate the rebates that will be provided to third-party payors based upon (i) our contracts with these third-party payors, (ii) the government mandated discounts applicable to government-funded programs, (iii) a range of possible outcomes that are probability-weighted for the estimated payor mix, and (iv) information obtained from our specialty pharmacies.

If any, or all, of our actual experience vary from the estimates above, we may need to adjust prior period accruals, affecting revenue in the period of adjustment.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2024, our cash and cash equivalents were in cash accounts or were invested in money market funds. Our investments in money market funds are not insured by the federal government. As of December 31, 2024, our marketable securities were invested in US treasury notes with an original maturity of six months or less.

As of December 31, 2024, we had $574.9 million of 2028 Convertible Notes outstanding. Our 2028 Convertible Notes bear interest at a coupon rate of 0.75%. In addition, as of December 31, 2024, we had our $500.0 million Term Loans outstanding. The Term Loans accrue interest quarterly at a fixed rate of 9.6% per annum. The Royalty Financing Agreement pays interest at 4.0% of ARIKAYCE global net sales prior to September 1, 2025 and 4.5% thereafter as well as 0.75% of brensocatib global net sales, if approved. If a 10% change in interest rates had occurred on December 31, 2024, it would not have had a material effect on the fair value of our debt as of that date, nor would it have a material effect on our future earnings or cash flows.

The majority of our business is conducted in US dollars. However, we do conduct certain transactions in other currencies, including Euros, British Pounds and Japanese Yen. Historically, fluctuations in foreign currency exchange rates have not materially affected our results of operations. During the years ended December 31, 2024, 2023 and 2022, our results of operations were not materially affected by fluctuations in foreign currency exchange rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by Item 8 is included in our Financial Statements and Supplementary Data set forth in Item 15 of Part IV of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit with the SEC is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2024 at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act, as a process designed by, or under the supervision of, our principal executive and principal financial and accounting officers and effected by our board of directors and management to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with US generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of our management and board of directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—

Integrated Framework. Based on management's assessment, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2024.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report on Internal Control over Financial Reporting

Ernst & Young LLP, our independent registered public accounting firm, issued an attestation report on our internal control over financial reporting. The report of Ernst & Young LLP is contained in Item 15 of Part IV of this Annual Report on Form 10-K.

ITEM 9B. OTHER INFORMATION

During the three months ended December 31, 2024, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated any “Rule 10b5-1 trading arrangement” or any “non Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 10 of Form 10-K is incorporated by reference from the discussion responsive thereto under the captions *Election of Class I Directors, Corporate Governance, Delinquent Section 16(a) Reports and Compensation and Discussion and Analysis* in our definitive proxy statement for our 2025 annual meeting of shareholders to be filed with the SEC no later than 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 of Form 10-K is incorporated by reference from the discussion responsive thereto under the captions *Compensation Discussion and Analysis*, *Compensation Committee Report*, *Compensation Committee Interlocks and Insider Participation* and *Director Compensation* in our definitive proxy statement for our 2025 annual meeting of shareholders to be filed with the SEC no later than 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 12 of Form 10-K is incorporated by reference from the discussion responsive thereto under the captions *Compensation Discussion and Analysis* and *Security Ownership of Certain Beneficial Owners, Directors, and Management* in our definitive proxy statement for our 2025 annual meeting of shareholders to be filed with the SEC no later than 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by Item 13 of Form 10-K is incorporated by reference from the discussion responsive thereto under the captions *Corporate Governance* and *Certain Relationships and Related Party Transactions* in our definitive proxy statement for our 2025 annual meeting of shareholders to be filed with the SEC no later than 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 of Form 10-K is incorporated by reference from the discussion responsive thereto under the caption *Corporate Governance* and *Ratification of the Appointment of Independent Registered Public Accounting Firm* in our definitive proxy statement for our 2025 annual meeting of shareholders to be filed with the SEC no later than 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report.

1. FINANCIAL STATEMENTS. The following consolidated financial statements of the Company are set forth herein, beginning on page 89:

(i) Reports of Independent Registered Public Accounting Firm (PCAOB ID: 42)

(ii) Consolidated Balance Sheets as of December 31, 2024 and 2023

(iii) Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2024, 2023 and 2022

(iv) Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2024, 2023 and 2022

(v) Consolidated Statements of Cash Flows for the Years Ended December 31, 2024, 2023 and 2022

(vi) Notes to Consolidated Financial Statements

2. FINANCIAL STATEMENT SCHEDULES.

None required.

3. EXHIBITS.

The exhibits that are required to be filed or incorporated by reference herein are listed in the Exhibit Index.

EXHIBIT INDEX

3.1	Articles of Incorporation of Insmed Incorporated, as amended through June 14, 2012 (incorporated by reference from Exhibit 3.1 to Insmed Incorporated's Annual Report on Form 10-K filed on March 18, 2013).
3.2	Amended and Restated Bylaws of Insmed Incorporated (incorporated by reference from Exhibit 3.1 to Insmed Incorporated's Current Report on Form 8-K filed on May 11, 2023).
4.1	Specimen stock certificate representing common stock, $0.01 par value per share, of the Registrant (incorporated by reference from Exhibit 4.2 to Insmed Incorporated's Registration Statement on Form S-4/A (Registration No. 333-30098) filed on March 24, 2000).
4.2	Indenture, dated as of January 26, 2018, by and between the Company and Wells Fargo Bank, National Association (incorporated by reference from Exhibit 4.1 to Insmed Incorporated's Current Report on Form 8-K filed on January 26, 2018).
4.3	Second Supplemental Indenture, dated as of May 13, 2021, by and between the Company and Wells Fargo Bank, National Association (incorporated by reference from Exhibit 4.2 to Insmed Incorporated's Current Report on Form 8-K filed on May 13, 2021).
4.4	Form of 0.75% Convertible Senior Note due 2028 (included in Exhibit 4.3).
4.5	Description of Securities Registered Under Section 12 of the Securities Exchange Act of 1934 (incorporated by reference from Exhibit 4.5 of Insmed Incorporated's Annual Report on Form 10-K filed on February 25, 2021).
10.1**	Insmed Incorporated 2013 Incentive Plan (incorporated by reference from Exhibit 99.1 to Insmed Incorporated's Registration Statement on Form S-8 filed on May 24, 2013).
10.1.1**	Form of Award Agreement for Incentive Stock Options pursuant to the Insmed Incorporated 2013 Incentive Plan (incorporated by reference from Exhibit 10.5 to Insmed Incorporated's Annual Report on Form 10-K filed on March 6, 2014).
10.1.2**	Form of Award Agreement for Non-Qualified Stock Options pursuant to the Insmed Incorporated 2013 Incentive Plan (incorporated by reference from Exhibit 10.6 to Insmed Incorporated's Annual Report on Form 10-K filed on March 6, 2014).
10.2**	Insmed Incorporated 2015 Incentive Plan (incorporated by reference from Exhibit 99.1 to Insmed Incorporated's Registration Statement on Form S-8 filed on May 28, 2015).

10.2.1**	Form of Award Agreement for Non-Qualified Stock Options pursuant to the Insmed Incorporated 2015 Incentive Plan (incorporated by reference from Exhibit 10.2 to Insmed Incorporated's Quarterly Report on Form 10-Q filed May 3, 2017).
10.3**	Insmed Incorporated 2017 Incentive Plan (incorporated by reference from Exhibit 10.3 to Insmed Incorporated's Quarterly Report on Form 10-Q filed August 3, 2017).
10.3.1**	Form of Award Agreements for Restricted Stock Units pursuant to the Insmed Incorporated 2017 Incentive Plan (incorporated by reference from Exhibit 10.4 to Insmed Incorporated's Quarterly Report on Form 10-Q filed August 3, 2017).
10.3.2**	Amendment to Form of Award Agreement for Restricted Stock Units pursuant to the Insmed Incorporated 2017 Incentive Plan (incorporated by reference from Exhibit 10.4.2 to Insmed Incorporated's Annual Report on Form 10-K filed on February 17, 2022).
10.3.3**	Form of Award Agreement for Non-Qualified Stock Options pursuant to the Insmed Incorporated 2017 Incentive Plan (incorporated by reference from Exhibit 10.5 to Insmed Incorporated's Quarterly Report on Form 10-Q filed August 3, 2017).
10.4**	Insmed Incorporated Amended and Restated 2019 Incentive Plan (incorporated by reference from Appendix A to Insmed Incorporated's Proxy Statement on Schedule 14A filed on March 31, 2023).
10.4.1**	Amendment No. 1 to Insmed Incorporated Amended and Restated 2019 Incentive Plan (incorporated by reference from Appendix A to Insmed Incorporated's Proxy Statement on Schedule 14A filed on April 1, 2024).
10.4.2**	Form of Award Agreement for Restricted Stock Units pursuant to the Insmed Incorporated Amended and Restated 2019 Incentive Plan (incorporated by reference from Exhibit 10.1.3 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 8, 2024).
10.4.3**	Form of Award Agreement for Restricted Stock Units to non-US employees pursuant to the Insmed Incorporated Amended and Restated 2019 Incentive Plan (incorporated by reference from Exhibit 10.1.4 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 8, 2024).
10.4.4**	Form of Award Agreement for Non-Qualified Stock Options pursuant to the Insmed Incorporated Amended and Restated 2019 Incentive Plan (incorporated by reference from Exhibit 10.1.1 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 8, 2024).
10.4.5**	Form of Award Agreement for Non-Qualified Stock Options issued to non-US employees pursuant to the Insmed Incorporated Amended and Restated 2019 Incentive Plan (incorporated by reference from Exhibit 10.1.2 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 8, 2024).
10.4.6**	Form of Award Agreement for Restricted Stock Units issued to directors pursuant to the Insmed Incorporated Amended and Restated 2019 Incentive Plan (incorporated by reference from Exhibit 10.1.5 of Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 3, 2023).
10.4.7**	Form of Award Agreement for Performance-Based Restricted Stock Units pursuant to the Insmed Incorporated Amended and Restated 2019 Incentive Plan (incorporated by reference from Exhibit 10.1.6 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 3, 2023).
10.4.8**	Form of Award Agreement for Performance-Based Restricted Stock Units to non-US employees pursuant to the Insmed Incorporated Amended and Restated 2019 Incentive Plan (incorporated by reference from Exhibit 10.1.7 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 3, 2023).
10.5**	Omnibus Amendment to Insmed Incorporated Incentive Plans, dated December 10, 2020 (incorporated by reference from Exhibit 10.6 of Insmed Incorporated's Annual Report on Form 10-K filed on February 25, 2021).
10.5.1**	Omnibus Amendment to Insmed Incorporated Incentive Awards and Inducement Awards, dated May 8, 2024 (incorporated by reference from Exhibit 10.2 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 8, 2024).

10.6**	Insmed Incorporated Senior Executive Bonus Plan (incorporated by reference from Exhibit 10.2 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on November 5, 2013).
10.7**	Form of Non-Qualified Stock Option Inducement Award Agreement (incorporated by reference from Exhibit 10.3 to Insmed Incorporated's Quarterly Report on Form 10-Q filed August 8, 2024).
10.8**	Form of Non-Qualified Stock Option Inducement Award Agreement for non-U.S. employees (incorporated by reference from Exhibit 10.4 to Insmed Incorporated's Quarterly Report on Form 10-Q filed August 8, 2024).
10.9**	Form of Indemnification Agreement entered into with each of the Company's directors and officers (incorporated by reference from Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on January 16, 2014).
10.10**	Employment Agreement, effective as of September 10, 2012, between Insmed Incorporated and William Lewis (incorporated by reference from Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on September 11, 2012).
10.10.1**	Amendment to Employment Agreement, effective as of July 31, 2019, between Insmed Incorporated and William Lewis (incorporated by reference from Exhibit 10.5 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 1, 2019).
10.11**	Amended and Restated Employment Agreement, effective as of April 1, 2022, between Insmed Incorporated and S. Nicole Schaeffer (incorporated by reference from Exhibit 10.4 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on May 5, 2022).
10.12**	Amended and Restated Employment Agreement, effective as of April 1, 2022, between Insmed Incorporated and Roger Adsett (incorporated by reference from Exhibit 10.1 to Insmed Incorporated's Quarterly Report on Form 10-Q filed May 5, 2022).
10.12.1**	Side Letter to Amended and Restated Employment Agreement, effective as of August 8, 2022, between Insmed Incorporated and Roger Adsett (incorporated by reference from Exhibit 10.3 to Insmed Incorporated's Quarterly Report on Form 10-Q filed October 27, 2022).
10.13**	Amended and Restated Employment Agreement, effective as of April 1, 2022, between Insmed Incorporated and Sara Bonstein (incorporated by reference from Exhibit 10.2 to Insmed Incorporated's Annual Report on Form 10-Q filed May 5, 2022).
10.14**	Amended and Restated Employment Agreement, effective as of April 1, 2022, by and between Insmed Incorporated and Martina Flammer, M.D. (incorporated by reference from Exhibit 10.3 of Insmed Incorporated's Quarterly Report on Form 10-Q filed May 5, 2022).
10.15**	Amended and Restated Employment Agreement, effective as of April 1, 2022, by and between Insmed Incorporated and Michael Smith (incorporated by reference from Exhibit 10.5 of Insmed Incorporated's Quarterly Report on Form 10-Q filed May 5, 2022).
10.16**	Employment Agreement, effective as of May 23, 2022, by and between Insmed Incorporated and J. Drayton Wise (incorporated by reference from Exhibit 10.1 of Insmed Incorporated's Quarterly Report on Form 10-Q filed August 4, 2022).
10.17*	License Agreement, dated April 25, 2008, between Transave, Inc. and PARI Pharma GmbH, and Amendments No. 1-4 thereto (incorporated by reference from Exhibit 10.1 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on October 29, 2020).
10.17.1*	Amendment No. 5 to License Agreement between Insmed Incorporated and PARI Pharma GmbH, effective as of October 5, 2015 (incorporated by reference from Exhibit 10.14.1 to Insmed Incorporated's Annual Report on Form 10-K filed on February 25, 2016).
10.17.2*	Amendment No. 6 to License Agreement between Insmed Incorporated and PARI Pharma GmbH, effective as of October 9, 2015 (incorporated by reference from Exhibit 10.14.2 to Insmed Incorporated's Annual Report on Form 10-K filed on February 25, 2016).
10.17.3*	Amendment No. 7 to License Agreement between Insmed Incorporated and PARI Pharma GmbH, effective as of July 21, 2017 (incorporated by reference from Exhibit 10.1 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on November 2, 2017).

10.17.4*	Amendment No. 8 to License Agreement between Insmed Incorporated and PARI Pharma GmbH, effective as of December 19, 2018 (incorporated by reference from Exhibit 10.15.4 to Insmed Incorporated's Annual Report on Form 10-K filed on February 22, 2019).
10.18*	Contract Manufacturing Agreement, dated February 7, 2014, between Insmed Incorporated and Resilience Biotechnologies Inc. (successor to Therapure Biopharma Inc.) (incorporated by reference from Exhibit 10.2.1 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on October 29, 2020).
10.18.1*	Amending Agreement, dated March 13, 2014, between Insmed Incorporated and Resilience Biotechnologies Inc. (successor to Therapure Biopharma Inc.) (incorporated by reference from Exhibit 10.2.2 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on October 29, 2020).
10.19*	Commercialization Agreement dated July 8, 2014 between Insmed Incorporated and PARI Pharma GmbH (incorporated by reference from Exhibit 10.5 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 8, 2024).
10.19.1*	Amendment No. 1 to Commercialization Agreement between Insmed Incorporated and PARI Pharma GmbH, effective as of July 21, 2017 (incorporated by reference from Exhibit 10.5.1 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on August 8, 2024).
10.19.2*	Amendment No. 2 to Commercialization Agreement between Insmed Incorporated and PARI Pharma GmbH, effective as of July 20, 2018 (filed herewith).
10.20*	Manufacturing and Supply Agreement between Insmed Incorporated and Patheon UK Limited, dated as of October 20, 2017 (incorporated by reference from Exhibit 10.39 to Insmed Incorporated's Annual Report on Form 10-K filed February 23, 2018).
10.21*	Technology Transfer Agreement between Insmed Incorporated and Patheon UK Limited, dated as of October 20, 2017 (incorporated by reference from Exhibit 10.40 to Insmed Incorporated's Annual Report on Form 10-K filed February 23, 2018).
10.21.1*	Amendment to the Technology Transfer Agreement and to the Manufacturing and Supply Agreement, by and between Insmed Incorporated and Patheon UK Limited, dated as of March 11, 2021 (incorporated by reference from Exhibit 10.3 to Insmed Incorporated's Quarterly Report on Form 10-Q filed May 6, 2021).
10.22*	License Agreement, dated October 4, 2016, between Insmed Incorporated and AstraZeneca AB (incorporated by reference from Exhibit 10.29 to Insmed Incorporated's Annual Report on Form 10-K filed February 23, 2017).
10.23	Lease Agreement, dated September 11, 2018, by and between Insmed Incorporated and Bridgewater Biotech Center LLC (assumed from Exeter 700 Route 202/206, LLC) (incorporated by reference from Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on September 17, 2018).
10.24*	Master Commercial Manufacturing Services Agreement, dated January 8, 2024, by and between Insmed Incorporated and Patheon Inc. (filed herewith).
10.24.1*	Product Agreement pursuant to the Master Commercial Manufacturing Services Agreement, dated September 29, 2024, by and between Insmed Incorporated and Patheon Inc. (filed herewith).
10.25*	Revenue Interest Purchase Agreement, dated October 19, 2022, between Insmed Incorporated and OrbiMed Royalty & Credit Opportunities III, LP (incorporated by reference from Exhibit 10.1 to Insmed Incorporated's Quarterly Report on Form 10-Q filed on October 27, 2022).
10.25.1*	First Amendment to Revenue Interest Purchase Agreement, dated October 31, 2024, between Insmed Incorporated and OrbiMed Royalty & Credit Opportunities III, LP (filed herewith).
10.26*	Amended and Restated Loan Agreement, dated October 31, 2024, between Insmed Incorporated, BioPharma Credit PLC, BPCR Limited Partnership and BioPharma Credit Investments V (Master) LP (filed herewith).
10.27*	Commercial Manufacturing and Supply Agreement, dated September 5, 2024, between Insmed Incorporated and Esteve Química, S.A. (filed herewith).
19.1	Insmed Incorporated Insider Trading Policy (filed herewith).

21.1	Subsidiaries of Insmed Incorporated (filed herewith).
23.1	Consent of Ernst & Young LLP (filed herewith).
31.1	Certification of William H. Lewis, Chair and Chief Executive Officer (Principal Executive Officer) of Insmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2003 (filed herewith).
31.2	Certification of Sara Bonstein, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) of Insmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2003 (filed herewith).
32.1	Certification of William H. Lewis, Chair and Chief Executive Officer (Principal Executive Officer) of Insmed Incorporated, pursuant to 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003 (filed herewith).
32.2	Certification of Sara Bonstein, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) of Insmed Incorporated, pursuant to 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003 (filed herewith).
97	Compensation Recovery Policy (incorporated by reference from Exhibit 97 to Insmed Incorporated's Annual Report on Form 10-K filed on February 22, 2024).
101	The following materials from Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2024 formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2024 and 2023, (ii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2024, 2023 and 2022, (iii) Consolidated Statements of Shareholders' Equity for the years ended December 31, 2024, 2023 and 2022, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2024, 2023 and 2022, and (v) Notes to the Consolidated Financial Statements, and (vi) Cover Page.
104	The cover page from the Annual Report on Form 10-K for the year ended December 31, 2024, formatted in iXBRL and contained in Exhibit 101.
*	Certain portions of this exhibit have been redacted.
**	Management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on February 20, 2025.

INSMED INCORPORATED
a Virginia corporation
(Registrant)

By: /s/ WILLIAM H. LEWIS
William H. Lewis
Chair and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on February 20, 2025.

Signature	Title
/s/ WILLIAM H. LEWIS William H. Lewis	Chair and Chief Executive Officer (Principal Executive Officer)
/s/ SARA BONSTEIN Sara Bonstein	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ DAVID R. BRENNAN David R. Brennan	Lead Independent Director
/s/ ALFRED F. ALTOMARI Alfred F. Altomari	Director
/s/ ELIZABETH MCKEE ANDERSON Elizabeth McKee Anderson	Director
/s/ CLARISSA DESJARDINS, PH.D. Clarissa Desjardins, Ph.D.	Director
/s/ LEO LEE Leo Lee	Director
/s/ DAVID W.J. MCGIRR David W.J. McGirr	Director
/s/ CAROL A. SCHAFER Carol A. Schafer	Director
/s/ MELVIN SHAROKY, M.D. Melvin Sharoky, M.D.	Director

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Insmed Incorporated

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Insmed Incorporated (the Company) as of December 31, 2024 and 2023, the related consolidated statements of comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 20, 2025 expressed an unqualified opinion thereon.

Adoption of ASU No. 2020-06

As discussed in Note 10 to the consolidated financial statements, the Company changed its method of accounting for convertible notes in 2022 due to the adoption of Accounting Standards Update (ASU) No. 2020-06, Debt—(Subtopic 470-20 & 815-40), and the related amendments.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Variable consideration in contracts with customers

Description of the Matter

As discussed in Note 4 of the consolidated financial statements, the transaction price for product sales is typically adjusted for variable consideration, which includes rebates paid to government agencies, specifically Medicaid. The Company estimates Medicaid rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix.

Auditing the Company's estimate of Medicaid rebates was complex and judgmental due to uncertainty about the estimated payor mix at the time of shipment to the specialty pharmacies as well as the complexity of governmental pricing calculations. The transaction price is sensitive to assumptions used in Medicaid rebate calculations.

How We Addressed the Matter in Our Audit

We identified, evaluated and tested controls over management's review of the calculated reductions to gross product prices related to Medicaid rebates including management's review of the significant assumptions and the data utilized in its calculations.

To test the revenue adjustments related to Medicaid rebates our audit procedures included, among others, using internal government pricing specialists to assist with our evaluation of management's methodology and calculations used to measure Medicaid rebates. We also tested the underlying data and inputs used by the Company in its determination of the estimated payor mix. We compared the inputs used by management to historical trends, evaluated the change in the estimated rebates amounts recorded throughout the year and assessed the historical accuracy of management's estimates against actual results.

We have served as the Company's auditor since at least 1999, but we are unable to determine the specific year.

/s/ Ernst & Young LLP

Iselin, New Jersey

February 20, 2025

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Insmed Incorporated

Opinion on Internal Control Over Financial Reporting

We have audited Insmed Incorporated's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Insmed Incorporated (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and our report dated February 20, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Iselin, New Jersey

February 20, 2025

INSMED INCORPORATED
Consolidated Balance Sheets
(in thousands, except par value and share data)

	As of December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 555,030	$ 482,374
Marketable securities	878,796	298,073
Accounts receivable	52,012	41,189
Inventory	98,578	83,248
Prepaid expenses and other current assets	37,245	24,179
Total current assets	1,621,661	929,063
Fixed assets, net	80,052	65,384
Finance lease right-of-use assets	18,273	20,985
Operating lease right-of-use assets	17,257	18,017
Intangibles, net	58,652	63,704
Goodwill	136,110	136,110
Other assets	93,226	96,574
Total assets	$ 2,025,231	$ 1,329,837
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 285,209	$ 214,987
Finance lease liabilities	2,961	2,610
Operating lease liabilities	9,358	8,032
Total current liabilities	297,528	225,629
Debt, long-term	1,103,382	1,155,313
Royalty financing agreement	161,067	155,034
Contingent consideration	144,200	84,600
Finance lease liabilities, long-term	24,064	27,026
Operating lease liabilities, long-term	9,112	11,013
Other long-term liabilities	499	3,145
Total liabilities	1,739,852	1,661,760
Shareholders' equity:		
Common stock, $ 0.01 par value; 500,000,000 authorized shares, 179,382,635 and 147,977,960 issued and outstanding shares at December 31, 2024 and December 31, 2023, respectively	1,794	1,480
Additional paid-in capital	4,645,791	3,113,487
Accumulated deficit	(4,359,917)	(3,446,145)
Accumulated other comprehensive loss	(2,289)	(745)
Total shareholders' equity (deficit)	285,379	(331,923)
Total liabilities and shareholders' equity (deficit)	$ 2,025,231	$ 1,329,837

See accompanying notes to consolidated financial statements

INSMED INCORPORATED
Consolidated Statements of Comprehensive Loss
(in thousands, except per share data)

	Years Ended December 31,		
	2024	2023	2022
Product revenues, net	$ 363,707	$ 305,208	$ 245,358
Operating expenses:			
Cost of product revenues (excluding amortization of intangible assets)	85,742	65,573	55,126
Research and development	598,367	571,011	397,518
Selling, general and administrative	461,116	344,501	265,784
Amortization of intangible assets	5,052	5,052	5,053
Change in fair value of deferred and contingent consideration liabilities	91,682	28,697	(20,802)
Total operating expenses	1,241,959	1,014,834	702,679
Operating loss	(878,252)	(709,626)	(457,321)
Investment income	53,307	42,132	11,081
Interest expense	(84,913)	(81,694)	(26,446)
Change in fair value of interest rate swap	(236)	320	(1,526)
Other income (expense), net	29	1,856	(5,939)
Loss before income taxes	(910,065)	(747,012)	(480,151)
Provision for income taxes	3,707	2,555	1,383
Net loss	$ (913,772)	$ (749,567)	$ (481,534)
Basic and diluted net loss per share	$ (5.57)	$ (5.34)	$ (3.91)
Weighted average basic and diluted common shares outstanding	164,043	140,433	123,035
Net loss	$ (913,772)	$ (749,567)	$ (481,534)
Other comprehensive income (loss):			
Foreign currency translation and other (losses) gains	(1,855)	(2,214)	303
Unrealized gain (loss) on marketable securities	311	713	(515)
Total comprehensive loss	$ (915,316)	$ (751,068)	$ (481,746)

See accompanying notes to audited consolidated financial statements

INSMED INCORPORATED
Consolidated Statements of Shareholders' Equity
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
Balance at December 31, 2021	118,738	$ 1,187	$ 2,673,556	$ (2,265,243)	$ 968	$ 410,468
Cumulative impact of ASU 2020-06 adoption			(264,609)	50,199		(214,410)
Comprehensive loss:						
Net loss				(481,534)		(481,534)
Other comprehensive loss					(212)	(212)
Exercise of stock options and ESPP shares	1,328	14	19,486			19,500
Net proceeds from issuance of common stock	15,040	150	292,003			292,153
Issuance of common stock for vesting of RSUs	377	4				4
Deferred payments for Business Acquisition	171	2	4,294			4,296
Stock-based compensation expense			57,686			57,686
Balance at December 31, 2022	135,654	1,357	2,782,416	(2,696,578)	756	$ 87,951
Comprehensive loss:						
Net loss				(749,567)		(749,567)
Other comprehensive loss					(1,501)	(1,501)
Exercise of stock options and ESPP shares	1,142	12	18,387			18,399
Net proceeds from issuance of common stock	6,531	65	152,410			152,475
Issuance of common stock for vesting of RSUs	543	5				5
Deferred payments for Business Acquisition	177	2	3,895			3,897
Issuance of common stock for asset acquisitions	3,931	39	81,601			81,640
Stock-based compensation expense			74,778			74,778
Balance at December 31, 2023	147,978	$ 1,480	$ 3,113,487	$ (3,446,145)	$ (745)	$ (331,923)
Comprehensive loss:						
Net loss				(913,772)		(913,772)
Other comprehensive loss					(1,544)	(1,544)
Exercise of stock options and ESPP shares	5,026	50	113,193			113,243
Issuance of common stock upon conversion of convertible notes	5,744	58	224,267			224,325
Net proceeds from issuance of common stock	19,537	195	1,083,929			1,084,124
Issuance of common stock for vesting of RSUs	901	9				9
Deferred payments for Business Acquisition and Vertuis Bio, Inc.	197	2	14,080			14,082
Stock-based compensation expense			96,835			96,835
Balance at December 31, 2024	179,383	$ 1,794	$ 4,645,791	$ (4,359,917)	$ (2,289)	$ 285,379

See accompanying notes to audited consolidated financial statements

INSMED INCORPORATED
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2024	2023	2022
Operating activities			
Net loss	$ (913,772)	$ (749,567)	$ (481,534)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	5,961	5,527	5,278
Amortization of intangible assets	5,052	5,052	5,053
Stock-based compensation expense	96,835	74,778	57,686
Amortization of debt issuance costs	6,884	7,320	3,991
Paid-in-kind interest capitalized	19,233	23,372	4,165
Royalty financing non-cash interest expense	20,044	18,846	3,687
Accretion of discount on marketable securities, net	(19,160)	(9,383)	—
Finance lease amortization expense	2,712	2,712	1,960
Non-cash operating lease expense	3,588	9,206	11,976
Change in fair value of deferred and contingent consideration liabilities	91,682	28,697	(20,802)
Change in fair value of interest rate swap	236	(320)	1,526
Vertuis acquisition	—	10,250	—
Adrestia acquisition	—	76,481	—
Changes in operating assets and liabilities:			
Accounts receivable	(12,932)	(11,963)	(6,423)
Inventory	(17,044)	(13,613)	(1,714)
Prepaid expenses and other current assets	(14,182)	2,265	2,528
Other assets	8,335	(20,074)	(25,243)
Accounts payable and accrued liabilities	44,592	15,155	50,011
Other liabilities	(11,946)	(10,988)	(12,584)
Net cash used in operating activities	(683,882)	(536,247)	(400,439)
Investing activities			
Purchase of fixed assets	(21,923)	(13,288)	(9,878)
Purchase of marketable securities	(1,577,252)	(588,733)	(99,706)
Cash acquired in asset acquisition	—	3,417	—
Maturities of marketable securities	1,016,000	375,000	75,000
Net cash used in investing activities	(583,175)	(223,604)	(34,584)
Financing activities			
Proceeds from exercise of stock options and ESPP	113,243	18,399	19,504
Proceeds from issuance of common stock, net	1,084,124	152,475	292,153
Proceeds from issuance of Term Loans	150,000	—	350,000

INSMED INCORPORATED
Consolidated Statements of Cash Flows
(in thousands)

Proceeds from issuance Royalty Financing Agreement	—	—	150,000
Payment of debt issuance costs	(3,737)	(1,218)	(17,783)
Payments of finance lease principal	(2,610)	(1,217)	(601)
Net cash provided by financing activities	1,341,020	168,439	793,273
Effect of exchange rates on cash and cash equivalents	(1,307)	(250)	(996)
Net increase (decrease) in cash and cash equivalents	72,656	(591,662)	357,254
Cash and cash equivalents at beginning of period	482,374	1,074,036	716,782
Cash and cash equivalents at end of period	$ 555,030	$ 482,374	$ 1,074,036
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 40,567	$ 35,787	$ 10,157
Cash paid for income taxes	$ 2,499	$ 1,955	$ 1,717

See accompanying notes to audited consolidated financial statements

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. The Company and Basis of Presentation

Insmed is a people-first global biopharmaceutical company striving to deliver first- and best-in-class therapies to transform the lives of patients facing serious diseases. The Company's first commercial product, ARIKAYCE, is approved in the US as ARIKAYCE® (amikacin liposome inhalation suspension), in Europe as ARIKAYCE Liposomal 590 mg Nebuliser Dispersion and in Japan as ARIKAYCE inhalation 590 mg (amikacin sulfate inhalation drug product). ARIKAYCE received accelerated approval in the US in September 2018 for the treatment of MAC lung disease as part of a combination antibacterial drug regimen for adult patients with limited or no alternative treatment options in a refractory setting. In October 2020, the EC approved ARIKAYCE for the treatment of NTM lung infections caused by MAC in adults with limited treatment options who do not have CF. In March 2021, Japan's MHLW approved ARIKAYCE for the treatment of patients with NTM lung disease caused by MAC who did not sufficiently respond to prior treatment with a multidrug regimen. NTM lung disease caused by MAC (which the Company refers to as MAC lung disease) is a rare and often chronic infection that can cause irreversible lung damage and can be fatal.

The Company's pipeline includes clinical-stage programs, brensocatib, TPIP, and INS1201, as well as pre-clinical research programs. Brensocatib is a small molecule, oral, reversible inhibitor of DPP1, which the Company is developing for the treatment of patients with bronchiectasis and other neutrophil-mediated diseases, including CRSsNP and HS. TPIP is an inhaled formulation of the treprostinil prodrug treprostinil palmitil which may offer a differentiated product profile for PH-ILD and PAH. INS1201 is an intrathecally delivered gene therapy for patients with DMD. The Company's pre-clinical research programs encompass a wide range of technologies and modalities, including gene therapy, artificial intelligence-driven protein engineering, protein manufacturing, RNA end-joining, and synthetic rescue.

The Company was incorporated in the Commonwealth of Virginia on November 29, 1999 and its principal executive offices are located in Bridgewater, New Jersey. The Company has legal entities in the US, France, Germany, Ireland, Italy, the Netherlands, Switzerland, the UK, and Japan.

The Company had $ 555.0 million of cash and cash equivalents and $ 878.8 million of marketable securities as of December 31, 2024 and reported a net loss of $ 913.8 million for the year ended December 31, 2024. The Company has funded its operations through public offerings of equity securities, debt financings and revenue interest financings. The Company expects to continue to incur consolidated operating losses, including losses in its US and certain international entities, while funding R&D activities for ARIKAYCE, brensocatib, TPIP, INS1201, and its other pipeline programs, continuing commercialization and regulatory activities for ARIKAYCE and pre-commercial, regulatory and, if approved, commercialization activities for brensocatib, and funding other general and administrative activities.

The Company expects its future cash requirements to be substantial. While the Company currently has sufficient funds to meet its financial needs for at least the next 12 months, the Company may raise additional capital in the future to fund its operations, its ongoing commercialization and clinical trial activities, and its future product candidates, and to develop, acquire, in-license or co-promote other products or product candidates, including those that address orphan or serious diseases. The source, timing and availability of any future financing or other transaction will depend principally upon continued progress in the Company’s commercial, regulatory and development activities. Any future financing will also be contingent upon market conditions. If the Company is unable to obtain sufficient additional funds when required, the Company may be forced to delay, restrict or eliminate all or a portion of its development programs or commercialization efforts.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Celtrix Pharmaceuticals, Inc., Insmed France SAS, Insmed Gene Therapy LLC, Insmed Germany GmbH, Insmed Godo Kaisha, Insmed Holdings Limited, Insmed Innovation UK Limited, Insmed Ireland Limited, Insmed Italy S.R.L., Insmed Limited, Insmed Netherlands B.V., Insmed Netherlands Holdings B.V., and Insmed Switzerland GmbH.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies

Use of Estimates—The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and on various other assumptions. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of revenues and expenses reported for each period presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for revenue allowances, stock-based compensation, income taxes, loss contingencies, acquisition related intangibles including in process research and development (IPR&D) and goodwill, fair value of contingent consideration, the Royalty Financing Agreement, and accounting for research and development costs. Actual results could differ from those estimates.

Cash and Cash Equivalents—The Company considers cash equivalents to be highly liquid investments with maturities of three months or less from the date of purchase.

Accounts Receivable—Accounts receivable are recorded net of customer allowances for prompt pay discounts, chargebacks, and any estimated expected credit losses. The Company's measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. To date, credit losses have not been material.

Concentration of Credit Risk—Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company places its cash equivalents and marketable securities with high credit-quality financial institutions and may invest its investments in US treasury securities, mutual funds and government agency bonds. The Company has established guidelines relative to credit ratings and maturities that seek to maintain safety and liquidity.

The Company is exposed to risks associated with extending credit to customers related to the sale of products. The Company does not require collateral to secure amounts due from its customers. The Company uses an expected loss methodology to calculate allowances for trade receivables. The Company's measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. The Company does not currently have a material allowance for uncollectible trade receivables. The following table presents the percentage of gross product revenue represented by the Company's three largest customers for the year ended December 31, 2024 and their respective percentages for the year ended December 31, 2023.

	Years Ended December 31,	
	2024	**2023**
Customer A	34 %	35 %
Customer B	30 %	34 %
Customer C	21 %	19 %

The Company relies on third-party manufacturers and suppliers for manufacturing and supply of its products. The inability of the suppliers or manufacturers to fulfill supply requirements of the Company could materially impact future operating results. A change in the relationship with the suppliers or manufacturers, or an adverse change in their business, could materially impact future operating results.

Marketable Securities—Marketable securities consist of available-for-sale investments in US Treasury Notes. Marketable securities under this classification are recorded at fair value and unrealized gains and losses are recorded within accumulated other comprehensive loss. The estimated fair value of available-for-sale marketable securities is determined based on quoted market prices. Marketable securities maturing in one year or less are classified as current assets and marketable securities maturing in more than one year are classified as non-current assets. The Company did not have available-for-sale securities with a maturity of more than one year as of December 31, 2024 and December 31, 2023.

Fixed Assets, Net—Fixed assets are recorded at cost and are depreciated on a straight-line basis over the estimated useful lives of the assets. Estimated useful lives of three years to five years are used for computer hardware and software. Estimated useful lives of seven years are used for laboratory equipment, office equipment, manufacturing equipment and

furniture and fixtures. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset.

Finite-lived Intangible Assets—Finite-lived intangible assets are measured at their respective fair values on the date they were recorded. The fair values assigned to the Company's intangible assets are based on reasonable estimates and assumptions given available facts and circumstances. See *Note 6 - Intangibles, Net and Goodwill* for further details.

Impairment Assessment —The Company reviews the recoverability of its finite-lived intangible assets and long-lived assets for indicators of impairments. Events or circumstances that may require an impairment assessment include negative clinical trial results, a significant decrease in the market price of the asset, or a significant adverse change in legal factors or the manner in which the asset is used. If such indicators are present, the Company assesses the recoverability of affected assets by determining if the carrying value of such assets is less than the sum of the undiscounted future cash flows of the assets. If such assets are found to not be recoverable, the Company measures the amount of the impairment by comparing the carrying value of the assets to the fair value of the assets. The Company determined that no indicators of impairment of finite-lived intangible assets or long-lived assets existed at December 31, 2024.

Business Combinations and Asset Acquisitions—The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the requirements of a business. If determined to be a business combination, the Company accounts for the transaction under the acquisition method of accounting as indicated in ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquiree and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations, including contingent assets and liabilities, and non-controlling interest in the acquiree based on the fair value estimates as of the date of acquisition. In accordance with ASC 805, Business Combinations, the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

The consideration for the Company’s business acquisitions may include future payments that are contingent upon the occurrence of a particular event or events. The obligations for such contingent consideration payments are recorded at fair value on the acquisition date. The contingent consideration obligations are then evaluated each reporting period. Changes in the fair value of contingent consideration, other than changes due to payments, are recognized as a gain or loss and recorded within change in the fair value of deferred and contingent consideration liabilities in the consolidated statements of comprehensive loss.

If determined to be an asset acquisition, the Company accounts for the transaction under ASC 805-50, which requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes transaction costs in addition to consideration given. No gain or loss is recognized as of the date of acquisition unless the fair value of non-cash assets given as consideration differs from the assets’ carrying amounts on the acquiring entity’s books. Consideration transferred that is non-cash will be measured based on either the cost (which shall be measured based on the fair value of the consideration given) or the fair value of the assets acquired and liabilities assumed, whichever is more reliably measurable. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values. If the in-licensed agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and therefore have no alternative future use, the Company expenses payments made under such license agreements as acquired IPR&D expense within R&D expense in its consolidated statements of comprehensive loss.

Contingent consideration payments in asset acquisitions are recognized when the contingency is resolved and the consideration is paid or becomes payable, unless the contingent consideration meets the definition of a derivative, in which case the amount becomes part of the basis in the asset acquired. None of the Company's contingent consideration met the definition of a derivative. Upon recognition of the contingent consideration payment, the amount is included in the cost of the acquired asset or group of assets.

Indefinite-lived Intangible Assets—Indefinite-lived intangible assets consist of IPR&D. IPR&D acquired directly in a transaction other than a business combination is capitalized if the projects will be further developed or have an alternative future

use; otherwise, they are expensed. The fair values of IPR&D project assets acquired in business combinations are capitalized. The Company generally utilizes the Multi-Period Excess Earning Method to determine the estimated fair value of the IPR&D assets acquired in a business combination. The projections used in this valuation approach are based on many factors, such as relevant market size, patent protection, and expected pricing and industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate. Intangible assets with indefinite lives, including IPR&D, are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. The Company considers many factors in evaluating whether the value of its intangible assets with indefinite lives may not be recoverable, including, but not limited to, expected growth rates, the cost of equity and debt capital, general economic conditions, the Company's outlook and market performance of the Company's industry and recent and forecasted financial performance. The Company performs a qualitative test for its indefinite-lived intangible assets annually as of October 1. During the year ended December 31, 2024, the Company concluded that no impairment exists.

Goodwill—Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired as a result of the Company's business acquisitions accounted for using the acquisition method of accounting. Goodwill is not amortized and is subject to impairment testing at a reporting unit level on an annual basis or when a triggering event occurs that may indicate the carrying value of the goodwill is impaired. An entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that the fair value of the reporting unit is less than its carrying amount. The Company reassesses its reporting units as part of its annual segment review. As of December 31, 2024, the Company concluded that it continues to operate as one reporting unit. As of October 1, 2024, the Company performed a qualitative impairment test for goodwill and concluded that no impairment exists.

Leases—A lease is a contract, or part of a contract, that conveys the right to control the use of explicitly or implicitly identified property, plant or equipment in exchange for consideration. Control of an asset is conveyed to the Company if the Company obtains the right to obtain substantially all of the economic benefits of the asset or the right to direct the use of the asset. The Company recognizes right-of-use (ROU) assets and lease liabilities at the lease commencement date based on the present value of future, fixed lease payments over the term of the arrangement. ROU assets are amortized on a straight-line basis over the term of the lease or are amortized based on consumption, if this approach is more representative of the pattern in which benefit is expected to be derived from the underlying asset. Lease liabilities accrete to yield and are reduced at the time when the lease payment is payable to the vendor. Variable lease payments are recognized at the time when the event giving rise to the payment occurs and are recognized in the consolidated statements of comprehensive loss in the same line item as expenses arising from fixed lease payments.

Leases are measured at present value using the rate implicit in the lease or, if the implicit rate is not determinable, the lessee's implicit borrowing rate. As the implicit rate is not typically available, the Company uses its implicit borrowing rate based on the information available at lease commencement date to determine the present value of future lease payments. The implicit borrowing rate approximates the rate the Company would pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments. See *Note 9 - Leases* for further details.

Debt Issuance Costs—Debt issuance costs are amortized to interest expense using the effective interest rate method over the term of the debt. Unamortized debt issuance costs paid to the lender and third parties are reflected as a discount to the debt in the consolidated balance sheets. Unamortized debt issuance costs associated with extinguished debt are expensed in the period of the extinguishment.

Foreign Currency—The Company has operations in the US, France, Germany, Ireland, Italy, the Netherlands, Switzerland, the UK, and Japan. The results of the Company's non-US dollar based functional currency operations are translated to US dollars at the average exchange rates during the period. Assets and liabilities are translated at the exchange rate prevailing at the balance sheet date. Equity is translated at the prevailing exchange rate at the date of the equity transaction. Translation adjustments are included in total shareholders' equity (deficit), as a component of accumulated other comprehensive loss.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

The Company realizes foreign currency transaction gains and losses in the normal course of business based on movements in the applicable exchange rates. These gains and losses are included as a component of other income (expense), net.

Derivatives—In the normal course of business, the Company is exposed to the effects of interest rate changes. The Company may enter into derivative instruments, including interest rate swaps and caps, to manage or hedge interest rate risk. Derivative instruments are recorded at fair value on the balance sheet date. The Company did not elect hedge accounting treatment for the changes in the fair value of derivatives. Changes in the fair value of derivatives were recorded each period and were included in change in fair value of interest rate swap in the consolidated statements of comprehensive loss and consolidated statements of cash flows.

Inventory and Cost of Product Revenues (excluding amortization of intangible assets) —Inventory is stated at the lower of cost and net realizable value. Inventory is sold on a first-in, first-out (FIFO) basis. The Company periodically reviews inventory for expiry and obsolescence and, if necessary, writes down accordingly. If quality specifications are not met during the manufacturing process, such inventory is written off to cost of product revenues (excluding amortization of intangible assets) in the period identified.

Cost of product revenues (excluding amortization of intangible assets) consist primarily of direct and indirect costs related to the manufacturing of ARIKAYCE sold, including third-party manufacturing costs, packaging services, freight, and allocation of overhead costs, in addition to royalty expenses. Cost is determined using a standard cost method, which approximates actual cost, and assumes a FIFO flow of goods. Inventory used for clinical development purposes is expensed to R&D expense when consumed.

Research and Development—R&D expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in the Company's research and development functions. R&D expense also includes other internal operating expenses, the cost of manufacturing a product candidate, including the medical devices for drug delivery, for clinical study, the cost of conducting clinical studies, and the cost of conducting preclinical and research activities. In addition, R&D expenses include payments to third parties for the license rights to products in development (prior to marketing approval), such as brensocatib, and may include the cost of asset acquisitions (as described further above). The Company's expenses related to manufacturing its product candidates and medical devices for clinical study are primarily related to activities at CMOs that manufacture its clinical product supply of ARIKAYCE, brensocatib, TPIP, INS1201, and pre-clinical research. The Company's expenses related to clinical trials are primarily related to activities at CROs that conduct and manage clinical trials on the Company's behalf. These contracts set forth the scope of work to be completed at a fixed fee or amount per patient enrolled. Payments under these contracts primarily depend on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones as well as time-based fees. Expenses are accrued based on contracted amounts applied to the level of patient enrollment and to activity according to the clinical trial protocol. Deposits for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are then recognized as an expense as the related goods are delivered or the services are performed.

Stock-based Compensation—The Company recognizes stock-based compensation expense for awards of equity instruments to employees and directors based on the grant-date fair value of those awards. The grant-date fair value of the award is recognized as compensation expense ratably over the requisite service period, which generally equals the vesting period of the award. The Company may also grant performance-based stock options and performance stock units (PSUs) to employees from time to time. The grant-date fair value of performance-based stock options is recognized as compensation expense over the implicit service period using the accelerated attribution method once it is probable that the performance condition will be achieved. The grant-date fair value of PSUs is recognized as compensation expense on the date the performance conditions become probable, with an initial recording of the cumulative expense that would have been recognized if the PSU expense had been recognized on a straight-line basis since the date of grant. The remaining unamortized fair value of the awards will then be expensed prospectively on a straight-line basis over the remaining service period. Stock-based compensation expense is included in both R&D and SG&A expenses in the consolidated statements of comprehensive loss.

Investment Income and Interest Expense—Investment income consists of interest income earned on the Company's cash and cash equivalents and marketable securities. Interest expense consists primarily of contractual interest costs related to the Company's debt, non-cash interest expense related to the Company's Royalty Financing Agreement (see *Note 11 - Royalty Financing Agreement*), and amortization of debt issuance costs related to the Company's debt.

Income Taxes—The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying

2. Summary of Significant Accounting Policies (Continued)

amounts of existing assets and liabilities and their respective tax bases and operating loss carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

A valuation allowance is recorded to reduce the deferred tax assets to the amount that is expected to be realized. In evaluating the need for a valuation allowance, the Company takes into account various factors, including the expected level of future taxable income and available tax planning strategies. If actual results differ from the assumptions made in the evaluation of a valuation allowance, the Company records a change in valuation allowance through income tax expense in the period such determination is made.

The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based solely on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that is more likely than not to be sustained upon ultimate settlement. As any adjustment to the Company's uncertain tax positions would not result in a cash tax liability, it has not recorded any accrued interest or penalties related to its uncertain tax positions.

The Company's policy for interest and penalties related to income tax exposures is to recognize interest and penalties as a component of the income tax provision in the consolidated statements of comprehensive loss.

Net Loss Per Share—Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares and other dilutive securities outstanding during the period. Potentially dilutive securities from stock options, restricted stock (RS), restricted stock units (RSUs), PSUs and convertible debt securities would be anti-dilutive as the Company incurred a net loss. Potentially dilutive common shares resulting from the assumed exercise of outstanding stock options and from the assumed conversion of the Company's convertible notes are determined based on the treasury stock method.

The following table sets forth the reconciliation of the weighted average number of shares used to compute basic and diluted net loss per share for the years ended December 31, 2024, 2023 and 2022.

	Years Ended December 31,		
	2024	2023	2022
	(in thousands, except per share amounts)		
Numerator:			
Net loss	$ (913,772)	$ (749,567)	$ (481,534)
Denominator:			
Weighted average common shares used in calculation of basic net loss per share:	164,043	140,433	123,035
Effect of dilutive securities:			
Common stock options	—	—	—
RS and RSUs	—	—	—
PSUs	—	—	—
Convertible debt securities	—	—	—
Weighted average common shares outstanding used in calculation of diluted net loss per share	164,043	140,433	123,035
Net loss per share:			
Basic and diluted	$ (5.57)	$ (5.34)	$ (3.91)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average common shares outstanding as of December 31, 2024, 2023 and 2022 as their effect would have been anti-dilutive (in thousands).

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

	As of December 31,		
	2024	**2023**	**2022**
Common stock options	21,927	22,513	17,525
Unvested RS and RSUs	3,320	2,750	1,520
PSUs	660	666	671
Convertible debt securities	17,690	23,438	23,438

Recently Adopted Accounting Pronouncements—In November 2023, the Financial Accounting Standards Board (FASB) issued ASU 2023-07, Segment Reporting (Topic 280)–Improvements to Reportable Segment Disclosures, which updates reportable segment disclosure requirements primarily through enhanced disclosures about significant expenses. The amendments are effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. These amendments have been applied retrospectively to all prior periods presented in the financial statements. The adoption of ASU 2023-07 did not have a material impact on the Company's consolidated financial statements and additional required disclosures have been included in *Note 19 - Segment Reporting*.

Recent Accounting Pronouncements (Not Yet Adopted)—In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740)—Improvements to Income Tax Disclosures, in order to enhance the transparency and decision usefulness of income tax disclosures. ASU 2023-09 requires greater disaggregation of income tax disclosures related to the income tax rate reconciliation and income taxes paid. ASU 2023-09 will be effective for fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact of adoption of ASU 2023-09 on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement (Subtopic 220-40)—Expense Disaggregation Disclosures, which requires disclosure of disaggregated income statement expense information about specific categories (including purchases of inventory, employee compensation, depreciation, and intangible asset amortization) in the notes to financial statements. ASU 2024-03 will be effective for fiscal years beginning after December 15, 2026 and interim periods beginning after December 15, 2027. The guidance is applied on a prospective basis, with a retrospective option, and early adoption is permitted. The Company is currently evaluating the impact of adoption of ASU 2024-03 on its consolidated financial statements.

3. Fair Value Measurements

The Company categorizes its financial assets and liabilities measured and reported at fair value in the financial statements on a recurring basis based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels, which are directly related to the amount of subjectivity associated with the inputs used to determine the fair value of financial assets and liabilities, are as follows:

- Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the assets or liability through correlation with market data at the measurement date and for the duration of the instrument’s anticipated life.
- Level 3—Inputs reflect management’s best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Each major category of financial assets and liabilities measured at fair value on a recurring basis is categorized based upon the lowest level of significant input to the valuations. The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Financial instruments in Level 1 generally include US treasuries and mutual funds listed in active markets. The Company's cash and cash equivalents permit daily redemption and the fair values of these investments are based upon the quoted prices in active markets provided by the holding financial institutions.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Fair Value Measurements (Continued)

The following table shows assets and liabilities that are measured at fair value on a recurring basis and their carrying value (in millions):

	As of December 31, 2024			
		Fair Value		
	Carrying Value	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents	$ 555.0	$ 555.0	$ —	$ —
Marketable securities	$ 878.8	$ 878.8	$ —	$ —
Liabilities				
Contingent consideration	$ 168.9	$ —	$ —	$ 168.9

	As of December 31, 2023			
		Fair Value		
	Carrying Value	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents	$ 482.4	$ 482.4	$ —	$ —
Marketable securities	$ 298.1	$ 298.1	$ —	$ —
Collateral for interest rate swap	$ 6.0	$ 6.0	$ —	$ —
Liabilities				
Interest rate swap	$ 1.2	$ —	$ 1.2	$ —
Deferred consideration	$ 5.7	$ —	$ 5.7	$ —
Contingent consideration	$ 84.6	$ —	$ —	$ 84.6

During the year ended December 31, 2024, the Company purchased $ 1.6 billion of marketable securities consisting of US Treasury Notes.

As of December 31, 2024, the Company held $ 878.8 million of available-for-sale securities, including an unrealized gain of $ 0.3 million recorded in accumulated other comprehensive loss. As of December 31, 2023, the Company held $ 298.1 million of available-for-sale securities, net of an unrealized loss of $ 0.7 million that were in an unrealized gain or loss position.

During the year ended December 31, 2022, the Company entered into an interest rate swap in connection with the Company's Term Loan. The Company entered into the interest rate swap to hedge its variable interest rate in an exchange for a fixed interest rate. The collateral for interest rate swap and the interest rate swap were recorded in other assets and accounts payable and accrued liabilities, respectively, in the consolidated balance sheet as of December 31, 2023. The collateral for interest rate swap was cash, a Level 1 asset. The interest rate swap was a Level 2 liability as it used observable inputs other than quoted market prices in an active market. In connection with the Amended and Restated Loan Agreement, the Company settled and terminated the interest rate swap contract and collected the collateral during the fourth quarter of 2024.

There were no transfers in or out of Level 1, Level 2 or Level 3 during the years ended December 31, 2024 and 2023.

The Company reviews the status of each security quarterly to determine whether an other-than-temporary impairment has occurred. In making its determination, the Company considers a number of factors, including: (1) the significance of the decline; (2) whether the security was rated below investment grade; (3) failure of the issuer to make scheduled interest or principal payments; and (4) the Company's ability and intent to retain the investment for a sufficient period of time for it to recover. The Company has determined that there were no other-than-temporary impairments during the year ended December 31, 2024.

Deferred Consideration

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Fair Value Measurements (Continued)

The deferred consideration arose from the Business Acquisition in August 2021 (see *Note 18 - Acquisitions*). The Company was obligated to issue to Motus equityholders an aggregate of 184,433 shares of the Company's common stock on each of the first, second and third anniversaries of the closing date, subject to certain reductions. During August 2022, August 2023, and August 2024, the Company fulfilled the payments due on the first, second and third anniversary of the closing date by issuing 171,427 shares, 177,203 shares, and 182,182 shares of the Company's common stock, respectively, after certain reductions. A valuation of the deferred consideration was performed quarterly with gains and losses included within change in fair value of deferred and contingent consideration liabilities in the consolidated statements of comprehensive loss. As the deferred consideration was settled in shares, no discount rate was applied in the fair value calculation.

The deferred consideration was classified as a Level 2 recurring liability as its valuation utilized an input, the Insmed share price, which was a directly observable input at the measurement date and for the duration of the liabilities' lives. Deferred consideration expected to be settled within twelve months or less was classified as a current liability within accounts payable and accrued liabilities. As of December 31, 2024, there is no deferred consideration.

The following observable input was used in the valuation of the deferred consideration as of December 31, 2023:

	Fair Value as of December 31, 2023 (in millions)	Observable Input	Input Value
Deferred consideration	$ 5.7	Insmed share price on December 31, 2023	$ 30.99

Contingent Consideration Liabilities

The contingent consideration liabilities arose from the Business Acquisition in August 2021 (see *Note 18 - Acquisitions*). The contingent consideration liabilities consist of developmental and regulatory milestones, a priority review voucher milestone and net sales milestones. Upon the achievement of certain development and regulatory milestone events, the Company is obligated to issue to Motus equityholders up to 5,348,572 shares in the aggregate and AlgaeneX equityholders up to 368,867 shares in the aggregate. The fair value of the development and regulatory milestones are estimated utilizing a probability-adjusted approach. At December 31, 2024, the weighted average probability of success of the remaining milestones was 42 %. The development and regulatory milestones will be settled in shares of the Company's common stock. As such, there is no discount rate applied in the fair value calculation.

If the Company were to receive a priority review voucher from the FDA, the Company would be obligated to pay to the Motus equityholders a portion of the value of the priority review voucher, subject to certain reductions. The potential payout would be either 50 % of the after-tax net proceeds received by the Company from a sale of the priority review voucher or 50 % of the average of the sales prices for the last three publicly disclosed priority review voucher sales, less certain adjustments. The fair value of the priority review voucher milestone is estimated utilizing a probability-adjusted discounted cash flow approach. This obligation would be settled in cash. On December 20, 2024, the FDA's priority review voucher program expired. As of December 31, 2024, the Company determined that the likelihood of receiving a priority review voucher was remote and the milestone had no fair value.

The contingent consideration liabilities for net sales milestones were valued using an option pricing model with Monte Carlo simulation. As of December 31, 2024, the fair value of these net sales milestones were deemed immaterial to the overall fair value of the contingent consideration.

The contingent consideration liabilities have been classified as a Level 3 recurring liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market. If different assumptions were used for the inputs to the valuation approach, the estimated fair value could be significantly different than the fair value the Company determined. Contingent consideration liabilities expected to be settled within twelve months are classified as a current liability within accounts payable and accrued liabilities in the consolidated balance sheet. Contingent consideration expected to be settled in more than twelve months is classified as a non-current liability. As of December 31, 2024, the fair value of the current and non-current contingent consideration was $ 24.7 million and $ 144.2 million, respectively.

A valuation of the contingent consideration liabilities is performed quarterly with gains and losses included within change in fair value of deferred and contingent consideration liabilities in the consolidated statements of comprehensive loss. The following significant unobservable inputs were used in the valuation of the contingent consideration liabilities as of December 31, 2024 and 2023:

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Fair Value Measurements (Continued)

Contingent Consideration Liabilities	Fair Value as of December 31, 2024 (in millions)	Valuation Technique	Unobservable Inputs	Values
Development and regulatory milestones	$ 166.7	Probability-adjusted	Probabilities of success	14 % - 97

Contingent Consideration Liabilities	Fair Value as of December 31, 2023 (in millions)	Valuation Technique	Unobservable Inputs	Values
Development and regulatory milestones	$ 74.8	Probability-adjusted	Probabilities of success	14 % - 97
Priority review voucher milestone	$ 6.0	Probability-adjusted discounted cash flow	Probability of success	16.4 %
			Discount rate	10.0 %

A rollforward of the Company's valuations deferred and contingent consideration liabilities for the years ended December 31, 2024 and 2023 follows (in thousands):

	Deferred Consideration (Level 2 Liabilities)	Contingent Consideration (Level 3 Liabilities)
Balance as of December 31, 2022	$ 7,400	$ 58,100
Additions	—	—
Change in fair value	2,197	26,500
Payments	(3,897)	—
Balance as of December 31, 2023	5,700	84,600
Additions	—	—
Change in fair value	7,400	84,300
Payments	(13,100)	—
Balance as of December 31, 2024	$ —	$ 168,900

The change in fair value of deferred and contingent consideration liabilities are due to changes in factors such as the probability of achieving milestones, the Company's stock price, or certain other estimated assumptions. Payments are made in shares of the Company's common stock.

Convertible Notes

The fair value of the Company's 2028 Convertible Notes, which differs from their carrying value, is influenced by interest rates, the Company's stock price and stock price volatility (collectively, the Current Market Factors), and is determined by prices for the convertible notes observed in market trading which are Level 2 inputs.

The estimated fair value of the 2028 Convertible Notes (categorized as a Level 2 liability for fair value measurement purposes) as of December 31, 2024 was $ 1.2 billion, determined using the Current Market Factors and the ability of the Company to obtain debt on comparable terms to the 2028 Convertible Notes.

Royalty Financing Agreement

The fair value of the Royalty Financing Agreement at the time of the transaction was based on the Company's estimates of future royalties expected to be paid to OrbiMed over the life of the arrangement, which was determined using forecasts from market data sources, which are considered Level 3 inputs. This liability is being amortized using the effective interest method over the life of the arrangement, in accordance ASC 470, Debt and ASC 835, Interest. The Company will utilize the prospective method to account for subsequent changes in the estimated future payments to be made to OrbiMed and will update the effective interest rate on a quarterly basis. The carrying value of the Royalty Financing Agreement approximates fair value. For more information, see *Note - 11 Royalty Financing Agreement.*

Secured Senior Term Loan

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Fair Value Measurements (Continued)

The carrying value of the Term Loans are measured at amortized cost using the effective interest method and the carrying value approximates fair value. For more information, see *Note - 10 Debt.*

4. Product Revenues, Net

In accordance with ASC 606, Revenue from Contracts with Customers, the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for the goods or services provided. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (1) identify the contracts with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when or as the entity satisfies a performance obligation. At contract inception, the Company assesses the goods or services promised within each contract to determine which are performance obligations and to assess whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied. For all contracts that fall into the scope of ASC 606, the Company has identified one performance obligation: the sale of ARIKAYCE to its customers. The Company has not incurred or capitalized any incremental costs associated with obtaining contracts with customers.

Product revenues, net consist of net sales of ARIKAYCE. The Company's customers in the US include specialty pharmacies and specialty distributors. In December 2020, the Company began recognizing product revenue from commercial sales of ARIKAYCE in Europe. In July 2021, the Company began recognizing product revenue from commercial sales of ARIKAYCE in Japan. Globally, product revenues are recognized once the Company performs and satisfies all five steps of the revenue recognition criteria mentioned above.

The following table presents a geographic summary of the Company's product revenues, net for the years ended December 31, 2024, 2023 and 2022 (in thousands).

	Years Ended December 31,		
	2024	2023	2022
US	$ 254,800	$ 224,195	$ 185,994
Japan	87,699	65,733	56,506
Europe and rest of world	21,208	15,280	2,858
Total product revenues, net	$ 363,707	$ 305,208	$ 245,358

The Company also recognizes revenue related to various EAPs in Europe. EAPs are intended to make products available on a named-patient basis before they are commercially available in accordance with local regulations. During the fourth quarter of 2022, the Company agreed with French authorities on the final reimbursement price related to the temporary authorization for use (Autorisation Temporaire d'Utilisation or ATU) program in France. This final pricing resulted in a change in estimate that reduced revenue by approximately $ 5.8 million in the fourth quarter of 2022, which related to periods prior to 2022. The accrued France ATU reimbursement payable as of December 31, 2024 relates to current year sales. The accrued France ATU reimbursement payable is recorded within accounts payable and accrued liabilities in the consolidated balance sheets (see *Note 8 - Accounts Payable and Accrued Liabilities*).

Revenue is recorded at net selling price (transaction price), which includes estimates of variable consideration for which reserves are established for (a) customer credits, such as invoice discounts for prompt pay, (b) estimated government rebates, such as Medicaid and Medicare Part D reimbursements, and estimated managed care rebates, (c) estimated chargebacks, and (d) estimated costs of co-payment assistance. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (prompt pay discounts and chargebacks), prepaid expenses (co-payment assistance), or as a current liability (rebates). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the applicable contract. The amount of variable consideration included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Product Revenues, Net (Continued)

Customer credits: Certain of the Company's customers are offered various forms of consideration, including prompt payment discounts. The payment terms for sales to specialty pharmacies and specialty distributors for prompt payment discounts are based on contractual rates agreed with the respective specialty pharmacies and distributors. The Company anticipates that its customers will earn these discounts and, therefore, deducts the full amount of these discounts from total gross product revenues at the time such revenues are recognized.

Rebates: The Company contracts with certain government agencies and managed care organizations, or collectively, third-party payors, so that ARIKAYCE will be eligible for purchase by, or partial or full reimbursement from, such third-party payors. The Company estimates the rebates it will provide to third-party payors and deducts these estimated amounts from total gross product revenues at the time the revenues are recognized. These reserves are recorded in the same period in which the revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. The current liability is included in accounts payable and accrued liabilities on the consolidated balance sheets. The Company estimates the rebates that it will provide to third-party payors based upon (i) the Company's contracts with these third-party payors, (ii) the government mandated discounts applicable to government-funded programs, (iii) a range of possible outcomes that are probability-weighted for the estimated payor mix, and (iv) information obtained from the Company's specialty pharmacies.

Chargebacks: Chargebacks are discounts that occur when certain contracted customers, currently public health service institutions and federal government entities purchasing via the Federal Supply Schedule, purchase directly from the Company's specialty distributor. Contracted customers generally purchase the product at a discounted price and the specialty distributor, in turn, charges back to the Company the difference between the price the specialty distributor initially paid and the discounted price paid by the contracted customers. The Company estimates chargebacks provided to the specialty distributor and deducts these estimated amounts from gross product revenues, and from accounts receivable, at the time revenues are recognized.

Co-payment assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, the Company estimates the average co-pay mitigation amounts and the percentage of patients that it expects to participate in the program in order to establish accruals for co-payment assistance. These reserves are recorded in the same period in which the related revenue is recognized, resulting in a reduction of product revenue. The Company adjusts its accruals for co-pay assistance based on actual redemption activity and estimates of future redemptions related to sales in the current period.

If any or all of the Company's actual experience varies from its estimates, the Company may need to adjust prior period accruals, affecting revenue in the period of adjustment.

The following table provides a summary rollforward of the Company's sales allowances and related accruals for the years ended December 31, 2024 and 2023, which have been deducted in arriving at product revenues, net (in thousands).

	Customer Credits, Fees and Discounts	Rebates, Chargebacks and Co-pay Assistance	Total
Balance as of December 31, 2022	$ 14,232	$ 5,564	$ 19,796
Allowances for current period sales	12,494	33,834	46,328
Allowances for prior period sales	—	(118)	(118)
Payments and credits	(11,244)	(29,103)	(40,347)
Balance as of December 31, 2023	$ 15,482	$ 10,177	$ 25,659
Allowances for current period sales	14,410	41,082	55,492
Allowances for prior period sales	100	3,380	3,480
Payments and credits	(22,415)	(39,958)	(62,373)
Balance as of December 31, 2024	$ 7,577	$ 14,681	$ 22,258

5. Inventory

The Company's inventory balance consists of the following (in thousands):

	As of December 31,	
	2024	2023
Raw materials	$ 19,682	$ 24,562
Work-in-process	39,932	33,480
Finished goods	38,964	25,206
	$ 98,578	$ 83,248

Inventory is stated at the lower of cost and net realizable value and consists of raw materials, work-in-process, and finished goods. The Company has not recorded any significant inventory write-downs. The Company currently uses a limited number of third-party CMOs to produce its inventory.

6. Intangibles, Net and Goodwill

Intangibles, Net

Finite-lived Intangible Assets

As of December 31, 2024, the Company's finite-lived intangible assets consisted of acquired ARIKAYCE R&D and the milestones paid to PARI for the license to use Lamira for the delivery of ARIKAYCE to patients as a result of the FDA and EC approvals of ARIKAYCE in September 2018 and October 2020, respectively. The Company began amortizing its acquired ARIKAYCE R&D and PARI milestones intangible assets in October 2018, over ARIKAYCE's initial regulatory exclusivity period of 12 years. Amortization of these assets during each of the next five years is estimated to be approximately $ 5.1 million per year.

Indefinite-lived Intangible Assets

As of December 31, 2024, the Company's indefinite-lived intangible assets consisted of acquired IPR&D from the Business Acquisition (see *Note 18 - Acquisitions*). Indefinite-lived intangible assets are not amortized.

A rollforward of the Company's intangible assets for the years ended December 31, 2024 and 2023 follows (in thousands):

Intangible Asset	December 31, 2023	Additions	Amortization	December 31, 2024
Acquired ARIKAYCE R&D	$ 32,738	$ —	$ (4,850)	$ 27,888
Acquired IPR&D	29,600	—	—	29,600
PARI milestones	1,366	—	(202)	1,164
	$ 63,704	$ —	$ (5,052)	$ 58,652

Intangible Asset	December 31, 2022	Additions	Amortization	December 31, 2023
Acquired ARIKAYCE R&D	$ 37,588	$ —	$ (4,850)	$ 32,738
Acquired IPR&D	29,600	—	—	29,600
PARI milestones	1,568	—	(202)	1,366
	$ 68,756	$ —	$ (5,052)	$ 63,704

Goodwill

The Company's goodwill balance of $ 136.1 million as of December 31, 2024 and 2023 resulted from the August 2021 Business Acquisition (see *Note 18 - Acquisitions*).

7. Fixed Assets, Net

Fixed assets are stated at cost and depreciated using the straight-line method, based on useful lives as follows (in thousands):

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Fixed Assets, Net (Continued)

Asset Description	Estimated Useful Life (years)	As of December 31, 2024	As of December 31, 2023
Laboratory equipment	7	$ 26,753	$ 22,660
Furniture and fixtures	7	6,428	6,428
Computer hardware and software	3 - 5	6,485	6,001
Office equipment	7	171	89
Manufacturing equipment	7	1,336	1,336
Leasehold improvements	2 - 10	38,058	38,049
Construction in progress	—	51,127	35,449
		130,358	110,012
Less accumulated depreciation		(50,306)	(44,628)
		$ 80,052	$ 65,384

Depreciation expense was $ 6.0 million, $ 5.5 million and $ 5.3 million for the years ended December 31, 2024, 2023 and 2022, respectively.

8. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of the following (in thousands):

	As of December 31, 2024	As of December 31, 2023
Accounts payable and other accrued operating expenses	$ 73,033	$ 65,393
Accrued clinical trial expenses	26,068	23,711
Accrued professional fees	17,895	13,885
Accrued technical operation expenses	18,388	9,187
Accrued compensation and employee related costs	80,312	48,933
Accrued royalty and milestones payable	6,324	5,674
Accrued interest payable	359	2,175
Revenue Interest Payments payable	4,177	3,347
Accrued sales allowances and related costs	16,762	10,937
Accrued France ATU reimbursement payable	5,988	14,685
Deferred and contingent consideration	24,700	6,700
Other accrued liabilities	11,203	10,360
	285,209	214,987
	$	$

9. Leases

The Company's lease portfolio consists primarily of office and laboratory space, manufacturing facilities, research equipment, and fleet vehicles. All of the Company's leases are classified as operating leases, except for the Company's leases of its corporate headquarters and a research facility in San Diego, which are classified as finance leases. The terms of the Company's lease agreements that have commenced range from less than one year to ten years, ten months . In its assessment of the term of each such lease, the Company has not included any options to extend or terminate the lease due to the absence of economic incentives in its lease agreements. Leases that qualify for treatment as a short-term lease are expensed as incurred. These short-term leases are not material to the Company's financial position. Furthermore, the Company does not separate lease

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Leases (Continued)

and non-lease components for all classes of underlying assets. The Company's leases do not contain residual value guarantees and it does not sublease any of its leased assets.

The Company outsources its manufacturing operations to CMOs. Upon review of the agreements with its CMOs, the Company determined that these contracts contain embedded leases for dedicated manufacturing facilities. The Company obtains substantially all of the economic benefits from the use of the manufacturing facilities, the Company has the right to direct how and for what purpose the facility is used throughout the period of use, and the supplier does not have the right to change the operating instructions of the facility. The operating lease right-of-use assets and corresponding lease liabilities associated with the manufacturing facilities is the sum of the minimum guarantees over the life of the production contracts.

The Company records variable consideration for variable lease payments in excess of fixed fees or minimum guarantees. Variable costs related to CMO manufacturing agreements are direct costs related to the manufacturing of ARIKAYCE and are capitalized within inventory in the Company's consolidated balance sheet, while the variable costs related to other leasing arrangements, not related to the manufacturing of ARIKAYCE, have been classified within operating expenses in the Company's consolidated statements of comprehensive loss. The table below summarizes the Company's total lease costs included in its consolidated financial statements, as well as other required quantitative disclosures (in thousands).

	As of December 31, 2024	As of December 31, 2023
Finance lease cost:		
Amortization of right-of-use assets	$ 2,712	$ 2,712
Interest on lease liabilities	2,230	2,417
Total finance lease cost	$ 4,942	$ 5,129
Operating lease cost	10,415	10,385
Variable lease cost	25,818	14,148
Total lease cost	$ 41,175	$ 29,662
Other information:		
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows for finance leases	$ 2,230	$ 2,417
Operating cash flows for operating leases	$ 10,389	$ 9,098
Financing cash flows for finance leases	$ 2,610	$ 1,217
Right-of-use assets obtained in exchange for new finance lease liabilities	$ —	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 8,995	$ 5,329
Weighted average remaining lease term - finance leases	6.6 years	7.6 years
Weighted average remaining lease term - operating leases	2.9 years	2.5 years
Weighted average discount rate - finance leases	7.9 %	7.9 %
Weighted average discount rate - operating leases	9.0 %	7.6 %

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Leases (Continued)

The table below presents the maturity of lease liabilities on an annual basis for the remaining years of the Company's commenced lease agreements (in thousands).

Year Ending December 31,	Finance Leases	Operating Leases
2025	$ 4,967	$ 10,647
2026	5,097	4,244
2027	5,228	2,703
2028	5,361	2,457
2029	5,496	925
Thereafter	8,661	—
Total	34,810	20,976
Less: present value discount	7,785	2,506
Present value of lease liabilities	$ 27,025	$ 18,470
Balance Sheet Classification at December 31, 2024:		
Current lease liabilities	$ 2,961	$ 9,358
Long-term lease liabilities	24,064	9,112
Total lease liabilities	$ 27,025	$ 18,470

The Company entered into certain agreements with Patheon related to increasing its long-term production capacity for ARIKAYCE commercial inventory. The Company has determined that these agreements with Patheon contain an embedded lease for the manufacturing facility and the specialized equipment contained therein. As of December 31, 2024, costs of $ 59.0 million incurred by the Company under these additional agreements have been classified within other assets in the Company's consolidated balance sheet. Upon the commencement date, prepaid costs and minimum guarantees specified in the agreement will be combined to establish an operating lease ROU asset and operating lease liability.

10. Debt

Debt, long-term consists of the following commitments as of December 31, 2024 and 2023 (in thousands):

	As of December 31,	
	2024	2023
Convertible notes	$ 567,164	$ 788,909
Term Loans	536,218	366,404
Debt, long-term	$ 1,103,382	$ 1,155,313

In May 2021, the Company completed an underwritten public offering of $ 575.0 million aggregate principal amount of the 2028 Convertible Notes, including the exercise in full of the underwriters' option to purchase an additional $ 75.0 million in aggregate principal amount of 2028 Convertible Notes. The Company's net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses of $ 15.7 million, were approximately $ 559.3 million. The 2028 Convertible Notes bear interest payable semiannually in arrears on June 1 and December 1 of each year, beginning on December 1, 2021. The 2028 Convertible Notes mature on June 1, 2028, unless earlier converted, redeemed, or repurchased.

In January 2018, the Company completed an underwritten public offering of $ 450.0 million aggregate principal of the 2025 Convertible Notes, including the exercise in full of the underwriters' option to purchase an additional $ 50.0 million in aggregate principal amount of 2025 Convertible Notes. The Company's net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses of $ 14.2 million, were approximately $ 435.8 million. The 2025 Convertible Notes bore interest payable semiannually in arrears on January 15 and July 15 of each year, beginning on July 15, 2018. The 2025 Convertible Notes would have matured on January 15, 2025 but on June 27, 2024, the Company called the outstanding 2025 Convertible Notes for redemption, which was completed on August 9, 2024. See Redemption and Conversion of the 2025 Convertible Notes below for further details.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Debt (Continued)

A portion of the net proceeds from the 2028 Convertible Notes was used to repurchase $ 225.0 million of the Company's outstanding 2025 Convertible Notes. The Company recorded a loss on early extinguishment of debt of $ 17.7 million, primarily related to the premium paid on extinguishment of a portion the 2025 Convertible Notes.

On or after March 1, 2028, until the close of business on the second scheduled trading day immediately preceding June 1, 2028, holders may convert their 2028 Convertible Notes at any time. The initial conversion rate for the 2028 Convertible Notes is 30.7692 shares of common stock per $1,000 principal amount of 2028 Convertible Notes (equivalent to an initial conversion price of approximately $ 32.50 per share of common stock). Upon conversion of either the 2025 Convertible Notes or the 2028 Convertible Notes, holders may receive cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's option. The conversion rates will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest.

Holders may convert their 2028 Convertible Notes prior to March 1, 2028, only under the following circumstances, subject to the conditions set forth in the applicable indenture: (i) during the five business day period immediately after any five consecutive trading day period (the measurement period) in which the trading price per $1,000 principal amount of 2028 Convertible Notes, as determined following a request by a holder of such convertible notes, for each trading day of the measurement period was less than 98 % of the product of the last reported sale price of the common stock and the conversion rate on such trading day, (ii) the Company elects to distribute to all or substantially all holders of the common stock (a) any rights, options or warrants (other than in connection with a stockholder rights plan for so long as the rights issued under such plan have not detached from the associated shares of common stock) entitling them, for a period of not more than 45 days from the declaration date for such distribution, to subscribe for or purchase shares of common stock at a price per share that is less than the average of the last reported sale prices of the common stock for the 10 consecutive trading day period ending on, and including, the trading day immediately preceding the declaration date for such distribution, or (b) the Company's assets, debt securities or rights to purchase securities of the Company, which distribution has a per share value, as reasonably determined by the board of directors, exceeding 10 % of the last reported sale price of the common stock on the trading day immediately preceding the declaration date for such distribution, (iii) if a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs, or if the Company is a party to (a) a consolidation, merger, combination, statutory or binding share exchange or similar transaction, pursuant to which the common stock would be converted into, or exchanged for, cash, securities or other property or assets, or (b) any sale, conveyance, lease or other transfer or similar transaction in one transaction or a series of transactions of all or substantially all of the consolidated assets of the Company and its subsidiaries, taken as a whole, all or any portion of the 2028 Convertible Notes may be surrendered by a holder for conversion at any time from or after the date that is 30 scheduled trading days prior to the anticipated effective date of the transaction, (iv) if during any calendar quarter commencing after the calendar quarter ending on June 30, 2021 (and only during such calendar quarter), the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130 % of the conversion price on each applicable trading day (each, a Stock Price Convertibility Trigger), or (v) if the Company sends a notice of redemption, a holder may surrender all or any portion of its 2028 Convertible Notes to which the notice of redemption relates for conversion at any time on or after the date the applicable notice of redemption was sent until the close of business on (a) the second business day immediately preceding the related redemption date or (b) if the Company fails to pay the redemption price on the redemption date as specified in such notice of redemption, such later date on which the redemption price is paid.

The 2028 Convertible Notes can be settled in cash, common stock, or a combination of cash and common stock at the Company's option, and thus, the Company determined the embedded conversion option in the 2028 Convertible Notes is not required to be separately accounted for as a derivative. However, since the 2028 Convertible Notes are within the scope of the accounting guidance for cash convertible instruments, the Company is required to separate the 2028 Convertible Notes into liability and equity components. The carrying amount of the liability component of the 2028 Convertible Notes as of the date of issuance was calculated by measuring the fair value of a similar liability that did not have an associated equity component. The fair value was based on data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments. The carrying amount of the equity component representing the embedded conversion option of the 2028 Convertible Notes was determined by deducting the fair value of the liability component from the gross proceeds of the 2028 Convertible Notes. The excess of the principal amount of the liability component over its carrying amount is amortized to interest expense over the expected life of a similar liability that does not have an associated equity component using the effective interest method. The equity component is not remeasured as long as it continues to meet the conditions for equity classification in the accounting guidance for contracts in an entity’s own equity. The same accounting approach was taken for the 2025 Convertible Notes, which are no longer outstanding.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Debt (Continued)

The fair value of the liability component of the 2025 Convertible Notes on the date of issuance was estimated at $ 309.1 million using an effective interest rate of 7.6 % and, accordingly, the residual equity component on the date of issuance was $ 140.9 million. The fair value of the liability component of the 2028 Convertible Notes on the date of issuance was estimated at $ 371.6 million using an effective interest rate of 7.1 % and, accordingly, the residual equity component on the date of issuance was $ 203.4 million. The respective discounts were amortized to interest expense over the term of the applicable series of convertible notes through December 31, 2021, prior to the adoption of ASU 2020-06. The 2028 Convertible Notes have a remaining term of approximately 3.42 years.

The $ 567.2 million carrying value of the 2028 Convertible Notes as of December 31, 2024 is net of $ 7.8 million of unamortized debt issuance costs. The 2025 Convertible Notes were fully converted or redeemed by the Company on August 9, 2024, such that none were outstanding as of December 31, 2024. The following table presents the carrying value of the Company's convertible notes balance (in thousands):

	As of December 31,	
	2024	2023
Face value of outstanding convertible notes	$ 574,923	$ 800,000
Debt issuance costs, unamortized	(7,759)	(11,091)
Convertible notes	$ 567,164	$ 788,909

Redemption and Conversion of the 2025 Convertible Notes

On June 27, 2024, the Company issued a redemption notice for its 2025 Convertible Notes with a redemption date of August 9, 2024 (the Redemption Date). The Company elected to settle any conversions of the 2025 Convertible Notes that occurred on or before the business day prior to the Redemption Date in shares of the Company's common stock. Holders of $ 224.8 million aggregate principal amount of the then outstanding 2025 Convertible Notes elected to convert their notes into shares of the Company's common stock at a conversion rate of 25.5384 shares of common stock per $1,000 principal amount of 2025 Convertible Notes (equivalent to an initial conversion price of approximately $ 39.16 per share of common stock). These conversions resulted in the issuance of an aggregate of 5,741,063 shares of the Company's common stock.

The remaining $ 0.2 million aggregate principal amount of 2025 Convertible Notes outstanding were redeemed by the Company on the Redemption Date at a redemption price equal to 100 % of the principal amount of the 2025 Convertible Notes, plus accrued and unpaid interest on the 2025 Convertible Notes to, but excluding, the Redemption Date (the Redemption Price). For each $1,000 principal amount of 2025 Convertible Notes, the Redemption Price was approximately $ 1,001.17 .

Conversions of 2028 Convertible Notes

On July 1, 2024 and October 1, 2024, the 2028 Convertible Notes became convertible, through the end of the third quarter of 2024 and fourth quarter of 2024, respectively, by the holders of such notes due to the satisfaction of the Stock Price Convertibility Trigger applicable to such notes. The current conversion rate for the 2028 Convertible Notes is 30.7692 shares of common stock per $1,000 principal amount of notes (equivalent to an initial conversion price of approximately $ 32.50 per share of common stock). The Company has elected to settle any conversions of the 2028 Convertible Notes in shares of common stock. As of December 31, 2024, holders of seventy-seven thousand dollars of aggregate principal amount of 2028 Convertible Notes elected to convert their notes, resulting in an issuance of an aggregate of 2,362 shares of the Company's common stock. The 2028 Convertible Notes may be convertible in subsequent quarters if another convertibility-triggering event occurs.

Secured Senior Term Loan

In October 2022, the Company entered into the $ 350.0 million Tranche A Term Loan with Pharmakon that would have matured on October 19, 2027. The Tranche A Term Loan originally bore interest at a rate based upon the SOFR, subject to a SOFR floor of 2.5 %, in addition to a margin of 7.75 % per annum. Up to 50 % of the interest payable during the first 24 months from the closing of the Tranche A Term Loan could have been paid-in-kind at the Company's election. If elected, paid-in-kind interest would have been capitalized and added to the principal amount of the Tranche A Term Loan. The Tranche A Term Loan, including the paid-in-kind interest, would have been repaid in eight equal quarterly payments starting in the 13th quarter following the closing of the Tranche A Term Loan (i.e., the quarter ending March 31, 2026), except that the repayment start date could have been extended at the Company's option for an additional four quarters, so that repayments start in the 17th quarter following the closing of the Tranche A Term Loan, subject to the achievement of specified ARIKAYCE data thresholds and certain other conditions. Net proceeds from the Tranche A Term Loan, after deducting the lenders fees and deal expenses of $ 15.1 million, were $ 334.9 million.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Debt (Continued)

Amended and Restated Loan Agreement

In October 2024, the Company entered into the A&R Loan Agreement with BioPharma Credit PLC, BPCR Limited Partnership and BioPharma Credit Investments V (Master) LP, which are funds managed by Pharmakon, and the guarantors party to such agreement. The A&R Loan Agreement amends and restates the Loan Agreement, dated as of October 19, 2022, pursuant to which the Tranche A Term Loan was provided. The A&R Loan Agreement, among other items, provides an additional $ 150.0 million senior secured term loan tranche. The A&R Loan Agreement extends the maturity of the Term Loans to September 30, 2029, subject to acceleration to February 1, 2028 on the occurrence of certain prespecified events, and amends the interest rate on the Term Loans to a fixed rate of 9.6 % per annum. As consideration for the provision of the Tranche B Term Loan, the Company agreed to pay Pharmakon a fee equal to 2.0 % of the Tranche B Term Loan at the closing date of the Tranche B Term Loan and an additional exit fee of 2.0 % of the amount of each prepayment or repayment of the Term Loans. The Term Loans will be repaid in eight equal quarterly payments starting on January 3, 2028. Net proceeds from the Tranche B Term Loan, after deducting the lenders fees and administrative expenses of $ 3.7 million, were $ 146.3 million.

The Company evaluated whether the A&R Loan Agreement represented a debt modification or extinguishment in accordance with ASC 470-50, Debt – Modifications and Extinguishments. As the present value of the cash flows under the terms of the A&R Loan Agreement was less than 10% different from the remaining cash flows under the terms of the Tranche A Term Loan, the A&R Loan Agreement was accounted for as a debt modification. The unamortized balance of debt issuance costs incurred in connection with the Term Loans are being amortized through September 2029 utilizing the effective interest rate method. The effective interest rate of the Term Loans was 10.6 % at modification.

The following table presents the carrying value of the Company's Term Loans balance as of December 31, 2024 and 2023 (in thousands):

	As of December 31,	
	2024	2023
Principal	$ 500,000	$ 350,000
Paid-in-kind interest capitalized	46,770	27,537
Debt discount, net	(10,552)	(11,133)
Term Loans	$ 536,218	$ 366,404

As of December 31, 2024, future principal repayments of debt for each of the fiscal years through maturity were as follows (in thousands):

Year Ending December 31:	
2025	$ —
2026	—
2027	—
2028	916,654
2029	205,039
2030 and thereafter	—
	$ 1,121,693

The estimated fair value of the debt (categorized as a Level 2 liability for fair value measurement purposes) is determined using current market factors and the ability of the Company to obtain debt at comparable terms to those that are currently in place.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Debt (Continued)

Interest expense for the years ended December 31, 2024, 2023, and 2022, is as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Convertible debt contractual interest expense	$ 6,397	$ 8,250	$ 8,250
Term Loans contractual interest expense	51,587	46,743	8,330
Royalty Financing Agreement non-cash interest expense	20,044	18,846	3,687
Amortization of debt issuance costs	6,884	7,320	3,991
Swap interest (income) expense	(2,229)	(1,882)	380
Total debt interest expense	$ 82,683	$ 79,277	$ 24,638
Finance lease interest expense	2,230	2,417	1,808
Total interest expense	$ 84,913	$ 81,694	$ 26,446

In accordance with the Company's transition using the modified retrospective method upon adopting ASU 2020-06 on January 1, 2022, the Company ceased accreting debt discount. The impact of adopting ASU 2020-06 on January 1, 2022 resulted in an opening balance sheet adjustment increasing debt by approximately $ 221.9 million and issuance costs classified to debt by approximately $ 6.1 million, decreasing the deferred tax liability by $ 1.4 million, as well as an increase to retained earnings of approximately $ 50.2 million, with an offsetting reduction to additional paid-in-capital of $ 264.6 million, net of tax.

11. Royalty Financing Agreement

In October 2022, the Company entered into the Royalty Financing Agreement with OrbiMed. Under the Royalty Financing Agreement, OrbiMed paid the Company $ 150.0 million in exchange for the right to receive, on a quarterly basis, royalties in an amount equal to 4.0 % of ARIKAYCE global net sales prior to September 1, 2025 and 4.5 % of ARIKAYCE global net sales on or after September 1, 2025, as well as 0.75 % of brensocatib global net sales, if approved. In the event that OrbiMed has not received aggregate Revenue Interest Payments of at least $ 150.0 million on or prior to March 31, 2028, the Company must make a one-time payment to OrbiMed for the difference between the $ 150.0 million and the aggregated Revenue Interest Payments that have been paid. In addition, the royalty rate for ARIKAYCE will be increased beginning March 31, 2028 to the rate which would have resulted in aggregate Revenue Interest Payments as of March 31, 2028 equaling $ 150.0 million. The total Revenue Interest Payments payable by the Company to OrbiMed are capped at 1.8 x of the purchase price or up to a maximum of 1.9 x of the purchase price under certain conditions. Net proceeds from the Royalty Financing Agreement, after deducting the lenders fees and deal expenses of $ 3.6 million, were $ 146.4 million. The Royalty Financing Agreement was amended in October 2024 to, among other things, amend certain restrictions on the Company’s ability to incur indebtedness.

The fair value of the Royalty Financing Agreement at the time of the transaction was based on the Company’s estimates of future royalties expected to be paid to OrbiMed over the life of the arrangement, which was determined using forecasts from market data sources, which are considered Level 3 inputs. This liability is being amortized using the effective interest method over the life of the arrangement, in accordance ASC 470, Debt and ASC 835, Interest. The initial annual effective interest rate was determined to be 12.4 %. The Company is utilizing the prospective method to account for subsequent changes in the estimated future payments to be made to OrbiMed and updates the effective interest rate on a quarterly basis.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. Royalty Financing Agreement (Continued)

The following table presents the activity of the Company's Royalty Financing Agreement balance for the years ended December 31, 2024 and 2023 (in thousands):

	As of December 31,	
	2024	2023
Royalty financing agreement liability - beginning balance	$ 158,162	$ 151,538
Revenue Interest Payments paid and payable	(14,535)	(12,222)
Interest expense recognized	20,044	18,846
Royalty financing agreement liability - ending balance	$ 163,671	$ 158,162
Royalty financing issuance costs, unamortized - beginning balance	$ (3,128)	$ (3,523)
Amortization of issuance costs	524	521
Other	—	(126)
Deferred issuance costs, unamortized - ending balance	$ (2,604)	$ (3,128)
Royalty Financing Agreement	$ 161,067	$ 155,034

The Revenue Interest Payments payable in connection with the royalty financing agreement were $ 4.2 million and $ 3.3 million as of December 31, 2024 and 2023, respectively, which were recorded within accounts payable and accrued expenses on the consolidated balance sheets. Non-cash interest expense is recorded within interest expense in the consolidated statements of comprehensive loss.

12. Shareholders' Equity

Common Stock—As of December 31, 2024, the Company had 500,000,000 shares of common stock authorized with a par value of $ 0.01 per share and 179,382,635 shares of common stock issued and outstanding. In addition, as of December 31, 2024, the Company had reserved 21,927,128 shares of common stock for issuance upon the exercise of outstanding common stock options, 3,320,341 shares of common stock for issuance upon the vesting of RSUs and 660,466 shares for issuance upon the vesting of PSUs. The Company has also reserved 17,689,921 shares of common stock in the aggregate for issuance upon conversion of the remaining 2028 Convertible Notes, subject to adjustment in accordance with the applicable indentures. In connection with the Business Acquisition, the Company reserved 9,406,112 shares of the Company's common stock, subject to certain closing-related reductions. The shares of the Company's common stock reserved in connection with the Motus acquisition were partly issued as acquisition consideration at closing and on the first, second and third anniversaries of the closing date of the acquisition, and will also be issued upon the achievement of certain development and regulatory milestone events, subject to certain reductions. The shares of the Company's common stock reserved in connection with the AlgaeneX acquisition will be issued upon the achievement of a development milestone event, subject to certain reductions.

Of the 9,406,112 shares reserved, subject to certain closing-related reductions, the Company issued 3,420,149 shares of the Company's common stock in connection with the Business Acquisition (see *Note 18 - Acquisitions*) in the third quarter of 2021, after certain closing-related deductions. In the third quarter of 2022, the Company issued 171,427 shares of the Company's common stock to fulfill the payment required to Motus equityholders on the first anniversary of the Business Acquisition. In the third quarter of 2023, the Company issued 177,203 shares of the Company's common stock to fulfill the payment required to Motus equityholders on the second anniversary of the Business Acquisition. In the third quarter of 2024, the Company issued 182,182 shares of the Company's common stock to fulfill the payment required to Motus equityholders on the third anniversary of the Business Acquisition.

In the third quarter of 2024, in connection with the redemption and conversions of the 2025 Convertible Notes, the Company issued 5,741,063 shares of the Company's common stock. In the third and fourth quarter of 2024, in connection with the conversions of the 2028 Convertible Notes, the Company issued 2,362 shares of the Company's common stock.

In May 2024, the Company completed an underwritten offering of 14,514,562 shares of the Company's common stock at a public offering price of $ 51.50 per share. 1,893,203 of the shares of common stock were issued pursuant to the exercise in full of the underwriters' option to purchase additional shares. The Company's net proceeds from the sale of the shares, after deducting the underwriting discounts and estimated offering expenses of $ 34.3 million, were $ 713.2 million.

In the second quarter of 2023, in connection with the Company's acquisition of Adrestia, the Company issued 3,430,867 shares of the Company's common stock as consideration at closing. See *Note 18 - Acquisitions* for further details.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Shareholders' Equity (Continued)

In connection with the Company's acquisition of Vertuis, the Company reserved 550,000 shares of the Company's common stock, subject to future adjustment. An aggregate of 500,000 of the reserved shares were issued as acquisition consideration at closing. In July 2024, the Company issued the Vertuis equityholders an additional 14,773 shares of common stock. See *Note 18 - Acquisitions* for further details.

In the fourth quarter of 2022, the Company completed an underwritten offering of 13,750,000 shares of the Company's common stock, at an offering price of $ 20.00 per share. The Company's net proceeds from the sale of the shares, after deducting the underwriting discounts and offering expenses of approximately $ 16.2 million, were approximately $ 258.8 million.

In the first quarter of 2021, the Company entered into a sales agreement with Leerink Partners, to sell shares of the Company's common stock, with aggregate gross sales proceeds of up to $ 250.0 million, from time to time, through the ATM program, under which Leerink Partners acts as sales age nt. During the year ended December 31, 2023, the Company issued and sold an aggregate of 6,503,041 shares of common stock through the ATM program at a weighted-average public offering price of $ 24.12 per share and received net proceeds of $ 152.2 million. In the first quarter of 2024, the Company entered into the new sales agreement with Leerink Partners to sell shares of the Company's common stock, with aggregate gross sales proceeds of up to $ 500.0 million, from time to time, through the new ATM program, under which Leerink Partners acted as sales agent. In connection with entering into the new ATM program, the Company terminated the ATM program. During the third quarter of 2024, the Company issued and sold an aggregate of 5,022,295 shares of common stock through the new ATM program at a weighted-average public offering price of $ 75.64 per share and received net proceeds of $ 371.3 million. On November 18, 2024, the Company terminated the new sales agreement.

Preferred Stock—As of December 31, 2024 and 2023, the Company had 200,000,000 shares of preferred stock authorized with a par value of $ 0.01 and no shares of preferred stock were issued and outstanding.

13. Stock-Based Compensation

The Company's current equity compensation plan, the Insmed Incorporated Amended and Restated 2019 Incentive Plan (the 2019 Incentive Plan), was approved by shareholders at the Company's Annual Meeting of Shareholders on May 13, 2023. The 2019 Incentive Plan replaced the Insmed Incorporated 2019 Incentive Plan, as amended, pursuant to which the Company was authorized to grant incentive awards up to an aggregate of 13,750,000 shares. At the Company's 2023 Annual Meeting of Shareholders, in connection with approval of the 2019 Incentive Plan, the Company's shareholders approved the issuance of an additional 10,500,000 shares under the 2019 Incentive Plan. At the Company's 2024 Annual Meeting of Shareholders, the Company's shareholders approved Amendment No. 1 to the 2019 Incentive Plan, which provides for the issuance of an additional 3,000,000 shares under the plan. As of December 31, 2024, 5,051,894 shares remained for future issuance under the 2019 Incentive Plan.

The 2019 Incentive Plan is administered by the Compensation Committee of the Board of Directors of the Company. Under the terms of the 2019 Incentive Plan, the Company is authorized to grant a variety of incentive awards based on its common stock, including stock options (both incentive stock options and non-qualified stock options), RSUs, performance options/shares and other stock awards to eligible employees and non-employee directors. The 2019 Incentive Plan will terminate on May 16, 2029 unless it is extended or terminated earlier pursuant to its terms. In addition, from time to time, the Company makes inducement grants of stock options to new hires, which awards are made pursuant to the Nasdaq's inducement grant exception to the shareholder approval requirement for grants of equity compensation. During the years ended December 31, 2024, 2023 and 2022, the Company granted inducement stock options covering 1,444,850 , 2,674,290 and 1,068,310 shares, respectively, of the Company's common stock to new employees.

On May 15, 2018, the 2018 Employee Stock Purchase Plan was approved by shareholders at the Company's 2018 Annual Meeting of Shareholders. The ESPP allows eligible employees to acquire an ownership interest in the Company by purchasing common stock, at a discount, through payroll deductions. The Company reserved an aggregate of 4,530,488 shares of common stock for issuance under the ESPP. The ESPP is compensatory under GAAP and the Company recorded stock-based compensation expense of $ 3.3 million, $ 1.9 million and $ 1.3 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Stock Options—The Company calculates the fair value of stock options granted using the Black-Scholes valuation model. The following table summarizes the grant date fair value and assumptions used in determining the fair value of all stock options granted, including grants of inducement options, during the years ended December 31, 2024, 2023 and 2022.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. Stock-Based Compensation (Continued)

	2024	2023	2022
Volatility	61 % - 69 %	62 % - 70 %	69 % - 70 %
Risk-free interest rate	3.51 % - 4.64 %	3.36 % - 4.72 %	1.37 % - 4.27 %
Dividend yield	0.0 %	0.0 %	0.0 %
Expected option term (in years)	6.11	6.05	5.93
Weighted average fair value of stock options granted	$ 20.11	$ 13.12	$ 13.19

The volatility factor was based on the Company's historical volatility during the expected option term. The Company accounts for forfeitures as they occur.

From time to time, the Company has granted performance-conditioned options to certain of its employees. Vesting of these options is subject to the Company achieving certain performance criteria established at the date of grant and the grantees fulfilling a service condition (continued employment). As of December 31, 2024 and December 31, 2023, the Company had performance-conditioned options covering 114,780 shares outstanding. As of December 31, 2024 and December 31, 2023, the performance conditions are not probable and therefore, no stock-based compensation was recorded in the consolidated statements of comprehensive loss.

The following table summarizes stock option activity for stock options granted for the years ended December 31, 2024, 2023 and 2022 as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value (in '000)
Options outstanding at December 31, 2021	14,088,960	$ 22.00		
Granted	5,614,220	$ 20.89		
Exercised	(1,151,341)	$ 14.41		
Forfeited and expired	(1,026,543)	$ 25.70		
Options outstanding at December 31, 2022	17,525,296	$ 21.93		
Exercisable at December 31, 2022	8,587,820	$ 20.35		
Granted	6,650,880	$ 20.20		
Exercised	(871,933)	$ 16.03		
Forfeited and expired	(791,674)	$ 24.01		
Options outstanding at December 31, 2023	22,512,569	$ 21.58		
Exercisable at December 31, 2023	11,125,232	$ 21.41		
Granted	4,963,628	$ 32.59		
Exercised	(4,813,336)	$ 22.10		
Forfeited and expired	(735,733)	$ 23.48		
Options outstanding at December 31, 2024	21,927,128	$ 23.89	6.99	$ 991,993
Exercisable at December 31, 2024	10,772,458	$ 21.41	5.45	$ 512,988

The total intrinsic value of stock options exercised during the years ended December 31, 2024, 2023 and 2022 was $ 173.4 million, $ 6.0 million and $ 11.1 million, respectively.

As of December 31, 2024, there was $ 153.9 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.5 years.

Restricted Stock and Restricted Stock Units—The Company may grant RS and RSUs to employees and non-employee directors. Each share of RS vests upon and each RSU represents a right to receive one share of the Company's common stock upon the completion of a specific period of continued service.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. Stock-Based Compensation (Continued)

RS and RSU awards granted are valued at the market price of the Company's common stock on the date of grant. The Company recognizes non-cash compensation expense for the fair values of these RS and RSUs on a straight-line basis over the requisite service period of these awards.

The following table summarizes RSU awards granted during the years ended December 31, 2024, 2023 and 2022:

	Number of RSUs	Weighted Average Grant Price
Outstanding at December 31, 2021	1,019,714	$ 27.33
Granted	1,021,219	$ 20.34
Released	(417,894)	$ 26.79
Forfeited	(103,139)	$ 24.04
Outstanding at December 31, 2022	1,519,900	$ 23.00
Granted	1,934,822	$ 19.26
Released	(574,219)	$ 22.89
Forfeited	(130,209)	$ 20.87
Outstanding at December 31, 2023	2,750,294	$ 20.50
Granted	1,679,702	$ 27.37
Released	(926,933)	$ 21.14
Forfeited	(182,722)	$ 22.82
Outstanding at December 31, 2024	3,320,341	$ 23.67

As of December 31, 2024, there was $ 56.7 million of unrecognized compensation expense related to unvested awards, which is expected to be recognized over a weighted average period of 2.5 years.

Performance Stock Units—In January 2022, the Company issued 271,612 PSUs. For these PSUs, there are two performance conditions, a service condition, and a market condition. The performance conditions are the issuance of a press release announcing certain top-line results from a clinical trial and the acceptance of an NDA by the FDA for brensocatib. The service condition is continuous employment with the Company through the later of the third anniversary of the grant date of the PSU award and the date an NDA for brensocatib is accepted by the FDA. The potential payout of the awards ranges from 0 % to 250 % of the target, dependent on a market condition that is based on the Company's total shareholder return compared to the NASDAQ Biotechnology Index, subject to certain adjustments (the Peer Group). Due to the multiple vesting conditions, uncertain timing and variable payout of these PSUs, a Monte Carlo simulation was performed to determine the fair value of the awards. Compensation cost will be recognized on the date the performance conditions become probable, with an initial recording of the cumulative expense that would have been recognized if the PSU expense had been recognized on a straight-line basis since the date of grant. The remaining unamortized fair value of the awards will then be expensed prospectively on a straight-line basis over the remaining service period. Since the market condition is reflected in the grant-date fair value and is not a condition for the award to vest, it does not impact the requisite service period. The volatility, risk-free interest rate and weighted-average grant date fair value of the PSUs granted are 65.4 %, 1.03 % and $ 39.12 , respectively. Any forfeitures that occur after compensation cost recognition commences will result in the cumulative reversal of expense in the period in which the forfeiture occurs.

The Company achieved the first performance condition for the PSUs by issuing a press release announcing certain topline results from the ASPEN trial by June 30, 2024, and achieved the second performance condition, the acceptance of an NDA by the FDA for brensocatib, in February 2025. During the second quarter of 2024, the Company's total shareholder return was compared to the Company's Peer Group and the potential payout of the awards was determined to be 250 % of the target. As of December 31, 2024, there were 660,466 PSUs outstanding with an unrecognized compensation expense of $ 10.3 million. In the first quarter of 2025, the PSUs vested and the Company recognized the compensation expense.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. Stock-Based Compensation (Continued)

The following table summarizes the aggregate stock-based compensation expense recorded in the consolidated statements of comprehensive loss related to stock options, RSUs and ESPP during the years ended December 31, 2024, 2023 and 2022 (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Research and development expenses	$ 47,674	$ 35,880	$ 26,379
Selling, general and administrative expenses	49,161	38,898	31,307
Total stock-based compensation expense	$ 96,835	$ 74,778	$ 57,686

There was no stock-based compensation expense recorded in the consolidated statements of comprehensive loss related to PSUs during the years ended December 31, 2024, 2023 and 2022, as the performance conditions associated with the PSU awards were not probable as of these dates.

14. Income Taxes

For the years ended December 31, 2024, 2023 and 2022, the Company recorded a provision for income taxes of $ 3.7 million, $ 2.6 million and $ 1.4 million, respectively, and the effective rate was approximately 0 % for each of these years. The provisions recorded are primarily a result of certain of the Company's international subsidiaries, which had taxable income during the periods and certain state taxes in the US which effectively impose income tax on modified gross revenues. In jurisdictions where the Company had net losses, there was a full valuation allowance recorded against the Company's deferred tax assets and therefore no tax benefit was recorded.

The Company's loss before income taxes in the US and globally was as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
US	$ (814,531)	$ (666,181)	$ (406,262)
Foreign	(95,534)	(80,831)	(73,889)
Total	$ (910,065)	$ (747,012)	$ (480,151)

The Company's income tax provision consisted of the following (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Current:			
Federal	$ —	$ —	$ —
State	356	378	269
Foreign	3,380	2,231	1,345
	3,736	2,609	1,614
Deferred:			
Federal	—	(13)	13
State	(29)	(41)	(244)
Foreign	—	—	—
	(29)	(54)	(231)
Total	$ 3,707	$ 2,555	$ 1,383

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. Income Taxes (Continued)

The reconciliation between the federal statutory tax rates and the Company's effective tax rate is as follows:

	Years Ended December 31,					
	2024		2023		2022	
Statutory federal tax rate	21	%	21	%	21	%
Permanent items	(1)	%	(1)	%	—	%
State income taxes, net of federal benefit	3	%	3	%	1	%
R&D and other tax credits	3	%	3	%	3	%
Foreign income taxes	(1)	%	(1)	%	—	%
Change in valuation allowance	(25)	%	(21)	%	(22)	%
Asset acquisitions (see Note 18 - Acquisitions)	—	%	(3)	%	—	%
Change in fair value of contingent consideration	(2)	%	—	%	—	%
Stock-based compensation	2	%	(1)	%	(2)	%
Other	—	%	—	%	(1)	%
Effective tax rate	—	%	—	%	—	%

Deferred tax assets and liabilities are determined based on the difference between financial statement and tax bases using enacted tax rates in effect for the year in which the differences are expected to reverse. The components of the deferred tax assets and liabilities consist of the following:

	As of December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss and other carryforwards	$ 672,735	$ 563,869
General business credits	217,859	182,006
Inventory	2,276	2,341
Lease liabilities	9,341	12,000
Stock-based compensation	30,701	27,916
Capitalized R&D	178,021	115,299
Other	26,916	19,286
Deferred tax assets	1,137,849	922,717
Valuation allowance	(1,125,370)	(904,078)
Deferred tax assets, net of valuation allowance	$ 12,479	$ 18,639
Deferred tax liabilities:		
Intangibles	$ (5,581)	$ (9,139)
Right-of-use assets	(6,953)	(9,585)
Deferred tax liabilities	$ (12,534)	$ (18,724)
Net deferred tax liabilities	$ (55)	$ (85)

The deferred tax assets, net of valuation allowance of $ 12.5 million and $ 18.6 million at December 31, 2024 and 2023, respectively, primarily consist of net operating loss, tax credit carryforwards and capitalized R&D for income tax purposes. As required by the 2017 Tax Cuts and Jobs Act, effective January 1, 2022, the Company's research and development expenditures were capitalized, resulting in a deferred tax asset. Due to the Company's history of operating losses, the Company recorded a valuation allowance on its net deferred tax assets by increasing the valuation allowance by $ 221.3 million and $ 158.9 million in 2024 and 2023, respectively, as it was more likely than not that such tax benefits will not be realized. In 2023, an immaterial amount was reclassified within the intangibles deferred tax liability to conform with the current year presentation.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. Income Taxes (Continued)

At December 31, 2024, the Company had federal net operating loss (NOL) carryforwards for income tax purposes of approximately $ 2.2 billion and federal tax credit carryforwards of $ 224.3 million. Due to the limitation on NOLs as more fully discussed below, $ 2.0 billion of the NOLs are available to offset future taxable income, if any. The NOL carryovers and general business tax credits expire in various years beginning in 2025. For state tax purposes, the Company has approximately $ 1.4 billion of NOLs in various states available to offset against future taxable income and state tax credit carryforwards of $ 11.9 million, expiring in various years beginning in 2025. The Company has $ 334.0 million of non-trading loss carryforwards in Ireland and loss carryforwards in the United Kingdom and Switzerland of $ 48.9 million and $ 144.3 million, respectively. The loss carryforwards in Ireland and the United Kingdom carry forward indefinitely while the loss carryforward in Switzerland begins to expire in 2030. The Company has disallowed interest expense carryover of $ 40.9 million which carries forward indefinitely.

The Company completed an Internal Revenue Code Section 382 (Section 382) analysis in order to determine the amount of losses that are currently available for potential offset against future taxable income, if any. It was determined that the utilization of the Company's NOL and general business tax credit carryforwards generated in tax periods up to and including December 2010 were subject to substantial limitations under Section 382 due to ownership changes that occurred at various points from the Company's original organization through December 2010. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of shareholders that own, directly or indirectly, 5% or more of a corporation's stock, in the stock of a corporation by more than 50 percentage points over a testing period (usually 3 years). Since the Company's formation in 1999, it has raised capital through the issuance of common stock on several occasions which, combined with the purchasing shareholders' subsequent disposition of those shares, have resulted in multiple changes in ownership, as defined by Section 382. These ownership changes resulted in substantial limitations on the use of the Company's NOLs and general business tax credit carryforwards up to and including December 2010. The Company continues to track all of its NOLs and tax credit carryforwards but has provided a full valuation allowance to offset those amounts.

Law Changes

On August 16, 2022, the IRA was enacted into law containing corporate income tax provisions such as the corporate alternative minimum tax and an excise tax on the repurchase of corporate stock. These provisions are not expected to have a material impact on the Company’s income taxes in the near term.

The Organisation for Economic Co-operation and Development recently published a framework to implement a global corporate minimum income tax rate of 15% on income arising in low-tax jurisdictions (Pillar Two). The Pillar Two proposed legislation is applicable to multinational corporations with global revenue exceeding €750 million for at least two years of the preceding four years. Over 140 countries have agreed in principle to implement Pillar Two and many have, or are in the process of, enacting related legislation. The Pillar Two legislation is not anticipated to be effective for the Company until the Company’s annual global revenues have exceeded the €750 million threshold. The Company is still evaluating the potential consequences of Pillar Two on its longer-term financial position.

The financial statement recognition of the benefit for a tax position is dependent upon the benefit being more likely than not to be sustainable upon audit by the applicable taxing authority. If this threshold is met, the tax benefit is then measured and recognized at the largest amount that is greater than 50% likely of being realized upon ultimate settlement. If such unrecognized tax benefits were realized and not subject to valuation allowances, the Company would recognize a tax benefit of $ 19.0 million. The following table summarizes the gross amounts of unrecognized tax benefits (in thousands):

	2024	2023
Balance as of January 1,	$ 14,753	$ 11,539
Additions related to prior period tax positions	—	230
Additions related to current period tax positions	4,261	2,984
Balance as of December 31,	$ 19,014	$ 14,753

The Company is subject to US federal and state income taxes and the statute of limitations for tax audit is open for the federal tax returns for the years ended 2021 and later, and is generally open for certain states for the years 2020 and later. The Company has incurred net operating losses since inception, except for the year ended December 31, 2009. Such loss carryforwards would be subject to audit in any tax year in which those losses are utilized, notwithstanding the year of origin.

The Company's policy is to recognize interest accrued related to unrecognized tax benefits and penalties in income tax expense. The Company has recorded no such expense. As of December 31, 2024 and 2023, the Company has recorded reserves

14. Income Taxes (Continued)

for unrecognized income tax benefits of $ 19.0 million and $ 14.8 million, respectively. As any adjustment to the Company's uncertain tax positions would not result in a cash tax liability, it has not recorded any accrued interest or penalties related to its uncertain tax positions. If any of these unrecognized tax benefits were released, there would be no impact to the Company's effective tax rate. The Company does not anticipate any material changes in the amount of unrecognized tax positions over the next 12 months.

15. License and Other Agreements

In-License Agreements

PARI Pharma GmbH—In April 2008, the Company entered into a licensing agreement with PARI for use of the optimized Lamira Nebulizer System for delivery of ARIKAYCE in treating patients with NTM lung infections, CF and bronchiectasis. Under the licensing agreement, the Company has rights under several US and foreign issued patents and patent applications involving improvements to the optimized Lamira Nebulizer System, to exploit the system with ARIKAYCE for the treatment of such indications, but the Company cannot manufacture the nebulizers except as permitted under the commercialization agreement with PARI, which is described in further detail below. The Lamira Nebulizer System has been approved for use in the US (in combination with ARIKAYCE), the EU and Japan. Under the licensing agreement, the Company paid PARI an upfront license fee and certain milestone payments. Upon FDA acceptance of the Company's NDA and the subsequent FDA and EMA approval of ARIKAYCE, the Company paid PARI additional milestone payments of € 1.0 million, € 1.5 million and € 0.5 million, respectively. In October 2017, the Company exercised an option to buy-down the royalties that will be paid to PARI on ARIKAYCE net sales. As a result, PARI is entitled to receive royalty payments in the mid-single digits on the annual global net sales of ARIKAYCE, pursuant to the licensing agreement, subject to certain specified annual minimum royalties. See below for information related to the commercialization agreement with PARI.

Other Agreements

PPD Development, L.P.—In April 2020, the Company entered into a master services agreement with PPD pursuant to which it retained PPD to perform clinical development services in connection with certain of its clinical research programs. The master services agreement has an initial term of five years . Either party may terminate (i) any project addendum under the master services agreement for any reason and without cause upon 30 days' written notice, (ii) any project addendum in the event of the other party's breach of the master services agreement or such project addendum upon 30 days' written notice, provided that such breach is not cured within such 30 -day period, (iii) the master services agreement or any project addendum immediately upon the occurrence of an insolvency event with respect to the other party or (iv) any project addendum upon 30 days' written notice if (a) the continuation of the services under such project addendum would post material ethical or safety risks to study participants, (b) any approval from a regulatory authority necessary to perform the applicable study is revoked, suspended or expires without renewal or (c) in the reasonable opinion of such party, continuation of the services provided under such project addendum would be in violation of applicable law. The Company entered into project addenda with PPD to perform clinical development services over several years for, but not limited to, its ARISE, ENCORE and ASPEN studies and other trials involving brensocatib and TPIP.

Patheon UK Limited—In October 2017, the Company entered into certain agreements with Patheon related to the increase of its long-term production capacity for ARIKAYCE commercial inventory. The agreements provide for Patheon to manufacture and supply ARIKAYCE for its anticipated commercial needs. Under these agreements, the Company is required to deliver to Patheon the required raw materials, including active pharmaceutical ingredients, and certain fixed assets needed to manufacture ARIKAYCE. Patheon's supply obligations will commence once certain technology transfer and construction services are completed. The Company's manufacturing and supply agreement with Patheon will remain in effect for a fixed initial term, after which it will continue for successive renewal terms unless either party has given written notice of termination. The technology transfer agreement will expire when the parties agree that the technology transfer services have been completed. The agreements may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or the other party's insolvency. These early termination clauses may reduce the amounts due to the relevant parties.

AstraZeneca AB—In October 2016, the Company entered into a license agreement (AZ License Agreement) with AstraZeneca, a Swedish corporation. Pursuant to the terms of the AZ License Agreement, AstraZeneca granted the Company exclusive global rights for the purpose of developing and commercializing AZD7986 (renamed brensocatib). In consideration of the licenses and other rights granted by AstraZeneca, the Company made an upfront payment of $ 30.0 million, which was included as research and development expense in the fourth quarter of 2016. In December 2020, the Company incurred a $ 12.5 million milestone payment obligation upon the first dosing in a Phase 3 clinical trial of brensocat ib. In May 2024, upon the

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. License and Other Agreements (Continued)

Company's release of an official public statement that the Company intended to file an NDA, the Company incurred an additional $ 12.5 million milestone payment obligation. Upon regulatory approval by the FDA of an NDA, the Company will owe AstraZeneca an additional $ 30.0 million. Subsequent to this milestone, the Company is also obligated to make a series of additional contingent milestone payments totaling up to an additional $ 30.0 million upon the achievement of regulatory filing milestones. If the Company elects to develop brensocatib for a second indication, the Company will be obligated to make an additional series of contingent milestone payments to AstraZeneca totaling up to $ 42.5 million, the first of which occurs at the initiation of a Phase 3 trial in the additional indication. The Company is not obligated to make any additional milestone payments for additional indications. In addition, the Company will pay AstraZeneca tiered royalties ranging from a high single-digit to mid-teens on net sales of any approved product based on brensocatib and one additional payment of $ 35.0 million upon the first achievement of $ 1.0 billion in annual net sales. The AZ License Agreement provides AstraZeneca with the option to negotiate a future agreement with the Company for commercialization of brensocatib in chronic obstructive pulmonary disease or asthma.

PARI Pharma GmbH—In July 2014, the Company entered into the Commercialization Agreement for the manufacture and supply of the Device, which is an e-Flow® nebulizer modified and optimized for use with ARIKAYCE. Under the Commercialization Agreement, PARI manufactures the Device except in the case of certain defined supply failures, when the Company will have the right to make the Device and have it made by third parties (but not certain third parties deemed under the Commercialization Agreement to compete with PARI). The Commercialization Agreement has an initial term of fifteen years from the first commercial sale of ARIKAYCE in October 2018. The term of the agreement may be extended by the Company for an additional five years by providing written notice to PARI at least one year prior to the expiration of the Initial Term. Notwithstanding the foregoing, the parties have certain rights and obligations under the agreement prior to the commencement of the Initial Term.

Resilience Biotechnologies Inc. (successor to Therapure Biopharma Inc.) —In February 2014, the Company entered into a contract manufacturing agreement with Therapure Biopharma Inc., which was assumed by Resilience for the manufacture of ARIKAYCE, on a non-exclusive basis, at a 200 kg scale. Pursuant to the agreement, the Company and Resilience collaborated to construct a production area for the manufacture of ARIKAYCE in Resilience's existing manufacturing facility in Canada. The agreement had an initial term of five years , which began in October 2018, and renews automatically for successive periods of two years each, unless terminated by either party by providing the required two years prior written notice to the other party. Notwithstanding the foregoing, the parties have rights and obligations under the agreement prior to the commencement of the initial term. Under the agreement, the Company is obligated to pay a minimum of $ 6.0 million, subject to inflation increases, for commercial ARIKAYCE batches produced and certain manufacturing activities each calendar year.

Cystic Fibrosis Foundation Therapeutics, Inc.—In 2004 and 2009, the Company entered into research funding agreements with CFFT whereby it received $ 1.7 million and $ 2.2 million, respectively, in research funding for the development of ARIKAYCE. As a result of the US approval of ARIKAYCE and in accordance with the agreements, as amended, the Company owes milestone payments to CFFT of $ 13.4 million in the aggregate payable through 2025, of which $ 10.4 million has been paid through December 31, 2024. Furthermore, if certain global sales milestones were met within five years of the commercialization of ARIKAYCE, the Company would have owed up to an additional $ 3.9 million. The Company met and paid $ 1.7 million of these additional global sales milestone payments.

Patheon Inc.—In January 2024, the Company entered into certain agreements with Patheon Inc. related to the manufacture and supply of brensocatib by Patheon Inc. for the Company’s anticipated long-term commercial needs. Under these agreements, the Company is required to deliver to Patheon Inc. the active pharmaceutical ingredient needed to manufacture brensocatib. The master commercial manufacturing services agreement with Patheon Inc. will remain in effect for a fixed initial term, after which it will continue for successive renewal terms unless either the Company or Patheon Inc. has given written notice of termination. The agreements may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or the other party’s insolvency. Patheon Inc.'s supply obligations are governed by individual product agreements entered into from time to time under the master commercial manufacturing services agreement. The product agreements specify, among other things, the term and pricing for Patheon Inc.’s supply obligations.

Esteve Química, S.A—In September 2024, the Company entered into a commercial manufacturing and supply agreement with Esteve for the manufacture and supply of brensocatib's active pharmaceutical ingredient. The commercial manufacturing and supply agreement has an initial term of three years , after which it will continue for successive 12 -month renewal terms unless either the Company or Esteve has given written notice of termination. The agreement may also be terminated under certain other circumstances, including by either party due to a material uncured breach of the other party or

15. License and Other Agreements (Continued)

the other party's insolvency, the discontinue of specified dosages or changes in the regulatory landscape. Esteve's supply obligations are based on rolling forecasts of the Company's anticipated demand for brensocatib.

16. Commitments and Contingencies

Commitments

In September 2018, the Company entered into a lease for its new corporate headquarters in Bridgewater, New Jersey. The initial lease term commenced in October 2019 and expires in September 2030. In July 2016, the Company signed an operating lease for laboratory space, also located in Bridgewater, for which the initial lease term was extended through December 2026. In July 2023, the Company signed an amendment to expand the laboratory space in Bridgewater until 2027. In January 2022, the Company entered into a lease for research activities in San Diego, California. The lease term commenced in February 2022 and expires in June 2032. In February 2023, the Company signed an agreement to lease warehouse space in San Diego through March 2029. Future minimum rental payments under the Bridgewater leases and San Diego leases are $ 18.9 million and $ 20.6 million, respectively.

Rent expense charged to operations was $ 11.9 million, $ 9.2 million and $ 8.0 million for the years ended December 31, 2024, 2023 and 2022, respectively. Rent expense is recorded on a straight-line basis over the term of the applicable leases.

In addition to rent, the Company has several firm purchase commitments, primarily related to the manufacturing of ARIKAYCE and annual minimum royalties on global net sales of ARIKAYCE. Future firm purchase commitments under these agreements, the last of which ends in 2034, total $ 66.6 million. These amounts do not represent the Company's entire anticipated purchases in the future, but instead represent only purchases that are the subject of contractually obligated minimum purchases. The minimum commitments disclosed are determined based on non-cancelable minimum spend amounts or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

Legal Proceedings

From time to time, the Company is a party to various lawsuits, claims and other legal proceedings that arise in the ordinary course of business. While the outcomes of these matters are uncertain, management does not expect that the ultimate costs to resolve these matters will have a material adverse effect on the Company's consolidated financial position, results of operations or cash flows.

17. Retirement Plan

The Company has a 401(k) defined contribution plan for the benefit of most US employees and permits voluntary contributions by employees subject to IRS-imposed limitations. During the years ended December 31, 2024, 2023 and 2022, the Company matched 100 % of eligible employee contributions on the first 4 % of employee compensation (up to the IRS maximum). Employer contributions for the year ended December 31, 2024, 2023 and 2022 were $ 7.4 million, $ 5.5 million and $ 4.6 million, respectively. Effective January 1, 2025, the Company is matching 100 % of eligible employee contributions on the first 5 % of employee compensation (up to the IRS maximum).

18. Acquisitions

Asset Acquisitions

Adrestia Therapeutics Ltd.

In June 2023, the Company acquired all of the issued and outstanding share capital of Adrestia, a privately held, preclinical stage company. At the closing of the transaction, the Company issued an aggregate of 3,430,867 shares of the Company's common stock to Adrestia's former shareholders (collectively, the Adrestia shareholders). The closing share price on the date of the transaction was $ 21.10 , resulting in a purchase price of $ 72.4 million. The Adrestia shareholders may also become entitled to receive contingent payments up to an aggregate of $ 326.5 million in cash upon the achievement of certain development, regulatory and commercial milestone events, as well as royalty payments based upon a low single-digit percentage of net sales of certain products, both subject to the terms and conditions of the agreement.

The shares of the Company's common stock issued to the Adrestia shareholders were issued pursuant to Section 4(a)(2) of the Securities Act of 1933 (and, with respect to certain Adrestia shareholders, in reliance on Regulation S

promulgated under the Securities Act of 1933). The Company did not receive any net proceeds from the issuance of common stock to the Adrestia shareholders.

The Company evaluated the acquisition under ASC 805 and ASU 2017-01 and concluded that substantially all of the fair value of the gross assets acquired are concentrated in a single identifiable asset or a group of similar identifiable assets and accounted for the transaction as an asset acquisition. The Company determined that the IPR&D acquired did not have any future alternative use and, in accordance with ASC 730, Research and Development, expensed the assets within research and development in the consolidated statement of comprehensive loss as of the date of the acquisition. The Company recognized $ 76.5 million as IPR&D expense for the year ending December 31, 2023, after adjusting for working capital assumed in connection with the asset acquisition.

Vertuis Bio, Inc.

In January 2023, the Company acquired Vertuis, a privately held, preclinical stage company. At the closing of the transaction, the Company issued an aggregate of 500,000 shares of the Company's common stock to Vertuis' former stockholders and an individual who are entitled to receive a portion of the acquisition consideration (collectively, the Vertuis equityholders). The closing share price on the date of the transaction was $ 18.50 . In July 2024, the Company issued the Vertuis equityholders an additional $ 1.0 million of shares of the Company's common stock, or 14,773 shares of common stock, based on the share price on June 28, 2024. The Company is obligated to pay the Vertuis equityholders up to an aggregate of $ 23.0 million in cash upon the achievement of certain development and regulatory milestone events, and up to an aggregate of $ 63.8 million in cash upon the achievement of certain net sales-based milestone events, in each case, subject to certain reductions.

The shares of the Company's common stock issued to the Vertuis equityholders were issued pursuant to Section 4(a)(2) of the Securities Act of 1933. The following table summarizes the purchase price (in millions).

Shares of Insmed common stock issued on closing	$	9.25
Shares of Insmed common stock issuable on July 1, 2024		1.00
Total purchase price	$	10.25

The Company evaluated the acquisition under ASC 805 and ASU 2017-01 and concluded that substantially all of the fair value of the gross assets acquired are concentrated in a single identifiable asset or a group of similar identifiable assets and accounted for the transaction as an asset acquisition. The Company determined that the assets acquired did not have any future alternative use and, in accordance with ASC 730, Research and Development, expensed the assets within research and development in the consolidated statement of comprehensive loss as of the date of the acquisition. The Company recognized $ 10.3 million as IPR&D expense for the year ending December 31, 2023.

Business Combination

On August 4, 2021, the Company acquired all of the equity interests of Motus and AlgaeneX, each a privately held, preclinical stage company. In connection with the closing of the Company's acquisition of Motus, the Company issued an aggregate of 2,889,367 shares of the Company's common stock, following certain closing-related reductions, to Motus's former stockholders and option holders and certain individuals who are entitled to receive a portion of the acquisition consideration (collectively, Motus equityholders), subject to certain adjustments. The Company was obligated to issue to Motus equityholders an aggregate of 184,433 shares of the Company's common stock on each of the first, second and third anniversaries of the closing date. During August 2022, August 2023 and August 2024, the Company fulfilled the payments due on the first, second and third anniversaries of the closing date by issuing 171,427 shares, 177,203 shares and 182,182 shares of the Company's common stock, respectively, after certain reductions. The Company is obligated to issue to Motus equityholders up to 5,348,572 shares in the aggregate upon the achievement of certain development and regulatory milestone events, and to pay to the Motus equityholders an aggregate of $ 35 million upon the achievement of certain net sales-based milestones and a portion of the value of a priority review voucher (to the extent issued to the Company), in each case, subject to certain reductions.

At the closing of the Company's acquisition of AlgaeneX, the Company paid $ 1.5 million in cash to AlgaeneX's former stockholders and certain individuals who are entitled to receive a portion of the acquisition consideration (collectively, the AlgaeneX equityholders). The Company is obligated to issue to AlgaeneX's equityholders an aggregate of 368,867 shares of the Company's common stock upon the achievement of a development milestone event and pay to AlgaeneX equityholders a

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

18. Acquisitions (Continued)

mid-single digits licensing fee on certain future payments received by the Company in licensing transactions for AlgaeneX's manufacturing technology, in each case, subject to certain reductions.

The shares of the Company's common stock issued to the Motus equityholders and the AlgaeneX equityholders were issued, and the shares issuable in the future will be issued, pursuant to Section 4(a)(2) of the Securities Act of 1933, and the numbers of such issued and issuable shares was calculated based on a per share value of $ 27.11 , which was the weighted average price per share of the Company's common stock preceding the closing of the Business Acquisition for the 45 consecutive trading day period beginning on May 24, 2021. The Company will not receive any proceeds from the issuance of common stock to the Motus equityholders or the AlgaeneX equityholders.

The Company evaluated the Business Acquisition under ASC 805 and ASU 2017-01. The Company concluded that substantially all of the fair value of the gross assets acquired is not concentrated in a single identifiable asset or a group of similar identifiable assets. The transaction does not pass the screen test and thus management performed a full assessment to determine if the acquired entities met the definition of a business. For the full assessment, management considered whether it has acquired (a) inputs, (b) substantive processes, and (c) outputs. Under ASC 805, to be considered a business, a set of activities and assets is required to have only the first two of the three elements, which together are or will be used in the future to create outputs. Management determined that the acquired entities met the definition of a business since the Company acquired inputs and substantive processes capable of producing outputs.

Therefore, the transaction has been accounted for under the acquisition method of accounting. Under the acquisition method, the total purchase price of the acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on the fair values as of the date of the acquisition.

The fair value of the consideration totaled approximately $ 165.5 million, summarized as follows (in thousands):

	Fair Value of Consideration
Cash consideration	$ 10,500
Fair value of Insmed common stock issued	71,570
Estimated fair value of contingent consideration liabilities	69,706
Estimated fair value of deferred consideration	13,700
	$ 165,476

The Company recorded the assets acquired and liabilities assumed as of the date of the acquisition based on the information available at that date. As of December 31, 2021, the Company finalized the fair values of the assets acquired and liabilities assumed. No purchase price adjustments were recorded during the measurement period, which is the period from the acquisition date through the period ended December 31, 2021. The following table presents the allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date (in thousands).

	Purchase Price Allocation
Cash and cash equivalents	$ 3,580
Intangible assets - IPR&D	29,600
Fixed assets	228
Other assets	17
Liabilities assumed	(558)
Deferred tax liability	(3,501)
Fair value of net assets acquired	29,366
Goodwill	136,110
	$ 165,476

The Company incurred approximately $ 0.6 million in acquisition-related expenses, which were included in selling, general and administrative expenses in the consolidated statements of comprehensive loss for the period ended December 31,

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

18. Acquisitions (Continued)

2021. The results of Motus's and AlgaeneX's operations have been included in the consolidated statements of comprehensive loss beginning on the acquisition date.

The fair value of IPR&D was capitalized as of the acquisition date and accounted for as indefinite-lived intangible assets until completion or disposition of the assets or abandonment of the associated research and development efforts. Upon successful completion of the development efforts, the useful lives of the IPR&D assets will be determined based on the anticipated period of regulatory exclusivity and will be amortized within operating expenses. Until that time, the IPR&D assets will be subject to impairment testing and will not be amortized. The goodwill recorded related to the acquisition is the excess of the fair value of the consideration transferred by the acquirer over the fair value of the net identifiable assets acquired and liabilities assumed at the date of acquisition. The goodwill recorded is not deductible for tax purposes.

19. Segment Reporting

The Company manages its business activities on a consolidated basis and operates as a single operating segment. The Company derives its revenues from the development and commercialization of therapies for patients facing serious diseases. The accounting policies of the segment are the same as those described in Note 2 – *Summary of Significant Accounting Policies* .

The Company has a single management team that reports to the Chief Executive Officer, the chief operating decision maker (CODM), who comprehensively manages the entire business. When evaluating the Company’s financial performance, the CODM regularly reviews total revenues, total expenses, and expenses by function, and makes decisions using this information on a global basis. The CODM uses net loss, as reported in the consolidated statements of comprehensive loss, in evaluating the performance of the segment. Decisions regarding resource allocation are made primarily during the annual budget planning process and augmented as needed throughout the year. The measure of segment assets is reported on the balance sheet as total assets. The Company does not operate separate lines of business with respect to its products or product candidates. Accordingly, the Company has one reportable segment.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. Segment Reporting (Continued)

Segment loss, including significant segment expenses, for the years ended December 31, 2024, 2023 and 2022 is as follows (in thousands):

	For the Years Ended December 31,		
	2024	**2023**	**2022**
Product revenues, net	$ 363,707	$ 305,208	$ 245
Less:			
Cost of product revenues (excluding amortization of intangible assets)	85,742	65,573	5
ARIKAYCE external R&D expenses	60,269	62,418	6
Brensocatib external R&D expenses	98,569	108,556	10
TPIP external R&D expenses	65,935	50,185	3
Other external R&D expenses	90,604	132,652	3
R&D compensation and benefit-related expenses	194,907	140,861	10
SG&A compensation and benefit-related expenses	168,498	117,926	9
Other segment items[(a)]	374,947	295,211	23
Depreciation	5,961	5,527	
Amortization of intangible assets	5,052	5,052	
Change in fair value of deferred and contingent consideration liabilities	91,682	28,697	(2
Investment income	(53,307)	(42,132)	(1
Interest expense	84,913	81,694	2
Provision for income taxes	3,707	2,555	
Segment net loss	$ (913,772)	$ (749,567)	$ (48

[(a)] Other segment items include stock-based compensation, professional fees, and facility-related expenses.

Exhibit 10.19.2

Pursuant to Item 601(b)(10)(iv) of Regulation S-K, confidential information (indicated by [***]) has been omitted from Exhibit 10.19.2 because it (i) is not material and (ii) is the type of information the Company both customarily and actually treats as private or confidential.

AMENDMENT NO. 2
TO COMMERCIALIZATION AGREEMENT BETWEEN
INSMED INCORPORATED AND PARI PHARMA GMBH

This second amendment ("**Amendment No. 2**") effective 20 July 2018 ("**Amendment No. 2 Effective Date**") to the Commercialization Agreement dated and effective the 8th of July 2014 (the "**Agreement**") between PARI Pharma GmbH, a German corporation with a principal place of business at Moosstrasse 3, D-82319 Starnberg, Germany ("**PARI**") and Insmed Incorporated, a Virginia corporation with a principal place of business at 10 Finderne Avenue, Building 10, Bridgewater, NJ 08807-3365 ("**Insmed**"), is entered into between PARI and Insmed. PARI and Insmed shall be referred to collectively as the "**Parties**".

WHEREAS, the Parties desire to further amend the terms and conditions of the Agreement (in addition to Amendment No. 1) to reflect certain business discussions between the Parties.

NOW, THEREFORE, in consideration of the recitals set forth above, the mutual covenants, terms and conditions set forth below, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment No. 2 shall have the meanings ascribed to them in the Agreement.

"[***]" mean the following components: [***]

2. Exhibit I. Exhibit I to the Agreement is hereby amended by adding the following subsection:

"3. [***] **Price**. The price for each unit of [***] shall be determined as follows:

Description	Price for United States and Canada
For each unit of [***]	$[***]

3. Miscellaneous. Upon execution, this Amendment No. 2 shall be made part of the Agreement and shall be incorporated therein by reference. Except as provided herein, all other terms and conditions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the Parties have executed this Amendment No. 2 as of the Amendment No. 2 Effective Date indicated above.

Insmed Incorporated **PARI Pharma GmbH**

By: /s/ Drayton Wise	By: /s/ Martin Knoch
Name: Drayton Wise	Name: Dr. Martin Knoch
Title: General Manager	Title: President
Date: 14-Aug-2018	Date: 23 Aug 2018

Exhibit 10.24

Pursuant to Item 601(b)(10)(iv) of Regulation S-K, confidential information (indicated by [***]) has been omitted from Exhibit 10.24 because it (i) is not material and (ii) is the type of information the Company both customarily and actually treats as private or confidential.

Master Commercial Manufacturing Services Agreement

PARTIES

PATHEON INC.
a company existing under the laws of Canada, with a place of business at, Whitby Operations: 111 Consumers Drive, Whitby, Ontario L1N 5Z5, Canada ("**Patheon**"),

- and -

INSMED INCORPORATED
a company existing under the laws of Virginia, with its registered office/principal place of business at 700 US Highway 202/206, Bridgewater, NJ 08807-1704 ("**Client**").

Table of Contents

1.1 Master Agreement. 4
1.2 Product Agreements. 4
1.3 Definitions. 4
1.4 Interpretation. 9

2. Patheon's Manufacturing Services 9

2.1 Manufacturing Services. 9
2.2 Subcontracting. 9

3. Client's Obligations 10

3.1 Payment. 10
3.2 Processing Instructions. 10
3.3 DP, DS and Components. 10
3.4 Packaging and Artwork. 11

4. Price and Price Adjustments 12

4.1 First Year Pricing. 12
4.2 Annual Price Adjustments. 12
4.3 Price Adjustments at any Time. 12

5. Purchasing Product 13

5.1 Orders and Forecasts. 13
5.2 Obsolete Stock. 16
5.3 Storage. 17
5.4 Invoices and Payment. 17
5.5 Delivery and Shipping. 17

6. Product Claims and Recalls 18

6.1 Product Claims. 18
6.2 Product Recalls and Returns. 19
6.3 Disposition of Deficient Product. 19

7. Co-operation and Regulatory Affairs 20

7.1 Governance. 20
7.2 Governmental Agencies. 20
7.3 Records. 20
7.4 Audits. 20
7.5 Regulatory Filings. 21

7.6 Release. 22
7.7 Withdrawal on Completion. 22

8. Term and Termination 22

8.1 Initial Term. 22
8.2 Termination for Cause. 22
8.3 [Consequences of Termination by Client. 23
8.4 Consequences of Termination by Patheon. 24
8.5 Consequences of Termination or Expiry 25
8.6 Technology Transfer. 25

9. Representations, Warranties and Covenants 26

9.1 Authority. 26
9.2 Client Warranties. 26
9.3 Patheon Warranties. 27
9.4 Permits. 28
9.5 No Warranty. 28

10. Limitation of Liability and Remedies 28

10.1 Limitation of Liability - Consequential Damages. 28
10.2 Remedies and Limitation of Liability. 28
10.3 Patheon Indemnity. 29
10.4 Client Indemnity. 30
10.5 Reasonable Allocation of Risk. 30
10.6 Validation Batches. 30

11. Confidentiality 31

11.1 Confidential Information. 31
11.2 Use of Confidential Information. 31
11.3 Exclusions. 31
11.4 Photographs and Recordings. 32
11.5 Permitted Disclosure. 32
11.6 Marking. 32
11.7 Return of Confidential Information. 33
11.8 Remedies. 33

12. Intellectual Property 33

12.1 Inventions. 33
12.2 Intellectual Property. 34

13. Miscellaneous 34

13.1 Insurance. 34
13.2 Independent Contractors. 35
13.3 No Waiver. 35
13.4 Assignment. 35
13.5 Force Majeure. 35
13.6 Additional Product and Services. 36
13.7 Notices. 36
13.8 Severability. 37
13.9 Entire Agreement. 37
13.10 Other Terms. 37
13.11 No Third Party Benefit or Right. 37
13.12 Execution in Counterparts. 37
13.13 Use of Name. 38
13.14 Taxes. 38
13.15 Governing Law and Jurisdiction. 39
13.16 Dispute Resolution. 39
13.17 Government Contracts Requirements. 39

APPENDIX 1 – Form of Product Agreement 42

Schedule A – Commercial Pricing Proposal 45

APPENDIX 2 – Dispute Resolution 46

Negotiation 46
Mediation 46
Technical Disputes 46

APPENDIX 3 – DS Yield Calculation 48

Actual Annual Yield 48
Target Yield and Credit Calculation 48
Limits on DS Liability 49

APPENDIX 4 – Price Adjustments 50

Price Adjustment Calculation Due To Inflation 50

With effect from the date stated as of the last date of signature below (the " **Effective Date**"), the parties have agreed to the following terms:

1. Structure of Agreement and Interpretation

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon in the business of performing commercial manufacturing services may perform Manufacturing Services for Client or any Affiliate of Client. This master form of agreement is intended to allow the parties, or any of their Affiliates, to contract for the manufacture of Product through Patheon's global network of manufacturing sites by entering into specific Product Agreements without having to re-negotiate the general terms and conditions that apply. Client's Affiliates are identified in Schedule B. This Agreement shall be separate and distinct from and shall not interfere with the Master Agreement for Pharmaceutical Development and Technology Transfer Services between the Parties, effective May 23, 2018, for the provision of pharmaceutical development or technology transfer services.

1.2 Product Agreements.

This Agreement is structured so that Product Agreements may be entered into by the parties (or their Affiliates) for the manufacture of Product at any Patheon manufacturing site. Each Product Agreement will be governed by and will incorporate the terms and conditions of this Agreement, except to the extent that the parties to the Product Agreement expressly modify the terms and conditions of this Agreement in the Product Agreement. Unless otherwise agreed by the parties, each Product Agreement will be substantially in the general form, and contain the information referred to, in Appendix 1.

1.3 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party; or

(b) a business entity which is controlled by a party, either directly or indirectly; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party;

For this definition, "control" or “controlling” means the lawful right to determine (by ownership of shares or more than 50% of voting securities or the capital stock of, or other comparable equity or ownership interest) the election of the majority of directors (or equivalent managers) of a business entity;

"**Annual Volume**" means, if agreed by the parties in the applicable Product Agreement, then for the purpose of the Price, Patheon’s assumed minimum volume of Product to be manufactured in any Year as set out in the “Annual Volume Forecast” section of Schedule A of the applicable Product Agreement.

"**Applicable Laws**" means: (i) for Patheon, the Laws applicable to the performance of the Manufacturing Services in the jurisdiction where the Manufacturing Site is located, including but not limited to cGMPs; and (ii) for Client and the Product, the Laws applicable in all jurisdictions where Product is manufactured, distributed, and marketed as these are agreed by the parties in the Product Agreement, including but not limited to cGMPs;

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal, with competent jurisdiction over a party, the Manufacturing Services, or the relevant Product (or its use);

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in Patheon’s resident jurisdiction, Client’s resident jurisdiction, or the jurisdiction where the Manufacturing Site is located;

“**Capital Equipment Agreement**” means the separate agreement that the parties may enter into that addresses the rights and responsibilities of the parties regarding capital equipment and facility modifications that may be required to perform the Manufacturing Services under a particular Product Agreement;

"**cGMPs**" means current good manufacturing practices together with applicable rules and guidance documents issued by the applicable Regulatory Authority pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time in each case as applicable in the country where the Manufacturing Site is situated;

“**Client Intellectual Property**” means Intellectual Property generated, derived or controlled by Client before entering into the applicable Product Agreement or made or acquired by Client during the term of this Agreement and outside the scope of this Agreement, or by Patheon while performing any Manufacturing Services which Intellectual Property is specific to, or dependent upon, the Product;

“**Client-Supplied Components**” means those Components supplied or to be supplied by or on behalf of Client as identified in Schedule A of a Product Agreement;

"**Components**" means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture or package Product in accordance with the Processing Instructions, other than the DS or DP;

"**Confidential Information**" has the meaning specified in Section 11.1;

"**DEA**" means the Drug Enforcement Administration of the United States Department of Justice;

"**Deficient Product**" has the meaning specified in Section 6.1(b)(i);

"**Disclosing Party**" has the meaning specified in Section 11.1;

"**DP**" or "**Drug Product**" means the bulk finished good listed in the applicable Product Agreement;

"**DS**" or "**Drug Substance**" means the active materials listed in the applicable Product Agreement (references to "Active Materials" or "Active Pharmaceutical Ingredient" in documents forming part of this Agreement or of a Product Agreement will mean "DS");

"**DS Credit Value**" means the value of the DS for certain purposes of this Agreement, as set out in the applicable Product Agreement;

"**EMA**" means the European Medicines Agency;

"**FDA**" means the United States Food and Drug Administration;

"**Firm Order**" has the meaning specified in Section 5.1(d);

"**Initial Product Term**" has the meaning specified in Section 8.1;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, data and know how;

"**Invention**" means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means, at a point in time, all inventories of Components and work-in-process under Patheon's care or control used for the manufacture or packaging of Product;

"**Laws**" means all relevant international, national, federal, state and local laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

"**Long Term Forecast**" has the meaning specified in Section 5.1(a);

"**Manufacturing Services**" means the manufacturing, quality control, quality assurance, stability testing, packaging, and related services, as set out in the relevant Product Agreement, for the manufacture of commercial Product for distribution in the Territory;

"**Manufacturing Site**" means the facility identified in a Product Agreement where the Manufacturing Services will be performed;

"**Minimum Order Quantity**" means, for each manufacturing campaign ordered, the minimum number of batches or units of a Product that Client must purchase, as set out in Schedule A of the applicable Product Agreement;

"**Obsolete Stock**" has the meaning specified in Section 5.2(b);

"**Patheon**" means in respect to this Agreement the Patheon entity identified on the first page of the Agreement, and in respect of any Product Agreement the Thermo Fisher Scientific Inc. entity, within the global network of service sites providing Manufacturing Services (as designated by Thermo Fisher Scientific Inc.), which enters into the applicable Product Agreement.

"**Patheon Competitor**" means a business that derives greater than [***]% of its revenues from performing contract pharmaceutical or biopharmaceutical development or commercial manufacturing services;

"**Patheon Intellectual Property**" means Intellectual Property generated or derived by Patheon or its Affiliates before performing any Manufacturing Services, developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property is not specific to, or dependent upon, Client Intellectual Property or the Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products or drug delivery systems unrelated to (i) the Client Intellectual Property or (ii) the specific requirements of the Product;

"**Price**" means the fees to be charged by Patheon for:

(a) performing the Manufacturing Services;

(b) the cost of Components (other than Client-Supplied Components); and

(c) any separate cost items and other fees,

as set out in Schedule A of the applicable Product Agreement;

"**Processing Instructions**" means the agreed file, for each Product, which contains documents relating to the Product, including, without limitation:

(a) quality control testing methods for DS, DP and Components;

(b) manufacturing instructions, directions, and processes;

(c) any storage requirements for the DS, DP, Components, or Product;

(d) all environmental, health and safety information for the Product including material safety data sheets; and

(e) the finished Product quality control testing methods, packaging instructions and shipping requirements for the Product;

"**Product**" means a commercial product listed in Schedule A of a Product Agreement;

"**Product Agreement**" means the agreement between Patheon and Client (or their applicable Affiliates) substantially in the form set out in Appendix 1 under which Patheon will perform Manufacturing Services;

"**Product Claims**" has the meaning specified in Section 6.1(a);

"**Quality Agreement**" means a separate agreement that sets out the quality assurance standards for the Manufacturing Services;

"**Recall**" has the meaning specified in Section 6.2(a);

"**Recipient**" has the meaning specified in Section 11.1;

"**Regulatory Approval**" has the meaning specified in Section 7.5(a);

"**Regulatory Authority**" means the FDA and EMA and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical or biopharmaceutical products, including the Products, in the Territory;

"**Release Date**" means in relation to each batch of Product the scheduled date by which the Product will be released by Patheon's quality department (by confirmation or certification) as agreed in the Quality Agreement and made available for shipment, and as confirmed by Patheon in a Firm Order;

"**Representatives**" means, a party's or its Affiliate's directors, officers, employees, agents, consultants, subcontractors, service partners or professional advisors;

"**Rolling Forecast**" has the meaning specified in Section 5.1(b);

"**Technical Dispute**" has the meaning specified in Appendix 2;

"**Territory**" means the geographic area described in a Product Agreement where Product manufactured by Patheon will be distributed by or on behalf of Client;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**VAT**" has the meaning specified in Section 13.14; and

"**Year**" means in the first year of this Agreement or a Product Agreement, the time from the Effective Date up to and including December 31 of the same calendar year, and after that will mean a calendar year.

1.4 Interpretation.

The division of this Agreement into Sections, Subsections, Appendices and Schedules, and the insertion of headings, are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix or Schedule refers to the specified Section, Appendix or Schedule to this Agreement. In this Agreement, the term "**this Agreement**" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, Appendix or Schedule of this Agreement. Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

2. Patheon's Manufacturing Services

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services as set out in the relevant Product Agreement for the Price and in accordance with the Quality Agreement. Subject to the preceding sentence, Patheon will convert DS and Components into Product, and provide supportive Manufacturing Services such as

quality assurance (for example quality controls, analytical testing, and stability programs), primary and secondary packaging, and any other related Manufacturing Services as agreed between the parties.

Patheon will not be obliged to perform Manufacturing Services for any Product that will be distributed in any Territory which is listed as an embargoed country in the Thermo Fisher Scientific sanctioned country policy as may be updated from time to time (each an "**Embargoed Country**" and together "**Embargoed Countries**"). The Territories listed as Embargoed Countries as of the Effective Date of this Agreement are Cuba, Iran, North Korea, Sudan and Syria. Where a Territory is defined as Rest of World, Global or other geographic areas including more than one country, the definition will be interpreted to exclude any Embargoed Country.

2.2 Subcontracting.

Patheon may subcontract the Manufacturing Services under a Product Agreement to any of its Affiliates, as agreed in the Product Agreement, provided that Patheon will remain exclusively liable to Client for breach of this Agreement or negligence by its Affiliates in the course of performing: (a) subcontracted Manufacturing Services under a Product Agreement; or (b) obligations under the Quality Agreement. Patheon may arrange for non-Affiliate subcontractors to perform specific services arising under any Product Agreement with the express prior written consent of Client ("**Third Party Subcontractors**"). Patheon shall be responsible for the direction and coordination of the specific services of such Third Party Subcontractors and shall ensure such Third Party Subcontractors' compliance with the terms and conditions of this Agreement and the applicable Product Agreement and Quality Agreement. All such Third Party Subcontractors shall be retained directly by Patheon and no contractual relationship shall be created between Client and Third Party Subcontractors, other than Client's position as a third-party beneficiary of the services of such Third Party Subcontractors. Client shall have no obligation to pay any such Third Party Subcontractors. Patheon will be liable to Client for the failure by any Third Party Subcontractor to perform any part of the subcontracted services. But Patheon's liability for Third Party Subcontractors will remain subject to all limitations on Patheon's liability as set out in this Agreement. Patheon will have no liability arising from the performance of services by Third Party Subcontractors: (i) that are chosen by Client and are suppliers or service providers not validated and utilized by Patheon prior to the date of this Agreement, or (ii) to the extent that the Third Party Subcontractor is following the direct instructions of Client.

3. Client's Obligations

3.1 Payment.

In consideration of the provision of Manufacturing Services in accordance with the terms of this Agreement, Client will pay Patheon the applicable Price in accordance with Sections 4 and 5. All cost items that are not included in the Price (as specified in the applicable Product Agreement) are subject to additional fees to

be paid by Client as documented in a change order to the Product Agreement or separate written and executed service order subject to the terms of this Agreement.

3.2 Processing Instructions.

Before the start of commercial manufacturing of Product under this Agreement, Client will give Patheon a copy of the Processing Instructions, which must be accompanied by the applicable DS, Component and finished product specifications (if applicable, precisely matching the specifications approved by the applicable Regulatory Authority). If the Processing Instructions or accompanying documents received are amended or no longer reflect those currently approved by the Regulatory Authority, then Client will give Patheon a copy of the revised documents (if applicable, precisely matching the revised specifications approved by the applicable Regulatory Authority). Upon acceptance of the revised Processing Instructions and accompanying documents, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance. At Patheon's request, Client will provide evidence of the executed original documents submitted by or on behalf of Client to the Regulatory Authority.

3.3 DP, DS and Components .

(a) Client will at its sole cost and expense deliver the DP, DS and any Client-Supplied Components to the Manufacturing Site DDP (Incoterms 2020). Client's obligation will include obtaining the release of the DP, DS and any Client-Supplied Components from the applicable customs agency and Regulatory Authority. Unless otherwise agreed in writing, Client or Client's designated broker will be the "**Importer**" or "**Importer of Record**" (or equivalent, as understood under Applicable Laws) for DP, DS, Client-Supplied Components and drug products and intermediates imported to the Manufacturing Site, and Client is responsible for compliance with Applicable Laws (and the cost of compliance) relating to that role. For DP, DS or Client-Supplied Components which may be subject to import or export to or from the United States, Client's vendors and carriers must comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism.

(b) Unless otherwise agreed in writing between the parties, the DP, DS and any Client-Supplied Components must be delivered by the Client to the Manufacturing Site at least [***] days before the scheduled manufacture date for Product covered by a Firm Order in sufficient quantity to enable Patheon to manufacture the agreed quantities of Product. If Patheon is unable to provide storage of DP, DS or Client-Supplied Components, a Patheon's Affiliate or qualified third party may be used for storage outside the Facility If Client fails to deliver the DP, DS or Client-Supplied Components within the agreed time period and, making commercially reasonable efforts, Patheon is unable to manufacture Product on the scheduled date because of the delay, the Firm Order will be considered postponed by Client for a period of time proportionate to such delay and Section 5.1(e) will apply.

(c) Patheon will control the unloading of DP, DS and Client-Supplied Components arriving at the Manufacturing Site and Client will comply, and require that its carrier complies, with all related reasonable and safe directions of Patheon. The DP, DS and Client-Supplied Components will be held by Patheon on behalf of Client as set out in this Agreement. The DP, DS and Client-Supplied Components will at all times remain the property of Client. Any DP, DS and Client-Supplied Components received by Patheon will only be used by Patheon to perform the Manufacturing Services.

(d) Client will ensure that: (i) all delivered DS meets the specifications for that DS; and (ii) all shipments of DS are accompanied by the required documentation as specified in the applicable Quality Agreement).

(e) Patheon will promptly advise Client if it encounters DS or Component supply problems, including delays or delivery of non-conforming DS or Components from a Client designated additional supplier. The parties will cooperate to reduce or eliminate any supply problems from these additional suppliers. If supply problems persist, Patheon may suspend the Manufacturing Services affected by the problems until it is satisfied that the Client has resolved the problems with its supplier or appointed an alternative supplier. Client will qualify or certify (as appropriate) all Client designated additional suppliers on an annual basis at its expense and will provide Patheon with copies of the relevant annual reports. If Patheon agrees to certify or qualify a Client designated additional supplier on behalf of Client, it will do so for an additional fee payable by Client.

3.4 Packaging and Artwork.

Client will be responsible for the cost of artwork development and approval of all artwork. Client will be responsible for changes to labels, product inserts, and other packaging for the Product, including obtaining all required approvals. Client will be responsible for the cost of labelling obsolescence as contemplated in Section 5.2. Patheon's name will not appear on the label or anywhere else on the Product unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name. Within a reasonable time to be agreed between the parties in writing before the start of the Manufacturing Services for which new or modified artwork is required, Client will provide at no cost to Patheon and in accordance with the applicable specifications, final camera ready artwork for all packaging Components to be used in the manufacture of the Product. Client will be responsible for the costs associated with complying with any and all regulatory requirements for the labelling and tracking of the manufactured Product, including product serialisation, product data transfer and anti-counterfeiting requirements in the Territory.

4. Price and Price Adjustments

4.1 First Year Pricing.

The Price for each Product will be listed in Schedule A of a Product Agreement and may be adjusted under this Section 4.

4.2 Annual Price Adjustments.

Patheon may adjust the Price effective January 1st of each Year as follows:

(a) Inflation. Patheon may adjust the Price for inflation in accordance with Appendix 4.

(b) Currency Fluctuations. If the parties agree in a Product Agreement to invoice in a currency other than USD, the parties will agree on an approach to adjust the Price to account for currency fluctuations and include such mutually agreed upon approach in the Product Agreement. The adjustment will be calculated after all other annual Price adjustments under this Section 4.2 have been made.

(c) Pricing Basis. Client acknowledges that the Price in any Year is agreed based upon the applicable Annual Volume and Minimum Order Quantity for that Year. Patheon may adjust the Price if it reasonably concludes, or is notified by Client in writing, that the Annual Volume or Minimum Order Quantity will not be ordered in a Year. Such adjustment shall be documented in writing.

(d) Tier Pricing. If the Pricing is divided into tiers, unless otherwise agreed in a Product Agreement, Client will be invoiced during the Year based at the closest estimated volume tier. Within [***] days after the end of each Year or on termination of the Product Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by Client during the Year at the actual applicable Pricing tiers. If the reconciliation shows an over or under payment, the appropriate party will issue a credit to the other party for the amount of the overpayment within [***] days after the end of the Year or will reimburse the overpayment within [***] days after termination. The parties will work together to resolve any disagreement over the reconciliation.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about August 1 of each Year (unless otherwise agreed in writing) a letter stating the adjusted Pricing under a Product Agreement together with justification for the adjusted Pricing and evidence of the same (subject to reasonable redaction to reflect third party confidentiality concerns) to be effective for Product to be delivered on or after January 1 of the next Year including any Firm Orders accepted by Patheon before that date. Any omitted adjustment in a Year does not waive Patheon's right to apply that adjustment cumulatively with the next permitted adjustment.

4.3 Price Adjustments at any Time.

The Prices may be adjusted by Patheon at any time upon written notice to Client as follows:

(a) Extraordinary Increases in Component Costs. If the cost of a Component increases cumulatively by at least [***]% since the last annual adjustment as a result of market factors outside of Patheon's control, then Patheon will be entitled to adjust the Price as agreed in the Product Agreement.

(b) Changes in scope of Manufacturing Services. The scope of the Manufacturing Services is set by the agreed Processing Instructions, the Regulatory Approvals, the Quality Agreement and any assumptions, inclusions, exclusions and other parameters set out in the applicable Product Agreement. Changes to the scope of the Manufacturing Services and related changes to the Price must be agreed in writing by the parties (using a "**Change of Scope**" agreement, or similar, setting out the agreed activities and costs of implementation) and are subject to the change control provisions of the Quality Agreement. Where Patheon requests a change to the Manufacturing Services the change will be implemented following written approval of Client, which Client will not unreasonably withhold, condition or delay. Absent agreement, Client may terminate the applicable Product Agreement and shall not be liable for any failure to order the Yearly Forecast Volume under Section 5.1(f).

(c) For any Price adjustment under this Section 4.3, Patheon will deliver to Client:

(i) a letter stating the adjusted Pricing under a Product Agreement;

(ii) justification for the adjusted Pricing and evidence of the same (subject to reasonable redaction to reflect third party confidentiality concerns);

(iii) where Patheon requests a change to Manufacturing Services under Section 4.3(b) which also impacts is other clients, justification, such as written rationale, that such increase in Patheon's costs has been allocated proportionally and reasonably amongst Patheon's other clients; and

(iv) a revised Schedule A to the Product Agreement for any Price adjustment under Section 4.3(a), as applicable, and 4.3(b).

(d) Patheon shall provide at least [***] notice any Price adjustments under this Section 4.3 or (in respect of increases of Component Costs under 4.3(a) such shorter notice period as is reasonable in the circumstances , and the adjusted Price shall be effective from the first Firm Order after the expiry of such notice period.

5. Purchasing Product

5.1 Orders and Forecasts.

(a) Long Term Forecast. On or before June 1 of each Year, Client will give Patheon a non-binding written forecast of Client's volume requirements for the Product for each of the next [***] ("**Long Term Forecast**"). If Patheon foresees any capacity constraint affecting any portion of the Long Term Forecast, it will notify Client by July 1 of each year.

(b) Rolling Forecast. Before each Product Agreement is executed, Client will give Patheon a written forecast of the volume of Product that Client expects to order in each of the next [***] unless otherwise agreed to in the applicable Product Agreement (the " **Rolling Forecast**"). The Rolling Forecast should be consistent with the Long Term Forecast. Client will provide an updated Rolling Forecast: (i) on or before the fifteenth day of each month; and (ii) if at any time it determines that the total forecast volumes estimated in the most recent Rolling Forecast have changed by more than [***]%. Each updated Rolling Forecast supersedes all previous Rolling Forecasts.

(c) Orders. On or before the [***] day of each month, Client will issue a new purchase order for any required Product. Each purchase order must meet the Minimum Order Quantity and specify the purchase order number, quantities by Product type, and requested release dates for the Product (which must occur at least [***] after the first day of the next month).

(d) Acceptance of Purchase Orders. To the extent that a purchase order covers Product that is forecast in the Rolling Forecast, Patheon will accept the purchase order by sending an acknowledgement to Client, including the confirmed Release Dates. Subject to Section 5.1(f), if Patheon fails to acknowledge receipt of a purchase order within [***] Business Days, the purchase order will be considered accepted by Patheon. An accepted purchase order will be binding on the parties (a "**Firm Order**"), except that Client may request to change any Release Date beyond [***] after the first day of the next month. The parties will negotiate and agree on any requested alternative Release Date. Patheon may not unreasonably reject an alternative Release Date requested under this Section 5.1(d), but, if the parties cannot agree, the original Release Date confirmed by Patheon will apply.

(e) Cancellation or Postponement. Patheon will determine the manufacturing schedule of all Product covered by Firm Orders. If Client cancels or reduces a Firm Order, or wishes to postpone the applicable Release Date (subject to Section 5.1(d)), Client will remain liable to pay Patheon [***]% of the Price for the Firm Order.

(f) Capacity Reservation. Unless otherwise agreed in a Product Agreement, in advance of each Year of a Product Agreement, Patheon will use the Rolling Forecast to reserve its manufacturing capacity in that Year for Product as follows:

(i) for the first Year, by reference to the first Rolling Forecast;

(ii) for the second Year, if the Effective Date of the Product Agreement occurs after June 1, by reference to the first Rolling Forecast; and

(iii) in all other cases, by reference to the Rolling Forecast applicable at June 1 of the previous Year,

the relevant forecast for the Year being the "**Yearly Forecast Volume**".

In respect to **sterile** Products, at the end of each Year, if the aggregate actual volume of Product ordered by Client with a confirmed Release Date within the Year, taking into account any Product paid for but not ordered, ("**Actual Yearly Volume**") is less than [***]% of the Yearly Forecast Volume, then Patheon may invoice and Client will pay Patheon [***]% of the Price for the shortfall of Product below the tolerance during the Year in an amount calculated as follows:

Amount due to Patheon = [***]

Provided that no amount shall be due to Patheon under this Section 5.1(f) if Client terminates during the relevant Year under Section 8.2(a) (Termination for Cause).

If the quantity of Product requested by Client in a Year (in purchase orders received by Patheon) exceeds the Yearly Forecast Volume for that Year, Patheon will use commercially reasonable efforts to supply the additional Product volumes. Patheon will not be considered to have accepted any purchase order for additional Product volumes without written confirmation.

In respect to **oral solid dose** Products and **secondary packaging** only, at the end of each Year, if the aggregate actual volume of Product ordered by Client with a confirmed Release Date within the Year, taking into account any Product paid for but not ordered, ("**Actual Yearly Volume**") is less than [***]% of the Yearly Forecast Volume, then Patheon may invoice and Client will pay Patheon [***]% of the Price for the shortfall of Product below the tolerance during the Year in an amount calculated as follows:

Amount due to Patheon = [***]

Provided that no amount shall be due to Patheon under this Section 5.1(f) if Client terminates during the relevant Year under Section 8.2(a) (Termination for Cause).

If the quantity of Product requested by Client in a Year (in purchase orders received by Patheon) exceeds the Yearly Forecast Volume for that Year, Patheon will use commercially reasonable efforts to supply the additional Product volumes. Patheon will not be considered to have accepted any purchase order for additional Product volumes without written confirmation.

(g) Controlled Substance Quota Requirements (if applicable). Client will give Patheon the information set out below for obtaining any required DEA or equivalent agency quotas ("**Quota**") needed to perform the Manufacturing Services. Patheon will be responsible for routine management of Quota information in accordance with Applicable Laws. The parties will cooperate to communicate the information and to assist each other in Regulatory Authority information requirements related to the Product as follows: (i) by April 1 of each Year for the applicable Product, Client will provide to Patheon the next Year's annual Quota requirements for the Product; (ii) by August 1 of each Year, Client will provide to Patheon any changes to the next Year's Quota requirements; (iii) Client will pro-actively communicate any changes to the Quota requirements for the then-current Year in sufficient time to allow Patheon to file and finalize Regulatory Authority filings supporting the changes; (iv) upon Patheon receiving the necessary forecast information from Client in order to request additional Quota, Patheon will submit to the applicable Regulatory Authority, on a timely basis, all filings necessary to obtain Quotas for DS and will use commercially reasonable efforts to secure sufficient Quota from the applicable Regulatory Authority so as to achieve Release Dates for Product as set out in applicable purchase orders and forecasts submitted to Patheon by Client or its designee; and (v) Patheon will not be responsible for any Regulatory Authority's refusal or failure to grant sufficient Quota for reasons beyond the reasonable control of Patheon (including where Client fails to provide the required information in accordance with this Section 5.1(g)).

(h) Patheon shall notify Client immediately in writing if it does not anticipate that it will be able to manufacture the Yearly Forecast Volume. If Patheon fails to, or expects to fail to, supply Product ordered by Client in accordance with the terms of this Agreement regarding the quantity or quality of Products supplied to Client, then Patheon shall use commercially reasonable efforts to remedy the problem or secure an alternative manufacturing source of within [***] at no cost to Client, and any such alternative source of supply shall be on terms substantially identical with the terms of this Agreement either at an alternative Patheon site or through a third party. If Patheon is unable to remedy the problem or secure an alternative source of supply within [***] after its initial failure to supply, then Patheon shall consult with Client and the parties shall work together to remedy the problem, including the pro rata adjustment or forgiveness of any current Firm Order and Actual Yearly Volume. If Patheon is unable to remedy the supply problem after [***] (or longer as agreed in writing by the parties), commencing with the date upon which such failure to supply began, then Client may at its option, and upon notice to Patheon, manufacture the Products itself or through a third party without further penalty under this Agreement. In all instances of Patheon's inability to manufacture the Yearly Forecast Volume, Patheon shall use commercially reasonable efforts to support the

Technology Transfer in accordance with Section 8.6 of this Agreement to an alternative Patheon site or to a third party to remedy the manufacturing issue.

5.2 Obsolete Stock.

(a) Client understands and acknowledges that Patheon will rely on purchase orders, Firm Orders, the Long Term Forecast and the Rolling Forecast in ordering the Components (other than Client-Supplied Components) required to meet anticipated Firm Orders. Patheon shall purchase the Components in sufficient volumes, and reasonably in advance of the expected use of the Component (taking into account lead times), to meet the production requirements for Products covered by anticipated Firm Orders or to meet the production requirements of any longer period agreed to by the parties.

(b) Client will reimburse Patheon for the cost of Components ordered by Patheon in relation to and required for Firm Orders or for such longer period as the parties may agree in writing on a case by case basis if the Components have expired or are rendered obsolete due to changes in any forecast, Processing Instructions, GMP, artwork or Applicable Laws (" **Obsolete Stock**"). This reimbursement will include Patheon's reasonably documented cost to purchase and destroy the Obsolete Stock (plus a [***]% handling fee) or a fee as mutually agreed in the Product Agreement. If any non-expired Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

5.3 Storage.

Patheon will provide [***] free of charge storage for released Product, Obsolete Stock, and any equipment, or DS, or starting components (other than existing Patheon equipment) that is stored at the Manufacturing Site at any time prior to its use in the Manufacturing Services. If Patheon is unable to store any material due to capacity constraints, Patheon may use an Affiliate or qualified third party to store (outside the Manufacturing Site) any material under this Agreement upon written notice to Client. At all times, Client retains title to all Client-Supplied Materials while at the Facility. After the limited storage periods stated above, Client will assume all risk of loss or damage to materials and Client will be responsible for having appropriate insurance coverage in place for this risk.

5.4 Invoices and Payment.

For shipments of Product, Patheon will issue invoices to Client on or after the Release Date of the Product. Otherwise, Patheon will issue invoices for Manufacturing Services on completion or as agreed in the Product Agreement. Patheon will also submit to Client, with each shipment of Product, a duplicate copy of the invoice covering the shipment. Invoices will be sent by email to [***]. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit

price, freight charges, and the total amount to be paid by Client. Client will pay all undisputed portions of invoices within [***] days of the date of the invoice. If any portion of an invoice is disputed, Client will pay Patheon for the undisputed amount and the parties will reconcile the disputed amount as soon as practicable. For undisputed invoiced amounts that are owed under this Agreement, Client agrees that a monthly finance charge of the lower of [***]% per month or the highest interest rate allowable by law will accrue against undisputed amounts not paid within [***]of the date on which they are due. Patheon may, on giving [***] written notice to Client, suspend all Manufacturing Services, including release and shipment of Product, until all undisputed past due invoices have been paid in full. Patheon will have no liability to Client for losses caused by this suspension, including without limitation, losses due to delayed Product delivery or Product shortages.

5.5 Patheon must issue invoices to Client by [***] for all Manufacturing Services completed in the prior calendar year.

5.6 Delivery and Shipping.

Client retains title to DS and DP and when [***], immediately after which, any title to Product that Patheon has will transfer to Client. Delivery of Product and any other materials will be made EXW (Incoterms 2020) from Patheon's Manufacturing Site unless otherwise agreed in a Product Agreement. Subject to Section 8.3, risk of loss or of damage to Product will remain with Patheon until Patheon loads the Product onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. Patheon may, in accordance with Client's instructions and as agent for Client, at Client's risk, arrange for shipping (to Client or any third party nominated by Client) to be paid by Client. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Product and may monitor Patheon's shipping and freight activity under this Agreement.

6. Product Claims and Recalls

6.1 Product Claims.

(a) Rejection. Client may reject any manufactured Product that it reasonably considers to be deficient based on the results of the agreed release testing documentation provided by Patheon or Client's own inspection or testing of delivered Product.

(b) Product Claims.

(i) Client may claim a remedy (a "**Product Claim**") for any portion of any batch of Product for which Patheon did not perform the Manufacturing Services in accordance with the agreed Processing Instructions, cGMPs, or Applicable Laws ("**Deficient Product**"). Client will inspect Product

manufactured by Patheon, or batch documentation provided by Patheon, upon receipt and will give Patheon written notice of all Product Claims within [***] after receipt (or, in the case of any deficiency not reasonably susceptible to discovery upon receipt, within [***] after discovery by Client, but not after the expiration date of the Product). If Client fails to provide a Product Claim within the applicable [***] period, then the Product will be considered to have been accepted by Client on the [***].

(ii) This Section 6 sets out the only liability of Patheon for Deficient Products. Patheon will provide a remedy for Product Claims as specified in Section 10.2, but Patheon will have no obligation for any Product Claims to the extent the Deficient Product was caused by: (i) deficiencies in the Processing Instructions, specifications (ii) a defect in the DS or an incorporated Component that was not reasonably discoverable by Patheon using the test methods set out in the Processing Instructions; (iii) actions of Client or third parties occurring after the Product is delivered by Patheon; (iv) packaging design or labelling defects or omissions for which Patheon was not responsible; (v) any unascertainable reason despite Patheon having performed the Manufacturing Services in strict compliance with the Processing Instructions, cGMPs, and Applicable Laws; or (vi) any other breach by Client of its obligations under this Agreement. If after a full investigation as set out in the Quality Agreement and this Section 6.1(b)(ii), it is determined that Patheon manufactured Product in accordance with the agreed Processing Instructions, but a batch or portion of batch of Product is not released, Client will pay Patheon the Price for the Product. Patheon's liability for DS yield loss is set out in Appendix 3.

(c) Determination of Deficiency. Upon receipt of a Product Claim, Patheon will have [***] days or longer period if required for technical reasons to advise Client by notice in writing whether it disagrees with the contents of the Product Claim. If the parties fail to agree within [***] days after Patheon's notice to Client as to whether any Product identified in the Product Claim is Deficient Product, the parties will investigate the matter in accordance with the Quality Agreement. If, after joint testing or investigation has been performed, the parties still cannot agree on the root cause, the dispute will be handled as a Technical Dispute and at the written request of either party may be referred to an expert in accordance with Appendix 2.

(d) Shortages and Price Disputes. Claims for shortages in the amount of Product shipped by Patheon or a Price dispute will be dealt with by reasonable agreement of the parties. Any claim for a shortage or a Price dispute will be considered waived by Client if it has not been presented within [***] of the date of the relevant invoice.

6.2 Product Recalls and Returns.

(a) Records and Notice. The parties will each maintain records necessary to permit a Recall of any Product delivered to Client or customers of Client. Each party will promptly notify the other orally with

notification in writing to follow of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product in accordance with the Quality Agreement. Upon receiving this written notice or upon this discovery, each party will stop making any further shipments of any Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. "**Recall**" will mean any action: (i) by Client to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); (ii) by any Regulatory Authority to detain or destroy any of the Product; or (iii) by either party to refrain from selling or shipping quantities of the Product to third parties which would be subject to a Recall if sold or shipped.

(b) Recalls. If: (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled; (ii) a court of competent jurisdiction orders a Recall; or (iii) Client determines that any Product should be Recalled or that a "**Dear Doctor**" letter is required relating the restrictions on the use of any Product, then Patheon will co-operate as reasonably required by Client, having regard to all Applicable Laws.

(c) Recalled Product. To the extent that a Recall results from, or arises from Deficient Product, Patheon will be responsible for the [***] of the Recall and will [***] to replace the Deficient Product with replacement Products as per Section 10. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense.

6.3 Disposition of Deficient Product.

Client will not dispose of any damaged, returned, or Deficient Product for which it intends to assert a Product Claim against Patheon without Patheon's prior written authorization to do so. Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of return and disposition of any Deficient Products. In all other circumstances, Client will bear the cost of return and disposition.

7. Co-operation and Regulatory Affairs

7.1 Governance.

Within [***] of execution of this Agreement, each party will appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet [***] to review the current status of the business relationship, including review of key performance indicators such as, but not limited to, DS and Component delivery, on-time Product shipments, right first time, and product forecasts and

manage any issues that have arisen. If at such [***] meeting, the key performance indicators have not been achieved in the prior [***], the parties will mutually agree upon a corrective action plan to remedy the situation or failing that, the parties shall resolve the matter in accordance with Section 13.16 (Dispute Resolution).

7.2 Governmental Agencies.

Subject to any restrictions in the Quality Agreement, each party may communicate with any Regulatory Authority responsible for granting Regulatory Approval for the Product and any other relevant Authority regarding the Product if, in the opinion of that party's counsel and upon consultation with Client prior to such communication with the Regulatory Authority, the communication is necessary to comply with the terms of this Agreement or the requirements of the Authority or Applicable Laws. Otherwise, the parties will consult each other in relation to regulatory communications relating to the Product in accordance with the Quality Agreement.

7.3 Records.

Patheon will keep records of the manufacture, testing, and shipping of the Product, and retain samples of the Product as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, Applicable Laws, cGMP and the Quality Agreement. Copies of the records and samples will be retained as and for the period specified in the Quality Agreement. Patheon reserves the right to destroy or return to Client, at Client's sole expense, any document or samples for which the retention period specified in the Quality Agreement has expired if Client fails to arrange for destruction or return within [***] days of receipt of notice from Patheon.

7.4 Audits.

(a) Subject to the limits agreed in the Quality Agreement, Patheon will give Client reasonable access at agreed times to the areas of the Manufacturing Site in which the Product is manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Processing Instructions, cGMPs, and Applicable Laws. If Client wishes to audit Patheon beyond the agreed limits, except where the audit is required due to Patheon's material breach (for cause), or suspected breach, Client will pay to Patheon a fee of /USD [***] for each additional audit day and /USD [***] per audit day for each additional auditor. Under no circumstances will: (a) Client have a right of access to Patheon's financial records, provided however Patheon will provide reasonable supporting information responsive to requests associated with disputed invoices or (b) any Patheon Competitor be permitted access to the Manufacturing Site.

7.5 Regulatory Filings.

(a) Regulatory Authority Documentation. Client will provide copies of all relevant documents relating to Regulatory Authority approval for the commercial manufacture, distribution and sale of the Product

("**Regulatory Approval**") to Patheon on request and as required under the Quality Agreement. Patheon will review and verify the accuracy of these documents in accordance with the Quality Agreement. Client is not entitled to submit Regulatory Approvals referring to Patheon or its Affiliates or the Manufacturing Services until approved by Patheon within the time frame set forth below and in the Quality Agreement, unless Patheon's approval is unreasonably withheld or delayed.

(b) Deficiencies. At least [***] days prior to any filing deadline, if, in Patheon's sole discretion, acting reasonably, Patheon determines that any regulatory information given by Client is inaccurate or deficient in any manner whatsoever (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to the date of filing of the relevant application and in any event before any pre-approval inspection or before the Product is placed on the market if a pre-approval inspection is not performed.

(c) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under this Section 7.5 or the Quality Agreement within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion and upon reasonable prior written notice to Client, delay or postpone any inspection by the Regulatory Authority until Patheon has received the requested documents and is satisfied with their contents. Client's breach of this requirement will be considered a material breach of this Agreement.

(d) Pharmacovigilance. Client will be responsible, at its expense, for all pharmacovigilance obligations for the Product in accordance with Applicable Laws and the monitoring and management of post-marketing complaints and queries at its cost (including, without limitation, the cost of assistance required of Patheon under the Quality Agreement). Unless required by Applicable Law, neither party will be obliged to exchange with the other party any information or data which it compiles in carrying out pharmacovigilance obligations or activities.

(e) No Patheon Responsibility. Except as otherwise agreed in the Quality Agreement, Patheon will not assume any responsibility for: (a) the submission, accuracy or cost of any application for Regulatory Approval or related documentation (or the success of those applications); (b) any activity that is required by Applicable Laws for Regulatory Approval (including pharmacovigilance and complaints handling, and preparation and submission of any regular quality or other update); or (c) any dealings with the relevant Regulatory Authority on behalf of Client for Regulatory Approval. If a Regulatory Authority, or other governmental body, requires Patheon to incur fees, costs or activities in relation to the Products which Patheon (acting reasonably) considers unexpected and extraordinary, then Patheon will notify Client in writing and the parties will discuss appropriate mutually acceptable actions, including fee/cost sharing, or termination of all or any part of this Agreement or a Product Agreement. Patheon will not be obliged to undertake these activities or to pay for the fees or costs until the parties reach agreement on scope and fees for Patheon's assistance.

7.6 Release.

The parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Product will not by itself indicate compliance by Patheon with its obligations relating to the Manufacturing Services. Nothing in this Agreement will remove or limit the authority of the relevant quality function (as specified by the Quality Agreement) to determine whether the Product will be released for shipment, sale or distribution.

7.7 Withdrawal on Completion.

No later than [***] following completion or permanent cessation of the Manufacturing Services at the applicable Manufacturing Site, Client will: (a) ensure that any regulatory filings relating to the Product are withdrawn or amended to remove all references to the Manufacturing Site and, as applicable, Patheon or its Affiliates and their facilities (except in an historic context); and (b) provide to Patheon written confirmation of its compliance with this Section 7.7. If this time is not sufficient to meet the requirements of certain Regulatory Authorities, despite Client's reasonable efforts, then Patheon may agree to extend the period based on the written reassurances of Client.

8. Term and Termination

8.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue until December 31 of the fifth (5 th) Year of the Agreement (the " **Initial Term**"), unless terminated earlier by one of the parties. This Agreement will automatically renew after the Initial Term for twelve (12) Month periods if there is a Product Agreement in effect, unless either party gives written notice to the other party of its intention not to renew this Agreement at least twenty-four (24) months prior to the end of the then current term. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect. Unless otherwise agreed in the Product Agreement, each Product Agreement will have an initial term from the Effective Date of the Product Agreement until December 31 of the Year agreed to by the parties in the Product Agreement (each, an "**Initial Product Term**"). Product Agreements will automatically renew after the Initial Product Term for successive terms of two (2) Years each unless either party gives written notice to the other party of its intention not to renew the Product Agreement at least 18 months prior to the end of the then current term. If Client forecasts [***] volume for [***] during the term of a Product Agreement (excluding the registration period), then the parties may negotiate other terms and conditions on which the Product Agreement will remain in effect.

8.2 Termination for Cause.

(a) Either party may terminate this Agreement or a Product Agreement upon written notice where the other party has failed to remedy a material breach of this Agreement or the Product Agreement within [***], or such longer period as mutually agreed between the parties, in writing provided the breaching party has initiated and diligently pursued a remedy within such [***] period (the "**Remediation Period**") following receipt of a written notice of the breach from the aggrieved party that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate this Agreement or a Product Agreement under this Section 8.2(a) may only be exercised for [***] following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be considered to have waived the breach described in the Breach Notice. The right to terminate a Product Agreement under this Section 8.2(a) does not extend to any other Product Agreements where there has been no material breach of those other Product Agreements.

(b) Either party may immediately terminate this Agreement or a Product Agreement upon written notice to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy or insolvency is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement or a Product Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate a Product Agreement upon [***] prior written notice if (i) any Authority takes any action, or raises any objection, that permanently prevents Client from selling the Product in the Territory; (ii) if material regulatory issues arise which result in the withdrawal of the relevant Manufacturing Site manufacturing license; or (iii) if Patheon challenges Client's ownership of, or right to use, Client's IP.

(d) Client may terminate a Product Agreement upon [***] prior written notice if it intends to no longer order Manufacturing Services for a Product due to the Product's discontinuance in the market.

(e) Either party may terminate this Agreement or any Product Agreement upon [***] prior written notice if the other party assigns under Section 13.4 any of its rights under this Agreement or a Product Agreement to an assignee that, in the reasonable opinion of the terminating party, is: (i) unlikely to be able to meet the obligations of this Agreement or a Product Agreement; or (ii) a Competitor.

(f) Patheon may terminate this Agreement or any Product Agreement if payment in full of overdue, undisputed invoices is not received within [***] following the date of suspension of Manufacturing Services by Patheon under Section 5.4.

8.3 Consequences of Termination by Client.

Without prejudice to Sections 8.5 and 8.6, upon termination of any Product Agreement by Client for the reasons set forth below, the following shall apply accordingly:

(a) upon termination for any reason and at Client' request, Patheon shall notify Client in writing of the quantity and description of finished Product, semi-finished Product and Inventory held by Patheon in relation to such Product Agreement as at the date of termination;

(b) upon Client's termination for cause pursuant to [***], Client will take delivery of and pay for all undelivered Product that is manufactured or packaged in compliance with terms with this Agreement and the applicable Product Agreement pursuant to a Firm Order, at the Price in effect at the time the Firm Order was released. Client may, at its option, in the above circumstances (i) cancel Firm Orders that have not commenced manufacturing or packaging under such Product Agreement or (ii) place an Order with Patheon for all Inventory that was purchased (or will be purchased under existing unfulfilled orders for Components), maintained or produced by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2, at Patheon's cost (including all costs incurred by Patheon for the purchase, handling, and processing of the Inventory). At Client's request and subject to all Applicable Laws, Patheon shall at Client's cost destroy any Inventory not purchased by Client in accordance with this Section 8.3(b).

(c) Upon termination by Client pursuant to [***], Client will take delivery of and pay for all undelivered Product that is manufactured or packaged in accordance with this Agreement under a Firm Order, at the Price in effect at the time the Firm Order was released. Client will purchase all Inventory that was purchased (or will be purchased under existing unfulfilled orders for Components), maintained or produced by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2, at Patheon's cost (including all costs incurred by Patheon for the purchase, handling, and processing of the Inventory); and

(d) Notwithstanding Patheon's obligations in Section 8.3(a), (b) and (c), Client, at its own expense, will remove from the Manufacturing Site, within [***] following the completion, termination, or expiration of the Product Agreement, all unused DS and Client-Supplied Components, all applicable Inventory (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at the Manufacturing Site or that is otherwise under Patheon's care and control ("**Client Property**"). Patheon may ship Client Property to Client or to an external warehouse at Client's risk and expense. If Client fails to remove Client Property within [***] following the completion, termination, or expiration of the Product Agreement, Client will assume all risk of loss or damage to the stored Client Property and it will be Client's responsibility to have appropriate insurance coverage in place for this risk. If Client asks Patheon to destroy any Client Property, Client will be responsible for the cost of destruction.

8.4 Consequences of Termination by Patheon.

Without prejudice to Sections 8.5 and 8.6, upon termination of any Product Agreement by Patheon in accordance with [***], the following shall apply:

(a) Patheon shall notify Client in writing of the quantity and description of finished Product, semi-finished Product and Inventory held by Patheon in relation to such Product Agreement as at the date of termination;

(b) Client will purchase all Inventory that was purchased (or will be purchased under existing unfulfilled orders for Components), maintained or produced by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2, at Patheon's cost (including all costs incurred by Patheon for the purchase, handling, and processing of the Inventory); and

(c) Client, at its own expense, will remove from the Manufacturing Site, within [***] following the completion, termination, or expiration of the Product Agreement, all unused DS and Client-Supplied Components, all applicable Inventory (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at the Manufacturing Site or that is otherwise under Patheon's care and control ("**Client Property**"). Patheon may ship Client Property to Client or to an external warehouse at Client's risk and expense. If Client fails to remove Client Property within [***] following the completion, termination, or expiration of the Product Agreement, Client will assume all risk of loss or damage to the stored Client Property and it will be Client's responsibility to have appropriate insurance coverage in place for this risk. If Client asks Patheon to destroy any Client Property, Client will be responsible for the cost of destruction.

8.5 Consequences of Termination or Expiry

Upon completion, termination, or expiration of this Agreement or any Product Agreement for any reason:

(a) any prior outstanding obligations or payments due will not be affected nor will any other remedies that the parties may have under this Agreement or a Product Agreement or any related Capital Equipment Agreement be prejudiced;

(b) none of the obligations and responsibilities of the parties under Sections 5.1(e), 5.1(f), 5.4, 5.5, 8.3, 8.4, 8.5, 8.6, 10, 11, 12, 13.14, 13.15 and 13.16 shall be affected, all of which shall survive any completion, termination or expiration, as well as any other provisions that are by implication or otherwise intended to survive any completion, termination or expiration. Where Patheon has agreed to provide stability services beyond the final supply of Product, the relevant provisions of this Agreement will survive for the agreed duration of those stability services; and

(c) the license granted in Section 12.1(a) shall terminate, save where Client requests a Technology Transfer in accordance with Section 8.6 in which case the license shall subsist to the extent necessary to allow Patheon to perform its obligations under Section 8.6, and Patheon shall not make any use for any purpose whatsoever of any Client Intellectual Property or any information contained in the Quality Agreement, except to the extent necessary to (i) fulfil any Firm Order or order placed by Client in accordance with Section 8.3 or 8.4; and/or (ii) perform its obligations under Section 8.6.

8.6 Technology Transfer.

Upon the occurrence of Patheon's inability to manufacture the Yearly Forecast Volume per Section 5.1(h), following termination of a Product Agreement for any reason, or at Client's request within [***] before the end of the term of the Product Agreement, Patheon will provide assistance to transfer part or all of Client's manufacturing process, know-how and analytical testing methodology for the Product to Client ("**Technology Transfer**") to assist Client to manufacture the Product. Patheon will also disclose to Client the Patheon Intellectual Property used by Patheon to manufacture the Product subject to the Patheon IP License in Section 12.1(c). Patheon will, upon request of Client, prepare a written proposal to perform the Technology Transfer. The parties will enter into a mutually agreed upon agreement for the Technology Transfer, and Client will pay the reasonable and mutually agreed fees for the Technology Transfer performed by Patheon.

9. Representations, Warranties and Covenants

9.1 Authority.

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations under this Agreement.

9.2 Client Warranties.

(a) Non-Infringement. Client covenants, represents, and warrants that:

(i) the Processing Instructions and specifications for the Product are its or its Affiliate's property, or alternatively, that Client has a license to the Processing Instructions, and that Client may lawfully disclose the Processing Instructions and specifications to Patheon for use in accordance with this Agreement;

(ii) any Client Intellectual Property used by Patheon in performing the Manufacturing Services (A) is Client's or its Affiliate's unencumbered property or is licensed to Client, (B) may be lawfully used

as directed by Client and agreed in this Agreement, and (C) does not infringe and will not infringe any Third Party Rights;

(iii) to the best of Client's knowledge as of the effective date of this Agreement, the performance of the Manufacturing Services by Patheon or the use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement or any Product Agreement does not and will not infringe any Third Party Rights; and

(iv) to the best of Client's knowledge as of the effective date of this Agreement, there are no actions or other legal proceedings involving Client or its Affiliates that concerns the infringement of Third Party Rights related to any of the Processing Instructions or specifications, or any of the DS or Client-Supplied Components, or the sale, use, or other disposition of Product made in accordance with the Processing Instructions.

(b) Quality and Compliance. Client covenants, represents, and warrants that:

(i) the Processing Instructions and specifications for the Product conforms to all applicable cGMPs and Applicable Laws;

(ii) the Product, if labelled and manufactured in accordance with the Processing Instructions and in compliance with applicable cGMPs and Applicable Laws may be lawfully sold and distributed in every jurisdiction in which Client markets the Product; and

(iii) on receipt by Patheon, the DS will conform to the specifications for the DS that Client has given to Patheon and that the DS will be adequately contained, packaged, and labelled in accordance with Applicable Laws and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Processing Instructions, cGMPs, and Applicable Laws;

(b) the ownership and operation of the Patheon facility(ies) shall be in compliance with cGMP and all Applicable Laws;

(c) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights;

(d) all records as are necessary and appropriate to demonstrate compliance with Applicable Laws shall be maintained by Patheon;

(e) it is (i) not excluded from a Federal health care program as outlined in Sections 1128 and 1156 of the Social Security Act (see the Office of Inspector General of the Department of Health and Human Services List of Excluded Individuals/Entities at http://exclusions.oig.hhs.gov); (ii) not debarred by the FDA under 21 U.S.C. 335a (see the FDA Office of Regulatory Affairs Debarment List at www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/); (iii) not otherwise excluded from contracting with the federal government (see the Excluded Parties Listing System at www.sam.gov/); (d) to its knowledge is not under investigation or otherwise aware of any circumstances which may result in its being debarred or excluded from participating in any federal or state healthcare program; and (iv) if required based on the services to be provided, duly licensed and in good standing in accordance with applicable state laws. It will not employ, contract with, or retain any person directly or indirectly to perform the services under this Agreement if such person fails to satisfy one or more of the requirements set forth in this section. In the event that Patheon fails at any time to satisfy one or more of the requirements set forth in this section, Client may immediately terminate this Agreement. Unless prohibited by law or regulation, Client shall pay to Patheon any payments due at the time of termination, including any costs incurred in preparation for or during any Batch manufacturing; and

(f) it does not currently have, and it will not hire, as an officer or an employee any person whom it knows has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States Federal Food, Drug, and Cosmetic Act.

9.4 Permits.

(a) Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Product, Processing Instructions or specifications, including, without limitation, all marketing and post-marketing approvals, and any specific approvals referred to in the Quality Agreement.

(b) Patheon will maintain at all relevant times when performing the Manufacturing Services all required governmental permits, licenses, approval, and authorities.

9.5 No Warranty.

EXCEPT AS EXPLICITLY SET FORTH IN THIS SECTION 9, EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, PATHEON MAKES NO WARRANTY OR CONDITION OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

10. Limitation of Liability and Remedies

10.1 Limitation of Liability - Consequential Damages.

Except for damages available for breaches of confidentiality obligations, neither party will be responsible for or liable to the other for any special, consequential, incidental, exemplary, punitive, or other indirect damages of any kind (whether arising under contract, tort, or otherwise) including but not limited to (i) any delay, penalty, loss of profits, of anticipated savings, of goodwill, of use of the Product or loss of business opportunity; or (ii) for any other liability, damage, costs, penalty, or expense of any kind incurred by the other party of an indirect or consequential nature, even if advised of the possibility of such damages.

10.2 Remedies and Limitation of Liability.

(a) Remedies for Deficient Product. If Client makes a Product Claim under Section 6.1 and the parties agree the Product is Deficient Product, or the Product is determined to be Deficient Product under Section 6, Patheon will, at Client's election, either:

(i) replace the Product at Patheon's cost (after which Patheon may invoice for the replacement if Deficient Product had not been invoiced previously) as soon as reasonably possible given Patheon's commitments to third parties if Patheon is able to manufacture the replacement Product at the Manufacturing Site and contingent upon the receipt from Client of all DS and Client Supplied Components required for the manufacture of the replacement Product. Such replacement DS shall be included in the Quantity Dispensed as per Appendix 3;or

(ii) refund [***]% of the Price paid for the Deficient Product (by credit or offset against other amounts due to Patheon under the Product Agreement).

Except for the indemnity set out in Section 10.3 and any claim or remedy that Client may have under Sections 6.1 and 6.2(c), the remedies described in this Section 10.2 will be Client's sole remedy in contract, tort, negligence, equity or otherwise, for Deficient Product.

The remedy under this Section 10.2, if applicable (including in the case of Recall), will apply only to the extent that the affected Deficient Product is returned, destroyed or otherwise disposed of by Client or at Client's direction in accordance with this Agreement.

(b) Remedies for Loss or Damage of DS. Except as expressly set out in Appendix 3, under no circumstances whatsoever will Patheon be liable to Client in contract, tort, negligence, indemnity, breach of statutory duty, or otherwise for any loss or damage to the DS. Patheon's maximum aggregate liability for loss of or damage to the DS will not exceed on a per Product basis [***]% of

revenues (being payments of the Price) received by Patheon for that Product under the applicable Product Agreement during the previous Year (or, in the case of the first Year, the expected revenue for that Product if the agreed Yearly Forecast Volumes were ordered) This limit will not apply if and to the extent that the liability arises from the gross negligence, fraud, or wilful misconduct of Patheon.

(c) Maximum Liability. In any Year, in addition to the specific remedies under Section 10.2(a) for Deficient Product, Patheon's maximum aggregate liability to Client under or in connection with this Agreement or any Product Agreement (however arising, including contract, tort, negligence, indemnity, breach of statutory duty, losses of DS, or otherwise) will not exceed on a per Product basis [***]% of revenues (being payments of the Price) received by Patheon for that Product under the applicable Product Agreement during the previous Year (or, in the case of the first Year, the expected revenue for that Product if the agreed Yearly Forecast Volumes were ordered).

(d) Exclusion from Limitation of Liability. This limits of liability in this Section 10.2 will not apply if and to the extent that the liability arises from the gross negligence, fraud or wilful misconduct of Patheon.

(e) Death, Personal Injury and Fraudulent Misrepresentation. Nothing contained in this Agreement will act to exclude or limit either party's liability for personal injury or death caused by the negligence of either party or fraudulent misrepresentation.

10.3 Patheon Indemnity.

(a) Patheon will defend and indemnify Client, and its Affiliates, and their officers and directors, employees, agents, successors, and assigns, from all losses, damages, costs, claims, demands, subpoenas, judgments and liability to, from and in favour of third parties (other than Affiliates) for any claim of personal injury or property damage to the extent that the injury or damage is (i) the result of an error, omission, intentional misconduct or a failure by Patheon in performance of the Manufacturing Services in compliance with the Processing Instructions, cGMPs, and Applicable Laws; or (ii) breach of any Patheon representation or warranty contained in this Agreement except to the extent that the losses, damages, costs, claims, demands, subpoenas, judgments, and liability are due to the negligence or wrongful acts of Client, its Affiliates, or their officers and directors, employees, agents, successors assigns.

(b) If a claim occurs, Client will: (i) promptly notify Patheon of the claim; (ii) use commercially reasonable efforts to mitigate the effects of the claim; (iii) reasonably cooperate with Patheon in the defense of the claim; and (iv) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense. No settlement of any such matter where Client is a party to the claim or defendant, shall be made without the written consent of Client, (which shall not be unreasonably withheld), except for a settlement that involves only the payment of money and includes no acknowledgment or acceptance of liability on behalf of Client, which payment is in fact made by Patheon or its insurer.

10.4 Client Indemnity.

(a) Client will defend and indemnify Patheon, and its Affiliates, and their officers and directors, employees, agents, successors, and assigns, from all losses, damages, costs, claims, demands, subpoenas, judgments and liability to, from and in favour of third parties (other than Affiliates) for (i) any claim of infringement of any Third Party Rights in or by the Products or that relates to the manufacture of the Product by a proprietary process disclosed by Client or to Patheon's use of Client Intellectual Property to perform the Manufacturing Services, or any portion of them, or (ii) any claim of personal injury or property damage to the extent that the injury or damage arises from an error, omission, intentional misconduct, or failure or regulatory non-compliance by Client in manufacturing, sale or distribution of DS or the finished dosage form that contains the Product, except to the extent that the losses, damages, costs, claims, demands, subpoenas, judgments, and liability are due to the negligence or wrongful acts of Patheon, its Affiliates, or their officers, employees, agents, successors, assigns.

(b) If a claim occurs, Patheon will: (i) promptly notify Client of the claim; (ii) use commercially reasonable efforts to mitigate the effects of the claim; (iii) reasonably cooperate with Client in the defense of the claim; and (iv) permit Client to control the defense and settlement of the claim, all at Client's cost and expense. No settlement of any such matter where Patheon is a party to the claim or defendant, shall be made without the written consent of Patheon, (which shall not be unreasonably withheld) except for a settlement that involves only the payment of money and no acknowledgment or acceptance of liability on behalf of Patheon, which payment is in fact made by Client or its insurer.

10.5 Reasonable Allocation of Risk.

This Agreement (including, without limitation, this Section 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Product. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Product because Client has developed and holds the marketing approval for the Product, Client requires Patheon to manufacture and label the Product strictly in accordance with the Processing Instructions, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Product.

10.6 Validation Batches.

Where Product is manufactured by Patheon (or any of its Affiliates) under a separate pharmaceutical development or technology transfer agreement (the "**Development Agreement**"), specifically the Master Agreement for Pharmaceutical Development and Technology Transfer Services between the Parties, effective May 23, 2018, and then released by Patheon for commercial sale or distribution by Client, the performance of the applicable pharmaceutical development or technology transfer services including the manufacture of the Product

will be governed by the terms of the Development Agreement and will not be subject to the terms and conditions of this Agreement. The terms of this Agreement and the applicable Product Agreement will apply to any Product after release by Patheon.

11. Confidentiality

11.1 Confidential Information.

"**Confidential Information**" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party's patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients and its clients' confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any party's Representatives containing Confidential Information will be considered Confidential Information. Samples or materials provided under this Agreement as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. A party's rights and obligations under this Section 11 will apply to any Confidential Information that is disclosed by or received by that party's Representatives. For the purposes of this Section 11, a party receiving Confidential Information under this Agreement (including through its Representatives) is a "**Recipient**", and a party disclosing Confidential Information under this Agreement (including through its Representatives) is the "**Disclosing Party**". The existence, parties to, and terms of this Agreement or of any Product Agreement will be considered Confidential Information.

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will not be less than those exercised by Recipient for its own confidential or proprietary Confidential Information of a similar nature.

11.3 Exclusions.

The obligations of confidentiality in this Section 11 will not apply to the extent that Confidential Information:

(a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, if the other source is not known by the Recipient, to the best of its knowledge, to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party for the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient’s written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information is not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information are covered by exceptions in this Section 11.3, unless the combination itself is covered by any of those exceptions.

11.4 Photographs and Recordings.

Neither party will take any photographs or videos of the other party’s facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other party’s facilities, without that party’s express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in writing in advance of the disclosure and limit the required disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out in this Agreement. If any

public disclosure is required by law, the parties will consult concerning the form of announcement prior to the public disclosure being made.

11.6 Marking.

The Disclosing Party will use reasonable efforts to summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information within [***] days of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form.

11.7 Return of Confidential Information .

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies, summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records. The retained copy will remain subject to all confidentiality provisions contained in this Agreement. Client will not unreasonably require the return of Confidential Information that is necessary or useful to perform the Manufacturing Services.

11.8 Remedies.

The parties acknowledge that monetary damages may not be sufficient to remedy a breach by either party of this Section 11 and agree that the non-breaching party will be entitled to seek specific performance, injunctive or other equitable relief to prevent breaches of this Section 11 and to specifically enforce Section 11 in addition to any other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Section 11 but will be in addition to any and all other remedies available at law or in equity.

12. Intellectual Property

12.1 Inventions.

(a) For the term of this Agreement, Client shall grant to Patheon a non-exclusive, paid-up, royalty-free, non-transferable, sub-licensable (in connection with authorized sub-contracting in accordance with Section 2.2), non-assignable limited license to use the Client Intellectual Property solely to extent necessary for Patheon to perform the Manufacturing Services for Client pursuant to this Agreement.

Patheon shall not challenge, contest or otherwise impair Client's ownership or control of Client's Intellectual Property or the validity or enforceability of intellectual property rights of Client.

(b) Client shall solely own and retain exclusive worldwide right, title and interest in all Client Intellectual Property and all proprietary Confidential Information which it owned or controlled on or prior to the effective date of this Agreement, and shall also own any and all Confidential Information and intellectual property rights and proprietary information that are (i) improvements, derivatives or modifications to any of the foregoing and (ii) developed during the term of this Agreement that is specific to Product. Patheon shall provide Client with written notifications should any improvements, derivations or modifications or intellectual property rights arise related to Client Intellectual Property that may be subject to patent application of such Invention.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Unless Patheon identifies in advance any specific Patheon Intellectual Property that will be subject to a separate licensing agreement between the parties, Patheon grants to Client a non-exclusive, perpetual, paid-up, royalty-free, transferable license of the Patheon Intellectual Property necessary for Client to use, offer to sell or sell the Product (the "**Patheon IP License**").

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be considered to be improvements or other modifications of the Product, processes or technology owned or otherwise controlled by the party.

12.2 Intellectual Property.

Except as set forth in Section 12.1, neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13. Miscellaneous

13.1 Insurance.

Patheon will procure and maintain during the term of this Agreement and for [***] following the expiration date of this Agreement (i) Product/Completed Operations Liability insurance with limits not less than $[***] per claim and in the aggregate, (ii) Commercial General Liability insurance amount with limits not less than $[***] per claim and

in the aggregate, which may cover any operation of Patheon, (iii) Workers' Compensation insurance to cover all employees involved in the manufacturing of Product in accordance with applicable statutes and (iv) Professional Liability/Errors & Omissions liability insurance with limits not less than $[***] per claim and in the aggregate. If requested by Client, Patheon will provide Client a certificate of insurance evidencing the above.

Client shall procure and maintain, during the term and for a period of [***] following the expiration date of this Agreement, (i) Product/Completed Operations Liability insurance with limits not less than $[***] per claim and in the aggregate and (ii) Commercial General Liability insurance amount with limits not less than $[***] per claim and in the aggregate, which may cover any operation of Client, Client will provide a certificate of insurance evidencing the above insurance coverage upon written request from Patheon.

If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will without delay notify the other party in writing and the parties will negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.2 Independent Contractors.

The parties are independent contractors and this Agreement and any Product Agreement does not create between the parties any other relationship such as, by way of example only, that of employer and employee, principal and agent, joint-venturers, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.3 No Waiver.

Neither party's failure to require the other party to comply with any provision of this Agreement or any Product Agreement will be considered a waiver of the provision or any other provision of this Agreement or any Product Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.4 Assignment.

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld.

(b) Subject to Section 8.2(e), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement or the Product Agreement, and Client will remain liable under this Agreement in relation to any partial assignment. Any partial assignment will be subject to Patheon's cost review of the assigned Product and Patheon may terminate this Agreement or any Product

Agreement or any assigned part of them, on [***] prior written notice to Client and the assignee if discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time. Client will reimburse Patheon for any costs incurred by Patheon in connection with the partial assignment including any expenses incurred by Patheon for any due diligence audits in connection with the partial assignment.

(c) Despite the preceding provisions of this Section 13.4, Client may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business without the prior consent of Patheon. In the case of a permitted assignment under this Section, this Agreement shall be binding upon, and inure to the benefit of, the successors, executors, heirs, representatives, administrators and assigns of the parties hereto.

13.5 Force Majeure.

Neither party will be liable for the failure or delay to perform its obligations under this Agreement or any Product Agreement if the failure or delay is caused by an event beyond that party's reasonable control, including, but not limited to, third-party strikes or other third-party labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, cyber-attacks, fires, floods, storms, interruption of or delay in third-party transportation services, , or compliance with any order, regulation, or enforcement decision of any government entity (a "**Force Majeure Event**"). The party affected by the Force Majeure Event will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents or delays the performance. Such party will also submit written notice with proof of receipt, where applicable, of the existence of the Force Majeure Event Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement or any Product Agreement.

13.6 Additional Product and Services.

Additional Product may be added to, or existing Product deleted from, any Product Agreement by amendment to the Product Agreement including its Schedules as applicable. If Client requests services other than those expressly set out in this Agreement or in any Product Agreement (such as qualification of a new packaging configuration or shipping studies, or validation of alternative batch sizes), or any cost items that are specifically excluded from the Price, Patheon will provide a written quote of the fee for the additional services and Client will advise Patheon whether it wishes to have the additional services performed by Patheon. The scope of work and fees will be agreed in writing by the parties.

13.7 Notices.

Unless otherwise agreed in a Product Agreement, any notice, approval, instruction or other written communication required or permitted under this Agreement will be sufficient if made or given to the other party by personal delivery or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses or email addresses set out below:

If to Client:

Insmed Incorporated
700 US Highway 202/206, Bridgewater, NJ 08807-1704
Attention: SVP, General Counsel
Email address: [***]

If to Patheon:

Patheon Inc.,111 Consumers Drive, Whitby, Ontario L1N 5Z5, Canada
Attention: Legal Department

or to any other addresses or email addresses given to the other party in accordance with the terms of this Section 13.7. Notices or written communications made or given by personal delivery, or email will be considered to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, [***] days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt (supported by reasonable written evidence), whichever is sooner.

13.8 Severability.

If any provision of this Agreement or any Product Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.9 Entire Agreement.

This Agreement, together with its Appendices, the applicable Product Agreement, Capital Equipment Agreement (if any), and the Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter of the Agreement and supersedes all previous written or oral

negotiations, commitments, representations, collateral warranties, agreements, transactions, or understandings concerning the subject matter of this Agreement. The basis of the parties' agreement is set out expressly and they have not been induced by or relied on any statement or representation that is not set out in this Agreement. Any modification, amendment, or supplement to this Agreement or any Product Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Product Agreement, and the Quality Agreement (except that the Quality Agreement will prevail in relation to quality matters).

13.10 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by the parties will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement or any Product Agreement, regardless of any failure of a party to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement or the applicable Product Agreement and is signed by both parties.

13.11 No Third Party Benefit or Right.

Nothing in this Agreement or any Product Agreement will confer or be construed as conferring on any third party any benefit, collateral warranties, or the right to enforce any express or implied term of this Agreement or any Product Agreement (except that Patheon Affiliates acting as subcontractors under this Agreement may enforce Sections 10.1 and 10.2). The rights of the parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any other person.

13.12 Execution in Counterparts.

This Agreement and any Product Agreement may be executed in two or more counterparts, by original or electronic (including " **pdf**") signature, each of which will be considered an original, but all of which together will constitute one and the same instrument.

13.13 Use of Name.

Neither party may use the other party's name, trademarks or logo or any variations of them, alone or with any other word or words, without the prior written consent of the other party.

13.14 Taxes.

(a) VAT.

Any payment due to Patheon under this Agreement in consideration for the provision of Manufacturing Services to Client by Patheon is exclusive of value added taxes ("**VAT**"), turnover taxes, sales taxes or similar taxes, including any related interest and penalties (together, " **Transaction Tax**") which will be added to the invoice amount where applicable and payable by Client.

Where applicable, Patheon will use its reasonable commercial efforts to ensure that its invoices to Client are issued in a way to meet the requirements for deduction of input VAT by Client, if Client is permitted by law to do so.

If Patheon is acting as Client's buying agent, Patheon will always charge to Client the Transaction Tax in the relevant territory in addition to the amount paid by Patheon to supplier.

Reference to the Manufacturing Services in this Section also includes any element (or the entirety) of the Manufacturing Services characterized as a supply of goods by Patheon, its subcontractors or any tax authority for Transaction Tax purposes.

(b) Duties.

(c) Client will bear the cost of all duties, levies, tariffs and similar charges (and any related interest and penalties) (together, " **Duties**") however designated, arising from the performance of the Manufacturing Services by Patheon, including (without limitation) those imposed as a result of the shipping of materials (including drug substance, materials, components and finished Product) to, from or between Patheon sites. If these Duties are incurred by Patheon, then Patheon will be entitled to invoice Client for these Duties at the time that they are incurred.

(d) Withholding Tax.

Where any sum due to be paid to Patheon hereunder is subject to any withholding or similar tax, Client will pay the withholding or similar tax to the appropriate Government Authority and deduct the amount then due to Patheon, in a timely manner and promptly transmit to Patheon an official certificate or other evidence of the withholding sufficient to enable Patheon to claim payment of these taxes. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate or enable the recovery of any tax withholding or similar obligations for royalties, milestone payments, and other payments made by Client to Patheon under this Agreement.

Patheon will provide Client any tax forms that may be reasonably necessary in order for Client not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty.

Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, or similar obligations resulting from payments made under this Agreement, this recovery to be for the benefit of the Party bearing the withholding tax.

13.15 Governing Law and Jurisdiction.

This Agreement and any Product Agreement, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with them or their subject matter or formation are governed by the laws of (i) the State of Delaware if the applicable Patheon party is registered in the United States or Canada, or (ii) England if the applicable Patheon party is registered outside the United States or Canada, in each case without regard to any conflicts-of-law principle that directs the application to another jurisdiction's law. Both parties hereby submit to the exclusive jurisdiction of the courts in the applicable location. The parties further expressly agree that the UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

13.16 Dispute Resolution.

All disputes that arise under or in connection with this Agreement will be resolved in accordance with Appendix 2.

13.17 Government Contracts Requirements.

13.18 As applicable, the Government Contracts Requirements (as defined below) are incorporated in this Agreement by this reference, with the same force and effect as if they were given in full text. Nothing in this Agreement shall be construed to prohibit or otherwise restrict either Party from lawfully reporting waste, fraud, or abuse related to the performance of a government contract to a designated investigate or law enforcement representative of a federal department or agency authorized to receive such information.

13.19 For purposes of this Agreement, Government Contracts Requirements shall mean:

- 48 C.F.R. 52.203-6, Restrictions on Contractor Sales to the Government
- 48 C.F.R. 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment
- 48 C.F.R. 52.203-13 Contractor Code of Business Ethics and Conduct

- 48 C.F.R. 52.203-17 Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights
- 48 C.F.R. 52.203-19 Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
- 48 C.F.R. 52.204-21 Basic Safeguarding of Covered Contractor Information Systems
- 48 C.F.R. 52.219-8 Utilization of Small Business Concerns
- 48 C.F.R. 52.222-21 Prohibition of Segregated Facilities
- 48 C.F.R. 52.222-26 Equal Opportunity
- 48 C.F.R. 52.222-35 Equal Opportunity for Veterans
- 48 C.F.R. 52.222-36 Affirmative Action for Workers with Disabilities
- 48 C.F.R. 52.222-37 Employment Reports on Veterans
- 48 C.F.R. 52.222-40 Notification of Employee Rights Under the National Labor Relations Act
- 48 C.F.R. 52.222-50 Combating Trafficking in Persons
- 48 C.F.R. 52.224-3 Privacy Training
- 48 C.F.R. 52.232-40 Providing Accelerated Payment to Small Business Contractors
- 48 C.F.R. 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
- 48 C.F.R. 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment

The full text of a clause may also be accessed electronically at www.acquisition.gov. The Government Contracts Requirements may be updated upon notice by Client to Patheon.

Client and Patheon shall abide by the requirements of 41 CFR 60-300.5(a), as applicable. This regulation prohibits discrimination against qualified protected veterans, and requires affirmative action by covered prime contractors and Contractors to employ and advance in employment qualified protected veterans.

[Signature page to follow]

This Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

PATHEON INC.	INSMED INCORPORATED
By: /s/ Bobbi Ellis	By: /s/ Don Nociolo
Name: Bobbi Ellis	Name: Don Nociolo
Title: Senior Director and General Manager	Title: VP Technical Operations
Date: 11 January 2024	Date: 24 May 2024

APPENDIX 1 – Form of Product Agreement

Product Agreement for [INSERT PRODUCT NAME]

This Product Agreement (this " **Product Agreement**") is issued under the Master Manufacturing Services Agreement dated [INSERT DATE] between PATHEON INC. and INSMED INCORPORATED (the " **Master Agreement**"), and is entered into as of the last date of signature (the " **Effective Date**") between [PATHEON ENTITY], a corporation existing under the laws of [ ], having a principal place of business at [PATHEON ENTITY ADDRESS] (" **Patheon**") and INSMED INCORPORATED a Virginia corporation, having a principal place of business at 700 US Highway 202/206, Bridgewater, NJ 08807-1704 (" **Client**"). For the purpose of this Product Agreement, references in the Master Agreement to "Patheon" and "Client" mean the entities defined respectively as Patheon and Client in this Product Agreement.

The terms and conditions of the Master Agreement are incorporated into this Product Agreement except to the extent this Product Agreement expressly modifies specific provisions in the Master Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

1. **Initial Product Term**: will be from the Effective Date until December 31, 20[YY]
2. **Manufacturing Site**: The Manufacturing Services will be performed at the following Manufacturing Site: [ ]
3. **Territory**:
4. **Notices**: (if different from Section 13.7 of the Master Agreement): [insert contact details]
5. **DS Name**: [insert DS name]
6. **Product:**
7. **DS Credit Value:** Client's actual cost for DS not to exceed [ ] per kilogram. DS value to be provided by Client and supported by such reasonable evidence as Patheon requests.
8. **Inflation Index**: [if different from the Master Agreement]
9. **Governing Law:** [if different from the Master Agreement]
10. **Minimum Shelf Life (if any):**

11. **Other Modifications to the Master Agreement (if any)** :

Schedule A – Commercial Pricing Proposal : Description of the Manufacturing Services and related terms of this Product Agreement.

In case of conflict between Schedule A and the other parts of this Product Agreement, those other parts of the Product Agreement will prevail.

This Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

PATHEON INC.	INSMED INCORPORATED
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

Schedule A – Commercial Pricing Proposal

[***]

[End of Product Agreement]

APPENDIX 2 – Dispute Resolution

(a) [***]

APPENDIX 3 – DS Yield Calculation

[***]

APPENDIX 4 – Price Adjustments

[***]

14. SCHEDULE B

CLIENT AFFILIATES

[***]

Exhibit 10.24.1

Pursuant to Item 601(b)(10)(iv) of Regulation S-K, confidential information (indicated by [***]) has been omitted from Exhibit 10.24.1 because it (i) is not material and (ii) is the type of information the Company both customarily and actually treats as private or confidential.

PRODUCT AGREEMENT

Product Agreement for Brensocatib Film Coated Tablets (10mg and 25mg) and Bottling

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated 24 May, 2024 between PATHEON INC. and INSMED INCORPORATED (the " **Master Agreement**"), is entered into as of the last date of signature (the "**Effective Date**") between PATHEON INC, a corporation existing under the laws of Canada, having a principal place of business at Whitby Operations: 111 Consumers Drive, Whitby, Ontario L1N 5Z5, Canada (" **Patheon**") and INSMED INCORPORATED a Virginia corporation, having a principal place of business at 700 US Highway 202/206, Bridgewater, NJ 08807-1704 ("**Client**"). For the purpose of this Project Agreement, references in the Master Agreement to "Patheon" and "Client" mean the entities defined respectively as Patheon and Client in this Product Agreement.

The terms and conditions of the Master Agreement are incorporated into this Product Agreement except to the extent this Product Agreement expressly modifies specific provisions in the Master Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

1. **Initial Product Term**: will be from the Effective Date until December 31, 2029
2. **Manufacturing Site**: The bulk manufacturing and bottle packaging services will be performed at the following site: 111 Consumers Drive, Whitby, ON, L1N 5Z5, Canada.
3. **Notices**: Per Section 13.7 of the Master Agreement
4. **DS Name**: Brensocatib (formerly named INS-1007)
5. **Product:** Brensocatib IR Tablets (10mg and 25mg)
6. **DS Credit Value:** Client's actual cost for DS not to exceed $[***] per kilogram. DS value to be provided by Client and supported by such reasonable evidence as Patheon requests.
7. **Inflation Index**: per Appendix 4 in the Master Agreement
8. **Governing Law:** per Section 13.15 of the Master Agreement
9. **Minimum Shelf Life (if any):** Not applicable
10. **Other Modifications to the Master Agreement (if any)**:
    a. Patheon Whitby site will receive the corresponding forecast according to the service to be provided (bulk tablets and full service as referenced in 2.1 of Schedule A) and will issue corresponding invoices following

Section 5.4 of the Master Agreement. The bulk tablets would be requested for delivery to a packaging site at Client direction. Patheon would make bulk tablet pick-up available during normal business hours.

Solely for the purposes of this Product Agreement, the Master Agreement Section 5.1(f) Capacity Reservation will be deleted and replaced with the following.

In advance of each Year, Patheon will use the Rolling Forecast to reserve manufacturing capacity in that Year for Product as follows:

(i) for the Years 2024 and 2025, or, there is no Capacity Reservation applicable.

(ii) From 2026 onwards, by reference to the Rolling Forecast applicable at June 1 of the previous Year, the relevant and applicable forecast for the Year being the "Yearly Forecast Volume".

At the end of Year 2026, if the aggregate actual volume of Product ordered by Client with a confirmed Release Date within the Year, taking into account any Product paid for but not ordered, ("Actual Yearly Volume") is less than [***]% of the Yearly Forecast Volume, then Patheon may invoice and Client will pay Patheon [***]% of the Price for the shortfall of Product below the tolerance during the Year in an amount calculated as follows:

Amount Due to Patheon
= [***]

At the end of Year 2027 and each subsequent Year, if the aggregate actual volume of Product ordered by Client with a confirmed Release Date within the Year, taking into account any Product paid for but not ordered, ("Actual Yearly Volume") is less than [***]% of the Yearly Forecast Volume, then Patheon may invoice and Client will pay Patheon [***]% of the Price for the shortfall of Product below the tolerance during the Year in an amount calculated as follows:

Amount Due to Patheon
= [***]

Provided that no amount shall be due to Patheon under this Section 5.1(f) if Client terminates during the relevant Year under Section 8.2(a) (Termination for Cause) or if Patheon breaches its warranty under Section 9.3(g).

If the quantity of Product requested by Client in a Year (in purchase orders received by Patheon) exceeds the Yearly Forecast Volume for that Year, Patheon will use commercially reasonable efforts to supply the additional Product volumes. Patheon will not be considered to have accepted any purchase order for additional Product volumes without written confirmation.

c. Soley for the purposes of this Product Agreement, a new warranty shall be added to Section 9.3 (Patheon Warranties) of the Master Agreement as 9.3(g):

Patheon covenants, represents and warrants that:

(g) it will provide the Capacity Reservation as per Section 5.1(f) as amended by this Product Agreement.

d. The parties acknowledge and agree that Client may outsource some of Client's responsibilities to its Affiliate, Insmed Netherlands B.V., Stadsplateau 7, 3521 AZ Utrecht, in the Netherlands ("Affiliate Contractor"). With respect to Section 5 of the Master Agreement, Patheon may accept and rely on Purchase Orders provided by Affiliate Contractor and shall treat such as being provided by Client. Patheon will send invoices to Affiliate Contractor in accordance with Section 5.4 of the Master Agreement. Such sending of an invoice to Affiliate Contractor will be deemed sent to Client in accordance with section 5.4 of the Master Agreement. Though Client will be ultimately responsible for ensuring payment of invoices in accordance with 5.4 of the Master Agreement, any payments remitted by Affiliate Contractor in relation to such invoices shall be accepted by Patheon and shall be deemed to be remitted by Client. Patheon shall not incur any additional or duplicated liability under the Master Agreement as a result of this outsourcing arrangement by the Client.

e. Schedule A – Commercial Pricing Proposal: Description of the Manufacturing Services and related terms of this Product Agreement. In case of conflict between Schedule A and the other parts of this Product Agreement, those other parts of the Product Agreement will prevail.

f. Client shall have the right to request additional stock ("Safety Stock") above Rolling Forecast and Firm Order requirements. The parties shall negotiate in good faith and shall enter into a mutually agreed upon Change of Scope for Safety Stock identifying the individual item materials,

components, quantities, and financial obligations inclusive of relevant storage charges related to Safety Stock.

This Product Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

PATHEON INC	INSMED INCORPORATED
By: /s/ Bobbi Ellis	By: /s/ Don Nociolo
Name: Bobbi Ellis	Name: Don Nociolo
Title: Senior Director and General Manager	Title: VP Technical Operations
Date: 26 September 2024	Date: 29 September 2024

SCHEDULE A

C-WRC-116308-R5 Brensocatib Supply Proposal

Part A: Project Overview

Patheon offers expertise in the manufacturing and packaging of oral solid dose products. Patheon has selected its Whitby facility for the commercial supply presented in this Product Agreement.

Patheon will be responsible for the following core services:

1.1 Supply of raw materials and packaging components, with the exception of the Active Pharmaceutical Ingredient ("API"), which is to be furnished by Insmed.

1.2 Bulk manufacturing, tabletting, and packaging of Brensocatib IR Film Coated 10mg and 25mg Tablets ("Product").

1.3 Full API testing and all QC testing requirements for raw materials, packaging components and finished Product.

1. Product Features and Assumptions

1.1 API: BRENSOCATIB

- Indication: novel oral reversible inhibitor of dipeptidyl peptidase 1 (DPP1). DPP1 is an enzyme that catalyzes the activation of neutrophil serine proteases
- Patheon's categorisation: Category 2

1.2 Key Product parameter overview:

Product	Strength	Solid Form	Packaging Configuration
Brensocatib Tablet	10mg	Tablet	Bulk, 30ct Bottles
Brensocatib Tablet	25mg	Tablet	Bulk, 30ct Bottles

1.3 Territories –

30 ct Bottles, USA

Bulk, USA, EU

1.4 Commercial launch date: 2025

Part B: Pricing

1. Annual Volume Forecasts

Insmed has provided a very early forecast in the range of [***] tablets by 2025 assuming a ramp from 2022 to that level. Annual Volume forecast used to determine pricing is outlined in the table below. Insmed stated and Patheon acknowledges that Forecast provided is either 10mg or 25mg, and a possibility that both strengths could also be required.

Product Name	Strength (mg)	SKU Primary Count	SKU Type	Annual Volume Forecast (Tablets)				
				2025	2026	2027	2028	2029
INS1007	10	1000	Bulk	[***]	[***]	[***]	[***]	[***]
INS1007	25	1000	Bulk	[***]	[***]	[***]	[***]	[***]
Total				[***]	[***]	[***]	[***]	[***]

The forecast presented above is a critical driver for important parameters such as batch size, campaign length, equipment train and site selection, as well as influencing the business model outlined within this Product Agreement. Adjustments to the forecast will likely have a material impact on the Pricing and other business considerations described herein, leading to a review by Patheon and revision of this Product Agreement.

2. Pricing Tables

2.1 Commercial Manufacturing Prices – **Bulk Tablets – 300kg Batch** – Include Tablets manufacturing, quality testing, and bulk packaging.

Product / Strength	Batch Size (Tablets)	Mfg Campaign Length (Batches)	Minimum Order Quantity (Tablets)	Price per 1000 Tablets		
				Material Price	Conversion Price	Total Bulk Price
Brensocatib 25mg 300kg batch	[***]	[***]	[***]	$[***]	$[***]	$[***]
	[***]	[***]	[***]	$[***]	$[***]	$[***]
	[***]	[***]	[***]	$[***]	$[***]	$[***]
Brensocatib 10mg 300kg batch	[***]	[***]	[***]	$[***]	$[***]	$[***]
	[***]	[***]	[***]	$[***]	$[***]	$[***]
	[***]	[***]	[***]	$[***]	$[***]	$[***]

2.2 Commercial Manufacturing Prices – Full Service –**30ct Bottles – 300kg Batch –**Include Tablets manufacturing, quality testing, bottle packaging, and serialization.

Product, Strength & SKU	Batch Size (Bottles)	Mfg Campaign Length (Batches)	Pkg Campaign Length (Batches)	Minimum Order Quantity (Bottles)	Price per Bottle		
					Material Price	Conversion Price	Full Service Price
Brensocatib 25mg	[***]	[***]	[***]	[***]	$[***]	$[***]	$[***]
	[***]	[***]	[***]	[***]	$[***]	$[***]	$[***]
	[***]	[***]	[***]	[***]	$[***]	$[***]	$[***]
Brensocatib 10mg	[***]	[***]	[***]	[***]	$[***]	$[***]	$[***]
	[***]	[***]	[***]	[***]	$[***]	$[***]	$[***]
	[***]	[***]	[***]	[***]	$[***]	$[***]	$[***]

2.3 Commercial Packaging Prices – Packaging Only – 30ct Bottles – 300kg Batch – Include Tablets packaging, and serialization.

Product, Strength & SKU	Batch Size (Cartons)	Pkg Campaign Length (Batches)	Minimum Order Quantity (Cartons)	Price per Bottle		
				Material Price	Conversion Price	Packaging only Price
Bensocatib - 10mg or 25mg	[***]	[***]	[***]	$[***]	$[***]	$[***]
	[***]	[***]	[***]	$[***]	$[***]	$[***]
	[***]	[***]	[***]	$[***]	$[***]	$[***]

2.4 Patheon Serialization Fees

The commercial pricing includes serialization to meet regulatory requirements. Aggregation from the saleable unit through to the pallet is included as Patheon's standard as well. Patheon will integrate from its serialization vendor, Tracelink, to the client's respective system. IT connectivity between respective systems will be confirmed as part of the overall project plan. The integration and connectivity tasks necessary to receive client serial numbers and to return serialized and aggregated information will be quoted separately as part of the tech transfer or development proposals.

2.5 Documentation

After batch record copies for the first [***] commercial batches, and [***] commercial bath per Year thereafter which is included in batch pricing. The following additional documentation would be provided at Insmed request

1.1 LIMS report for each batch USD [***] per batch

1.2 4 manufacturing batch record packages per year USD [***]

1.3 4 packaging batch records per year USD [***]

1.4 1 Quality Control testing full data package per year including all the reports, notebook pages, etc. USD [***]

3. Costs Included in Price

3.1 [***]

4. Costs Not Included in Price

4.1 [***]

Part E. Key Technical Parameters

1. Manufacturing Parameters

1.1 API – API will be stored under controlled ambient room conditions

1.2 Batch Size/Yields - The core tablet weight, theoretical manufacturing batch size and product yields considered by Patheon are summarized in the following table.

Product	Core Tablet Weight (mg)	Batch Size before losses (Tablets)	Batch Size (kg)	Mfg. Yield (%)	Pkg. Yield (%)	
					Bulk	Bottle
Brensocatib 10mg Tablets	[***]	[***]	[***]	[***]	[***]	[***]
Brensocatib 25mg Tablets	[***]	[***]	[***]	[***]	[***]	[***]

1.3 Manufacturing campaign - The commercial pricing presented considers manufacturing in campaign. As such, a Minimum Order Quantity of one batch is applicable.

1.4 Hold times – It is assumed that the process is carried out at room temperature and the holding times throughout the process are suitable for the batch size proposed. It is assumed that only standard light protection is employed and that no special precautions are required during formulation or packaging.

1.5 Other Technical Parameters-

Other Technical Parameter	
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

1.6 Manufacturing Equipment Train.

Process Step	300kg Batch
[***]	[***]

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

2. Packaging Parameters

2.1 Packaging Components:

Bulk Tablets *	30ct Bottles
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

*HL assumption until Bulk containers for tablets have been finalized.

2.2 Secondary packaging – Further assessment and discussion will follow once the secondary packaging requirements are fully defined. Packaging orders must be placed in multiples of [***]. Patheon assumes that a whole bulk batch will be packed off into a single Stock Keeping Unit (SKU).

2.3 Secondary packaging campaign - The commercial pricing presented considers packaging in campaign.

3. Testing Conditions

3.1 The analytical testing included in this Product Agreement are listed below:

Testing Requirements		
In-Process Controls	**API Testing**	**Finished Product Testing**
[***]	[***]	[***]

*Palladium testing included as a high-level estimate.

3.2 Testing labour may be subject to change after the final agreements on testing Specifications and requirements.

4. Supply Chain

4.1 Patheon will procure Components for the manufacture of Brensocatib Tablet from Patheon qualified suppliers. Should Insmed require Patheon to source any materials from specified suppliers, then these suppliers will remain under the quality audit control of Insmed unless an agreement is reached for Patheon to take on this responsibility.

4.2 Patheon recommends review of the Common Materials and Supplies source to reduce the risk of delays and ensure delivery continuity e.g. secondary source suppliers.

4.3 Components will be supplied by Patheon in accordance with the Specifications agreed. Patheon will issue formal Patheon specifications for each Component.

4.4 Each lot of incoming Components will be sampled and tested according to the agreed Specifications.

4.5 The API will be provided free issue/released to Patheon by Insmed or its qualified supplier.

4.6 The API and all excipients used for the manufacture will be GMP grade and from TSE/BSE certified sources.

Exhibit 10.25.1

Pursuant to Item 601(b)(10)(iv) of Regulation S-K, confidential information (indicated by [***]) has been omitted from Exhibit 10.25.1 because it (i) is not material and (ii) is the type of information the Company both customarily and actually treats as private or confidential.

FIRST AMENDMENT TO REVENUE INTEREST PURCHASE AGREEMENT

This FIRST AMENDMENT TO REVENUE INTEREST PURCHASE AGREEMENT (this "**First Amendment**"), dated and effective as of October 31, 2024, is made by and between INSMED INCORPORATED, a Virginia corporation (as "**Company**") and ORBIMED ROYALTY & CREDIT OPPORTUNITIES IV, LP, a Delaware limited partnership ("**OrbiMed**" or the "**Purchaser**").

Recitals

A. Company and OrbiMed have entered into that certain Revenue Interest Purchase Agreement, dated as of October 19, 2022 (as amended or otherwise modified, the "**RIPA**").

B. In accordance with Section 7.08 of the RIPA, and subject to the terms and conditions set forth in this First Amendment, the Company and Purchaser desire to amend the RIPA to modify certain terms and conditions, in each case on the terms and conditions set forth herein.

Agreement

Now, Therefore, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. All capitalized terms used in this First Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the RIPA. The rules of interpretation set forth in the first paragraph of Section 7.09 of the RIPA shall be applicable to this First Amendment and are incorporated herein by this reference.

2. Amendments to RIPA. As of, and subject to the occurrence of, the First Amendment Effective Date (defined below), the RIPA shall be amended to (x) delete the stricken text (indicated textually in the same manner as the following example: ~~stricken text~~) and to add the double-underlined text (indicated textually in the same manner as the following example: double-underlined text) as set forth in the pages of the RIPA attached as Exhibit A hereto

3. Conditions to Effectiveness. This First Amendment shall become effective upon the prior or simultaneous satisfaction of each of the following conditions in a manner reasonably satisfactory to the Purchaser (the date when all such conditions are so satisfied being the "**First Amendment Effective Date**"):

a. Executed First Amendment. The Purchaser shall have received a copy of this First Amendment duly executed by the Company and the Purchaser.

b. BioPharma Loan Agreement. The Purchaser shall have received a copy, in form and substance reasonably satisfactory to it, of the Amended and Restated Loan Agreement, dated as of October 31, 2024, by and among the Company, the guarantors party thereto, Biopharma Credit PLC and the lenders party thereto ("**A&R Loan Agreement**"), together with all other agreements and documents,

if any, related thereto and executed and delivered in connection therewith, in each case duly executed and delivered by all parties thereto.

c. Representations and Warranties. The representations and warranties of the Company set forth in Section 4 hereof shall be true and correct on and as of the First Amendment Effective Date.

4. Representations and Warranties; Reaffirmation.

a. Company hereby represents and warrants to Purchaser as follows:

i. Company has all necessary power and authority to enter into, execute and deliver this First Amendment and to perform all of the obligations to be performed by it hereunder and to consummate the transactions contemplated hereunder.

ii. This First Amendment has been duly authorized, executed and delivered by Company and is a legal, valid and binding obligation of such Person, enforceable against such Person in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally, by general principles of equity.

iii. The execution, delivery and performance by Company of this First Amendment have been duly authorized and do not and will not: (a) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, any provisions of: (i) any law, rule, ordinance or regulation of any Governmental Authority, or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which the Company or any Subsidiary or any of their respective assets or properties may be subject or bound; or (ii) any material contract, agreement, commitment or instrument to which the Company or any Subsidiary is a party or by which the Company or its Subsidiary or any of their respective assets or properties is bound or committed; (b) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, any provisions of the articles or certificate of incorporation or bylaws (or other organizational or constitutional documents) of the Company or any Subsidiary; (c) except for the filing of the UCC Financing Statements and any other notices of security or notices of charge required under the Transaction Documents and filings with the United States Patent and Trademark Office, require any notification to, filing with, or consent of, any Person or Governmental Authority, except such consents that are obtained at or prior to the First Amendment Effective Date; (d) give rise to any right of termination, cancellation or acceleration of any right or obligation of the Company, any Subsidiary or any other Person or to a loss of any benefit relating to the Revenue Interests; (e) other than pursuant to this Agreement, any other Transaction Document or any Term

Transaction Document, result in the creation or imposition of any Lien on (i) the assets or properties of the Company or any Subsidiaries or (ii) the Revenue Interests or any Collateral, except, in the case of the foregoing clauses (a) or (c), as would not, individually or in the aggregate, have a Material Adverse Effect.

b. Both before and immediately after giving effect to this First Amendment, no Put Option Event has occurred and is continuing and no Put Option Event could reasonably be expected to result from the consummation of this First Amendment and the A&R Loan Agreement and the transactions contemplated thereby.

c. On and as of the First Amendment Effective Date, all of the conditions set forth in Section 3 have been satisfied.

d. Company hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the RIPA to which it is a party and agrees that the RIPA remain in full force and effect, undiminished by this First Amendment, except as expressly provided herein. By executing this First Amendment, Company acknowledges that it has read, consulted with its attorneys regarding, and understands, this First Amendment.

5. No Implied Amendment or Waiver. Except as expressly set forth in this First Amendment, this First Amendment shall not, by implication or otherwise, limit, impair, constitute a waiver of or otherwise affect any rights or remedies of the Purchaser under the RIPA or the other Transaction Documents, or alter, modify, amend or in any way affect any of the terms, obligations or covenants contained in the RIPA or the other Transaction Documents, all of which shall continue in full force and effect. Nothing in this First Amendment shall be construed to imply any willingness on the part of the Purchaser to agree to or grant any similar or future amendment, consent or waiver of any of the terms and conditions of the RIPA or the other Transaction Documents.

6. References to and Effect on RIPA. Except as specifically set forth herein, the execution, delivery and effectiveness of this First Amendment shall not, directly or indirectly, (i) constitute an approval or waiver of any past, present or future breaches, violations or defaults of or under any provisions of the RIPA nor constitute a novation of any of the Obligations under the RIPA, (ii) amend, modify or operate as a waiver of any provision of the RIPA or any right, power or remedy of the Purchaser, (iii) constitute a course of dealing or other basis for altering the RIPA or any other Transaction Document or (iv) in any way affect any of the provisions of the RIPA, which shall remain in full force and effect and is hereby ratified and confirmed in all respects. On and after the Consent Effective Date, all references in the RIPA to “this Agreement,” “hereto,” “hereof,” “hereunder,” or words of like import shall mean the RIPA as amended by this First Amendment. Except as specifically set forth herein, the Purchaser reserves all of its rights, powers, and remedies under the Transaction Documents and applicable Law. Company acknowledges and agrees that the amendments set forth in Section 5 above do not in any manner whatsoever limit any right of the Purchaser to insist upon strict compliance by Company with the RIPA (as amended by this First Amendment). This First Amendment constitutes a Transaction Document

for all purposes of the RIPA (as amended by this First Amendment) and the other Transaction Documents.

7. Successors and Assigns. This First Amendment binds and is for the benefit of Company and the Purchaser and each of their respective successors and permitted assigns.

8. Governing Law; Venue; Jury Trial Waiver. THIS FIRST AMENDMENT SHALL BE CONSTRUED IN ACCORDANCE WITH AND GOVERNED BY THE LAW OF THE STATE OF NEW YORK. The provisions of Section 7.14 (*Governing Law, Jurisdiction*) and Section 7.15 (*Waiver of Jury Trial*) of the RIPA shall apply hereto as if more fully set forth herein as if references therein to "this Agreement" were references to the RIPA as amended by this First Amendment.

9. Counterparts. This First Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one First Amendment. Delivery of an executed counterpart of this First Amendment by facsimile or other electronic imaging means (e.g. "pdf" or "tif") shall be effective as delivery of an original executed counterpart of this First Amendment.

10. Electronic Execution of Certain Other Documents. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this First Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Purchaser, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the undersigned hereto have caused this First Amendment to be executed as of the date first written above by each of their officers thereunto duly authorized.

INSMED INCORPORATED,
as the Company on its own behalf and on behalf of each other Subsidiary Guarantor

By: /s/ Sara Bonstein
Name: Sara Bonstein
Title: Chief Financial Officer

ORBIMED ROYALTY & CREDIT OPPORTUNITIES IV, LP,
as Purchaser

By: OrbiMed ROF IV LLC, its General Partner

By: OrbiMed Advisors LLC, its Managing Member

By /s/ Matthew Rizzo
Name: Matthew Rizzo
Title: Member

[Signature page to First Amendment]

Exhibit A
See attached.

Execution Version

REVENUE INTEREST PURCHASE AGREEMENT

DATED AS OF OCTOBER 19, 2022

BETWEEN

INSMED INCORPORATED,

AND

ORBIMED ROYALTY & CREDIT OPPORTUNITIES IV, LP

TABLE OF CONTENTS

Section 1.01. Definitions. 5

Section 1.02. Irish terms. 52

ARTICLE II. PURCHASE OF REVENUE INTEREST PAYMENTS; PAYMENTS 52

Section 2.01. Purchase of Revenue Interest Payments. 52

Section 2.02. Payments by the Company. 52

Section 2.03. Purchase Price; Conditions Precedent. 54

Section 2.04. No Assumed Obligations. 56

Section 2.05. Taxes. 56

Section 2.06. Additional Costs; Changes in Law Generally. 58

ARTICLE III. REPRESENTATIONS AND WARRANTIES OF THE COMPANY 58

Section 3.01. Organization. 58

Section 3.02. Authorization; Enforceability. 59

Section 3.03. Governmental Authorization. 59

Section 3.04. Ownership. 59

Section 3.05. Financial Statements; No Material Adverse Effect. 60

Section 3.06. [Intentionally Omitted]. 60

Section 3.07. Solvency; No Fraudulent Transfer. 60

Section 3.08. Litigation. 61

Section 3.09. Compliance with Laws. 61

Section 3.10. Conflicts; Adverse Agreements. 61

Section 3.11. Intellectual Property. 62

Section 3.12. Regulatory Approvals, Etc. 63

Section 3.13. Material Contracts. 66

Section 3.14. Place of Business. 66

Section 3.15. [Intentionally Omitted]. 66

Section 3.16. Section 3.16. Perfection; Subordination. 66

Section 3.17. Insurance. 67

Section 3.18. Tax. 67

Section 3.19. Disclosures. 67

Section 3.20. Investment Company Act; Margin Stock Regulation. 67

Section 3.21. Anti-Corruption Laws; Anti-Money Laundering Laws; Sanctions; Export and Import Laws. 68

Section 3.22. Broker's Fees. 69

Section 3.23. Data Privacy and Information Security. 69

Section 3.24. Benefit Plans. 71

Section 3.25. Internal Controls. 72

Section 3.26. Fiscal Unity. 72

ARTICLE IV. REPRESENTATIONS AND WARRANTIES OF THE PURCHASER 72

Section 4.01. Organization. 72

Section 4.02. Authorization. 72

Section 4.03. Broker's Fees. 72

Section 4.04. Conflicts. 72

ARTICLE V. COVENANTS 73

Section 5.01. Notices; Access; Information. 73

Section 5.02. Reports. 76

Section 5.03. Compliance with Law; Existence and Maintenance of Properties; Material Contracts; Payment of Obligations. 78

Section 5.04. Confidentiality; Public Announcement. 79

Section 5.05. Security Interest. 80

Section 5.06. Further Assurances; Creation/Acquisition of Subsidiaries; Additional Collateral. 80

Section 5.07. Put Option; Call Option. 82

Section 5.08. Intellectual Property; Regulatory Approvals. 84

Section 5.09. Use of Proceeds. 85

Section 5.10. Protective Covenants. 85

Section 5.11. Insurance. 87

Section 5.12. Taxes. 87

Section 5.13. Material Contracts. 88

Section 5.14. Benefit Plans and Arrangements. 89

Section 5.15. Compliance with Sanctions and Anti-Money Laundering Laws. 89

Section 5.16. Transactions with Affiliates. 90

Section 5.17. Fiscal Unity. 90

Section 5.18. Operating Accounts; Control Agreements. 90

Section 5.19. Post-Closing Obligations. 91

ARTICLE VI. TERMINATION 92

Section 6.01. Termination Date. 92

Section 6.02. Effect of Termination. 92

ARTICLE VII. MISCELLANEOUS 93

Section 7.01. Limitations on Damages. 93

Section 7.02. Notices. 93

Section 7.03. Successors and Assigns. 94

Section 7.04. Indemnification. 95

Section 7.05. No Implied Representations and Warranties; Survival of Representations and Warranties. **96**

Section 7.06. Independent Nature of Relationship. **96**

Section 7.07. Entire Agreement. **96**

Section 7.08. Amendments; No Waivers. **97**

Section 7.09. Interpretation. **97**

Section 7.10. Headings and Captions. **97**

Section 7.11. Counterparts; Effectiveness; Electronic Signature. **97**

Section 7.12. Severability. **98**

Section 7.13. Expenses. **98**

Section 7.14. Governing Law; Jurisdiction. **98**

Section 7.15. Waiver of Jury Trial. **98**

Exhibit A - Form of Guaranty and Security Agreement
Exhibit B - Intercompany Reorganization

REVENUE INTEREST PURCHASE AGREEMENT

This **REVENUE INTEREST PURCHASE AGREEMENT** (as amended, supplemented or otherwise modified from time to time, this "Agreement") is made and entered into as of October 19, 2022, by and between Insmed Incorporated, a Virginia corporation (the "Company"), and ORBIMED ROYALTY & CREDIT OPPORTUNITIES IV, LP (the "Purchaser").

WHEREAS, the Company wishes to obtain financing for general corporate purposes, future acquisitions and to pay fees and expenses associated with the foregoing; and

WHEREAS, the Purchaser wishes to purchase the right to receive the Revenue Interest Payments (as hereinafter defined) and other payments required to be made hereunder from the Company, and the Company wishes to agree to make the Revenue Interest Payments and other payments required to be made hereunder to the Purchaser in consideration for its payment of the Purchase Price (as hereinafter defined) all upon and subject to the terms and conditions hereinafter set forth.

NOW, **THEREFORE**, in consideration of the mutual covenants, agreements, representations and warranties set forth herein, the parties hereto agree as follows:

Article I.

DEFINITIONS

Section 1.01. Definitions.

Unless otherwise specified herein, the following terms that are defined in the UCC (as hereinafter defined), when used in this Agreement, will have the meanings provided for such terms in the UCC (and, in the event any such term is defined differently for purposes of Article 9 of the UCC than for any other purpose or purposes of the UCC, the Article 9 definition shall govern): Account, Chattel Paper, Commercial Tort Claim, Commodity Account, Commodity Intermediary, Deposit Accounts, Documents, Electronic Chattel Paper, Equipment, General Intangibles, Goods, Instruments, Inventory, Investment Property, Letter of Credit Rights, Proceeds, Securities Account, Securities Intermediary and Tangible Chattel Paper. In addition, the following, as used herein, shall have the following meanings:

"1x Return Date" means the date on which the Purchaser has received aggregate Revenue Interest Payments (excluding, for avoidance of doubt, any payment of interest made in accordance with Section 2.02(d)) equal to 100.0% of the Purchase Price.

~~"2025 Convertible Notes" means the 1.75% Convertible Senior Notes due January 15, 2025 issued by the Company pursuant to that certain First Supplemental Indenture, dated as of January 26, 2018, by and between the Company and Wells Fargo Bank, National Association.~~

"2028 Convertible Notes" means the 0.75% Convertible Senior Notes due June 1, 2028 issued by the Company pursuant to that certain Second Supplemental Indenture, dated as of May 13, 2021, by and between the Company and Wells Fargo Bank, National Association.

"Acquisition" means (a) any Stock Acquisition, or (b) any Asset Acquisition.

"Affiliate" means any Person that Controls, is Controlled by, or is under common Control with another Person.

"Agreement" has the meaning set forth in the first paragraph hereof.

"ANDA" has the meaning set forth inSection 3.11(d).

"Anti-Money Laundering Laws" has the meaning set forth inSection 3.21(b).

"APPI" means the Japanese Act on the Protection of Personal Information (Act No. 57 of 2003 as amended in 2015), as amended by the Amended Act on the Protection of Personal Information (Act No. 57 of 2003 as amended in 2020), and including all related guidelines issued by the Japanese Personal Information Protection Commission or other relevant Governmental Authority.

"Applicable Law" means, as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, order, policy, rule or regulation or determination of an arbitrator or a court or other Governmental Authority (including all statutes, rules, regulations, standards, guidelines, policies and orders administered or issued by any foreign Governmental Authority) in each case, applicable to and binding upon such Person or any of its assets or properties or to which such Person or any of its assets or properties are subject, including, with respect to the Company, the rules or requirements of any applicable U.S. national securities exchange applicable to the Company or any of its Equity Interests.

"Applicable Percentage" means as of any time of determination:

(a) with respect to Arikayce, (i) at all times prior to, but not including, September 1, 2025, 4.00% and (ii) at all times on and after September 1, 2025, 4.50%; and

(b) with respect to Brensocatib, 0.75%;

provided that if the Purchaser has not received aggregate Revenue Interest Payments (excluding, for avoidance of doubt, any payment made in accordance with Section 2.02(d)) under this Agreement for all fiscal quarters ending on or prior to March 31, 2028, in an aggregate amount equal to or greater than 100.0% of the Purchase Price, the Applicable Percentage with respect to Arikayce shall be increased for all subsequent fiscal quarters to a single defined percentage amount that would have provided the Purchaser with an amount equal to 100.0% of the Purchase Price for all fiscal quarters ended on or prior to March 31, 2028 had such percentage amount applied at all times from and after the Closing Date. Solely as used in this definition of "Applicable Percentage" and notwithstanding anything to the contrary elsewhere in this Agreement, the amount of Revenue Interest Payments shall be calculated without giving effect to payments made in accordance with Section 2.02(d).

"Arikayce" means amikacin liposome inhalation suspension and the Lamira® Nebulizer System, or other nebulizer approved for use by the FDA, used for the treatment of *Mycobacterium avium* complex (MAC) or any lung disease, condition or disorder, including the product approved by the FDA under NDA 207356 and any supplements thereto or any other approval of a product including amikacin in any form for inhalation or non-systemic delivery to patients that is owned or controlled by Purchaser.

"Asset Acquisition" means, with respect to the Company or any of its Subsidiaries, any purchase, exclusive or nonexclusive in-license or other acquisition of any properties or assets of any other Person (other than assets used and acquired in the ordinary course of business consistent with past practice for consideration that does not include any Contingent Obligation or other contingent consideration), including any purchase or other acquisition of any business unit, line of business or division of such Person). Notwithstanding the foregoing, "Asset Acquisition" does not include any in-license or any collaboration, co-promotion or co-marketing arrangement pursuant to which the Company or any Subsidiary acquires rights to research, develop, use, make, promote, sell, lease or market the products of another Person.

"Audit Costs" means, with respect to any audit of the books and records of the Company and its Affiliates and Licensees with respect to amounts payable or paid under this Agreement, the reasonable and documented out-of-pocket cost of such audit, including all reasonable and documented fees, costs and expenses incurred in connection therewith.

"Audited Financial Statements" has the meaning set forth in the definition of "Financial Statements".

"Bankruptcy Event" means the occurrence of any of the following:

(a) the Company or any Subsidiary shall commence any case, proceeding or other action (i) under the laws of any jurisdiction, domestic or foreign, relating to bankruptcy, insolvency, reorganization, examinership or similar relief, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, administration, protection, liquidation, examinership or dissolution (other than a solvent winding-up, dissolution or liquidation of a Subsidiary into the Company or a Subsidiary Guarantor), or (ii) seeking appointment of a receiver, interim receiver, receiver and manager, trustee, administrator, administrative receiver, custodian, examiner or other similar official for it or for all or any portion of its assets, or the Company or any Subsidiary shall make a general assignment for the benefit of its creditors or enter into a composition, assignment or arrangement with any of its creditors (whether by way of a voluntary arrangement, scheme of arrangement, deed of compromise or otherwise);

(b) there shall be commenced against the Company or any Subsidiary any case, proceeding or other action seeking to adjudicate it bankrupt or insolvent, or seeking dissolution, liquidation, administration, winding up, reorganization, arrangement, adjustment, protection, examinership, or seeking the entry of an order for relief or the appointment of a receiver, interim receiver, receiver and manager, trustee, administrator, administrative receiver, custodian, examiner or other similar official for any such Person or for any substantial part of its property, and either such proceeding shall remain undismissed or unstayed for a period of sixty (60) days or any of the actions sought in such proceeding (including, without limitation, the entry of an order for relief against any such Person or the appointment of a receiver, interim receiver,

receiver and manager, trustee, administrator, administrative receiver, custodian, examiner or other similar official for it or for any substantial part of its property) shall occur;

(c) the Company or any Subsidiary shall be generally not paying its debts as such debts become due or shall admit in writing its inability to pay its debts generally as such debts become due;

(d) an affirmative vote by the applicable Board to commence any case, proceeding or other action described in clause (a) above or any other action by the Company or any Subsidiary to otherwise cause, consent to, approve or acquiesce in any of the acts described in clauses (a) through (c) inclusive above; or

(e) without limiting the generality of clauses (a) to (d) above, in relation to ~~any Subsidiary of the Company~~ Credit Party incorporated in Switzerland and/or having its registered office in Switzerland, the (insolvency) terms referred to above shall include any steps and actions under Swiss law which are analogous to those described above, in particular, without limitation of the scope of clauses (a) ~~to~~ through (d) above, in respect of the following proceedings: "Drohende Zahlungsunfähigkeit (threat of illiquidity/insolvency) within the meaning of art. 725 and 820 of the Swiss Code of Obligations, "Zahlungsunfähigkeit" (inability to pay its debts), "Zahlungseinstellung" (suspending making payments), "hälftiger Kapitalverlust" or "Überschuldung" within the meaning of art. ~~725~~725a, 725b and art. 820 ~~para. 1~~ of the Swiss Code of Obligations (half of the share capital and the legal reserves not covered; over-indebtedness, i.e. liabilities not covered by the assets), duty of filing of the balance sheet with the judge due to over-indebtedness or insolvency pursuant to art. 725b and art. 820 para. 1 of the Swiss Code of Obligations, "Nachlassverfahren" (composition with creditors) including in particular "Nachlassstundung" (moratorium) and proceedings regarding "Nachlassvertrag" (composition agreements) and "Notstundung" (emergency moratorium), "Fälligkeitsaufschub" (postponement of maturity of indebtedness), "Konkursaufschub / Gesellschaftsrechtliches Moratorium" (postponement of the opening of bankruptcy; moratorium proceedings) pursuant to art. 725, 725a, 725b and 820 CO, notification of the courts under these provisions and actions for "*Auflösung* / *Liquidation*" (dissolution/liquidation).

"Benefit Plan" means any employee benefit plan, as defined in section 3(3) of ERISA, that is either (i) a "multiemployer plan," as defined in section 3(37) of ERISA, (ii) subject to section 412 of the Code, section 302 of ERISA or Title IV of ERISA, (iii) has assets that are invested in Equity Interests of the Company or any Subsidiaries or any of their respective ERISA Affiliates, (iv) provides welfare benefits to terminated employees, other than to the extent required by section 4980B(f) of the Code and the corresponding provisions of ERISA or similar local law (other than employer-subsidized COBRA premiums whereby the terminated employee pays no less than active employee rates), or (v) provides medical insurance, dental insurance, vision insurance, life insurance or long-term disability benefits and is not fully insured by a third-party insurance company. The term "Benefit Plan" excludes (A) any defined contribution retirement plan, (B) any medical insurance, dental insurance, vision insurance, life insurance or long-term disability benefits that are fully insured by a third-party insurance company, (C) any plan sponsored by a governmental entity to which the employer's only obligation is to make legally required contributions and (D) any equity incentive plan and any award granted thereunder; provided that such equity incentive plan was approved by the Board of the Company (or a committee thereof).

"Board" means the Board of Directors of the Company or board of directors or similar governing body of any Subsidiary, as applicable.

"Board of Governors" means the Board of Governors of the United States Federal Reserve System, or any successor thereto.

"Books" means all books and records including ledgers, records regarding an Obligor's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Brensocatib" means any proposed or approved pharmaceutical product owned or controlled by Purchaser that contains as an active ingredient brensocatib, in any form, for any indication including treatment of cystic fibrosis and related conditions, non-cystic fibrosis bronchiectasis and related conditions, or any other lung disease, disorder or condition.

"Business Day" means any day other than a Saturday, a Sunday, any day which is a legal holiday under the laws of the State of New York, or any day on which banking institutions located in the State of New York are required by law or other governmental action to close.

"Buy-Out Price" means, as of any date of determination:

(a) in the case of an exercise by the Company or the Purchaser of a Change of Control Purchase Option, (i) if such Change of Control Purchase Option is consummated on or before the 18 month anniversary of the Closing Date, an amount equal to 125.0% of the Purchase Price (i.e., $187,500,000), (ii) if such Change of Control Purchase Option is consummated after the 18 month anniversary of the Closing Date but on or before the 24 month anniversary of the Closing Date, an amount equal to 130.0% of the Purchase Price (i.e., $195,000,000), (iii) if such Change of Control Purchase Option is consummated after the 24 month anniversary of the Closing Date but on or before the 36 month anniversary of the Closing Date, an amount equal to 150.0% of the Purchase Price (i.e., $225,000,000), and (iv) if such Change of Control Purchase Option is consummated after the 36 month anniversary of the Closing Date, an amount equal to 180.0% of the Purchase Price (i.e., $270,000,000), minus, in each case, the sum of all Revenue Interest Payments made by the Company to the Purchaser prior to the consummation of such Change of Control Purchase Option (which, for avoidance of doubt, shall exclude any payment of interest made in accordance with Section 2.02(d)); provided that the Buy-Out Price shall not be less than zero;

(b) in the case of an exercise by the Company of any Call Option other than a Change of Control Call Option (i) if such Call Option is consummated on or before the eighth (8th) anniversary of the Closing Date, an amount equal to 180% of the Purchase Price (i.e., $270,000,000.00), and (ii) if such Call Option is consummated after the eighth (8th) anniversary of the Closing Date, an amount equal to 190% of the Purchase Price (i.e., $285,000,000.00), minus, in each case, the sum of all Revenue Interest Payments made by the Company to the Purchaser prior to the consummation of such Call Option (which, for avoidance of doubt, shall exclude any payment of interest made in accordance with Section 2.02(d)); provided that the Buy-Out Price shall not be less than zero; and

(c) in the case of an exercise by the Purchaser of its Put Option (other than under clause (d) of the definition of "Put Option Event"), (i) if such Put Option is exercised on or before the eighth (8th) anniversary of the Closing Date, an amount equal to 180% of the Purchase Price (i.e., $270,000,000.00), and (ii) if such Put Option is exercised after the eighth (8th)

anniversary of the Closing Date, an amount equal to 190% of the Purchase Price (i.e., $285,000,000.00)minus, in each case, the sum of all Revenue Interest Payments made by the Company to the Purchaser prior to the exercise of such Call Option, as applicable (which, for avoidance of doubt, shall exclude any payment of interest made in accordance with Section 2.02(d)); provided that the Buy-Out Price shall not be less than zero.

For the avoidance of doubt, the Buy-Out Price shall be calculated as of the date such Buy-Out Price is required to be paid.

"Call Closing Date" has the meaning set forth inSection 5.07(b).

"Call Option" has the meaning set forth inSection 5.07(b).

"Capital Lease" means, as applied to any Person, any lease of, or other arrangement conveying the right to use, any property by that Person as lessee that has been or should be accounted for as a capital lease on a balance sheet of such Person prepared in accordance with GAAP.

"Capital Lease Obligations" means, at any time, with respect to any Capital Lease, any lease entered into as part of any sale leaseback transaction of any Person or any synthetic lease, the amount of all obligations of such Person that is (or that would be, if such synthetic lease or other lease were accounted for as a Capital Lease) capitalized on a balance sheet of such Person prepared in accordance with GAAP.

"Cash Equivalents" means:

(a) securities issued or directly and fully guaranteed or insured by the United States government or any agency or instrumentality of the United States government or by the government of any other member country of the Organisation for Economic Co-operation and Development ("OECD") (provided that the full faith and credit of the United States or such other member country of OECD, as applicable, is pledged in support of those securities) or any agency or instrumentality of the OECD, in each case, having maturities of not more than two (2) years from the date of acquisition;

(b) certificates of deposit, time deposits with maturities of one year or less from the date of acquisition, bankers' acceptances with maturities not exceeding one year and overnight bank deposits and demand deposits, in each case, with any commercial bank having (i) capital and surplus in excess of $500,000,000 in the case of U.S. banks or (ii) capital and surplus in excess of $100,000,000 (or the U.S. dollar equivalent as of the date of determination) in the case of non-U.S. banks or a rating for its long-term unsecured and noncredit enhanced debt obligations of "A" or higher by Standard & Poor's Rating Services or Fitch Ratings Ltd or "A2" or higher by Moody's Investors Service Limited;

(c) commercial paper or marketable short-term money market or readily marketable direct obligations and similar securities having a credit rating of either A-1 or higher by Standard & Poor's Rating Service or F1 or higher by Fitch Ratings Ltd or P-1 or higher Moody's Investors Service Limited, and, in each case, maturing within two (2) years after the date of acquisition;

(d) repurchase obligations with a term of not more than seven (7) days for underlying securities of the types described in clauses (a) and (c) above entered into with any financial institution meeting the qualifications specified inclause (b) above;

(e) investment funds investing ninety-five percent (95.0%) of their assets in securities of the types described in clauses (a) through (d) above and clause (f) below;

(f) investments in money market funds which have a credit rating of either A-1 or higher by Standard & Poor's Rating Service or F1 or higher by Fitch Ratings Ltd or P-1 or higher by Moody's Investors Service Limited (or, if at any time none of Fitch Ratings Ltd, Moody's Investors Service Limited or Standard & Poor's Rating Service shall be rating such obligations, an equivalent rating from another rating agency) and that have portfolio assets of at least $1,000,000,000; and

(g) other investments in accordance with the Company's investment policy as of the Closing Date or otherwise approved in writing by the Purchaser (such approval not to be unreasonably withheld, conditioned or delayed).

"CCPA" means the provisions and implementing regulations of the California Consumer Privacy Act, as amended and codified at Cal. Civ. Code § 1798.100 *et seq*.

"Change in Law" means the occurrence, after the Closing Date (or, with respect to any successors or assigns of the Purchaser, after the date such Person acquires its interest hereunder), of any of the following: (a) the adoption or taking effect of any law, rule, regulation or treaty, (b) any change in any law, rule, regulation or treaty or in the administration, interpretation, implementation or application thereof by any court or other Governmental Authority or (c) the making or issuance of any request, rule, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided that notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to be a "Change in Law", regardless of the date enacted, adopted or issued.

"Change of Control" means, at any time, the occurrence of any of the following events or circumstances:

(a) the acquisition by any "person" or "group" (within the meaning of Sections 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended) of beneficial ownership of any Equity Interests of the Company, if after such acquisition, such "person" or "group" would be the "beneficial owner" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities entitled to vote generally in the election of directors;

(b) a merger or consolidation of the Company with any other Person, other than a merger or consolidation of the Company in which the Company is the surviving Person and in which the persons holding more than fifty percent (50%) of the combined voting power of the Company's voting securities outstanding immediately prior to such merger or consolidation, continue to hold at least fifty percent (50%) of the combined voting power of the Company's voting securities outstanding immediately after such merger or consolidation; or

(c) any Transfer of all of the assets of the Company and its Subsidiaries on a consolidated basis to a Third Party.

"Change of Control Call Option" means a Call Option exercised by the Company in connection with a Change of Control; provided that no Call Option shall qualify as a Change of Control Call Option unless the Buy-Out Price payable in connection therewith is paid in full in cash no earlier than the date on which the related Change of Control is consummated and no later than two (2) days following such date of consummation.

"Change of Control Purchase Option" means a Change of Control Call Option or a Put Option exercised by the Purchaser pursuant to clause (d) of the definition of Put Option Event.

"Clinical Trial" means any clinical trial or investigation of any Specified Product conducted by or on behalf of the Company or any Subsidiary.

"Clinical Updates" means material information and developments with respect to each Clinical Trial.

"Closing Date" means October 19, 2022.

"CMIA" means the California Confidentiality of Medical Information Act, Cal. Civ. Code pt. 2.6 § 56*et seq*.

"Code" means the U.S. Internal Revenue Code of 1986, as amended.

"Collateral" means collectively, "Collateral", as such term is defined in the Guaranty and Security Agreement, "Collateral," as such term is defined in the Dutch Security Documents, "Secured Assets," as such term is defined in the Irish Security Documents and "Pledged Portfolio," as such term is defined in the Japanese Equity Pledge, any tangible or intangible assets, equity or other property pledged or assigned for security purposes, as the case may be, under the Swiss Security Documents, any tangible or intangible assets, equity or other property pledged under the English Security Documents, and any and all other assets and properties of whatever kind and nature subject or purported to be subject from time to time to a Lien under any Security Document, but in any event excluding all Excluded Property (as defined in the Guaranty and Security Agreement).

"Collateral Account" means any Deposit Account of an Obligor maintained with a bank or other depository or financial institution located in the United States, any Securities Account of an Obligor maintained with a securities intermediary located in the United States, or any Commodity Account of an Obligor maintained with a commodity intermediary located in the United States, in each case, other than an Excluded Account.

"Commercial Updates" means material information and developments with respect to the Company's Commercialization plans and prospects for the Specified Products.

"Commercialization" means any and all activities, other than Manufacturing, directed to the preparation for sale of, or sale of any Specified Product, including activities related to

marketing, promoting, distributing, and importing any such Specified Product, and interacting with Regulatory Agencies regarding any of the foregoing. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization, and "Commercialized" has a corresponding meaning.

"Company" has the meaning set forth in the first paragraph hereof.

"Competitor" means, at any time of determination, any Person (and the Affiliates of such Person) that is directly and primarily engaged in the same, substantially the same, or similar line of business as the Company and its Subsidiaries as of such time.

"Confidential Information" means all confidential business information, financial data and other like information and other proprietary information or material, together with such other information that either party identifies to the other as confidential or the nature of which or the circumstances of the disclosure of which could reasonably indicate that such information is confidential.

"Contingent Obligation" means, for any Person, (a) any direct or indirect liability, contingent or not, of that Person for any indebtedness, lease, dividend, letter of credit or other obligation of another Person directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable (other than by endorsements of instruments in the course of collection) and (b) any obligation of that Person to pay an earn-out payment, milestone payment or ~~similar~~ other contingent payment or contingent compensation (including purchase price adjustments ~~but excluding~~, royalties and milestone payments payable and ~~sales milestones based on~~upon achievement of levels of net sales) to a counterparty incurred or created in connection with an Acquisition, Transfer or, Investment or otherwise in connection with any license, collaboration, development or similar agreement, in each instance where such contingent payment or compensation becomes due and payable upon the occurrence of an event or the performance of an act (and not solely with the passage of time). The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the amount required to be shown as liability on the balance sheet of such Person in accordance with GAAP (or, if not required to be so shown, the maximum reasonably anticipated amount reasonably determined by a Responsible Officer of such Person in good faith); but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement. Notwithstanding anything to the contrary in the foregoing, Permitted Equity Derivatives shall not constitute a Contingent Obligation.

"Control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of a Person, whether through the ability to exercise voting power, by contract or otherwise; provided that with respect to any Intellectual Property, "control" means that the applicable Persons owns or has a license to such item or right and has the ability to grant to a party a license, sublicense, or rights of access and use under such item or right without (a) violating the terms or conditions of any agreement or other arrangement between such Person and any Third Party in existence as of the time such party would be required hereunder to grant such license, sublicense, or rights of access and use, and (b) paying

any consideration to any Third Party. “Controlling” and “Controlled” have meanings correlative thereto.

“Control Agreement” means, with respect to any Deposit Account, Securities Account, Commodity Account, securities entitlement or commodity contract, an agreement, in form and substance reasonably satisfactory to the Purchaser, among the Purchaser, the Term Loan Agent (if the obligations of the Company under the Term Loan Agreement have not been paid in full), the financial institution or other Person located in the United States at which such account is maintained or with which such entitlement or contract is carried and the Obligor maintaining such account, effective to grant “control” (as defined under the relevant UCC) over such account to the Purchaser (or to the Intercreditor Agent), subject to the terms of the Intercreditor Agreement as applicable.

“Convertible Indebtedness Scheduled Maturity Date” means (i) with respect to the ~~2025 Convertible Notes and the~~ 2028 Convertible Notes~~, as applicable~~, the respective scheduled maturity date for the Indebtedness evidenced thereby as in effect on the date hereof, and (ii) with respect to any other Permitted Convertible Indebtedness, the scheduled maturity date (or equivalent) therefore as in effect as of the date of issuance thereof.

“CPRA” means the California Privacy Rights Act.

“Data Processors” means any Third Party service providers, software developers, outsourcers, or others to which Company or its Subsidiaries engage and allow access to Personal Data or IT Assets (including, for clarity, all information and transactions stored or contained therein or transmitted thereby).

“Data Protection Laws” means any and all applicable foreign or domestic (including U.S. federal, state and local), statutes, ordinances, orders, rules, regulations, judgments, Regulatory Approvals, or any other requirements of Governmental Authorities relating to the privacy, security, notification of breaches or confidentiality of Personal Data, including, to the extent applicable to the Company or any of its Subsidiaries, HIPAA, Section 5 of the FTC Act and other consumer protection laws, GDPR, APPI, CCPA, CPRA and other comprehensive state privacy laws, CMIA and other U.S. state medical information privacy laws and genetic testing laws.

“Development” means all activities related to discovery, research, development, creation and prosecution of Intellectual Property, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Agency as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, “Develop” means to engage in Development.

"Disclosure Letter" means that certain Confidential Disclosure Letter, dated as of the Closing Date, delivered by the Company to the Purchaser.

"Dispute" has the meaning set forth inSection 3.11(d).

"Disqualified Equity Interests" means Equity Interests that, by their terms (or by the terms of any security or other Equity Interest into which they are convertible or for which they are exchangeable), or upon the happening of any event or condition, (a) mature (excluding any maturity as the result of an optional redemption by the issuer thereof) or are mandatorily redeemable, pursuant to a sinking fund obligation or otherwise, or are redeemable at the option of the holder thereof, in whole or in part, (b) are convertible into or exchangeable for (i) debt securities or (ii) any Equity Interests referred to in clause (a) above, (c) contain any repurchase obligation or (d) provide for required scheduled payments or the payment of cash dividends or distributions; provided that if such Equity Interests are issued pursuant to a plan for the benefit of the Company or any Subsidiary or their directors, officers, employees and/or consultants or by any such plan to directors, officers, employees or consultants of the Company or any Subsidiary, such Equity Interests shall not constitute Disqualified Equity Interests solely because they may be required to be repurchased by the Company or any Subsidiary in order to satisfy applicable statutory or regulatory obligations or as a result of such director, officer, employee or consultant's termination, death or disability.

"Disqualified Persons" has the meaning set forth in the definition of "Eligible Assignee".

"Domestic Subsidiary" means any Subsidiary that is incorporated or organized under the laws of the United States.

"Drug Approval Application" means a New Drug Application as defined in the FFDCA, or any analogous foreign application.

"Dutch CC" means the Dutch Civil Code (*Burgerlijk Wetboek*).

"Dutch Obligor" means any Subsidiary Guarantor which is incorporated or established under Dutch law.

"Dutch Security Documents" means

(d) the Dutch law governed deed of pledge of receivables, moveable assets and IP security assets between (i) Insmed Netherlands B.V. as a pledgor, (ii) Insmed Netherlands Holdings B.V., as a pledgor and (ii) the Purchaser as pledgee; and

(e) the Dutch law governed deed of pledge of shares in the capital of Insmed Netherlands B.V. between Insmed Ireland Limited as pledgor, the Purchaser as pledgee and Insmed Netherlands B.V. as company.

"Electronic Signature" means an electronic sound, symbol or process attached to, or associated with, a contract or other record and adopted by a Person with the intent to sign, authenticate or accept such contract or record.

"Eligible Assignee" is (i) the Purchaser, (ii) any Affiliate of the Purchaser or any fund or investment vehicle managed by the Purchaser or an Affiliate of the Purchaser or under common management with the Purchaser and (iii) any Person that, to the knowledge of the Purchaser, is a "qualified institutional buyer" (as defined in Rule 144A under the Securities Act of 1933, as amended) or an "accredited investor" (as defined in Rule 501(a)(1), (2), (3) or (7)) with assets under management (together with its Affiliates) of at least $150,000,000, as determined by the Purchaser in its good faith discretion; provided that, notwithstanding the foregoing, "Eligible Assignee" shall not include, unless a Put Option Event has occurred and is continuing, (x) any Competitor, (y) any Person identified to the Purchaser by the Company in writing on or prior to the Closing Date, and in case any Affiliate thereof that is identifiable as such by name (or otherwise known to the Purchaser to be an Affiliate of such Person), or (z) any stockholder activist fund (each such Person described in clauses (x), (y) and (z), collectively, "Disqualified Persons").

"ENCORE Event" means the occurrence of a statistically significant improvement in the change from baseline to Month 13 in the respiratory symptom score and the proportion of subjects achieving durable culture conversion at Month 15 between the ARIKAYCE® treatment group and the placebo control group

"English Obligor" means Insmed Ltd.

"English Security Documents" means:

(a) the English law governed debenture dated 22 February 2024 between (i) Insmed Innovation UK Ltd. as chargor and (ii) the Purchaser; and

(b) the English law governed share charge dated 22 February 2024 between (i) Insmed Incorporated as chargor and (ii) the Purchaser.

"Environmental Laws" means any and all federal, state, local, foreign and other applicable statutes, laws, regulations, ordinances, rules, judgments, orders, decrees, permits, concessions, grants, franchises, licenses, agreements or governmental restrictions relating to pollution and the protection of the environment or the release of any materials into the environment, including those related to hazardous substances or wastes, air emissions and discharges to waste or public systems.

"Equity Cash Proceeds" means, with respect to any issuance of Equity Interests after the Closing Date, the amount in excess of $[***] in cash proceeds (net of reasonable costs associated therewith) actually received by the Company from all such issuances, which have not been previously used to redeem Permitted Convertible Indebtedness.

"Equity Interests" means any and all shares, interests, participations or other equivalents (however designated) of equity interests of a corporation, any and all equivalent ownership interests in a Person other than a corporation (including, without limitation, partnership interests, membership interests and similar ownership interests), any and all warrants, rights or options to purchase or other arrangements or rights to acquire any of the foregoing, and all other ownership or profit interests in a Person (including partnership, member or trusts interests in such Person),

in each case whether voting or non-voting and whether or not outstanding on any date of determination.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended from time to time.

"ERISA Affiliate" means, as applied to any Person, (i) any corporation that is a member of a controlled group of corporations within the meaning of section 414(b) of the Code of which that Person is a member, (ii) any trade or business (whether or not incorporated) that is a member of a group of trades or businesses under common control within the meaning of section 414(c) of the Code of which that Person is a member, or (iii) any member of an affiliated service group within the meaning of section 414(m) or 414(o) of the Code of which that Person, any corporation described in clause (i) above or any trade or business described in clause (ii) above is a member.

"EU" means the European Union.

"EU GDPR" has the meaning set forth in the definition of "GDPR"

"EU5 Countries" means, collectively, the United Kingdom, Germany, France, Spain and Italy.

"Excluded Accounts" means (a) accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of any Obligor's employees, (b) zero balance accounts; provided that, within two (2) Business Days of any deposit made into any such zero balance account, such deposit is swept in full to an account subject to a Control Agreement, (c) accounts (including trust accounts) used exclusively for escrow, customs, insurance or fiduciary purposes, (d) merchant accounts, (e) accounts used exclusively for compliance with any Applicable Law to the extent such Applicable Law prohibits the granting of a Lien thereon, (f) accounts which constitute cash collateral in respect of a Permitted Lien and (g) any other account, established or maintained in the ordinary course of business or in furtherance of a bona fide general corporate purpose, designated as an Excluded Account by a Responsible Officer of the Company in writing delivered to the Purchaser, with respect to which the aggregate amount on deposit at any time in aggregate with all other such accounts excluded under this clause (g), does not exceed $[***].

"Excluded Liabilities" has the meaning set forth inSection 2.04.

"Excluded Subsidiaries" means, collectively: (i) any Subsidiary with respect to which the grant to the Purchaser of a security interest in and Lien upon, and the pledge to the Purchaser of such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Transaction Document and the Equity Interests in such Subsidiary to secure the Obligations (and any guaranty thereof) are validly prohibited by Applicable Laws (for the avoidance of doubt, not including the organizational or governing documents of such Subsidiary, except to the extent covered in clause (ii) or (iii) below); (ii) any Subsidiary with respect to which the grant to the Purchaser of a security interest in and Lien upon, and the pledge to the

Purchaser, of, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Transaction Document and the Equity Interests in such Subsidiary to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party (other than the Company or an Affiliate of the Company) and any such consent, approval or waiver has not been obtained, directly or indirectly, by the Company following the Company's direct and indirect commercially reasonable efforts to obtain the same; (iii) any Subsidiary that is a non-Wholly-Owned Subsidiary, with respect to which, the grant to the Purchaser of a security interest in and Lien upon, and the pledge to the Purchaser of the properties and assets of such non-Wholly-Owned Subsidiary to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than the Company or an Affiliate of the Company) the right to terminate its obligations under, such non-Wholly-Owned Subsidiary's Organization Documents or the joint venture agreement or shareholder agreement with respect thereto or any other contract with such third party relating to such non-Wholly-Owned Subsidiary, including any contract evidencing Indebtedness of such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Applicable Laws), but only, in each case, to the extent, and for so long as such Organization Document, joint venture agreement, shareholder agreement or other contract is in effect; (iv) any Subsidiary that owns properties and assets with an aggregate fair market value (as reasonably determined in good faith by a Responsible Officer of the Company) of less than $[***]; (v) each of (A) Celtrix Pharmaceuticals, Inc., (B) any Foreign Subsidiary organized under the laws of France, the United Kingdom, Italy or Germany and existing as of the Closing Date, and (C) any other Subsidiary not organized in Japan, Ireland, the Netherlands, Switzerland and the United States, unless, in each case of sub-clauses (A), (B) and (C) above, such Subsidiary at any time (w) owns, co-owns or otherwise maintains any material Intellectual Property, (x) licenses any Product Intellectual Property from any third party, (y) enters into any Material Contract or otherwise becomes a party thereto or bound thereby or (z) otherwise engages in any business operations material to any aspect of the research, development, manufacture, production, use, Commercialization, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Product (in which case the parties hereto agree that any such Subsidiary shall constitute an Obligor for all purposes under the Transaction Documents as of the date of such ownership, co-ownership, maintenance, license, entry or becoming so bound, or engagement); and (vi) any other Subsidiary with respect to which, the Company and the Purchaser reasonably determine by mutual agreement that the cost (including Tax costs) of granting the Purchaser, a security interest in and Lien upon, and pledging to the Purchaser such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Transaction Document and the Equity Interests of such Subsidiary to secure the Obligations (and any guaranty thereof) are excessive relative to the value to be afforded to the Purchaser. Notwithstanding the foregoing or any other provision of this Agreement, no Subsidiary existing as of the Closing Date or organized, formed or acquired, directly or indirectly, by any Obligor from and after the Closing Date (including any Intercompany Reorganization Subsidiary), that (A) owns, co-owns or otherwise maintains any material Product Assets, (B) licenses any Product Intellectual Property from any third party, (C) enters into any Material Contract or otherwise becomes a party thereto or bound thereby or (D) otherwise engages in any business operations material to any aspect of the research,

development, Manufacture, production, use, Commercialization, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of any Specified Product in the United States, Japan, France, Germany, Italy Spain or the United Kingdom shall be (or shall be deemed to be) an Excluded Subsidiary without the prior written consent of the Purchaser.

"Excluded Taxes" means any of the following Taxes imposed on or with respect to the Purchaser or required to be withheld or deducted from a payment to the Purchaser: (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed as a result of the Purchaser being organized under the laws of, or having its principal office or its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes; (b) U.S. federal withholding Taxes imposed on amounts payable to or for the account of the Purchaser with respect to an applicable interest in the Obligations (i) to the extent they are imposed pursuant to a law in effect on the date on which (A) the Purchaser acquires such interest in the Obligations or (B) the Purchaser changes its applicable lending office, except in each case to the extent that, pursuant to Section 2.05, amounts with respect to such Taxes were payable either to the Purchaser's assignor immediately before such Purchaser became a party hereto or to such Purchaser immediately before it changed its applicable lending office, or (ii) because the transactions hereunder are not treated in accordance with the Intended Tax Treatment as a result of any administrative or judicial decision; provided that in such case such U.S. federal withholding Taxes shall be Excluded Taxes only to the extent such U.S. federal withholding Taxes exceed the amount of U.S. federal withholding Taxes (if any) imposed that would not be Excluded Taxes if the Intended Tax Treatment had applied; (c) Taxes attributable to the Purchaser's failure to comply with Section 2.05(e); and (d) any withholding Taxes imposed under FATCA.

"Exclusive License" means any outbound License of Product Intellectual Property that (i) is exclusive (whether as to use, field, geography or otherwise) within the United States and (ii) has a term that is longer than twelve (12) months from the date of the original effective date of such License or is subject to any automatic renewal right or similar obligation binding on the parties thereto that would cause the term of such License to extend automatically beyond such twelve (12) month period.

"Export and Import Laws" means any applicable law, regulation, order or directive that applies to the import, export, re-export, transfer, disclosure or provision of goods, software, technology or technical assistance including, without limitation, restrictions or controls administered pursuant to the U.S. Export Administration Regulations, 15 C.F.R. Parts 730-774, administered by the U.S. Department of Commerce, Bureau of Industry and Security; U.S. Customs regulations; and similar import and export laws, regulations, orders and directives of other jurisdictions to the extent applicable.

"FATCA" means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official

interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Code and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Code.

"FCPA" has the meaning set forth in Section 3.21(a).

"FDA" means the United States Food and Drug Administration or any successor federal agency thereto.

"FDA Approval Date" means the date on which the FDA has granted approval (including accelerated approval) of an NDA for brensocatib in any form for the treatment of bronchiectasis, or an indication that is substantially the same.

"FFDCA" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

"Financial Statements" means (a) the audited consolidated balance sheets of the Company as of December 31, 2021 and 2020 and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and shareholders' (deficit) equity and cash flows for the years then ended (the "Audited Financial Statements"), (b) the unaudited balance sheets of the Company as of March 31, 2022 and June 30, 2022 and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' (deficit) equity and cash flows for the three (3) month periods then ended (the "Interim Financial Statements") and (c) each financial statement delivered pursuant to Section 5.02(b).

"Foreign Subsidiary" means any Subsidiary that is not a Domestic Subsidiary.

"Foreign Security Documents" means the Irish Security Documents, the Dutch Security Documents, the Swiss Security Documents, the Japanese Security Documents, the English Security Documents and any other pledge, security or other collateral agreement pursuant to which the assets owned by a Foreign Subsidiary are made subject to a Lien in favor of the Purchaser and which is governed by the laws of the jurisdiction in which such Foreign Subsidiary is formed, in each case in form and substance reasonably satisfactory to the Purchaser and in each case as amended, restated, supplemented or otherwise modified from time to time.

"GAAP" means generally accepted accounting principles in the United States in effect from time to time. Notwithstanding anything in this Agreement to the contrary, for purposes of determining compliance with any covenant contained in Section 5 or the existence of any Put Option Event, in determining whether any lease is required to be accounted for as a capital lease or an operating lease, such determination shall be made based on GAAP as in effect prior to the issuance by the Financial Accounting Standards Board on February 25, 2016 of Accounting Standards Update No. 2016-02.

"GDPR" means, collectively, (i) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (the "EU GDPR") and (ii) the EU GDPR as it forms part of the laws of the United Kingdom by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (the "UK GDPR").

"Governmental Authority" means any nation or government, any state or other political subdivision thereof, any agency (including Regulatory Agencies, data protection authorities, and agencies acting as supervisory governmental organizations on issues of privacy protection), government department, authority (including state attorneys general), instrumentality, regulatory body, ministry, commission, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization, whether U.S. or non-U.S., federal, state, provincial, local or supranational (domestic or foreign), including each Patent Office, the FDA, the United States National Institutes of Health or non-U.S. equivalent, the Centers for Medicare and Medicaid Services, the United States Department of Health and Human Services Office of the Inspector General, and the United States Department of Justice.

"Guarantee" of or by any Person (the "guarantor") means any obligation, contingent or otherwise, of the guarantor guaranteeing or having the economic effect of guaranteeing any Indebtedness or other obligation of any other Person (the "primary obligor") in any manner, whether directly or indirectly, and including any obligation of the guarantor, direct or indirect, (a) to purchase or pay (or advance or supply funds for the purchase or payment of) such Indebtedness or other obligation or to purchase (or to advance or supply funds for the purchase of) any security for the payment thereof, (b) to purchase or lease property, securities or services for the purpose of assuring the owner of such Indebtedness or other obligation of the payment thereof, (c) to maintain working capital, equity capital or any other financial statement condition or liquidity of the primary obligor so as to enable the primary obligor to pay such Indebtedness or other obligation or (d) as an account party in respect of any letter of credit or letter of guaranty issued to support such Indebtedness or obligation; provided that the term Guarantee shall not include endorsements for collection or deposit in the ordinary course of business.

"Guaranty and Security Agreement" means the Second Lien Guaranty and Security Agreement, dated as of October 19, 2022, by and among the Company, each Subsidiary Guarantor and the Purchaser providing for, among other things, the grant by the Company in favor of the Purchaser of a valid continuing, perfected Lien on and security interest in the Collateral described therein, which shall be substantially in the form of Exhibit A, as amended, restated, supplemented or otherwise modified from time to time.

"Hedging Agreement" means any interest rate, currency, commodity or equity swap, collar, cap, floor or forward rate agreement, or other agreement or arrangement designed to protect a Person against fluctuations in interest rates, currency exchange rates or commodity or equity prices or values (including any option with respect to any of the foregoing and any

combination of the foregoing agreements or arrangements), and any confirmation execution in connection with any such agreement or arrangement. Notwithstanding anything to the contrary in the foregoing, any Permitted Equity Derivative shall not constitute a Hedging Agreement.

"Indebtedness" means, with respect to any Person, without duplication: (a) all indebtedness for advanced or borrowed money of, or credit extended to, such Person; (b) all obligations issued, undertaken or assumed by such Person as the deferred purchase price of assets, properties, services or rights (other than (i) accrued expenses and trade payables entered into in the ordinary course of business which are not more than one hundred and eighty (180) days past due or subject to a bona fide dispute, (ii) obligations to pay for services provided by employees and individual independent contractors in the ordinary course of business which are not more than one hundred and twenty (120) days past due or subject to a bona fide dispute, (iii) liabilities associated with customer prepayments and deposits, and (iv) prepaid or deferred revenue arising in the ordinary course of business), including (A) any obligation or liability to pay deferred purchase price or other similar deferred consideration for such assets, properties, services or rights where such deferred purchase price or consideration becomes due and payable solely upon the passage of time, and (B) any obligation described in clause (b) of the definition of "Contingent Obligation"; (c) the face amount of all letters of credit issued for the account of such Person and, without duplication, all drafts drawn thereunder and all reimbursement or payment obligations with respect to letters of credit, surety bonds, performance bonds and other similar instruments issued by such Person; (d) all obligations of such Person evidenced by notes, bonds, debentures or other debt securities or similar instruments (including debt securities convertible into Equity Interests, including Permitted Convertible Indebtedness), including obligations so evidenced incurred in connection with the acquisition of properties, assets or businesses; (e) all indebtedness of such Person created or arising under any conditional sale or other title retention agreement or incurred as financing, in either case with respect to property acquired by such Person (even though the rights and remedies of the seller or bank under such agreement in the event of default are limited to repossession or sale of such property); (f) all Capital Lease Obligations of such Person; (g) the principal balance outstanding under any synthetic lease, off-balance sheet loan or similar off balance sheet financing product by such Person; (h) Disqualified Equity Interests; (i) all indebtedness referred to in clauses (a) through (g) above of other Persons secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien upon or in assets or properties (including accounts and contracts rights) owned by such Person, even though such Person has not assumed or become liable for the payment of such indebtedness of such other Persons; and (i) all Contingent Obligations of such Person described in clause (a) of the definition thereof. For the avoidance of doubt, "Indebtedness" shall include Permitted Convertible Indebtedness, but shall not include any Permitted Equity Derivative.

"Indemnified Liabilities" means, collectively, all Excluded Liabilities and any and all liabilities, obligations, losses, assessments, awards, causes of action, damages, penalties, claims, charges, fines, judgments, reasonable and documented costs, expenses and disbursements of any kind or nature whatsoever (including reasonable and documented expenses of investigation and the reasonable and documented fees and disbursements of counsel for Indemnified Parties), whether direct, indirect or consequential, whether based on any federal, state or foreign laws,

statutes, rules or regulations (including securities and commercial laws, statutes, rules or regulations), on common law or equitable cause or on contract or otherwise, imposed on, incurred by, or asserted against any such Indemnified Party, in any manner relating to or arising out of this Agreement or the other Transaction Documents or the transactions contemplated hereby or thereby (including any enforcement of any of the Transaction Documents (including any sale of, collection from, or other realization upon any of the Collateral)).

"Indemnified Party" has the meaning set forth inSection 7.04(a).

"Indemnified Taxes" means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of any Obligor under any Transaction Document and (b) to the extent not otherwise described in (a), Other Taxes.

"Intellectual Property" means all intellectual property and other proprietary rights of any kind or nature, whether registered or unregistered and whether registrable or not, protected, created or arising under any law, including any and all rights in: proprietary information; technical data; laboratory notebooks; clinical data; priority rights; regulatory rights providing full or partial market exclusivity such as the U.S. Orphan Drug Exclusivity, "GAIN" exclusivity, Pediatric Exclusivity and any similar right in the U.S. and non-U.S.; Trade Secrets; know-how; confidential information; inventions (whether patentable or unpatentable and whether or not reduced to practice or claimed in a pending patent application); Patents; registered or unregistered trademarks, trade names, service marks, trade dress, logos, slogans, including all goodwill associated therewith; domain names; registered and unregistered copyrights and all applications thereof and all rights in works of authorship of any type, in all forms or media, designs rights, registered designs, database rights and rights in compilations of data.

"Intellectual Property Updates" means a summary, prepared in reasonable detail, of any new Patents, trademarks or copyrights issued or patent, trademark or copyright applications filed, amended or supplemented, constituting Product Intellectual Property (in form sufficient to allow Purchaser to prepare appropriate filings in respect thereof to protect its Liens thereon).

"Intended Tax Treatment" has the meaning set forth inSection 5.12(b).

"Intercreditor Agent" means BioPharma Credit PLC, acting as gratuitous bailee and non-fiduciary agent on behalf of, and for the benefit of, the Purchaser, and its successors and assigns.

"Intercreditor Agreement" means the Intercreditor Agreement, dated as of the date hereof, by and between the Intercreditor Agent and the Purchaser, and acknowledged and agreed to by the Company, as may be amended, restated, amended and restated, supplemented, replaced or otherwise modified from time to time in accordance with the terms set forth therein.

"Intercompany Reorganization" means any and all entity formations, asset transfers, capital contributions, Indebtedness, licensing and supply transactions and any other arrangements solely between or among the Company and its Wholly-Owned Subsidiaries or Company's Wholly-Owned Subsidiaries, to effect the reorganization of the organizational structure or capital structure of the Company and its Subsidiaries for the purpose of optimizing the overall economic

performance and efficiency of the Company and its Subsidiaries as a whole, to occur and be consummated: (a) on or before March 31, 2023 as to the agreements and transactions described on Exhibit B hereto; and (b) thereafter; provided, however, that in each case under clause (b) above, such formation, transfer, contribution, Indebtedness, transaction or arrangement has been approved by the Purchaser prior to the consummation thereof, such approval not to be unreasonably withheld or delayed.

"Intercompany Reorganization Subsidiary" means any direct or indirect Wholly-Owned Subsidiary of the Company that is formed pursuant to the Intercompany Reorganization.

"Intercompany Subordination Agreement" means that certain Intercompany Subordination Agreement, dated as of the Closing Date, by and among the Company, its Subsidiaries party thereto, the Term Loan Agent and the Purchaser, as may be amended, restated, supplemented or otherwise modified from time to time.

"Interim Financial Statements" has the meaning set forth in the definition of "Financial Statements".

"Investment" means, with respect to any Person, (a) any investment by such Person in any other Person in the form of loans, guarantees, advances or other extensions of credit (excluding accounts receivable arising in the ordinary course of business), capital contributions or acquisitions of Indebtedness (including, any bonds, notes, debentures or other debt securities), (b) beneficial ownership interests in any Equity Interests of such Person, or (c) any Acquisition of such Person. The amount of any Investment shall be the original cost of such Investment plus the cost of all additions thereto, without any adjustments for increases or decreases in value, or write-ups, write-downs or write-offs with respect to such Investment.

"Irish Companies Act" means the Companies Act 2014 of Ireland.

"Irish Debenture" means the Irish law governed debenture by and among the Irish Obligors and the Purchaser, in form and substance reasonably satisfactory to the Purchaser, as amended, restated, supplemented or otherwise modified from time to time.

"Irish Security Documents" means the Irish Debenture and the Irish Share Charge.

"Irish Share Charge" means the Irish law governed share charge by the Company and the Purchaser, in form and substance reasonably satisfactory to the Purchaser, as amended, restated, supplemented or otherwise modified from time to time.

"Irish Obligors" means Insmed Holdings Limited and Insmed Ireland Limited.

"Japanese Equity Pledge" means Second Lien Membership Interest Pledge Agreement, dated as of ~~the Closing Date~~ October 31, 2024, by and among ~~the Company~~ Insmed Netherlands Holdings B.V., as pledgor, the Purchaser, as pledgee, and the Japanese Obligor, as amended, restated, supplemented or otherwise modified from time to time.

"Japanese Obligor" means Insmed Godo Kaisha.

"Japanese Security Documents" means the Japanese Equity Pledge, and any other documents designated as a Japanese Security Documents by the Purchaser and the Company (or that is specified in such document as being a Japanese Security Documents).

"IT Assets" means the computers and other information technology infrastructure and assets used by the Company or any of the Subsidiaries in the conduct of their business as operated and as proposed to be operated.

"Knowledge" means the actual knowledge, after reasonable inquiry of a Person. Knowledge of the Company" means the Knowledge of any Knowledge Person.

"Knowledge Person" means any of the persons listed onSchedule 1.01(a) of the Disclosure Letter.

"Legal Reservations" means, solely in respect of the English Obligor, (a) the principle that equitable remedies may be granted or refused at the discretion of a court and the limitation of enforcement by laws relating to insolvency, reorganization and other laws generally affecting the rights of creditors; (b) defences of set-off or counterclaim; and (c) the principle that security expressed to be fixed security may take effect a floating security.

"License" means any existing or future license (including sublicenses), Commercialization, co-promotion, collaboration, distribution, marketing, partnering or similar agreement entered into before or during the Revenue Interest Period by the Company or any of its Affiliates that grants a license to a Third Party under, or in respect of, any Product or Intellectual Property.

"Licensees" means any licensee or sublicensee under any License (other than licensees or sublicensees of the type described in clause (c) or clause (d) of the definition of Permitted Licenses).

"Liens" means all liens, encumbrances, security interests, mortgages, rights to preferential payments or charges of any kind, but excluding any Permitted Licenses.

"Manufacture" and "Manufacturing" means all activities and operations related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and holding of any Specified Product, or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control.

"Manufacturing Agreement" means (a) any contract or agreement entered into on or prior to the Closing Date by any Obligor or any of its Subsidiaries with third parties for (i) the clinical or commercial Manufacture or in-bound supply of any Specified Product for any indication, or (ii) for the commercial Manufacture or in-bound supply of any active pharmaceutical ingredient, prodrug, or medical device component material incorporated therein that was included in the Drug Approval Application for any Specified Product (with the Manufacturing Agreements in

effect as of the Closing Date being set forth in Schedule 5.13(b) of the Disclosure Letter), and (b) any future contract or agreement entered into after the Closing Date by any Obligor or any of its Subsidiaries with third parties for (i) the clinical or commercial Manufacture or in-bound supply of any Specified Product for any indication or (ii) for the commercial Manufacture or in-bound supply of any active pharmaceutical ingredient, prodrug, or medical device component material incorporated therein.

"Margin Stock" means "margin stock" within the meaning of Regulation U and Regulation X.

"Marketing Authorization" means, with respect to any Specified Product, the Regulatory Approval required by Applicable Law to sell such Specified Product in a country or region, including, to the extent required by Applicable Law for the sale of such Specified Product, all pricing approvals and government reimbursement approvals.

"Material Adverse Effect" means (a) the effect of a material adverse change in the business, operations, assets or condition (financial or otherwise) of the Company and its Subsidiaries, taken as a whole, (b) a material adverse effect on the validity or enforceability of any of the Transaction Documents, (c) a material adverse effect on the ability of the Company or any Obligor to perform any of its material obligations under the Transaction Documents, including its obligation to make Revenue Interest Payments as provided herein, (d) a material adverse effect on the rights or remedies of the Purchaser under any of the Transaction Documents, (e) a material adverse effect on (i) prior to receipt of FDA approval of Brensocatib, Arikayce and the Product Intellectual Property related thereto, taken as a whole, and (ii) upon and at all times after receipt of FDA approval of Brensocatib, the Specified Products and the Product Intellectual Property related thereto, taken as a whole, (f) a material adverse effect on the ability of the Company or a Person acting on behalf of the Company to Develop, Commercialize or Manufacture the Specified Products, taken as a whole, (g) the occurrence of any revocation, withdrawal, suspension or cancellation of any Regulatory Approval in the United States for Arikayce which results in the Company or any of its Subsidiaries being prevented from marketing or selling Arikayce in the United States, or (h) a material adverse effect on the validity, perfection (except to the extent permitted under the Security Documents) or priority of Liens in favor of the Purchaser (except to the extent permitted under the Intercreditor Agreement or resulting solely from any actions or inactions on the part of the Purchaser despite timely receipt of information regarding the Company and its Subsidiaries as required by this Agreement).

"Material Contract" means (a) any "material contract" (as such term is defined in Item 601(b)(10) of Regulation S-K of the Securities Act of 1933, as amended, other than those agreements and arrangements described in Item 601(b)(10)(iii)) with respect to Company or its Affiliates that relates to the Development, Manufacture, or Commercialization of any Specified Product; (b) any development agreement, collaboration agreement, marketing agreement, co-promotion agreement, license agreement, option agreement, distribution agreement, partnering agreement or similar agreement with respect to Company or its Affiliates related to the Development, Manufacture, or Commercialization of any Specified Product to the extent the

breach, non-performance or failure to renew could reasonably be expected to have a Material Adverse Effect; and (c) any agreement with respect to Company or its Affiliates relating to any Material Patent, including any license, option, assignment, or agreement related to control of such Material Patent, in each case, to the extent the breach, non-performance or failure to renew by the Company or its Affiliates or the respective counterparty could reasonably be expected to have a Material Adverse Effect.

"Material Indebtedness" means (i) Indebtedness outstanding under the Term Loan Agreement and (ii) any other Indebtedness of the Company or any of its Subsidiaries, the outstanding principal amount of which exceeds $[***].

"Material Patents" has the meaning set forth in Section 3.11(c).

"NDA" means a new drug application, submitted to the FDA pursuant to 21 U.S.C. § 355 seeking authorization to market a new drug in the United States, or any foreign equivalent.

"Net Sales" means for any period and with respect to any Specified Product, net revenue of the Company and its Subsidiaries on account of sales of such Specified Product, including, to the extent included in net revenues, license fees, royalty income, milestone payments, of the Company and the Subsidiaries during such period, as determined in accordance with GAAP. Net Sales shall be determined in a manner consistent with the methodologies, practices and procedures used in developing the Company's audited financial statements.

"Net Sales Report" has the meaning set forth in Section 2.02(a)(ii).

"Net Sales Report Date" means each date on which financial statements are required to be delivered pursuant to Section 5.02(a)(i) or (a)(ii), commencing on the first such date to occur following the Closing Date; provided that, if any such date shall occur on a day that is not a Business Day, the applicable Net Sales Report Date shall be the next succeeding Business Day.

"Obligations" means, without duplication, all obligations of the Company in respect of the Revenue Interests, including all obligations to make Revenue Interest Payments and to pay the applicable Buy-Out Price, and all present and future Indebtedness, taxes, liabilities, obligations, covenants, duties, and debts, Indemnified Liabilities owing by the Company to the Purchaser, arising under or pursuant to the Transaction Documents, including all Reimbursable Expenses (and including any interest, fees and other charges that would accrue but for the filing of a bankruptcy action with respect to the Company, whether or not such claim is allowed in such bankruptcy action).

"Obligors" means the Company and each Subsidiary Guarantor.

"OECD" has the meaning set forth in the definition of "Cash Equivalents".

"OFAC" means the U.S. Department of the Treasury's Office of Foreign Assets Control and any successor thereto.

"Organization Documents" means, (a) with respect to any corporation, the certificate or articles of incorporation and the bylaws (or equivalent or comparable constitutive documents with respect to any non-U.S. jurisdiction), (b) with respect to any limited liability company, the certificate or articles of formation or incorporation, organization and operating agreement or constitutional documents, and (c) with respect to any partnership, joint venture, trust or other form of business entity, the partnership, joint venture or other applicable agreement of formation or organization and any agreement, instrument, filing or notice with respect thereto filed in connection with its formation or organization with the applicable Governmental Authority in the jurisdiction of its formation or organization and, if applicable, any certificate or articles of formation or organization of such entity.

"Other Connection Taxes" means Taxes imposed as a result of a present or former connection between the Purchaser and the jurisdiction imposing such Tax (other than connections arising from the Purchaser having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Transaction Document, or sold or assigned an interest in any Obligation or Transaction Document).

"Other Taxes" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Transaction Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

"Patent Office" means the respective patent office, including the United States Patent and Trademark Office, the European Patent Office and any comparable patent office in any other jurisdiction, for any Patents.

"Patents" means patent and patent applications of any and every type issued under law in any jurisdiction and rights related to patents and patent applications, including by way of example, and not as a limitation, all issued national, regional and international patents and patent applications (and any patents that issue as a result of those patent applications or from an application that does or could claim priority from any of those), all certificates of invention and applications for certificates of invention, in-licensed and out-licensed patent and patent application rights and any renewals, restorations, reissues, reexaminations, *inter partes* review, or any other patent review proceedings, rulings and judgments related to patents by any court or Patent Office, extensions, improvements, continuations, continuations-in-part, divisions, revisions, registrations, revalidations, utility models, supplemental protection certificates, patent term extensions of any type, patent term adjustments, any regulatory exclusivity rights related to patents, pediatric exclusivity periods and substitutions relating to any of the issued patents and patent applications, in any jurisdiction.

"Payment Date" means the forty-fifth day following each of March 31st, June 30th, September 30th and December 31st, commencing on the first such date to occur following the Closing Date; provided that, if any such date shall occur on a day that is not a Business Day, the applicable Payment Date shall be the immediately preceding Business Day.

"PCI Cap" means an amount equal to the sum of (a) $[***] *plus* (b) such amount of proceeds that will be used solely to repay or retire existing Permitted Convertible Indebtedness and is placed into an escrow account solely dedicated to such use, *plus*, (c) so long as (i) no Put Option Event has occurred and is continuing, (ii) no Material Adverse Effect has occurred and (iii) the ENCORE Event has occurred, $[***].

"Permitted Acquisition" means any Acquisition, so long as:

(a) no Put Option Event shall have occurred and be continuing as of, or could reasonably be expected to result from, the consummation of such Acquisition;

(b) the properties or assets being acquired or licensed, or the Person whose Equity Interests are being acquired, are useful in or engaged in, as applicable, (i) the same, similar or related line of business as that then-conducted by the Company and its Subsidiaries, or (ii) a line of business that is related or ancillary to or in furtherance of a line of business as that then-conducted by the Company and its Subsidiaries;

(c) in the case of any Asset Acquisition, any and all assets are being acquired or licensed in such Acquisition by an Obligor and, within the timeframes expressly set forth in Section 5.06 with respect to all such assets constituting Collateral, such Obligor shall have executed and delivered or authorized, as applicable, any and all joinders, security agreements, financing statements and any other documentation, and made such other deliveries, required by Section 5.06 or reasonably requested by the Purchaser in order to include such newly acquired or licensed assets within the Collateral, in each case to the extent required by Section 5.06;

(d) in the case of any Stock Acquisition, any and all Equity Interests are being acquired in such Acquisition by an Obligor and, such Obligor shall have complied with its obligations under Section 5.06, in each case to the extent such Equity Interests are subject thereto; and

(e) any Indebtedness or Liens assumed in connection with such Acquisition are otherwise permitted under Section 5.10(a)(iii) or 5.10(a)(viii), respectively.

"Permitted Convertible Indebtedness" means Indebtedness of the Company or any Subsidiary of the Company that is an Obligor having a feature which entitles the holder thereof in certain circumstances to convert or exchange all or a portion of such Indebtedness into Equity Interests in the Company or such Subsidiary (or other securities or property following a merger event or other change of the common stock of the Company or such Subsidiary), cash or any combination of cash and such Equity Interests (or such other securities or property) based on the market price of such Equity Interests (or such other securities or property); provided, however, that (a) such Indebtedness shall be unsecured, (b) such Indebtedness shall not be guaranteed by any Subsidiary of the Company, (c) such Indebtedness shall bear interest at a rate *per annum* not to exceed the greater of [***] percent ([***]%) and such rate as is customary in the market at such time, as determined by the Company in its reasonable commercial judgment, (d) such Indebtedness shall not include covenants and defaults (other than covenants and defaults customary for convertible indebtedness but not customary for loans, as determined by the Company in its good faith judgment) that are, taken as a whole, more restrictive on the Obligors than the provisions of this Agreement (as determined by the Company in its good faith judgment), (e) immediately prior to and after giving effect to the incurrence of such

Indebtedness, no Put Option Event shall have occurred and be continuing or could reasonably be expected to occur as a result therefrom (after giving effect to this Agreement), (f) such Indebtedness shall not (i) mature or be mandatorily redeemable, pursuant to a sinking fund obligation or otherwise, (ii) be redeemable at the option of the holder thereof, in whole or in part or (iii) provide for the scheduled payment of dividends or distributions (other than scheduled cash interest payments) in cash, in each case of the foregoing sub-clauses (i), (ii) and (iii), prior to June 14, 2029 (it being understood, for the avoidance of doubt, that (w) a redemption right of the Company or such Subsidiary in respect of such Indebtedness, (x) conversion rights of holders in respect of such Indebtedness, (y) acceleration rights of holders of such Indebtedness upon the occurrence of an event of default specified in the agreement governing such Indebtedness and (z) the obligation to pay customary amounts to holders of such Indebtedness in connection with a "change of control" or "fundamental change", in each case, shall not be considered in connection with the determination of scheduled maturity date for purposes of this clause (f)); (g) at all times prior to the 1x Return Date, immediately after giving effect to the incurrence of any such Indebtedness, the difference of (x) the amount of all Permitted Convertible Indebtedness (including all Indebtedness under the ~~2025 Convertible Notes and the~~ 2028 Convertible Notes and the ~~indentures~~ indenture relating thereto) permitted hereunder and then outstanding *less* (y) the amount of proceeds of such Indebtedness that (1) will be used solely to repay or retire existing Permitted Convertible Indebtedness and (2) is placed into an escrow account solely dedicated to such use, shall not exceed the PCI Cap; and (h) the Company shall have delivered to the Purchaser a certificate of a Responsible Officer of the Company certifying as to the foregoing clauses (a) through (g) with respect to any such Indebtedness. For the avoidance of doubt, the ~~2025 Convertible Notes and the~~ 2028 Convertible Notes ~~constitute~~ constitutes Permitted Convertible Indebtedness.

"Permitted Convertible Redemption" means ~~(a)~~ the payment of the principal amount of any Indebtedness under the ~~2025 Convertible Notes or the~~ 2028 Convertible Notes (or the ~~indentures~~ indenture relating thereto) prior to maturity, with cash (other than any cash in the Cash Collateral Account), unless the last reported sale price of Company's common stock is at least 1.3 times the conversion price of such Indebtedness then in effect for at least twenty (20) Trading Days (whether or not consecutive) during any thirty (30) consecutive Trading Day period ending on the Trading Day prior to the date on which the Company provides the redemption notice in accordance with the indenture governing such Indebtedness~~, or (b) the redemption of the 2025 Convertible Notes with Equity Cash Proceeds~~.

"Permitted Distributions" means:

(a) dividends, distributions or other payments by any Wholly-Owned Subsidiary of the Company on its Equity Interests to, or the redemption, retirement or purchase by any Wholly-Owned Subsidiary of the Company of its Equity Interests from, the Company or any other Wholly-Owned Subsidiary of the Company;

(b) dividends, distributions or other payments by any non-Wholly-Owned Subsidiary on its Equity Interests to, or the redemption, retirement or purchase by any non-Wholly-Owned Subsidiary of its Equity Interests from, the Company or any other Subsidiary or each other owner of such non-Wholly-Owned Subsidiary's Equity Interests based on their relative ownership interests of the relevant class of such Equity Interests;

(c) exchanges, redemptions or conversions by the Company in whole or in part any of its Equity Interests for or into another class of its Equity Interests or rights to acquire its Equity Interests or with proceeds from substantially concurrent equity contributions or issuances of new Equity Interests;

(d) any such payments arising from (i) the Intercompany Reorganization (but only to the extent pursuant to any distribution described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such payments are described in Exhibit B hereto), (ii) a Permitted Acquisition or (iii) other Permitted Investment, in each case of this clause (d) by the Company or any of its Subsidiaries;

(e) [reserved];

(f) cash payments in lieu of the issuance of fractional shares arising out of stock dividends, splits or combinations or in connection with the exercise of warrants, options or other securities convertible into or exchangeable for Equity Interests, including Permitted Convertible Indebtedness;

(g) in connection with any Acquisition or other Investment by the Company or any of its Subsidiaries, (i) the receipt or acceptance of the return to the Company or any of its Subsidiaries of Equity Interests of the Company constituting a portion of the purchase price consideration in settlement of indemnification claims, or as a result of a purchase price adjustment (including earn-outs or similar obligations) and (ii) payments or distributions to equity holders pursuant to appraisal rights required under Applicable Laws;

(h) the distribution of rights pursuant to any shareholder rights plan or the redemption of such rights for nominal consideration in accordance with the terms of any shareholder rights plan;

(i) dividends, distributions or payments on its Equity Interests by any Subsidiary to any Obligor;

(j) dividends, distributions or payments on its Equity Interests by any Subsidiary that is not an Obligor to any other Subsidiary that is not an Obligor;

(k) purchases of Equity Interests of the Company or its Subsidiaries in connection with the exercise of stock options by way of cashless exercise, or in connection with the satisfaction of withholding tax obligations;

(l) issuance to directors, officers, employees or contractors of the Company or its Subsidiaries of awards or common stock of the Company pursuant to awards, of restricted stock, restricted stock units, or other rights to acquire common stock of the Company, in each case pursuant to plans or agreements approved by the Company's Board or stockholders;

(m) he repurchase, retirement or other acquisition or retirement for value of Equity Interests of the Company or any of its Subsidiaries held by any future, present or former employee, consultant, officer or director (or spouse, ex-spouse or estate of any of the foregoing or trust for the benefit of any of the foregoing or any lineal descendants thereof) of the Company or any of its Subsidiaries pursuant to any management equity plan or stock option plan or any other management or employee benefit plan or agreement, or any stock subscription or shareholder agreement or employment agreement; provided, however, that the aggregate payments made under this clause (m) do not exceed in any calendar year the sum of (i) $[***] *plus* (ii) the amount of any payments received in such calendar year under key-man life insurance policies;

(n) dividends or distributions on its Equity Interests by the Company or any of its Subsidiaries payable solely in additional shares of its common stock; and

(o) solely in connection with Permitted Convertible Indebtedness and any Refinancing Convertible Debt relating thereto, the Obligors or its Subsidiaries may enter into Permitted Equity Derivatives (and may settle, terminate or unwind any such Permitted Equity Derivatives in connection with any refinancing, early conversion or maturity of such Permitted Convertible Indebtedness).

"Permitted Equity Derivative" means any call or capped option (or substantively equivalent equity derivative transaction) or call spread transaction relating to the Equity Interests of the Company or any other Obligor purchased by the Company or such Obligor in connection with the issuance of Permitted Convertible Indebtedness and any Refinancing Convertible Debt relating thereto by the Company or such other Obligor; provided, that the purchase price for such call or capped option does not exceed the net cash proceeds received by the Company or such other Obligor from the issuance of such Permitted Convertible Indebtedness or Refinancing Convertible Debt.

"Permitted Indebtedness" means:

(a) Indebtedness owed to the Purchaser under this Agreement and the other Transaction Documents;

(b) Indebtedness existing on the Closing Date, including Indebtedness outstanding under the Term Loan Agreement, and disclosed on Schedule 5.10(a)(iii) of the Disclosure Letter;

(c) Permitted Convertible Indebtedness (including, for the avoidance of doubt, all Indebtedness under the ~~2025 Convertible Notes and the~~ 2028 Convertible Notes and the ~~indentures~~indenture relating thereto); provided that, the difference of (x) the amount of such Permitted Convertible Indebtedness permitted hereunder and then outstanding *less* (y) the amount of proceeds of such Indebtedness that (1) will be used solely to repay or retire existing Permitted Convertible Indebtedness and (2) is placed into an escrow account solely dedicated to such use, shall not at any time exceed the PCI Cap;

(d) (i) (A) Indebtedness incurred to finance the purchase, construction, repair, or improvement of fixed assets and ~~i~~(B) Capital Lease Obligations not covered under clause (d)(ii) of this definition; provided, however, that until the 1x Return Date, such Indebtedness shall not exceed (x) prior to the occurrence of the FDA Approval Date, $[***] in the aggregate, or (y) on or after the occurrence of the FDA Approval Date, $[***] in the aggregate, in either case at any time outstanding, and (ii) Capital Lease Obligations for new research and operations spaces and related equipment, and for the expansion of existing research and operations spaces and related equipment; provided, however, that until the 1x Return Date, such Indebtedness shall only be permitted following the FDA Approval Date and the aggregate amount of all such Indebtedness shall not exceed $~~[***] in the aggregate~~ [***] at any time outstanding;

(e) Indebtedness in connection with trade credit, corporate credit cards, purchasing cards or bank card products; provided that until the 1x Return Date, ~~any~~ the aggregate amount of all such Indebtedness that is secured by a Lien shall not exceed $[***]~~[***] in the aggregate~~ at any time outstanding;

(f) guarantees of Permitted Indebtedness;

(g) Indebtedness assumed in connection with any Permitted Acquisition, Permitted Transfer or Permitted Investment, so long as such Indebtedness was not incurred in connection with, or in anticipation of, such Permitted Acquisition, Permitted Transfer, Permitted Investment;

(h) Indebtedness of the Company or any of its Subsidiaries with respect to letters of credit, bank guarantees, bankers' acceptances, warehouse receipts or similar instruments outstanding and to the extent secured by a Lien, secured solely by cash or Cash Equivalents, in each case entered into in the ordinary course of business;

(i) Indebtedness owed: (i) by an Obligor to another Obligor; (ii) by a Subsidiary of the Company that is not an Obligor to another Subsidiary of the Company that is not an Obligor; (iii) by an Obligor to a Subsidiary of the Company that is not an Obligor; or (iv) by a Subsidiary of the Company that is not an Obligor to an Obligor, not to exceed (x) with respect to any Indebtedness of the type described in clause (iv), until the 1x Return Date, such Indebtedness shall not exceed(x) prior to the occurrence of the FDA Approval Date , $[***] in the aggregate, or (y) on or after the occurrence of the FDA Approval Date,$[***] in the aggregate, in either case at any time outstanding and (y) all such Indebtedness described in thisclauses (i) and (iii) shall be subordinated to the Obligations pursuant to the Intercompany Subordination Agreement;

(j) Indebtedness consisting of Contingent Obligations described inclause (a) of the definition thereof: (i) of an Obligor of Permitted Indebtedness of another Obligor (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder); (ii) of a Subsidiary of the Company which is not an Obligor of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of another Subsidiary of the Company which is not an Obligor; (iii) of a Subsidiary of the Company which is not an Obligor of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of an Obligor; or (iv) of an Obligor of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of a Subsidiary of the Company which is not an Obligor not to exceed, until the 1x Return Date, $[***] in the aggregate at any time outstanding;

(k) Indebtedness consisting of Contingent Obligations described inclause (b) of the definition thereof, not to exceed, until the 1x Return Date, $[***][***] in the aggregate at any time outstanding, and then due and payable, in each instance (i) incurred in connection with any Permitted Acquisition, Permitted Transfer, Permitted Investment or any in-licensing or any collaboration, co-promotion or, co-marketing arrangement, and (ii) only if such Indebtedness is due and payable upon the occurrence of an event or the performance of an act (and not solely with the passage of time);

(l) Indebtedness of any Person that becomes a (direct or indirect) Subsidiary of the Company (or of any Person not previously a Subsidiary that is merged or consolidated with or into a Subsidiary of the Company in a transaction permitted hereunder, including pursuant to the Intercompany Reorganization, but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such Indebtedness is described in Exhibit B hereto) after the Closing Date; provided that no such Indebtedness shall have been created or incurred in contemplation of or in connection with such Person becoming a (direct or indirect) Subsidiary of the Company (or merging or consolidating with or into a Subsidiary of the Company) or the Permitted Acquisition of related assets;

(m) (i) Indebtedness with respect to workers' compensation claims, payment obligations in connection with health, disability or other types of social security benefits, unemployment or other insurance obligations, reclamation and statutory obligations or (ii) Indebtedness related to employee benefit plans, including annual employee bonuses, accrued

wage increases and 401(k) plan matching obligations, in each case, incurred in the ordinary course of business;

(n) Indebtedness in respect of performance bonds, bid bonds, appeal bonds, surety bonds and completion guarantees and similar obligations arising in the ordinary course of business;

(o) Indebtedness in respect of netting services, overdraft protection and other cash management services, in each case in the ordinary course of business;

(p) Indebtedness consisting of the financing of insurance premiums in the ordinary course of business;

(q) Indebtedness consisting of guarantees resulting from endorsement of negotiable instruments for collection by any Obligor in the ordinary course of business;

(r) unsecured Indebtedness incurred in connection with any items of Permitted Distributions in clause (m) of the definition of "Permitted Distributions";

(s) to the extent constituting Indebtedness, Permitted Equity Derivatives;

(t) other unsecured Indebtedness in an aggregate amount not to exceed $[***][~~[***]~~] at any one time outstanding;

(u) any Indebtedness arising under a declaration of joint and several liability used for the purpose of section 2:403 of the Dutch CC (and any residual liability (*overblijvende aansprakelijkheid*) under such declaration arising pursuant to section 2:404(2) of the Dutch CC);

(v) Indebtedness in respect of any liability arising as a result of a fiscal unity (*fiscale eenheid*) between Obligors incorporated in the Netherlands (or equivalent in any other jurisdiction);

(w) Indebtedness under any (i) unsecured Hedging Agreements entered into for hedging and not speculative purposes, and (ii) Hedging Agreements with respect to interest rates that are secured by cash or Cash Equivalents and entered into for hedging and not speculative purposes; and

(x) subject to the proviso immediately below, extensions, refinancings, renewals, modifications, amendments, restatements and, in the case of any items of Permitted Indebtedness in clause (b) of the definition thereof or Permitted Indebtedness constituting notes governed by an indenture (including Permitted Convertible Indebtedness), exchanges, of any items of Permitted Indebtedness in clauses (a) through (w) above; provided that in the case of clause (b) above, the principal amount thereof is not increased (other than by any reasonable amount of premium (if any), interest (including post-petition interest), fees, expenses, charges or additional or contingent interest reasonably incurred in connection with the same and the terms thereof); provided further that in the case of any Indebtedness permitted under clause (c) above, (x) prior to the 1x Return Date, the maturity thereof shall not be not shortened, (y) the difference of (A) the amount of all Permitted Convertible Indebtedness permitted hereunder and then outstanding *less* (B) the amount of proceeds of such Indebtedness that (1) will be used solely to repay or retire existing Permitted Convertible Indebtedness and (2) is placed into an escrow account solely dedicated to such use, does not exceed the PCI Cap, and (z) there shall not be any change to or addition of any direct or indirect obligor with respect thereto unless such new obligor thereto is or shall become a Guarantor hereunder.

"Permitted Investments" means:

(a) Investments (including Investments in Subsidiaries) existing on the Closing Date and shown on Schedule 5.10(a)(iv) of the Disclosure Letter, including any extensions, renewals or reinvestments thereof;

(b) Investments consisting of cash and Cash Equivalents;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business;

(d) subject to Section 5.19, Investments consisting of deposit accounts or securities accounts;

(e) Investments in connection with (i) the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such Investments are described in Exhibit B hereto), (ii) Permitted Transfers, and (iii) the establishment and maintenance of an Intercompany Reorganization Subsidiary;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of the Company pursuant to employee stock purchase plans or agreements approved by the Company's Board;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of accounts receivable of, or prepaid royalties and other credit extensions or advances, to customers, suppliers or manufacturers who are not Affiliates, in the ordinary course of business or otherwise to support capacity demand; provided that this clause (h) shall not apply to Investments of any Obligor in any of its Subsidiaries;

(i) joint ventures or strategic alliances consisting of the licensing or development of technology or the providing of technical support;

(j) Investments (i) required in connection with a Permitted Acquisition (including the formation of any Subsidiary for the purpose of effectuating such Permitted Acquisition, the capitalization of such Subsidiary whether by capital contribution or intercompany loans to the extent otherwise permitted by the terms of this Agreement, related Investments in Subsidiaries necessary to consummate such Permitted Acquisition and the receipt of any non-cash consideration in such Permitted Acquisition) and (ii) consisting of earnest money or escrow deposits required in connection with a Permitted Acquisition or other acquisition of properties or assets not otherwise prohibited hereunder;

(k) Investments constituting the formation of any Subsidiary for the purpose of consummating a merger or acquisition transaction permitted by Section 6.3(a)(i) through (iv) hereof, which such transaction is otherwise a Permitted Investment;

(l) Investments of any Person that (i) becomes a Subsidiary of the Company (or of any Person not previously a Subsidiary of the Company that is merged or consolidated with or

into a Subsidiary of the Company in a transaction permitted hereunder) after the Closing Date, or (ii) are assumed after the Closing Date by the Company or any Subsidiary of the Company in connection with an acquisition of assets from such Person by the Company or such Subsidiary, in either case, in a Permitted Acquisition; provided, that in each case, any such Investment (w) does not constitute Indebtedness of such Person, (x) exists at the time such Person becomes a Subsidiary of the Company (or is merged or consolidated with or into a Subsidiary of the Company) or such assets are acquired, (y) was not made in contemplation of or in connection with such Person becoming a Subsidiary of the Company (or merging or consolidating with or into a Subsidiary of the Company) or such acquisition of assets, and (z) could not reasonably be expected to result in a Put Option Event;

(m) Investments arising as a result of the licensing of Intellectual Property in the ordinary course of business and not prohibited under this Agreement;

(n) to the extent constituting an Investment, any Permitted Equity Derivative, including the payment of premiums in connection therewith;

(o) Investments by: (i) any Obligor in any other Obligor; (ii) any Subsidiary of the Company which is not an Obligor in another Subsidiary of the Company which is not an Obligor; (iii) any Subsidiary of the Company which is not an Obligor in any Obligor; (iv) any Obligor in a Subsidiary of the Company which is not an Obligor, not to exceed $[***] in the aggregate outstanding at any time; and (v) the Company and its Subsidiaries consisting of Equity Interests in their respective Subsidiaries existing on the Closing Date;

(p) Repurchases of capital stock of the Company or any of its Subsidiaries deemed to occur upon the exercise of options, warrants or other rights to acquire capital stock of the Company or such Subsidiary solely to the extent that shares of such capital stock represent a portion of the exercise price of such options, warrants or such rights;

(q) Investments consisting of non-cash consideration received for any Permitted Transfer;

(r) Investments consisting of acquisitions from third parties of inventory, equipment, office supplies, software and other similar assets in the ordinary course of business;

(s) Investments consisting of in-licensing agreements, provided that no Indebtedness that is not Permitted Indebtedness is incurred or assumed in connection therewith;

(t) other Investments, not to exceed $[***] outstanding at any time; and

(u) (i) unsecured Hedging Agreements entered into for hedging and not speculative purposes, and (ii) Hedging Agreements with respect to interest rates that are secured by cash or Cash Equivalents and entered into for hedging and not speculative purposes

provided, however, that, none of the foregoing Investments shall be a "Permitted Investment" if any Indebtedness or Liens assumed in connection with such Investment are not otherwise permitted under Section 5.10(a)(iii) or 5.10(a)(viii), respectively.

"Permitted License" means (a) any License for the Commercialization of any Product; provided that, with respect to any such License for the Commercialization of any Specified Product or Product Intellectual Property, such License shall not qualify as a Permitted License if (i) such License qualifies as an Exclusive License, (ii) the terms of such License, directly or

indirectly, provide for a sale or assignment of any Product Intellectual Property or otherwise result in a legal transfer of title to the licensed property, (iii) except with the consent of the Purchaser (which consent not to be unreasonably withheld or delayed), the terms of such License, directly or indirectly, restrict, in any material respect, the ability of the Company or any Subsidiary, as applicable, to pledge or grant a security interest in or Lien on any Product Intellectual Property or related Product Assets in favor of the Purchaser as required pursuant to the Security Documents or restrict or interfere with the rights of the Purchaser in respect of such Product Intellectual Property of Product Assets as provided pursuant to the Security Documents; provided that this clause (iii) shall not be deemed to prohibit any customary anti-assignment or similar provision in respect of such License or contractual rights or interests arising thereunder, or (iv) the License fails to comply with the terms of Sections 5.08 and 5.18 hereof; (b) any License acquired in an Acquisition; (c) any License granted to any vendor or service provider in order to provide services for the benefit of the Company or its Subsidiaries with respect to the Development, Commercialization or Manufacturing of Products, but granting no exclusive rights to sell, offer to sell, have sold or otherwise Commercialize any Specified Product in the United States, the EU5 Countries and Japan; provided that any such License complies with Sections 5.08 and 5.18 hereof; (d) any sponsored research or similar agreement providing for the Development of any Product (including any Specified Product) that does not grant the counterparty any right to sell, offer to sell, have sold or otherwise Commercialize any Specified Product; and (e) for the avoidance of doubt, any License solely related to any Product other than any Specified Product.

"Permitted Liens" means:

(a) Liens in favor and for the benefit of the Purchaser securing the Obligations pursuant to any Transaction Document;

(b) Liens existing on the Closing Date and set forth on Schedule 5.10(a)(viii) of the Disclosure Letter;

(c) Liens for Taxes, assessments or governmental charges which (i) are not yet due and payable or (ii) if due and payable, are being contested in good faith and by appropriate proceedings; provided that, in each case, adequate reserves therefor have been set aside on the books of the applicable Person and maintained in conformity with GAAP;

(d) (i) pledges or deposits made in the ordinary course of business (other than Liens imposed by ERISA) in connection with workers' compensation, payroll taxes, employment insurance, unemployment insurance, old-age pensions, or other similar social security legislation, (ii) pledges or deposits made in the ordinary course of business securing liability for reimbursement or indemnification obligations of (including obligations in respect of letters of credit or bank guarantees for the benefit of) insurance carriers providing property, casualty or liability insurance to the Company or any of its Subsidiaries, (iii) statutory or common law Liens of landlords, (iv) Liens otherwise arising by operation of law in favor of the owner or sublessor of leased premises and confined to the property rented, (v) Liens that are restrictions on transfer of securities imposed by applicable securities laws, (vi) Liens resulting from a filing by a lessor as a precautionary filing for a true lease, and (vii) pledges or deposits to secure performance of tenders, bids, leases, statutory or regulatory obligations, surety and appeal bonds, government contracts, performance and return-of-money bonds and other obligations of like nature, in each case other than for borrowed money and entered into in the ordinary course of business;

(e) Liens arising from attachments or judgments, orders, or decrees in circumstances not constituting a Put Option Event or an "Event of Default" under Section 7.4 or 7.7 of the Term Loan Agreement;

(f) Liens (including the right of set-off) in favor of banks or other financial institutions incurred on deposits made in accounts held at such institutions in the ordinary course of business; provided that such Liens (i) are not given in connection with the incurrence of any Indebtedness, (ii) relate solely to obligations for administrative and other banking fees and expenses incurred in the ordinary course of business in connection with the establishment or maintenance of such accounts and (iii) are within the general parameters customary in the banking industry;

(g) Liens that are contractual rights of set-off (i) relating to pooled deposit or sweep accounts of the Company or any of its Subsidiaries to permit satisfaction of overdraft or similar obligations incurred in the ordinary course of business or (ii) relating to purchase orders and other agreements entered into with customers of the Company or any of its Subsidiaries in the ordinary course of business, including vendors' liens to secure payment arising under Article 2 of UCC or similar provisions of Applicable Law in the ordinary course of business, covering only the goods sold and securing only the unpaid purchase price for such goods and related expenses;

(h) Liens solely on any cash earnest money deposits made by the Company or any of its Subsidiaries in connection with any Permitted Acquisition, Permitted Investment or other acquisition of assets or properties not otherwise prohibited under this Agreement;

(i) Liens existing on assets or properties at the time of its acquisition or existing on the assets or properties of any Person at the time such Person becomes a Subsidiary of the Company, in each case after the Closing Date; provided that (i) neither such Lien was created nor the Indebtedness secured thereby was incurred in contemplation of such acquisition or such Person becoming a Subsidiary of the Company, (ii) such Lien does not extend to or cover any other assets or properties (other than the proceeds or products thereof and other than after-acquired assets or properties subject to a Lien securing Indebtedness and other obligations incurred prior to such time and which Indebtedness and other obligations are permitted hereunder that requires, pursuant to its terms and conditions in effect at such time, a pledge of after-acquired assets or properties, it being understood that such requirement shall not be permitted to apply to any assets or properties to which such requirement would not have applied but for such acquisition), (iii) the Indebtedness and other obligations secured thereby is permitted under Section 5.10(a)(iii) hereof and (iv) such Liens are of the type otherwise permitted under Section 5.10(a)(viii) hereof;

(j) Liens securing Indebtedness permitted under clause (d) of the definition of "Permitted Indebtedness" (including any extensions, refinancings, modifications, amendments or restatements of such Indebtedness permitted under clause (w) of the definition of "Permitted Indebtedness"); provided, that such Lien does not extend to or cover any assets or properties other than those that are (i) subject to such Capital Lease Obligations or (ii) acquired with or otherwise financed or refinanced by such Indebtedness;

(k) servitudes, easements, rights-of-way, restrictions and other similar encumbrances on real property imposed by Applicable Laws and encumbrances consisting of zoning or building restrictions, easements, licenses, restrictions on the use of property or minor defects or other irregularities in title which, in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any Obligor or any Subsidiary of any Obligor;

(l) to the extent constituting a Lien, escrow arrangements securing indemnification obligations associated with any Permitted Acquisition or Permitted Investment;

(m) (i) leases or subleases of real property granted in the ordinary course of business (including, if referring to a Person other than an Obligor or a Subsidiary, in the ordinary course of such Person's business), (ii) licenses, sublicenses, leases or subleases of personal property (other than Intellectual Property) granted to third parties in the ordinary course of business, in each case which do not interfere in any material respect with the operations of the business of any Obligor or any of its Subsidiaries and do not prohibit granting the Purchaser a security interest in any Obligor's personal property held at such location, (iii) Permitted Licenses, and (iv) retained interests of lessors or licensors or similar parties under any in-licenses;

(n) Liens on cash or other current assets pledged to secure: (i) Indebtedness in respect of corporate credit cards, purchasing cards or bank card products to the extent such Indebtedness qualifies as Permitted Indebtedness; or (ii) Indebtedness in the form of letters of credit or bank guarantees entered into in the ordinary course of business, provided, that any such Indebtedness is secured solely by cash or Cash Equivalents;

(o) Liens on any properties or assets of the Company or any of its Subsidiaries which do not constitute Collateral under the Transaction Documents, other than (i) any Intellectual Property that does not constitute Collateral under the Transaction Documents but is related to any research, development, Manufacture, production, use, Commercialization, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Specified Product and (ii) Equity Interests of any Subsidiary;

(p) Liens on any properties or assets of the Company or any of its Subsidiaries imposed by law or regulation which were incurred in the ordinary course of business, including landlords', carriers', warehousemen's, mechanics', materialmen's, contractors', suppliers of materials', architects' and repairmen's Liens, and other similar Liens arising in the ordinary course of business; provided that such Liens (i) do not materially detract from the value of such properties or assets subject thereto or materially impair the use of such properties or assets subject thereto in the operations of the business of the Company or such Subsidiary or (ii) are being contested in good faith by appropriate proceedings which conclusively operate to stay the sale or forfeiture of any portion of such properties or assets subject thereto, and for which adequate reserves have been set aside on the books of the applicable Person and maintained in conformity with GAAP, if required;

(q) Liens in favor of customs and revenue authorities arising under the Applicable Laws which were incurred in the ordinary course of business, to secure payment of customs duties in connection with the importation of goods in the ordinary course of business;

(r) Liens on any goods sold to the Company or any of its Subsidiaries in the ordinary course of business in favor of the seller thereof, but only to the extent securing the unpaid purchase price for such goods and any related expenses;

(s) Liens securing Permitted Indebtedness of an Obligor in favor of any other Obligor;

(t) Liens securing Indebtedness owed by a Subsidiary of the Company that is not an Obligor permitted under clause (i) of the definition of "Permitted Indebtedness," in favor of an Obligor or another Subsidiary of the Company that is not an Obligor;

(u) other Liens to the extent that the obligations secured thereby (determined as of the date such Lien is incurred) do not exceed $[***];

(v) any security interest or right to set-off arising under articles 24 or 25 respectively of the general terms and conditions (*algemene voorwaarden*) of any member of the Dutch Bankers' Association (*Nederlandse Vereniging van Banken*) or similar terms applied by an account bank;

(w) Liens on cash and Cash Equivalents securing Hedging Agreements with respect to interest rates that are entered into for hedging and not speculative purposes; and

(x) subject to the provisos immediately below, the modification, replacement, extension or renewal of the Liens described in clauses (a) through (w) above; provided, however, that any such modification, replacement, extension or renewal must (i) be limited to the assets or properties encumbered by the existing Lien (and any additions, accessions, parts, improvements and attachments thereto and the proceeds thereof) and (ii) not increase the principal amount of any Indebtedness secured by the existing Lien (other than by any reasonable premium or other reasonable amount paid and fees and expenses reasonably incurred in connection therewith); provided, further, that to the extent any of the Liens described in clauses (a) through (w) above secure Indebtedness of an Obligor, such Liens, and any such modification, replacement, extension or renewal thereof, shall constitute Permitted Liens if and only to the extent that such Indebtedness is permitted under Section 5.10(a)(iii) hereof.

"Permitted Transaction" means (w) the conversion to Equity Interests by holders of Permitted Convertible Indebtedness (including any cash payment upon conversion) or required payment of any interest with respect to any Permitted Convertible Indebtedness, in each case, in accordance with the terms of the indenture or other documentation governing such Permitted Convertible Indebtedness; (x) any Permitted Convertible Redemption, (y) the exchange of existing Permitted Convertible Indebtedness for or redemption of existing Permitted Convertible Indebtedness with (1) new Permitted Convertible Indebtedness (the "Refinancing Convertible Debt") (or the cash proceeds from the issuance of such Refinancing Convertible Debt) to the extent such Refinancing Convertible Debt is permitted to be issued under the terms of this Agreement and to the extent that such new Refinancing Convertible Debt bears interest at a rate *per annum* not to exceed the greater of [***] percent ([***]%) and such rate as is customary in the market at such time, as determined by the Company in its reasonable commercial judgment, (2) Equity Interests, (3) the cash proceeds, if any, received pursuant to the exercise, early unwind or termination of any Permitted Equity Derivative entered into in connection with such existing Permitted Convertible Indebtedness, or (4) cash in respect of accrued and unpaid interest on such exchanged existing Permitted Convertible Indebtedness, or (z) delivery of Equity Interests and cash in lieu of fractional shares or in respect of accrued and unpaid interest to any holder of Permitted Convertible Indebtedness to induce such holder to convert Permitted Convertible Indebtedness in accordance with the terms of the indenture governing such Permitted Convertible Indebtedness.

"Permitted Transfer" means:

(a) Transfers of Inventory in the ordinary course of business;

(b) Transfers of surplus, damaged, worn out or obsolete equipment that is, in the reasonable judgment of a Responsible Officer of the Company exercised in good faith, no longer economically practicable to maintain or useful in the ordinary course of business, and Transfers of other properties or assets in lieu of any pending or threatened institution of any proceedings

for the condemnation or seizure of such properties or assets or for the exercise of any right of eminent domain;

(c) Transfers made in connection with (i) the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such Transfers are described in Exhibit B hereto), (ii) Permitted Liens, (iii) Permitted Acquisitions or (iv) Permitted Investments;

(d) Transfers of cash and Cash Equivalents in the ordinary course of business for equivalent value and in a manner that is not prohibited under this Agreement or the other Transaction Documents;

(e) Transfers (i) between or among Obligors, including pursuant to the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such Transfers are described in Exhibit B hereto); provided that any and all steps as may be required to be taken in order to create and maintain a valid perfected security interest in and Lien upon such properties and assets in favor of the Purchaser are taken contemporaneously with the completion of any such Transfer, (ii) by Obligors to non-Obligors, not to exceed $[***] in the aggregate per fiscal year, and (iii) between or among non-Obligors, including pursuant to the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such Transfers are described in Exhibit B hereto).

(f) (i) the sale or issuance of Equity Interests of any Subsidiary of the Company to any Obligor or Subsidiary, provided, that any such sale or issuance by an Obligor shall be to another Obligor; and (ii) the sale, transfer, issuance or other disposition of a *de minimis* number of shares of the Equity Interests of any Subsidiary of the Company in order to qualify members of the governing body of such Subsidiary if required by Applicable Laws;

(g) the discount without recourse or sale or other disposition of unpaid and overdue accounts receivable arising in the ordinary course of business in connection with the compromise, collection or settlement thereof and not part of a financing transaction;

(h) any abandonment, disclaimer, forfeiture, dedication to the public, cancellation, non-renewal or discontinuance of use or maintenance of Product Intellectual Property that a Responsible Officer of the Company reasonably determines in good faith (i) is no longer economically practicable to maintain or useful in the ordinary course of business and that (ii) could not reasonably be expected to be adverse to the rights, remedies and benefits available to, or conferred upon, the Purchaser under any Transaction Document in any material respect;

(i) Transfers by the Company or any of its Subsidiaries pursuant to any Permitted License;

(j) intercompany licenses or grants of rights of distribution, co-promotion or similar commercial rights: (i) between or among Obligors; or (ii) between or among Obligors and Subsidiaries of the Company that are not Obligors that are otherwise permitted hereunder;

(k) any involuntary loss, damage or destruction of property or any involuntary condemnation, seizure or taking, by exercise of the power of eminent domain or otherwise, or confiscation or requisition of use of property;

(l) licenses, sublicenses, leases or subleases, in each case other than relating to any Product Intellectual Property, granted to third parties in the ordinary course of business and not material to any aspect of the research, development, Manufacture, production, use (by any

Obligor or its Subsidiaries), Commercialization, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of any Specified Product;

(m) the abandonment disclaimer, forfeiture, dedication to the public, or other disposition of any Product Intellectual Property that is (i) not material to any aspect of the research, development, Manufacture, production, use (by any Obligor or its Subsidiaries), Commercialization, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Specified Product or (ii) no longer used or useful in any material respect in any line of business of the Company and its Subsidiaries;

(n) any involuntary disposition or any sale, lease, license or other disposition of property (other than, for the avoidance of doubt, any Specified Product or Product Assets) in settlement of, or to make payment in satisfaction of, any property or casualty insurance;

(o) sales, leases, licenses, transfers or other dispositions of property to the extent that (i) such property is exchanged for credit against the purchase price of similar replacement property or (ii) the proceeds of such sale, lease, license, transfer or other disposition are promptly applied to the purchase price of similar replacement property;

(p) any early unwind, settlement or termination of any Permitted Equity Derivative;

(q) other Transfers made in the ordinary course of business on commercially reasonable arm's length terms; and

(r) other Transfers of assets or property, so long as the fair market value (as reasonably determined in good faith by a Responsible Officer of the Company) thereof does not exceed, individually or in the aggregate, $[***] per fiscal year.

"Person" means an individual, corporation, partnership, limited liability company, joint venture, association, trust or other entity or organization, but not including a government or political subdivision or any agency or instrumentality of such government or political subdivision.

"Personal Data" means any information that relates to an identifiable natural person or that is otherwise considered personally identifiable information or personal data under Applicable Law.

"Personal Data Breach" has the meaning set forth inSection 3.23(b).

"Prime Rate" means, for any day, the per annum rate of interest in effect for such day quoted by the Wall Street Journal as the "prime rate".

"Product" means any service or product developed, licensed, marketed, sold, distributed or otherwise commercialized by the Company or any of its Subsidiaries, including any such service or product in development or which may be developed.

"Product Assets" means (a) all Product Intellectual Property; (b) each Material Contract related to Specified Products; (c) all Regulatory Approvals related to Specified Products; (d) all inventory of Specified Products and any raw materials and work-in-process relating thereto; (e)

all accounts receivables and payment intangibles arising out of sales of any Specified Product or licenses of any Product Intellectual Property; (f) all other assets primarily related to the Development, Manufacture or Commercialization of any Specified Product and that are owned by, licensed to, or otherwise Controlled by the Company or any Subsidiary; (g) any other assets that are owned by, licensed to, or otherwise Controlled by the Company or any Subsidiary that are reasonably necessary for the Development, Commercialization, Manufacture, formulation, use, or sale of any Specified Products; (h) all books and records of the Company that at any time evidence or contain information relating to any of the foregoing or are otherwise necessary or helpful in the collection or realization thereof; and (i) all proceeds and products of any of the foregoing; provided that cash and Cash Equivalents shall not be deemed "Product Assets".

"Product In-License" means any in-license of Intellectual Property rights by the Company or any of its Subsidiaries to Develop, Manufacture or Commercialize a drug or pharmaceutical product, other than a non-exclusive license under which the Company is not granted any right to Develop or Commercialize a pharmaceutical product, therapeutic, medical device or diagnostic.

"Product Intellectual Property" means all Intellectual Property that is necessary for, or otherwise material to, the Development, Commercialization, and/or Manufacture of any Specified Product, including Intellectual Property that protects product market by exclusion of competitors including regulatory exclusivities and further includes any patents that are or are intended to be listed in the FDA's so-called "Orange Book" as covering a Specified Product, and similar regulatory listing worldwide that is owned, licensed or otherwise controlled by any Obligor as of the Closing Date or acquired by an Obligor thereafter.

"Purchase Price" means $150,000,000.

"Purchaser" has the meaning set forth in the first paragraph hereof.

"Purchaser Representative" has the meaning set forth in Section 5.01(c).

"Put Option" has the meaning set forth in Section 5.07(a).

"Put Option Closing Date" has the meaning set forth in Section 5.07(a).

"Put Option Event" means the occurrence of any one of the following events:

(a) any Bankruptcy Event;

(b) the Company fails to make any payment when due under Section 2.02; provided that, with respect to the first three (3) times that the Company fails to make any such payment (but no more than three (3) times) during the term of this Agreement, the Company shall be deemed to have cured such failure, and such failure shall not constitute a Put Option Event, if the Company makes such payment within five (5) Business Days of the applicable due date when such payment should have been made;

(c) the Company or any Subsidiary fails to pay any Material Indebtedness (other than the Indebtedness represented by this Agreement and the other Transaction Documents) within

any applicable grace period after such payment is due and payable (including at final maturity) or the due date of any such Material Indebtedness is accelerated by the holder(s) thereof because of a default, in each case, if the total amount of such Indebtedness unpaid or accelerated exceeds $[***];

(d) any Change of Control;

(e) any representation, warranty or statement made, or deemed made, by or on behalf of any Obligor in, or pursuant to, any Transaction Document shall: (i) prove to have been incorrect when made or deemed made to the extent that such representation or warranty is qualified by materiality, a Material Adverse Effect or similar qualifier; or (ii) prove to have been incorrect in any material respect when made or deemed made to the extent that such representation or warranty is not qualified by materiality, Material Adverse Effect or similar qualifier; or

(f) the Company breaches any covenant or agreement set forth in any Transaction Document (other than those specified in clause (b) above) and (i) the consequence of such breach results in (or could reasonably be expected to result in) a Material Adverse Effect, and (ii) solely in the case of a breach that is capable of cure, such breach is not cured within thirty (30) days after the earlier of (x) receipt of written notice of such breach from the Purchaser and (y) Knowledge of the Company of such breach.

"Qualified Equity Interests" of any Person means Equity Interests of such Person that are not Disqualified Equity Interests.

"Reconciliation Report" has the meaning set forth inSection 5.02(b).

"Refinancing Convertible Debt" has the meaning set forth in the definition of "Permitted Transaction".

"Register" has the meaning set forth inSection 7.03(b).

"Regulation" has the meaning set forth inSection 3.14(b).

"Regulation T" means Regulation T of the Board of Governors of the Federal Reserve System, as amended.

"Regulation U" means Regulation U of the Board of Governors of the Federal Reserve System, as amended.

"Regulation X" means Regulation X of the Board of Governors of the Federal Reserve System, as amended.

"Regulatory Agency" means the FDA and any other Governmental Authority with responsibility for the approval of the marketing and sale of pharmaceuticals or other regulation of pharmaceuticals.

"Regulatory Approval" means all approvals and exclusivities, including, without limitation, where applicable, Drug Approval Applications, including approval under pathways such as the Limited Population Pathway for Antibacterial and Antifungal Drugs pursuant to 21

U.S.C. § 356 and Accelerated Approval Pathway pursuant to 21 U.S.C. § 356(c), as well as designations conferring priority review status and marketing exclusivities, such as Fast Track designation pursuant to 21 U.S.C. § 356(b), Breakthrough Therapy designation pursuant to 21 U.S.C. § 356(a), Qualified Infection Disease Product designation pursuant to 21 U.S.C. 355f, including an award of "GAIN" exclusivity Orphan Drug designation pursuant to 21 U.S.C. § 360bb including an award of Orphan Drug exclusivity, and Priority Review designation, pricing and reimbursement approval, labeling approval and schedule classifications), licenses, registrations, certificates, permits or authorizations (including, without limitation, pre- and post-approval Marketing Authorizations) of any Governmental Authority necessary for the Manufacture, use, storage, import, export, transport, offer for sale, or sale of each Specified Product, together with all amendments, supplements and updates thereto and all benefits arising therefrom, including any orphan drug exclusivities or other non-patent exclusivities or priority review vouchers.

"Regulatory Filings" means all applications, filings, dossiers and other submissions submitted to a Regulatory Agency in support of or for the purpose of obtaining Regulatory Approval from that Regulatory Agency. Regulatory Filings shall include, but not be limited to, all Drug Approval Applications, including approval under pathways such as the Limited Population Pathway for Antibacterial and Antifungal Drugs pursuant to 21 U.S.C. § 356 and Accelerated Approval Pathway pursuant to 21 U.S.C. § 356(c), as well as submissions for Fast Track designation pursuant to 21 U.S.C. § 356(b), Breakthrough Therapy designation pursuant to 21 U.S.C. § 356(a), Qualified Infection Disease Program designation pursuant to 21 U.S.C. 355f, Orphan Drug designation pursuant to 21 U.S.C. § 360bb, and Priority Review designation.

"Regulatory Updates" means material information and developments with respect to any Regulatory Filing.

"Reimbursable Expenses" means all costs and expenses (including reasonable attorneys' fees and expenses, as well as appraisal fees, consulting fees, advisory fees, fees incurred on account of lien searches, inspection fees and filing fees) incurred as a result of or arising from or relating to or in connection with preparing, amending, executing, negotiating, administering, defending and enforcing the Transaction Documents (including, without limitation, those incurred in connection with appeals or any Bankruptcy Event) or otherwise incurred by the Purchaser in connection with the Transaction Documents.

"Responsible Officers" means, with respect to any Obligor, collectively, each of the Chief Executive Officer, Chief Financial Officer, General Counsel, Chief People Strategy Officer, Chief Medical Officer, Chief Operating Officer, and Chief Commercial Officer of such Obligor or, in each case, if none, of the Company.

"Restricted Payments" means (a) any dividend or other distribution, direct or indirect, on account of any shares (or equivalent) of any class of Equity Interests of any Person or any of its Subsidiaries, now or hereafter outstanding, (b) any redemption, retirement, sinking fund or similar payment, purchase or other acquisition for value, direct or indirect, of (i) any shares (or equivalent) of any class of Equity Interests of any Person or any of its Subsidiaries, now or hereafter outstanding or (ii) any call option on any shares (or equivalent) of any class of Equity

Interests or any Person or any of its Subsidiaries (irrespective of whether such call option can be cash, net share or physically settled), and (c) any payment made to retire, or to obtain the surrender of, any outstanding warrants, options or other rights to acquire shares of any class of Equity Interests of any Person or any of its Subsidiaries, now or hereafter outstanding; provided that except to the extent expressly prohibited pursuant Section 5.10(a)(x), Restricted Payments shall not include any payment of interest or payments to redeem, retire or otherwise repay amounts under ~~the 2025 Convertible Notes,~~ the 2028 Convertible Notes or any other Permitted Convertible Indebtedness.

"Return Cap" means, as of any date of determination, (i) an amount equal to 180.0% of the Purchase Price (i.e., $270,000,000) or (ii) if the Purchaser has not received the amount set forth in clause (i) on or before the 8th (eighth) anniversary of the Closing Date, an amount equal to 190.0% of the Purchase Price (i.e., $285,000,000).

"Revenue Base" means, as of any date of determination and with respect to any Specified Product, the amount of world-wide Net Sales resulting from sales of such Specified Product, including royalty payments, milestone payments, license payments and all other forms of consideration made to the Company and its Subsidiaries in respect of such Specified Product, calculated in accordance with GAAP, during the fiscal quarter ending immediately prior to such date of determination.

"Revenue Interest Payments" means, with respect to each fiscal quarter, or relevant portion thereof, during the Revenue Interest Period, payments to the Purchaser in an aggregate amount calculated by multiplying (i) the Applicable Percentage for each Specified Product by (ii) the Revenue Base for such Specified Product for such fiscal quarter; provided that for the fiscal quarter in which the Closing Date occurs, the Revenue Interest Payment shall be an aggregate amount calculated by multiplying the Revenue Interest Payment that would have otherwise been applicable to such fiscal quarter, by a percentage calculated by dividing (x) the number of days from the Closing Date to and including the last day of such fiscal quarter by (y) the total number of days in such fiscal quarter.

"Revenue Interest Period" means the period from the Closing Date through and including the date on which the Purchaser has received Revenue Interest Payments equal to the Return Cap, unless earlier terminated upon (i) the Purchaser's exercise, or deemed automatic exercise, of the Put Option in accordance with Section 5.07(a) or (ii) the Company's exercise of a Call Option in accordance with Section 5.07(b), in each case upon the indefeasible payment of the Buy-Out Price.

"Revenue Interests" means, with respect to the Specified Products, all of the right, title and interest of the Company and its Subsidiaries in and to that portion of the Revenue Base equal to the Revenue Interest Payments for each fiscal quarter (or portion thereof) during the Revenue Interest Period.

"Safety Notices" means any recalls, field notifications, market withdrawals, warnings, "dear doctor" letters, investigator notices, safety alerts or other notices of action issued or

instigated by the Company, any Subsidiary or any Governmental Authority relating to an alleged lack of safety or regulatory compliance of the Products.

"Sanctioned Country" means, at any time, a country or territory which is itself the subject or target of comprehensive Sanctions (currently, those portions of the Donetsk People's Republic and the Luhansk People's Republic regions (and such other regions) of Ukraine over which any Sanctions authority imposes comprehensive Sanctions, Crimea, Cuba, Iran, Syria and North Korea).

"Sanctioned Person" means an individual or entity that is, or is owned or controlled by individuals or entities that are: (i) the target of Sanctions; or (ii) located, organized or resident in a Sanctioned Country.

"Sanctions" has the meaning set forth inSection 3.21(c). "SEC" means the Securities and Exchange Commission.

"Section 5 of the FTC Act" means the Section 5(a) of the U.S. Federal Trade Commission Act (15 U.S.C. § 45), which prohibits unfair and deceptive acts or practices in or affecting commerce and serves as the primary basis for U.S. Federal Trade Commission authority on privacy and security.

"Security Incidents" has the meaning set forth inSection 3.23(b).

"Security Documents" means, collectively, the Guaranty and Security Agreement, the Foreign Security Documents, each intellectual property security agreement, the Control Agreements and all other instruments, documents and agreements delivered by any Obligor pursuant or incidental to this Agreement or any of the other Transaction Documents, in each case, in order to grant to the Purchaser, or perfect a Lien on any Collateral as security for the Obligations, and all amendments, restatements, modifications or supplements thereof or thereto.

"Security Program" has the meaning set forth inSection 3.23(b).

"Sensitive Information" means, collectively, (a) any Personal Data that is subject to any Data Protection Law, (b) any information in which the Company or any of its Subsidiaries have any Intellectual Property rights, (c) any information with respect to which the Company or any of its Subsidiaries have contractual non-disclosure obligations, and (d) nonpublic Regulatory Filings.

"Specified Product" means either (a) Arikayce, any authorized generic of Arikayce, or any amikacin liposome inhalation suspension approved for use by FDA under a Drug Approval Application used or controlled by Company to treat any lung disorder, or (b) Brensocatib, any authorized generic of Brensocatib, or any reversible inhibitor of dipeptidyl peptidase 1 (DPP1), developed by, or on behalf of, the Company for the treatment of patients with bronchiectasis and other neutrophil-mediated diseases or, if the context so requires, both clauses (a) and (b).

"Stock Acquisition" means the purchase or other acquisition by the Company or any of its Subsidiaries of any of the Equity Interests (by merger, stock purchase or otherwise) in any other Person.

"Subsidiary" means with respect to any Person, a corporation , partnership, limited liability company or other entity of which more than fifty percent (50.0%) of whose shares of stock or other ownership interests having ordinary voting power (other than stock or such other ownership interests having such power only by reason of the happening of a contingency) to elect a majority of the Board of such corporation, partnership or other entity are at the time owned, directly or indirectly through one or more intermediaries, or both, by such Person. Unless the context otherwise requires, each reference to a Subsidiary herein shall be a reference to a Subsidiary of an Obligor.

"Subsidiary Guarantor" means any Subsidiary of the Company that is a guarantor of the Obligations under the Guaranty and Security Agreement (or under another guaranty agreement in form and substance satisfactory to the Purchaser) or has granted to the Purchaser a Lien upon and security interest in its right, title and interest in, to and under the Collateral pursuant to the Security Documents; provided that no Excluded Subsidiary shall be required to be a Subsidiary Guarantor for so long as such Subsidiary remains an Excluded Subsidiary.

"Swap Agreement" means any agreement with respect to any swap, forward, future or derivative transaction or option or similar agreement involving, or settled by reference to, one or more currencies.

"Swiss Federal Tax Administration" means the tax authorities referred to in article 34 of the Swiss Withholding Tax Act.

"Swiss Security Documents" means:

(a) the Swiss law governed quota pledge agreement between (i) the Intercreditor Agent (acting for itself and as direct representative in the name and on behalf of the other pledgees), (ii) Insmed Incorporated as pledgor, and (iii) Insmed Switzerland GmbH as the company whose quotas are pledged; and

(b) the Swiss law governed bank accounts pledge agreement between (i) the Intercreditor Agent (acting for itself and as direct representative in the name and on behalf of the other pledgees), and (ii) Insmed Switzerland GmbH as pledgor; and

(c) the Swiss law governed intellectual property pledge agreement between (i) the Intercreditor Agent (acting for itself and as direct representative in the name and on behalf of the other pledgees), and (ii) Insmed Switzerland GmbH as pledgor; and

(d) the Swiss law governed security assignment agreement between (i) the Intercreditor Agent (acting for itself and for the benefit of the other secured parties) and (ii) Insmed Switzerland GmbH as assignor; and

(e) any other Foreign Security Document governed by the laws of Switzerland.

"Swiss Obligor" means an obligor incorporated in Switzerland and/or having its registered office in Switzerland and/or qualifying as a Swiss resident pursuant to art 9 of the Swiss Withholding Tax Act.

"Swiss Withholding Tax" means taxes imposed under the Swiss Withholding Tax Act.

"Swiss Withholding Tax Act" means the Swiss Federal Act on the Withholding Tax of 13 October 1965 (Bundesgesetz über die Verrechnungssteuer), together with the related ordinances, regulations and guidelines, all as amended and applicable from time to time.

"Systems" has the meaning set forth in Section 3.23(a).

"Tax" or "Taxes" means any present or future U.S. or non-U.S. federal, state, or local tax, levy, impost, duty, assessment, fee, deduction or withholding or other charge, including all excise, sales, use, value added, transfer, stamp, documentary, filing, recordation and other fees, imposed by any Governmental Authority (and including any interest, fines, penalties and additions applicable or related thereto).

"Tax Return" means any report, return, form (including elections, declarations, statements, amendments, claims for refund, schedules, information returns or attachments thereto) or other information supplied or required to be supplied to a Governmental Authority with respect to Taxes.

"Term" has the meaning set forth in Section 6.01.

"Term Lenders" means the "Lenders" under the Term Loan Agreement.

"Term Loan Agent" means BioPharma Credit plc, as collateral agent for the Term Lenders under the Term Loan Agreement.

"Term Loan Agreement" means that certain Amended and Restated Loan Agreement, dated as of ~~the date hereof~~ October 31, 2024, by and among the Company, certain subsidiaries of the Company from time to time party thereto, the Term Lenders and the Term Loan Agent.

"Term Transaction Documents" means the "Transaction Documents" under and as defined in the Term Loan Agreement.

"Third Party" means any Person other than (i) the Purchaser, the Company or any Subsidiary of the Company and (ii) any other Person Controlled by or under common Control with any of the foregoing.

"Third Party Claim" means any claim, action, suit or proceeding by a Third Party, excluding any lender, officer, directors, employee or agent or other representative of a party to this Agreement, including any investigation by any Governmental Authority.

"Trade Secret" means all forms and types of financial, business, scientific, technical, economic or engineering information, including patterns, plans, compilations, program devices,

formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically or in writing if (A) the owner thereof has taken reasonable measures to keep such information secret and (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another Person who can obtain economic value from the disclosure or use of the information, or as otherwise defined or construed under 18 U.S.C. Section 1839.

"Trading Day" means a day on which exchanges in the United States are open for the buying and selling of securities.

"Transaction Documents" means, collectively, this Agreement, the Security Documents, the Disclosure Letter, the Intercreditor Agreement, each intellectual property security agreement, the Control Agreements and any related ancillary documents or agreements (including without limitation waivers or consents), in each case as may be amended, restated, supplemented or otherwise modified from time to time.

"Transfer" means the sale, conveyance, transfer, license, sublicense, lease or other disposition of any property, including any sale, assignment, transfer or other disposal, with or without recourse, of any notes or accounts receivable or any rights and claims associated therewith.

"UCC" means the Uniform Commercial Code (or any similar or equivalent legislation) as in effect in any applicable jurisdiction.

"UCC Financing Statements" means the UCC-1 financing statements, in form and substance reasonably satisfactory to the Purchaser, that shall be filed by the Purchaser at or promptly following the Closing Date, as well as any additional UCC-1 financing statements or amendments thereto as reasonably requested from time to time, to perfect the Purchaser's security interest in the Collateral.

"UKBA" has the meaning set forth inSection 3.21(a).

"UK GDPR" has the meaning set forth in the definition of "GDPR"

"United States" and "U.S." mean the United States of America and each of its territories and possessions, including the Commonwealth of Puerto Rico.

"Withholding Agent" means the Obligors.

"Wholly-Owned Subsidiary" means, with respect to any Person, a Subsidiary of such Person, all of the Equity Interests of which (other than directors' qualifying shares or nominee or other similar shares required pursuant to Applicable Laws) are owned by such Person or another Wholly-Owned Subsidiary of such Person. Unless the context otherwise requires, each reference

to a Wholly-Owned Subsidiary herein shall be a reference to a Wholly-Owned Subsidiary of the Company.

Section 1.02. Irish terms.

In this Agreement, any reference to an "examiner" shall mean an examiner (including an interim examiner) appointed under section 509 of the Irish Companies Act and "examinership" shall be construed accordingly.

Article II.

PURCHASE OF REVENUE INTEREST PAYMENTS; PAYMENTS

Section 2.01. Purchase of Revenue Interest Payments.

(a) Upon the terms and subject to the conditions set forth in this Agreement, the Company agrees to sell, assign and transfer to the Purchaser, and the Purchaser agrees to purchase and accept from the Company, free and clear of all Liens, the right to receive the Revenue Interest Payments and, upon the exercise (or deemed exercise) by any applicable party of the Call Option or the Put Option, as the case may be, the Buy-Out Price in respect thereof. The Purchaser's right to receive the Revenue Interest Payments and, upon the exercise (or deemed exercise) by any applicable party of the Call Option or the Put Option, as the case may be, the Buy-Out Price in respect thereof shall vest immediately upon the Company's receipt of payment of the Purchase Price pursuant to Section 2.03(b), subject to the termination provisions of Section 6.01.

(b) The Company hereby consents to the Purchaser's recording and filing, at the Company's sole cost and expense, the UCC Financing Statements and other financing statements in the appropriate filing offices under the UCC (and continuation statements with respect to such financing statements when applicable) and any other notices of security or notices of charge meeting the requirements of Applicable Law in such manner and in such jurisdictions as are necessary or appropriate to perfect the Liens in the Collateral granted to the Purchaser under the Security Documents, subject as to priority only to the obligations arising in connection with the Term Loan Agreement as provided pursuant to the Intercreditor Agreement.

Section 2.02. Payments by the Company.

(a) Payments in Respect of the Revenue Interests.

(i) In consideration of the Purchase Price paid by the Purchaser, the Purchaser shall be entitled to receive, and the Company shall pay to the Purchaser, on the applicable Payment Dates, the Revenue Interest Payments during the Revenue Interest Period and, upon the exercise (or deemed exercise) by any applicable party of the Call Option or the Put Option, as the case may be, the Buy-Out Price in respect thereof.

(ii) With respect to each fiscal quarter, commencing with the first fiscal quarter ending after the Closing Date, the Company shall deliver to the Purchaser, on or before the forty-fifth (45th) day following the end of such fiscal quarter, a report with respect to the fiscal quarter most recently ended, setting forth a calculation of the Net Sales for such fiscal quarter and the applicable Revenue Interest Payment (each such report, a "Net Sales Report"). On each Payment Date, the Company shall pay to the Purchaser, the Revenue Interest Payment for the applicable fiscal quarter as specified in the applicable Net Sales Report; provided that all such payments in respect of any fiscal quarter shall be subject to reconciliation based on the final

Net Sales for the applicable fiscal year in which such fiscal quarter occurs based on the audited financial statements for such fiscal year on the Payment Date for the first fiscal quarter after delivery of such audited financial statements pursuant to Section 5.02(a)(ii), with such reconciliation to be prepared by the Company and delivered to the Purchaser in the form of a Reconciliation Report in accordance with Section 5.02(b). With respect to each reconciliation, any overpayments shall be credited against, and any underpayments shall be added to, subject to Section 2.02(d), the subsequent payments in respect of the Revenue Interests. For the avoidance of doubt, the Purchaser shall not be required to refund any Revenue Interest Payments.

(iii) If the Purchaser has not received Revenue Interest Payments (excluding, for avoidance of doubt, any payment of interest made in accordance with Section 2.02(d)) under this Agreement for all fiscal quarters ending on or prior to March 31, 2028 in an aggregate amount equal to or greater than 100.0% of the Purchase Price, the Company shall, on the date that is thirty days (30) days after the Payment Date with respect to the fiscal quarter ending March 31, 2028 (i.e., June 14, 2028), make a one-time payment to the Purchaser in an amount that, when added to the aggregate amount of Revenue Interest Payments received by the Purchaser as of such date, would equal to 100.0% of the Purchase Price.

(b) Reimbursable Expenses. The Company shall pay to the Purchaser all Reimbursable Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Closing Date, when due. It is the intention of the parties hereto that the Company shall pay Reimbursable Expenses directly; provided that, at the discretion of the Purchaser, any part of the Reimbursable Expenses incurred and outstanding as of the Closing Date may be deducted from the Purchase Price to the extent invoiced at least one (1) Business Day prior to the Closing Date. In the event the Purchaser pays any of such expenses directly, the Company will promptly reimburse the Purchaser for such expenses.

(c) Payment Procedure; Currency Conversion; Late Payments. Any payments to be made by the Company to the Purchaser hereunder or under any other Transaction Document shall be made in United States dollars by wire transfer of immediately available funds. All Revenue Interest Payments and other payments by the Company (other than payments in respect of Reimbursable Expenses and indemnification obligations pursuant to Section 7.04) shall be made to the Purchaser. If any currency conversion shall be required in connection with the calculation of amounts payable hereunder, such conversion shall be made using the average of the buying and selling rates on the last five (5) Business Days of the fiscal quarter to which such amounts pertain, as published by The Wall Street Journal, Internet Edition at www.wsj.com.

(d) Default Interest. All Revenue Interest Payments and any other Obligations required to be paid to the Purchaser on each Payment Date but not paid when due (other than good faith underpayments subject to reconciliation pursuant to Section 2.02(a)(ii)) shall bear interest at a rate of the Prime Rate plus three percent (3.00%) per annum (calculated on the basis of a three hundred sixty (360) day year and the actual days elapsed) from the due date until paid in full or, if less, the maximum interest rate permitted by Applicable Law.

(e) Minimum Interest Payments; Swiss Withholding Tax. The rates of interest provided for in this Agreement are minimum interest rates. When entering into this Agreement, the parties hereto have assumed that the interest payable at the rates set out in this Section 2.02 or in other Sections of this Agreement, if any, is not and will not become subject to Swiss Withholding Tax. This notwithstanding, if a Tax deduction is required by law in respect of any interest payable by any Obligor under any Transaction Document and should it be unlawful for any Obligor incorporated in Switzerland and/or having its registered office in Switzerland and/or qualifying as a Swiss resident pursuant to article 9 of the Swiss Withholding Tax Act to comply with Section 2.05 for any reason, where this would otherwise be required by the terms ofSection

2.05, then (i) the applicable interest rate in relation to that interest payment shall be the interest rate which would have applied to that interest payment as provided for by this Section 2.02 divided by one minus the rate at which the relevant Tax deduction is required to be made under Swiss domestic tax law and/or applicable double taxation treaties (where the rate at which the relevant Tax deduction is required to be made is for this purpose expressed as a fraction of one) and (b) such Obligor shall (x) pay the relevant interest at the adjusted rate in accordance with paragraph (i) above and (y) make the Tax deduction on the interest so recalculated, and all references to a rate of interest under any Transaction Document shall be construed accordingly.

Section 2.03. Purchase Price; Conditions Precedent.

(a) Purchase Price. Subject to the applicable conditions precedent set forth in clause (b) below, which may be waived by the Purchaser in its sole discretion, on the Closing Date, the Purchaser shall pay to the Company, and the Company shall accept, the Purchase Price (less any then unpaid Reimbursable Expenses) by wire transfer of immediately available funds.

(b) Conditions Precedent to the Closing Date and the Purchase Price. The Company and each other Obligor, as applicable, shall have delivered to the Purchaser:

(i) this Agreement, duly executed by the Company;

(ii) evidence that the Term Transaction Documents have been duly executed and delivered by all parties thereto, in form and substance reasonably satisfactory to the Purchaser, and that, pursuant to the terms thereof, not less $350,000,000 will be funded to the Company by the Term Lenders prior to or substantially simultaneously with the payment of the Purchase Price pursuant to Section 2.03(a) above;

(iii) the Guaranty and Security Agreement and short-form security agreements in respect of the Product Intellectual Property, in each case duly executed by the relevant Obligors;

(iv) the Japanese Equity Pledge, duly executed by the relevant Obligors;

(v) the Intercompany Subordination Agreement, duly executed by the Company and its Subsidiaries party thereto;

(vi) evidence that the Intercreditor Agreement has been duly executed and delivered by all parties thereto;

(vii) a UCC-1 financing statement in proper form for filing against each Obligor;

(viii) a completed Perfection Certificate, duly executed by the Company;

(ix) one or more legal opinions of counsel to each Obligor or the Purchaser, as the case may be, in each case in form and substance reasonably satisfactory to the Purchaser;

(x) the legal opinion of Matheson LLP, Irish counsel to the Purchaser, in form and substance reasonably satisfactory to the Purchaser;

(xi) a secretary's or director's certificate executed by an authorized officer or director of each Obligor attaching certified organizational or constitutional documents, certificates of good standing, up-to-date extract of the chamber of commerce and incumbency certificates of each Obligor (where applicable in the subject jurisdiction) and resolutions of the

governing body, holders of the issued shares or supervisory Board of each Obligor, as applicable, authorizing such Obligor to enter into the Transaction Documents and perform the transactions contemplated thereby;

(xii) the Purchaser's receipt of a letter of status with respect to any Obligor incorporated in Ireland, certified by a Director or the Secretary of such Obligor;

(xiii) evidence that the Obligors have obtained all consents required by the Obligors under any Applicable Law, their respective organizational or constitutional documents and Governmental Authorities necessary in connection with the execution, delivery and performance of the Transaction Documents and the consummation of the Transactions;

(xiv) subject to Section 5.18, duly executed Control Agreements in respect of each of the deposit accounts and securities accounts in the United States of the Company and the Subsidiary Guarantors (other than Excluded Accounts);

(xv) an officer's or director's certificate, certifying as to the following conditions: (I) the representations and warranties in Article III hereof and in any other Transaction Document shall be true, accurate and complete in all material respects on the Closing Date; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; provided, further, that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date; and (II) no Put Option Event shall have occurred and be continuing;

(xvi) to the extent not deducted from the Purchase Price, payment of Reimbursable Expenses then due as specified in Section 2.02(b), to the extent such Reimbursable Expenses are invoiced at least one (1) Business Day prior to the Closing Date;

(xvii) certificates of insurance evidencing that the insurance required to be maintained pursuant to Section 5.11 is in full force and effect, and, subject to Section 5.18, endorsements naming the Intercreditor Agent, on behalf of the Purchaser, as additional insured and loss payee thereunder, in each case, in form and substance reasonably satisfactory to the Purchaser; and

(xviii) In respect of each Dutch Obligor:

(A) a copy of a resolution of its Board approving its execution and the terms of, and the transactions contemplated by, the Guaranty to which it is a party;

(B) if required, a copy of a resolution of its board of supervisory directors (if any) approving its execution and the terms of, and the transactions contemplated by, the Guaranty to which it is a party;

(C) if applicable, copy of a resolution of its general meeting of shareholders approving its execution and the terms of, and the transactions contemplated by, the Guaranty to which it is a party; and

(D) if it is required by law or any arrangement binding on it to obtain works council advice in respect of its or any other person's entry into the Guaranty, a copy of a positive or neutral advice from its (central) works council (and, if such advice is not unconditional, confirmation from the Company that (i) the conditions set by the works council are and will be complied with and (ii) such compliance does and will not have a Material Adverse Effect) including the request for advice or, a confirmation of its

Board included in the board resolution that no works council has jurisdiction in respect of any of the transactions contemplated by the Transaction Documents to which it is a party.

(c) For the avoidance of doubt, each of the conditions precedent in Section 2.03 may be waived by the Purchaser in its sole discretion.

Section 2.04. No Assumed Obligations.

Notwithstanding any provision in this Agreement or any other writing to the contrary, the Purchaser is acquiring only the right to receive the Revenue Interest Payments and, upon the exercise (or deemed exercise) by any applicable party of the Call Option or the Put Option, as the case may be, the Buy-Out Price in respect thereof, and are not assuming any liability or obligation of the Company or any of its Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter, whether under any Transaction Document or otherwise. All such liabilities and obligations shall be retained by and remain obligations and liabilities of the Company or its Affiliates (the "Excluded Liabilities").

Section 2.05. Taxes.

(a) Payments Free of Taxes. Any and all payments by or on account of any Obligation shall be made without deduction or withholding for any Taxes, except as required by Applicable Law. If any Applicable Law requires the deduction or withholding of any Tax from any such payment by a Withholding Agent, then the applicable Withholding Agent shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with Applicable Law and, if such Tax is an Indemnified Tax, then the sum payable by such Obligor shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 2.05) the Purchaser receives an amount equal to the sum it would have received had no such deduction or withholding been made.

(b) Payment of Other Taxes. The Obligors shall timely pay to the relevant Governmental Authority in accordance with Applicable Law, or at the option of the Purchaser, timely reimburse it for the payment of any Other Taxes.

(c) Evidence of Payments. As soon as reasonably practicable after any payment of Taxes by an Obligor to a Governmental Authority pursuant to this Section 2.05, such Obligor shall deliver to the Purchaser the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to the Purchaser.

(d) Indemnification. The Obligors hereby agree to indemnify, hold harmless and reimburse the Purchaser, within ten (10) days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this Section 2.05) payable or paid by the Purchaser or required to be withheld or deducted from a payment to the Purchaser and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to the Company by the Purchaser shall be conclusive absent manifest error. The Purchaser hereby agrees to indemnify, hold harmless and reimburse each Obligor, within ten (10) days after demand therefor, of the full amount of Taxes (including any interest and penalties imposed in connection therewith) that such Obligor was

required to, but did not withhold as a result of the Purchaser failing to comply with Section 2.05(e) or the transactions contemplated by this Agreement failing to be treated according to the Intended Tax Treatment. A certificate as to the amount of such liability for withholding delivered to the Purchaser by the Company shall be conclusive absent manifest error.

(e) Status of Purchaser. The Purchaser shall deliver to the Company, from time to time upon reasonable request by the Company, properly completed and executed documentation by the Company as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, the Purchaser, if reasonably requested by the Company, shall deliver such other documentation prescribed by Applicable Law or reasonably requested by the Company as will enable the Company to determine whether or not the Purchaser is subject to backup withholding or information reporting requirements. Without limiting the generality of the foregoing, before the Purchaser becomes a party to this Agreement, the Purchaser shall deliver (i) if the Purchaser is a United States person within the meaning of Section 7701(a)(30) of the Code, IRS Form W-9 certifying that the Purchaser is not subject to backup withholding or (ii), if the Purchaser is not a United States person, IRS Form W-8BEN, IRS Form W-8BEN-E, IRS Form W-8EXP, IRS Form W-8ECI or IRS Form W-8IMY if applicable, as well as any applicable supporting documentation or certifications, certifying that the Purchaser is exempt from U.S. withholding tax and backup withholding with respect to payments of interest (as determined for U.S. federal income tax purposes).

(f) The Purchaser agrees that if any form or certification described in Section 2.05(e) it previously delivered to the Company expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify the Company in writing of its legal inability to do so.

(g) Survival. Each party's obligations under this Section 2.05 shall survive any assignment of rights by, or the replacement of, the Purchaser, and the repayment, satisfaction or discharge of all Obligations under any Transaction Document.

Section 2.06. Additional Costs; Changes in Law Generally.

If, on or after the date hereof (or such later date on which the Purchaser or its assignee becomes party to this Agreement), the adoption of any Applicable Law, or any Change in Law, shall impose, modify or deem applicable any reserve (including any such requirement imposed by the Board of Governors of the Federal Reserve System), special deposit, contribution, insurance assessment or similar requirement, against assets of, deposits with or for the account of, or credit extended by, the Purchaser or shall impose on the Purchaser any other condition affecting the Purchaser's interest in the Obligations or Transaction Documents, and the result of any of the foregoing is to increase the cost to the Purchaser of making or maintaining its interest in the Obligations or Transaction Documents, or to reduce the amount of any sum received or receivable by such the Purchaser under this Agreement or any other Transaction Document, or subject the Purchaser to any Taxes on its loans, loan principal, commitments or other obligations, or its deposits, reserves, other liabilities or capital (if any) attributable thereto (other than (i) Indemnified Taxes, (ii) Taxes described in clauses (b) through (d) of the definition of "Excluded Taxes" and (iii) and Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes), then the Company shall pay to the Purchaser within five (5) Business Days after any demand for such additional amount or amounts as will compensate the Purchaser for such increased cost or reduction.

Article III.

REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company hereby represents and warrants to the Purchaser as follows:

Section 3.01. Organization.

Each Obligor is duly incorporated or formed, as applicable, validly existing and in good standing under the laws of its respective jurisdiction of formation (to the extent that such concept is applicable in such jurisdiction) and has all corporate, limited liability company or similar powers and all licenses, authorizations, consents and approvals required to carry on its respective business as now conducted and as proposed to be conducted in connection with the transactions contemplated by the Transaction Documents. Each Obligor is duly qualified to do business as a foreign corporation or foreign limited liability company, as applicable, and is in good standing (to the extent that such concept is applicable in such jurisdiction) in every jurisdiction in which the failure to do so would be reasonably expected to have a Material Adverse Effect. As of the Closing Date, the Subsidiaries of the Company are listed on Schedule 3.01 of the Disclosure Letter.

Section 3.02. Authorization; Enforceability.

Each Obligor has all necessary power and authority to enter into, execute and deliver the Transaction Documents to which it is a party and to perform all of the obligations to be performed by it hereunder and thereunder and to consummate the transactions contemplated hereunder and thereunder. Each Transaction Document has been duly authorized, executed and delivered by each Obligor party thereto, and each Transaction Document constitutes the valid and binding obligation of each Obligor party thereto, enforceable against such Obligor in accordance with their respective terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally, general equitable principles or, solely in respect of the English Obligor, Legal Reservations.

Section 3.03. Governmental Authorization.

The execution and delivery by each Obligor of the Transaction Documents to which it is a party, and the performance by such Obligor of its obligations thereunder, does not require any notice to, action or consent by, or in respect of, or filing with, any Governmental Authority, except for the filing of the UCC Financing Statements, short-form intellectual property security agreements with the United States Patent and Trademark Office or the United States Copyright Office, and any filings with the SEC, and registration of the Dutch law security agreement at the Dutch tax authorities and any filings that may be required to be made in the Irish Companies Registration Office in respect of the Irish Security Agreements.

Section 3.04. Ownership.

(a) The Company owns, controls or holds a valid license granting all rights purported to be held by it to all of the Product Intellectual Property, Regulatory Filings and the Regulatory Approvals related to each Specified Product, in each case material to the Company, free and

clear of all Liens (other than Permitted Liens), has in its possession all records granting or assigning ownership of, or a valid license to, such Product Intellectual Property, Regulatory Filings and the Regulatory Approvals and is aware of no claims by any Person to its ownership of such Product Intellectual Property, Regulatory Filings and the Regulatory Approvals, or challenging the ownership rights of the Company as owner thereof or the validity or enforceability of any such rights.

(b) The Company, owns, and is the sole holder of all Collateral, free and clear of any and all Liens (other than Permitted Liens). Except as set forth on Schedule 3.04(b) of the Disclosure Letter or as permitted pursuant to this Agreement, no Obligor has Transferred or granted any Lien in respect of or agreed to Transfer or grant any Lien in respect of the Collateral, other than Permitted Liens. Except as set forth on Schedule 3.04(b) of the Disclosure Letter, no Person other than the Company or any of its Subsidiaries has any right to receive any payments in respect of Net Sales or the Revenue Base. The Company has the full right grant to the Purchaser the right to receive the payments hereunder in respect of the Revenue Interests pursuant to this Agreement and perform its obligations hereunder, without any requirement to obtain the consent of any Person, except such consents as are obtained at or prior to the Closing Date. At the Closing Date, the Purchaser shall have acquired good and valid rights and interests in the right to receive the Revenue Interest Payments and, upon the exercise (or deemed exercise) by any applicable party of the Call Option or the Put Option, as the case may be, the Buy-Out Price in respect thereof, free and clear of any and all Liens, subject to the terms of this Agreement.

Section 3.05. Financial Statements; No Material Adverse Effect.

(a) The Audited Financial Statements (i) were prepared in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, (ii) fairly present in all material respects the consolidated financial condition of the Company and its Subsidiaries as of the date thereof and their results of operations for the period covered thereby in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, and (iii) show all material liabilities required to be reflected in such financial statements under GAAP.

(b) The Interim Financial Statements (i) were prepared in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, (ii) fairly present in all material respects the consolidated financial condition of the Company and its Subsidiaries as of the date thereof and their results of operations for the period covered thereby, subject, in the case of clauses (i) and (ii), to the absence of footnotes and to normal year-end audit adjustments and (iii) show all material liabilities required to be reflected in such financial statements under GAAP.

(c) The financial statements delivered pursuant to Section 5.02(a) have been prepared in accordance with GAAP (except as may otherwise be permitted under Section 5.02(a)) and present fairly in all material respects (on the basis disclosed in the footnotes to such financial statements) the consolidated financial condition, results of operations and cash flows of the Company and its Subsidiaries as of the dates thereof and for the periods covered thereby.

(d) Since the date of the Audited Financial Statements, there has been no event or circumstance, either individually or in the aggregate, that has had or could reasonably be expected to have a Material Adverse Effect.

Section 3.06. [Intentionally Omitted].

Section 3.07. Solvency; No Fraudulent Transfer.

The Company and the Subsidiaries, taken as a whole, are not insolvent as defined in any statute of the United States Bankruptcy Code or in the fraudulent conveyance or fraudulent transfer statutes of the Commonwealth of Virginia. Assuming consummation of the transactions contemplated by the Transaction Documents and the Term Transaction Documents, (a) the present fair saleable value of the Company's and the Subsidiaries' assets is greater than the total amount of liabilities of the Company and the Subsidiaries as such liabilities mature, (b) the Company and the Subsidiaries, taken as a whole, do not have unreasonably small capital with which to engage in its business, and (c) the Company and the Subsidiaries, taken as a whole, have not incurred, nor do they have present plans to or intend to incur, debts or liabilities beyond their ability to pay such debts or liabilities as they become absolute and matured. No transfer of property was or is being made by any Obligor and no obligation was or is being incurred by any Obligor in connection with the transactions contemplated by this Agreement or the other Transaction Documents and the Term Transaction Documents with the intent to hinder, delay, or defraud either present or future creditors of such Obligor.

Section 3.08. Litigation.

Other than as set forth on Schedule 3.08 of the Disclosure Letter, there is no (a) action, suit, arbitration proceeding, claim, investigation or other proceeding (whether administrative, judicial or otherwise) pending or, to the Knowledge of the Company, threatened against the Company or any Subsidiary or (b) any governmental inquiry pending or, to the Knowledge of the Company, threatened against the Company or any Subsidiary, which in each case with respect to clauses (a) and (b) above, (x) as of the Closing Date, individually or in the aggregate, would reasonably result in liabilities in excess of $[***] or that would reasonably be likely to adversely affect this Agreement or the transactions contemplated herein or (y) at any time after the Closing Date, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect.

Section 3.09. Compliance with Laws.

Neither the Company nor any Subsidiary (a) is in violation of, has violated, or to the Knowledge of the Company, is under investigation with respect to, or (b) has been threatened to be charged with or been given notice of any violation of, any Applicable Law with respect to the Company or any of its Subsidiaries, the Revenue Interests or any Specified Product or any other Collateral, in each case of (a) and (b) which could reasonably be expected to have a Material Adverse Effect.

Section 3.10. Conflicts; Adverse Agreements.

Except as set forth on Schedule 3.10 of the Disclosure Letter, neither the execution and delivery of any of this Agreement or the other Transaction Documents to which any Obligor is a party nor the performance or consummation of the transactions contemplated hereby or thereby will: (a) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, any provisions of: (i) any law, rule, ordinance or regulation of any Governmental Authority, or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which the Company or any Subsidiary or any of their

respective assets or properties may be subject or bound; or (ii) any material contract, agreement, commitment or instrument to which the Company or any Subsidiary is a party or by which the Company or its Subsidiary or any of their respective assets or properties is bound or committed; (b) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, any provisions of the articles or certificate of incorporation or bylaws (or other organizational or constitutional documents) of the Company or any Subsidiary; (c) except for the filing of the UCC Financing Statements and any other notices of security or notices of charge required hereunder and filings with the United States Patent and Trademark Office, require any notification to, filing with, or consent of, any Person or Governmental Authority, except such consents that are obtained at or prior to the Closing Date; (d) give rise to any right of termination, cancellation or acceleration of any right or obligation of the Company, any Subsidiary or any other Person or to a loss of any benefit relating to the Revenue Interests; or (e) other than pursuant to this Agreement, any other Transaction Document or any Term Transaction Document, result in the creation or imposition of any Lien on (i) the assets or properties of the Company or any Subsidiaries or (ii) the Revenue Interests or any Collateral, except, in the case of the foregoing clauses (a) or (c), as would not, individually or in the aggregate, have a Material Adverse Effect. No Obligor or any of its Subsidiaries is a party to any contractual obligation or subject to any restriction or limitation in any organizational document or any judgment, order, regulation, ruling or other requirement of a court or other Governmental Authority, which (either individually or in the aggregate) could reasonably be expected (either individually or in the aggregate) to have, a Material Adverse Effect.

Section 3.11. Intellectual Property.

(a) Schedule 3.11(a) of the Disclosure Letter sets forth, as of the Closing Date, an accurate, true and complete list of all (i) worldwide Patents and patent applications, (ii) trade names, registered trademarks, registered service marks, and applications for trademark registration or service mark registration, (iii) registered copyrights, and (iv) domain name registrations and websites, in each case with respect to clauses (i), (ii), (iii) and (iv) above in this clause (a) that constitute Product Intellectual Property. Except as disclosed therein, to the Knowledge of the Company, each issued Patent and trademark listed on Schedule 3.11(a) of the Disclosure Letter is valid, enforceable and subsisting and has not lapsed, expired, been cancelled or become abandoned, except in the ordinary course of business and where such lapse or abandonment would not reasonably be likely to result in a Material Adverse Effect.

(b) Except for Product Intellectual Property licensed to or owned by any Obligor and set forth on Schedule 3.11(a) of the Disclosure Letter, to the Knowledge of the Company, no other Intellectual Property is necessary to use, Develop, Manufacture, import or Commercialize any Specified Product, including the use of Patents to protect product markets by excluding competitors. To the Knowledge of the Company, the use, Development, Manufacture, import or Commercialization of the Specified Products does not infringe any Patents or misappropriate any other Intellectual Property that is owned or controlled by a Third Party.

(c) To the Knowledge of the Company, there are no unpaid maintenance, annuity or renewal fees currently overdue for any of the Patents necessary for, or otherwise material to, the Development, Commercialization, and/or Manufacture, or other exploitation, of any Specified Product, including those listed on Schedule 3.11(c) of the Disclosure Letter (such Patents, collectively, "Material Patents").

(d) There is, and has been, no pending, decided or settled opposition, interference proceeding, reexamination proceeding, *inter partes* proceeding, cancellation proceeding, injunction, claim, lawsuit, declaratory judgment, administrative post-grant or patent review proceeding, other administrative or judicial proceeding, hearing, investigation, complaint, arbitration, mediation, International Trade Commission investigation, decree, notice of an Abbreviated New Drug Application ("ANDA"), notice of a Drug Approval Application under Section 505(b)(2) of the Federal Food, Drug, and Cosmetics Act, or notice or litigation under the so-called Hatch-Waxman amendments to the FFDCA or any other filed claim (collectively referred to hereinafter as "Disputes"), related to any of the Material Patents nor has any such Dispute been threatened in writing challenging the legality, validity, enforceability or ownership of any Material Patents or referencing a Specified Product. To the Knowledge of the Company, there are no Disputes by any Person or Third Party against the Company, its Affiliates or its Licensees or its licensor as pertaining to any Specified Product, and the Company has not received any written notice or claim of any such Dispute as pertaining to any Specified Product.

(e) To the Knowledge of the Company, the Company and its Affiliates have taken commercially reasonable measures and precautions to protect and maintain (i) the confidentiality and secrecy of all trade secrets with respect to each Specified Product and (ii) the value of all Intellectual Property related to each Specified Product, except where such failure to take action would not reasonably be expected to have a Material Adverse Effect.

(f) To the Knowledge of the Company, no material Trade Secret, including but not limited to clinical data supporting FDA approval of product and information about product development and use, of the Company or its Affiliates with respect to any Specified Product has been published or disclosed to any Person except pursuant to a written agreement requiring such Person to keep such Trade Secret confidential, except where such disclosure would not reasonably be expected to have a Material Adverse Effect.

Section 3.12. Regulatory Approvals, Etc.

(a) The Company and its Affiliates and Licensees have made available to the Purchaser any written reports or other written communications received from a Governmental Authority that would indicate that any Regulatory Agency (A) is likely to revise or revoke any current Regulatory Approval granted by any Regulatory Agency with respect to any Specified Product or may not accept for review or grant Regulatory Approval for any Specified Product or (B) is likely to pursue any material compliance actions against the Company. To the Knowledge of the Company there are no other facts or circumstances that could reasonably be expected to (i) indicate that any of the events specified in the immediately preceding clauses (A) or (B) may occur or (ii) cause the Company or any of its Subsidiaries to voluntarily revise, withdraw or not apply for any Regulatory Approval.

(b) The Company and its Subsidiaries possess all material Regulatory Approvals issued or required by the Regulatory Agencies, which Regulatory Approvals are necessary to conduct the business relating to the Specified Products, including to conduct the current clinical trials relating to the Specified Products, and neither the Company nor its Subsidiaries has received any notice of proceedings relating to, and there are no facts or circumstances to the Knowledge of the Company that could reasonably be expected to lead to, the revocation, suspension, termination or modification of any such Regulatory Approvals. All applications, notifications, submissions, information, claims, reports and statistics and other data and conclusions derived therefrom, utilized as the basis for or submitted in connection with any Regulatory Filings when submitted to the FDA or other Regulatory Agency were true, complete and correct in all material respects as of the date of submission, including any updates, changes, corrections or modifications to such Regulatory Filings when submitted to the FDA or other Regulatory Agency. None of the officers or directors, or, to the Knowledge of the Company,

Affiliates or employees of the Company or any Subsidiary or any agent or consultant has (i) made an untrue statement of material fact or fraudulent statement to any Regulatory Agency or failed to disclose a material fact required to be disclosed to a Regulatory Agency; or (ii) committed an act, made a statement, or failed to make a statement that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Reg. 46191 (September 10, 1991).

(c) The Company and its Affiliates and Licensees are in compliance with, and have complied with, all applicable federal, state, local and foreign laws, rules, regulations, standards, orders and decrees governing its business, including to the extent applicable, the following laws:

(d) the laws composing the Medicare and Medicaid Programs, including applicable provisions of the Social Security Act, (e.g., Civil Monetary Penalties Act, 42 U.S.C. Sec. 1320a-7a, and the Anti-Kickback Statute, 42 U.S.C. Section 1320a-7b(b)); (b) any other laws prohibiting rebates, kickbacks, fee-splitting or other financial incentives or inducements; (c) the False Claims Act, 31. U.S.C. 3729 *et seq.*; (d) the FFDCA and Public Health Service Act and (e) all regulations promulgated by each Regulatory Agency, the failure of compliance with which could reasonably be expected to result in a Material Adverse Effect; the Company and its Affiliates and Licensees have not received any notice citing action or inaction by any of them that would constitute any non-compliance with any applicable federal, state, local and foreign laws, rules, regulations, or standards, which could reasonably be expected to result in a Material Adverse Effect; and to the Knowledge of the Company, no prospective change in any applicable federal, state, local or foreign laws, rules, regulations or standards has been adopted which, when made effective, could reasonably be expected to result in a Material Adverse Effect.

(e) All preclinical and clinical trials conducted on behalf of the Company or its Affiliates or Licensees relating to each Specified Product were conducted in all material respects in compliance with Applicable Law and, in all material respects, in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards. The Company and its Affiliates and Licensees are in material compliance with the requirements and conditions of all Regulatory Approvals, including any requirements to conduct confirmatory studies as part of an Accelerated Approval pursuant to 21 U.S.C. § 356(c), as such requirements and conditions may have been amended by a Regulatory Agency or comparable authority. Neither the Company nor its Affiliates and Licensees has received any notices or correspondence from any Regulatory Agency or comparable authority requiring the termination, suspension, or clinical hold of any ongoing clinical trials conducted by or on behalf of the Company or its Affiliates and Licensees with respect to any Specified Product.

(f) Neither the Company nor any of its Affiliates or Licensees have received any notices from, (i) any Governmental Authority or (ii) any pricing and reimbursement representative of any Person, in each case exercising authority with respect to pricing and reimbursement for the Specified Products, that have resulted in any non-coverage decision in respect of, or material reduction in the expected pricing of, the Specified Products in the United States.

(g) All Manufacturing conducted by or on behalf of the Company and its Affiliates and Licensees relating to the Specified Products, to the Knowledge of the Company, with respect to Manufacturing conducted on behalf of the Company and its Affiliates, have been and are being conducted in compliance with applicable current good manufacturing practices set forth in 21 C.F.R. Parts 210 and 211 and applicable FDA guidance documents, except as could not

reasonably be expected to have a Material Adverse Effect. Without limiting the generality of the foregoing, with respect to any Specified Product being tested or manufactured by the Company and its Subsidiaries, as of the Closing Date, to the Knowledge of the Company, neither the Company nor any Subsidiary has received any written notice from any applicable Governmental Authority, including the FDA, that such Governmental Authority is conducting an investigation or review of (i) the Company and its Subsidiaries' (or any third party contractors therefor) manufacturing facilities and processes for Manufacturing any Specified Product or the marketing and sales of any Specified Product, in each case which have identified any material deficiencies or violations of Applicable Laws or the permits related to the Manufacture, marketing and/or sales of any Specified Product that could reasonably be expected to result in a Material Adverse Effect, or (ii) any such Regulatory Approval that could be reasonably expected to result in a revocation or withdrawal of such Regulatory Approval, nor has any such Governmental Authority issued any order or recommendation stating that the development, testing, manufacturing, marketing or sales of any Specified Product by the Company and its Subsidiaries should cease or that any Specified Product should be withdrawn from the marketplace. Neither the Company nor any Subsidiary of the Company has experienced any significant failures in the Manufacturing of any Specified Product for commercial sale that has had or could reasonably be expected to have, if such failure occurred again, a Material Adverse Effect.

(h) Neither the Company, its Affiliates, its Licensees nor, to the Knowledge of the Company, their respective officers, employees or agents, has been convicted of any crime or engaged in any conduct for which (i) debarment is mandated by 21 U.S.C. § 335a(a) or authorized by 21 U.S.C. § 335a(b); or (ii) exclusion is required pursuant to 42 U.S.C. § 1320a-7b and related regulations, nor is any such debarment or exclusion threatened or pending.

(i) Neither the Company nor any Subsidiary has received from the FDA a Warning Letter, Form FDA-483, "Untitled Letter," or similar written correspondence or notice alleging violations of laws and regulations enforced by the FDA, or any comparable correspondence from any other Governmental Authority with regard to any Specified Product or the manufacture, processing, packaging or holding thereof, the subject of which communication is unresolved and if determined adversely to the Company or such Subsidiary could reasonably be expected to have a Material Adverse Effect.

(j) There have been no Safety Notices, (i) to the Company's Knowledge, there are no unresolved material product complaints with respect to any Specified Product which could reasonably be expected to have a Material Adverse Effect, and (ii) to the Company's Knowledge, there are no facts that would be reasonably likely to result in (A) a material Safety Notice with respect to any Specified Product, (B) a material change in the labeling of any Specified Product or (C) a termination or suspension of marketing of any Specified Product.

(k) The Company and its Affiliates and Licensees are in material compliance with all applicable federal, state and local laws and regulations regarding the privacy and security of health information and electronic transactions, including, to the extent applicable, the Health Insurance Portability and Accountability Act (HIPAA), and has implemented adequate policies, procedures and training designed to assure continued compliance and to detect non-compliance.

Section 3.13. Material Contracts.

Schedule 3.13 of the Disclosure Letter sets forth a true and complete list of all Material Contracts, including any amendments or modifications thereto, as of the Closing Date. Neither the Company nor its Affiliates is in breach of any Material Contract or in default under any Material Contract which breach or default, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect. There is no event or circumstance that with

notice or lapse of time, or both, would reasonably be expected to (a) constitute a breach or default by the Company and/or its Affiliates or (to the Knowledge of the Company) any other party under any Material Contract, (b) give any Person the right to receive or require a rebate, chargeback, penalty or change in delivery schedule under any Material Contract, (c) give any Person the right to accelerate the maturity or performance of any Material Contract or (d) give any Person the right to cancel, terminate or modify any Material Contract. To the Knowledge of the Company, nothing has occurred and no condition exists that would permit any other party thereto to terminate any Material Contract. Neither the Company nor its Affiliates has received any notice or, to the Knowledge of the Company, any threat (in writing) of termination of any such Material Contract. To the Knowledge of the Company, no other party to a Material Contract is in breach of or in default under such Material Contract which breach or default, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect. All Material Contracts are valid and binding on the Company and its Affiliates and, to the Knowledge of the Company, on each other party thereto, and are in full force and effect.

Section 3.14. Place of Business.

(a) The Company's principal place of business, chief executive office and each office where each of the Company and its Subsidiaries keeps its records regarding the Collateral are, as of the Closing Date, each set forth on Schedule 3.14 of the Disclosure Letter. None of the Company (or any predecessor by merger or otherwise) and its Subsidiaries has, within the five (5) year period preceding the date hereof, had a name that differs from its name as of the date hereof.

(b) For the purposes of Regulation (EU) 2015/848 of 20 May 2015 on insolvency proceedings (recast) (the "Regulation"), each Obligor's centre of main interest (as that term is used in Article 3(1) of the Regulation) is situated in its jurisdiction of incorporation and it has no "establishment" (as that term is used in Article 2(10) of the Regulation) in any other jurisdiction.

Section 3.15. [Intentionally Omitted].

Section 3.16. Section 3.16. Perfection; Subordination.

The Transaction Documents create valid security interests in, and Liens on, the Collateral purported to be covered thereby, which security interests and Liens will be, upon the timely and proper filings, deliveries, notations and other actions contemplated in the Transaction Documents, perfected security interests and Liens (to the extent that such security interests and Liens can be perfected by such filings, deliveries, notations and other actions). Other than as permitted by this Agreement or provided for in the Intercreditor Agreement, the claims and rights of the Purchaser created by any Transaction Document are not, and shall not be, subordinated to any creditor of any Obligor or any other Person and the Liens created pursuant to the Transaction Documents will have first ranking priority and will not be subject to any prior ranking or pari passu ranking Lien other than Permitted Liens.

Section 3.17. Insurance.

There are in full force and effect insurance policies maintained by reputable insurance companies in accordance with standards customary for companies such as the Company, with

coverage of the Company and each of its Subsidiaries in amounts customary for companies of comparable size and condition similarly situated in the same industry as, including product liability insurance, directors and officers insurance and insurance against litigation liability, subject only to such exclusions and deductible items as are usual and customary in insurance policies of such type.

Section 3.18. Tax.

Each of the Company and its Subsidiaries has timely filed all federal income and other material Tax Returns and has paid when due all material Taxes levied or imposed upon them or their property, income or assets. There are no Liens in respect of Taxes applicable to the Company or any of its Subsidiaries except Permitted Liens. There is no material tax assessment proposed against the Company or its Subsidiaries for Taxes that is not being actively contested in good faith and by appropriate proceedings and for which reserves or other appropriate provisions, if any, as are required in conformity with GAAP have been made or provided therefor.

Section 3.19. Disclosures.

All written information heretofore furnished to the Purchaser by or on behalf of the Company for purposes of or in connection with any Transaction Document or any transaction contemplated hereby, after giving effect to all supplements thereto made prior to the Closing Date, is or will be, taken as a whole, true, complete and correct in all material respects and the Company has not omitted to state a material fact necessary in order to make such information, taken as a whole, not misleading in light of the circumstances under which they were furnished; provided that projections and other forward looking information are based on estimates believed by management to be reasonable on the date as of which such information is stated or certified (it being understood that forecasts and projections are subject to contingencies and no assurance can be given that any forecast or projection will be realized).

Section 3.20. Investment Company Act; Margin Stock Regulation.

(a) Neither the Company nor any of its Subsidiaries is an “investment company” or a company “controlled” by an “investment company,” within the meaning of the Investment Company Act of 1940.

(b) No Obligor nor any of its Subsidiaries is engaged principally, or as one of its important activities, in the business of extending credit for the purpose, whether immediate, incidental or ultimate, of buying or carrying Margin Stock, and no part of the proceeds of the Purchase Price will be used to buy or carry any Margin Stock in violation of Regulation T, Regulation U or Regulation X.

Section 3.21. Anti-Corruption Laws; Anti-Money Laundering Laws; Sanctions; Export and Import Laws.

(a) None of the Company, its Subsidiaries, their directors or officers, or, to the Knowledge of such Obligor, any agent or employee of the Company or any Subsidiary of the Company has, at any time in the last three (3) years, (i) used any corporate funds of the Company or any Subsidiary of the Company for any unlawful contribution, gift, entertainment or other

unlawful expense relating to political activity, (ii) made any direct or, to the Knowledge of such Obligor, indirect unlawful payment to any foreign or domestic government official or employee from corporate funds of the Company or any Subsidiary of the Company, (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), the U.K. Bribery Act 2010 ("UKBA") or any other applicable anti-corruption laws or (iv) made any bribe, improper rebate, payoff, influence payment, kickback or other unlawful payment, and no part of the proceeds of the Purchase Price will be used, directly or, to the Knowledge of such Obligor, indirectly, for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation of the FCPA, UKBA or any other applicable anti-corruption laws. No action, suit or proceeding by or before any Governmental Authority or any arbitrator involving the Company or any of its Subsidiaries with respect to the FCPA, UKBA or any other applicable anti-corruption laws is pending or to the Knowledge of such Obligor, threatened in writing, nor is there a basis for such an action, suit or proceeding.

(b) (i) The operations of the Company and its Subsidiaries are and have been conducted at all times in the last five (5) years with applicable financial recordkeeping and reporting requirements of the Bank Secrecy Act of 1970 (as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001) and the anti-money laundering laws, rules and regulations of each jurisdiction (foreign or domestic) in which the Company or any of its Subsidiaries is subject to such jurisdiction's Applicable Laws (collectively, the "Anti-Money Laundering Laws") and (ii) no action, suit or proceeding by or before any Governmental Authority or any arbitrator involving the Company or any of its Subsidiaries with respect to the Anti-Money Laundering Laws is pending or to the Knowledge of such Obligor, threatened in writing.

(c) None of the Company, its Subsidiaries, or, their directors, officers or, to the Knowledge of such Obligor, any employee or agent of the Company or any Subsidiary of the Company is, or is fifty percent (50.0%) or more owned or otherwise controlled by individuals or entities that are, the target or subject of any economic, trade or financial sanctions or restrictive measures administered and enforced by the OFAC, the U.S. Department of State, the United Nations Security Council, the European Union and each member state thereof, or Switzerland (the Swiss State Secretariat for Economic Affairs of Switzerland (SECO) or the Swiss Directorate of International Law (DIL)) or His Majesty's Treasury of the United Kingdom (collectively "Sanctions"). Neither the Company nor any of its Subsidiaries: (i) has assets located in, or otherwise directly or indirectly derives revenues from or engages in, investments, dealings, activities, or transactions in or with, any Sanctioned Country; or (ii) directly or indirectly derives revenues from, conducts any business or engages in investments, dealings, activities, or transactions with, any Sanctioned Person, including the making or receiving of any contribution of funds, goods or services to or for the benefit of any Sanctioned Person. the Company will not, directly or indirectly (including through an agent or any other Person), use the proceeds of the Purchase Price, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other Person, for (i) the purpose of financing the activities of any Person that is the target or subject of Sanctions or in any country or territory that at the time of such funding, is the subject of Sanctions, (ii) in any Sanctioned Country, or (iii) any purpose that could cause any Person to be in violation of Sanctions. No action, suit or proceeding by or before any Governmental Authority or any arbitrator involving the Company or any of its Subsidiaries with respect to Sanctions is pending or to the Knowledge of such Obligor, threatened in writing, nor is there a basis for such action, suit or proceeding.

(d) The Company will not, directly or, to the Knowledge of such Obligor, indirectly (including through an agent or any other Person), use any of the proceeds of the Purchase Price,

or lend, contribute or otherwise make available such proceeds of the Purchase Price to any Subsidiary, joint venture partner or other Person, (i) for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation of the FCPA, UKBA or any other applicable anti-corruption laws, (ii) in violation of any Anti-Money Laundering Laws, or (iii) in violation of Sanctions.

(e) The Company, its Subsidiaries, their respective officers and directors, and to the Knowledge of the Company their respective agents and employees, are in compliance in all respects with Sanctions. The Company and its Subsidiaries have instituted and maintain policies and procedures reasonably designed to ensure compliance with Sanctions, Anti-Money Laundering Laws, Export and Import Laws, and applicable anti-corruption laws, including the FCPA and UKBA.

(f) the Company and its Subsidiaries are in compliance in all material respects with applicable Export and Import Laws.

Section 3.22. Broker's Fees.

The Company and its Subsidiaries have not taken any action that would entitle any Person to any commission or broker's fee in connection with this Agreement (other than any fee payable to SVB Securities).

Section 3.23. Data Privacy and Information Security.

(a) Except as set forth in Schedule 3.23(a) of the Disclosure Letter, to the Knowledge of such Obligor, the information technology systems used in the business of each of the Company and its Subsidiaries ("Systems") operate and perform in all material respects as required to permit each of the Company and its Subsidiaries to conduct their respective businesses as presently conducted. To the Knowledge of such Obligor, no System contains any material ransomware, disabling codes or instructions, spyware, Trojan horses, worms, viruses or other software routines that are designed or intended to delete, destroy, disable, interfere with, perform unauthorized modifications to, or provide unauthorized access to any data, files, software, system, network, or other device. The Company and its Subsidiaries have and maintain back-up systems, consistent with the industry in which the Company and each of its Subsidiaries operate and the size and condition of the Company and its Subsidiaries, designed to provide continuing availability of the material functionality provided by the Systems in the event of any malfunction of, or other event interrupting access to and/or the functionality of, such Systems. The Company and its Subsidiaries use commercially reasonable efforts to promptly implement material security patches that are generally available for the Systems.

(b) Except as set forth on Schedule 3.23(b) of the Disclosure Letter, the Company and each of its Subsidiaries has implemented and maintains a commercially reasonable, enterprise-wide privacy and information security program ("Security Program") with plans, policies, and procedures for privacy, physical and cyber security, disaster recovery, business continuity, incident detection, and incident response, and that includes commercially reasonable and appropriate administrative, technical and physical safeguards to protect the integrity and availability of the Systems, consistent with the industry in which the Company and each of its Subsidiaries operate and the size and condition of the Company and its Subsidiaries, and to protect against (i) any unauthorized, accidental, or unlawful access to or acquisition, use, disclosure, processing, loss, destruction, or modification of Personal Data that would require notification to affected individuals or any Governmental Authority under any applicable Data Protection Law (each, a "Personal Data Breach"), (ii) any unauthorized, accidental, or unlawful

access to or acquisition, use, disclosure, or loss of Sensitive Information that is not Personal Data, and (iii) security incidents that would result in unauthorized, accidental, or unlawful access to or acquisition, use, control, disruption, destruction, or modification of any of the Systems (including cyber-attacks) that would reasonably be expected to result in a material and adverse effect on the operation of the Company's or any of its Subsidiaries' business operations as currently conducted (sub-clauses (i) through (iii), collectively, "Security Incidents").

(c) The Company and each of its Subsidiaries has conducted commercially reasonable privacy and security audits and penetration tests at reasonable intervals on all Systems that maintain, store, access, or process Sensitive Information, in each case consistent with the industry in which the Company and each of its Subsidiaries operate and the size and condition of the Company and its Subsidiaries, taken as a whole. The Company and each of its Subsidiaries has taken commercially reasonable steps to address and remediate all material privacy or data security issues identified as "critical," "high risk," or similar level of risk rating that are raised in any such audits or penetration tests (including any third party audits of the Systems).

(d) The Company and each of its Subsidiaries has conducted commercially reasonable privacy and data security diligence, consistent with the industry in which the Company and each of its Subsidiaries operate and the size and condition of the Company and its Subsidiaries, on all vendors (including CROs, CMSs and other service providers and contractors) that (i) collect, create, receive, access, maintain, store, or otherwise process Sensitive Information for or on behalf of the Company or any of its Subsidiaries, or (ii) access or maintain the Systems. Except as set forth on Schedule 3.23(d) of the Disclosure Letter, neither the Company nor any of its Subsidiaries has, in the past five (5) years, received notice from any vendor that such vendor experienced a Security Incident impacting the Company's or any of its Subsidiaries' Sensitive Information.

(e) Except as set forth on Schedule 3.23(e) of the Disclosure Letter, to the Knowledge of the Company neither the Company nor any of its Subsidiaries, has in the past five (5) years suffered any (i) Personal Data Breaches or (ii) other Security Incidents that could reasonably be expected to have a material adverse effect on the Company's or any of its Subsidiaries' business operations, such as a material disruption of drug development, manufacturing or Commercialization programs.

(f) The Company and each of its Subsidiaries is in material compliance with the requirements of (i) their respective Security Programs, (ii) their respective contractual obligations regarding the privacy, security, and notification of breaches of Personal Data, including customer, consumer, patient, clinical trial participant and employee information, (iii) their respective contractual non-disclosure obligations, (iv) their respective publicly available privacy notices and policies, and (v) all applicable Data Protection Laws.

(g) Except as set forth on Schedule 3.23(g) of the Disclosure Letter, in the past five (5) years: (i) neither the Company nor any of its Subsidiaries has received any written third party claims or, to the Knowledge of Company, any threat (in writing) of a third party claim, related to any Personal Data Breaches or other Security Incidents; and (ii) neither the Company nor any of its Subsidiaries has received any written notice of any claims or investigations (including investigations by any Governmental Authority) relating to any Personal Data Breaches or other Security Incidents, except in each case of sub-clauses (i) and (ii) as could not reasonably be expected to be material to the Company and its Subsidiaries, taken as a whole.

(h) In the past five (5) years, the Company and each of its Subsidiaries has maintained all database registrations required under applicable Data Protection Laws material to the Company and its Subsidiaries.

Section 3.24. Benefit Plans.

Except as set forth on Schedule 3.24 of the Disclosure Letter, none of the Company or any of the other Subsidiaries or any of their respective ERISA Affiliates sponsors, maintains, contributes to, is required to contribute to, or has any actual or potential liability with respect to, any Benefit Plan. None of the Company or any of the other Subsidiaries is a party to any collective bargaining agreement. Each "employee benefit plan," as defined in Section 3(3) of ERISA, that provides retirement benefits, is sponsored by the Company or any of their ERISA Affiliates, and is intended to be tax qualified under section 401 of the Code has a determination letter or opinion letter from the Internal Revenue Service on which it remains entitled to rely, and no assets of any such plan are invested in Equity Interests of the Company. Each Benefit Plan has complied, both in form and in operation, in all respects with its terms and Applicable Law, except as would not, individually or in the aggregate, result in any Material Adverse Effect.

Section 3.25. Internal Controls.

The Company acknowledges that its management is responsible for the preparation and fair presentation of the financial statements of the Company and each of its Subsidiaries delivered to the Purchaser pursuant to Sections 5.02(b), in each case, in accordance with GAAP. The Company has, suitable for a company of its size and stage of development, designed, implemented and maintained internal controls relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Section 3.26. Fiscal Unity.

No Obligor incorporated under Dutch law is or has been a member of a fiscal unity (*fiscale eenheid*) for Dutch corporate income tax or value added tax purposes (unless such fiscal unity consists solely of Obligors).

Article IV.

REPRESENTATIONS AND WARRANTIES OF THE PURCHASER

The Purchaser represents and warrants to the Company as follows:

Section 4.01. Organization.

The Purchaser is a duly organized and validly existing under the laws of its jurisdiction of organization.

Section 4.02. Authorization.

The Purchaser has all necessary power and authority to enter into, execute and deliver the Transaction Documents and to perform all of the obligations to be performed by it hereunder and thereunder and to consummate the transactions contemplated hereunder and thereunder. The Transaction Documents have been duly authorized, executed and delivered by the Purchaser and each Transaction Document constitutes the valid and binding obligation of the Purchaser, enforceable against the Purchaser in accordance with their respective terms, subject, as to

enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or general equitable principles.

Section 4.03. Broker's Fees.

The Purchaser has not taken any action that would entitle any Person to any commission or broker's fee in connection with this Agreement.

Section 4.04. Conflicts.

Neither the execution and delivery of this Agreement or any other Transaction Document to which the Purchaser is a party nor the performance or consummation of the transactions contemplated hereby or thereby will: (a) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any respects any provisions of: (i) any law, rule or regulation of any Governmental Authority, or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which the Purchaser or any of its assets or properties may be subject or bound; or (ii) any material contract, agreement, commitment or instrument to which the Purchaser is a party or by which the Purchaser or any of its assets or properties is bound or committed; (b) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, any provisions of the organizational or constitutional documents of the Purchaser; or (c) require any notification to, filing with, or consent of, any Person or Governmental Authority, except, in the case of the foregoing clauses (a) or (c), as would not, individually or in the aggregate, have a material adverse effect on the ability of the Purchaser to perform any of its obligations under the Transaction Documents.

Article V.

COVENANTS

From the date hereof through and including the end of the Revenue Interest Period, the following covenants shall apply:

Section 5.01. Notices; Access; Information.

(a) Notices. The Company shall provide the written notice to the Purchaser of the following events:

(i) promptly (and in any event within five (5) Business Days) upon the Company's obtaining Knowledge thereof, the occurrence of any Put Option Event;

(ii) promptly (and in any event within five (5) Business Days) upon the Company's obtaining Knowledge thereof, the occurrence of any Material Adverse Effect or any event which could reasonably be expected to have a Material Adverse Effect;

(iii) promptly (and in any event within five (5) Business Days) upon the Company's obtaining Knowledge thereof, any litigation or proceedings to which the Company or any Subsidiary is a party of the type and materiality described in Section 3.08 or any material

adverse development in any litigation or proceeding described on Schedule 3.08 of the Disclosure Letter;

(iv) promptly (and in any event within five (5) Business Days) upon the Company's obtaining Knowledge thereof, the occurrence of (x) any voluntary or involuntary withdrawal, suspension of sales or recall of any Specified Product in the United States, the EU or Japan, (y) the loss of marketing authorization for any Specified Product in the United States, the EU or Japan by the Company or any of its Subsidiaries or (z) the receipt by the Company any of its Subsidiaries of any written notice from the FDA or any other Regulatory Agency of a pending recommendation or final decision to withdraw marketing authorization for any Specified Product in the United States, the EU or Japan;

(v) promptly, and in any event, within five (5) Business Days after receipt thereof by the Company or any Subsidiary thereof, (A) copies of each notice or other correspondence received from any securities regulator or exchange to the authority of which the Company or any Subsidiary thereof may become subject from time to time (in any applicable U.S. or non-U.S. jurisdiction) concerning any investigation or possible investigation or other material inquiry by such agency regarding financial or other operational results of the Company or any such Subsidiary and (B) copies of any material written correspondence or any other material written communication from the FDA or any other Regulatory Agency, in the case of clause (B) that could reasonably be expected to result in a Material Adverse Effect;

(vi) promptly (and in any event within five (5) Business Days) upon the Company's obtaining Knowledge thereof, any infringement by any Third Party of Product Intellectual Property and any infringement by any Specified Product of any Third Party Intellectual Property;

(vii) not less than ten (10) calendar days prior thereto, any change in, or amendment or alteration of, any Obligor's legal name, form of legal entity or jurisdiction of organization;

(viii) to the extent permitted by Applicable Law, promptly following receipt by the Company of any written notice, claim or demand challenging the legality, validity, enforceability or ownership of any of the Product Intellectual Property or pursuant to which any Third Party commences or threatens (in writing) any action, suit or other proceeding against the Company and relating to any Specified Product that could reasonably be expected to result in a Material Adverse Effect, the Company shall (i) inform the Purchaser in writing (and in reasonable detail) of such receipt and (ii) furnish the Purchaser with a copy of such notice, claim or demand;

(ix) promptly (and in any event within five (5) Business Days), any material change in accounting policies or financial reporting practices by the Company or any Subsidiary (to the extent not previously disclosed in a public filing or furnishing by the Company to the SEC); ~~and~~

(x) such other financial and other information as the Purchaser may from time to time reasonably request.and

(xi) as promptly as practicable following the occurrence thereof, written notice with reasonable detail that the FDA Approval Date has occurred.

Notwithstanding anything to the contrary, the Company may provide to the Purchaser all notices and information required by Section 5.01(a) by publicly filing or furnishing such

information to the SEC or otherwise making such information publicly available (e.g., a press release), in which event the Company shall be deemed to have satisfied its applicable notice obligations hereunder; provided the Company shall also promptly notify the Purchaser of any public filing containing such notices or information, including where such public filing can be accessed and the provisions of this Agreement to which the notices or information contained therein is responsive.

(b) Maintenance of Books and Records. The Company shall keep and maintain, and cause its Affiliates to keep and maintain, at all times full and accurate books of account and records adequate to correctly reflect (and in sufficient detail to permit the Purchaser to confirm the accuracy of) all payments paid and/or payable with respect to the Revenue Interests. Such records shall be kept and maintained for a minimum of seven (7) years from the end of the calendar year to which they pertain.

(c) Inspection Rights. The Purchaser shall have the right, not more than once a year, to designate a Third Party independent public accounting firm (the "Purchaser Representative") to visit the Company's and its Subsidiaries' offices and properties where the Company and its Subsidiaries keep and maintain their books and records relating or pertaining to the Revenue Base or the Revenue Interests and the Collateral for purposes of conducting an audit of such books and records, and to inspect and audit such books and records, during normal business hours. With respect to the foregoing, with prior written notice given by the Purchaser to the Company, the Company will provide the Purchaser Representative reasonable access to such books and records, and shall permit the Purchaser Representative to discuss the business, operations, properties and financial and other condition of the Company or its Affiliates including, but not limited to, matters relating or pertaining to the Revenue Interests and any Collateral with officers of the Company; provided that any audit of the Company and its Subsidiaries conducted pursuant to this Section 5.01(c) shall be at the Purchaser's expense;provided that, in the event (i) a Put Option Event has occurred and is continuing or (ii) the audit reveals a shortfall in any Revenue Interest Payment in excess of [***] percent ([***]%) and the Company agrees with the underlying calculations evidencing such shortfall, the Company shall bear the Audit Costs of such audit. Notwithstanding the foregoing, after the occurrence and during the continuance of a Put Option Event, the Purchaser shall have the right, as often, and at such times and with such prior notice, as the Purchaser shall determine, in its reasonable discretion, to have the Purchaser Representative review the relevant documents and records of the Company and its Subsidiaries. Upon the reasonable request by the Purchaser, the Company shall use its commercially reasonable efforts to conduct an audit of any Licensee (to the extent that (i) the applicable License is for the Commercialization of any Specialized Product and (ii) such audit is permitted under the applicable License). To the extent that the Company conducts such audit, the Company shall, to the extent permitted by the applicable agreement with such Licensee, provide a general summary regarding the results of such audit. The Purchaser acknowledges and agrees that any such summary report shall be treated as Confidential Information of the Company.

(d) Purchaser Meetings. During the Revenue Interest Period, the Purchaser shall be entitled to a quarterly update call or meeting (in person, via teleconference or videoconference or at a location and time mutually agreed by the Purchaser and the Company) to discuss the reports delivered by the Company pursuant to Section 5.02(a) and the progress of sales and product development and marketing efforts made by the Company with respect to any Specified Product, the status and the historical and potential performance of any Specified Product, any regulatory developments or such other matters that the Purchaser deems appropriate (including, to the extent made publicly available on "EDGAR", with respect to any of the Specified Products, (a) Clinical Updates, (b) Regulatory Updates, (c) Commercial Updates and (d) Intellectual Property

Updates). Notwithstanding the foregoing, after the occurrence and during the continuance of a Put Option Event, the Purchaser shall have the right, as often, at such times and with such prior notice, as the Purchaser shall determine, in its reasonable discretion, to have such update meetings or inspect any records and operations of the Company and its Affiliates.

Section 5.02. Reports.

(a) Periodic Reports. The Company shall deliver to the Purchaser the following information:

(i) as soon as available and in any event no later than forty-five (45) days after the last day of each of the first three fiscal quarter of each fiscal year, (A) an unaudited consolidated balance sheet of the Company and its Subsidiaries as of the end of such fiscal quarter, and (B) the related unaudited consolidated statements of income, shareholders' equity and cash flows of the Company and its Subsidiaries for each such quarter and the portion of the fiscal year through the end of such fiscal quarter, in each case, prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the corresponding period in the preceding fiscal year, together with (C) a certificate of the chief financial officer of the Company stating that such financial statements (x) fairly present the financial condition of the Company and its Subsidiaries as at such date and the results of operations of the Company and its Subsidiaries for the period ended on such date, and (y) have been prepared in accordance with GAAP consistently applied, subject to changes resulting from normal, year-end audit adjustments and the addition of notes and (D) a statement, on a region by region (as reported in the Company's public filings with the SEC) and Specified Product by Specified Product basis, of the amount of Net Sales of Specified Products during the applicable fiscal quarter, the applicable Revenue Base for the period ending on the last day of such fiscal quarter, the calculation of the amount of Revenue Interest Payment due with respect to such fiscal quarter, and the exchange rates used, if applicable;

(ii) as soon as available and in any event no later than ninety (90) days after the end of each fiscal year, (A) the audited consolidated balance sheets of the Company and its Subsidiaries as of the end of such fiscal year, and (B) the related audited consolidated statements of income, shareholders' equity and cash flows of the Company and its Subsidiaries for such fiscal year, in each case prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the previous fiscal year, accompanied by a report and opinion thereon of Ernst & Young LLP or another firm of independent certified public accountants of recognized national standing reasonably acceptable to the Purchaser, which report and opinion shall be prepared in accordance with generally accepted auditing standards and shall not be subject to any "going concern" or like qualification (other than any "going concern" or like qualification or exemption with respect to, or resulting from, the impending maturity of the Indebtedness under the Term Transaction Documents) or exception or any qualification or exception as to the scope of such audit, and in the case of such consolidated financial statements, certified by a Responsible Officer of the Company;

(iii) within forty five (45) days following the end of each fiscal quarter, a Net Sales report as required pursuant to Section 2.02(a)(ii) above;

(iv) [reserved];

(v) upon request by the Purchaser, copies of any material statement or report furnished to any holder of debt securities of the Company or any Subsidiary pursuant to the terms of any indenture, loan or credit or similar agreement;

(vi) [reserved];

(vii) [reserved];

(viii) the information regarding insurance maintained by the Company and its Subsidiaries as required under Section 5.11; and

(ix) such other information respecting the operations, properties, business, liabilities or condition (financial or otherwise) of the Company and its Subsidiaries (including with respect to the Collateral) as the Purchaser may from time to time reasonably request.

Notwithstanding anything to the contrary (including herein or in any Transaction Document), the Company hereby acknowledges that the Purchaser may not wish to receive material non-public information with respect to the Company or its Affiliates, or the respective securities of any of the foregoing, and the Purchaser or its personnel may be engaged in investment and other market-related activities with respect to such Person's securities. The Company and the Purchaser covenant and agree that, notwithstanding anything to the contrary (including herein or in any Transaction Document) except for (x) the notices specified above in Section 5.01(a)(i) and Section 5.01(a)(ii), and (y) delivery of the Net Sales Reports pursuant to Section 5.02(a)(iii) above, none of the Company, any Subsidiary thereof, nor any Person acting on its or their behalf, will provide, or become obligated to provide, under any other provision of this Agreement, any other Transaction Document or otherwise, the Purchaser or its representatives or agents with any information that the Company reasonably believes constitutes material non-public information, unless prior thereto the Purchaser shall have notified the Company in writing that it has elected to receive such information. Neither the Company nor any of its Subsidiaries shall have liability to the Purchaser as a result of the delivery to the Purchaser of (w) notices specified in Section 5.01(a)(i) and Section 5.01(a)(ii), (x) the Net Sales Reports referenced above, (y) any other material non-public information that the Purchaser has requested in writing to receive from the Company or its Subsidiaries or (z) any other information delivered to the Purchaser that the Company or its Subsidiaries believed, acting reasonably and in good faith, was not material non-public information as of the time of such delivery.

Notwithstanding anything to the contrary, the Company may provide to the Purchaser all notices and information required by Section 5.02(a) by publicly filing or furnishing such information to the SEC or otherwise making such information publicly available (e.g., a press release), in which event the Company shall be deemed to have satisfied its applicable notice obligations hereunder; provided that, except with respect to deliverables under Section 5.02(a)(i) and Section 5.02(a)(ii), the Company shall also promptly notify the Purchaser of any public filing containing such notices or information, including where such public filing can be accessed and the provisions of this Agreement to which the notices or information contained therein is responsive.

(b) Reconciliation Reports. Concurrently with the delivery of financial statements pursuant to Section 5.02(a)(ii) above, the Company shall produce and deliver to the Purchaser a report (a "Reconciliation Report") showing Net Sales for the Specified Products for such fiscal year, and a reconciliation of all payments made by the Company to the Purchaser pursuant to this Agreement during such fiscal year, together with a certificate of the Company certifying that to the Knowledge of the Company, (i) such Reconciliation Report is a true and complete copy and (ii) any statements and any data and information therein prepared by the Company are true,

correct and accurate in all material respects. Upon request by the Purchaser, the Company and the Purchaser shall meet in person or by teleconference to discuss each Reconciliation Report.

Section 5.03. Compliance with Law; Existence and Maintenance of Properties; Material Contracts; Payment of Obligations.

(a) The Company shall, and shall cause its Subsidiaries to, (i) comply with all material federal, state, local and foreign laws, regulations and orders applicable to the Company or any Subsidiary or any of their respective assets, including all Environmental Laws, (ii) obtain and maintain any and all material licenses, permits, franchises, governmental authorizations, Intellectual Property or other rights necessary for the ownership of its properties and the advantageous conduct of its business and as may be required from time to time by Applicable Law and (iii) maintain each material Regulatory Approval necessary to sell the Specified Products, except in the case of (i) or (ii) where the failure to do so, individually or in the aggregate, would not reasonably be expected to result in a Material Adverse Effect.

(b) The Company and its Subsidiaries have instituted and shall maintain policies and procedures reasonably designed to ensure compliance with Sanctions, Anti-Money Laundering Laws, Export and Import Laws and applicable anti-corruption laws, including the FCPA and UKBA.

(c) The Company shall, and shall cause its Subsidiaries to, (i) maintain and preserve in full force and effect its legal existence, its good standing (to the extent that such concept is applicable in such jurisdiction) under the laws of the jurisdiction of its incorporation or formation, as the case may be, and its qualification to do business in every other jurisdiction where the nature of its business or its properties makes such qualification necessary (except where the failure to be so qualified or licensed would not reasonably be expected to have a Material Adverse Effect); and (ii) maintain all material tangible properties in good working order and condition (normal wear and tear and damage by casualty excepted) and from time to time make all necessary repairs to and renewals and replacements of such properties, except to the extent that any of such properties are obsolete or are being replaced or, in the good faith judgment of the Company, are no longer useful or desirable in the conduct of the business; provided that clause (i) of this Section 5.03(b) shall not restrict (A) mergers among Obligors (provided that if the Company is a party to such merger, it shall be the surviving Person), (B) mergers among non-Obligor Subsidiaries, (iii) mergers of non-Obligor Subsidiaries into Obligor Subsidiaries; provided that the Obligor Subsidiary shall be the surviving Person and (iv) the Intercompany Reorganization.

(d) Each of the Company and its Subsidiaries shall pay and discharge (i) prior to the date on which penalties attach thereto, all federal and state and other material Taxes imposed upon it or its properties or assets, unless the same are being contested in good faith by appropriate proceedings diligently conducted and adequate reserves in accordance with GAAP are being maintained by the Company or its Subsidiaries, (ii) as the same shall become due and payable, all lawful claims which, if unpaid, would by law become a Lien upon its property (other than Permitted Liens), and (iii) prior to the date on which such Indebtedness shall become delinquent or in default, all material Indebtedness, but subject to any subordination provisions contained in any instrument or agreement evidencing such Indebtedness.

Section 5.04. Confidentiality; Public Announcement.

(a) All Confidential Information furnished by the Purchaser to the Company or by the Company to the Purchaser in connection with this Agreement and any other Transaction Document and the transactions contemplated hereby and thereby, shall be kept confidential by the Company and the Purchaser. Notwithstanding the foregoing, the Company and the Purchaser

may disclose Confidential Information to the Term Lenders and the partners, directors, employees, managers, officers, investors, bankers, advisors, trustees and representatives of the Company, the Purchaser and the Term Lenders; provided that such Persons shall be informed of the confidential nature of such information and shall be obligated to keep such information confidential pursuant to the terms of this Section 5.04(a); provided, further, that unless a Put Option Event has occurred and is continuing, no such disclosure shall be made to any Disqualified Person. The Company will consult with the Purchaser, and the Purchaser will consult with the Company, on the form, content and timing of any such disclosures of Confidential Information of the other party, including, without limitation, any disclosures made pursuant to applicable securities laws or made to investment or other analysts. Notwithstanding the foregoing, the foregoing restrictions shall not apply to information that (A) is already in the public domain at the time the information is disclosed (other than as a result of its improper disclosure by the Company, the Purchaser or their respective Affiliates and representatives), (B) thereafter becomes lawfully obtainable from other sources who are not under an obligation of confidentiality and are not otherwise prohibited from disclosing such information by a contractual, legal or fiduciary obligation, (C) is required to be disclosed in any document filed with any Governmental Authority, (D) is required to be disclosed under securities laws, rules and regulations applicable to the Company or pursuant to the rules and regulations of any securities exchange or trading system on which securities of the Company may be listed for trading, (E) is requested or required by Governmental Authorities who have jurisdiction or supervisory oversight of the a party and/or its Affiliates, whether pursuant to exam, audit, inquiry, request or general supervisory oversight or (F) is disclosed by the Purchaser to (x) its Affiliates, (y) potential and actual assignees of any of the Purchaser's rights hereunder, and (z) potential and actual investors in, or lenders to, Purchaser (including in the foregoing cases, such Person's employees, advisors or consultants); provided that in the case of this clause (F), each such Person referred to in clause (x)-(z) shall be subject to reasonable obligations of confidentiality. Notwithstanding the foregoing, in the event a party is required to make a disclosure of another party's Confidential Information pursuant to (C) or (D) of the foregoing sentence, it will, except where illegal or impracticable, give reasonable advance notice to the other party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such party would use to protect its own confidential information, but in no event less than reasonable efforts.

(b) Except as required by law or the rules and regulations of any securities exchange or trading system or the FDA or any Governmental Authority with similar regulatory authority, or except with the prior written consent of the other party (which consent shall not be unreasonably withheld), no party shall issue any press release or make any other public disclosure with respect to the transactions contemplated by this Agreement or any other Transaction Document; provided that the Company and the Purchaser shall jointly prepare a press release for dissemination promptly following the Closing Date. For the avoidance of doubt, the Company shall consult with the Purchaser prior to filing of any Transaction Document (including proposed redaction of certain provisions of such Transaction Document) with any securities exchange or trading system or Governmental Authority with similar regulatory authority. Other than such obligation, the Company shall be entitled, without the prior approval of the Purchaser, to make any public disclosure as is required by applicable securities laws following the Closing Date; provided that the Purchaser shall be consulted by the Company in connection with any such public disclosure prior to its release and be provided with a copy thereof).

(c) The rights to review, consult with or consent, as applicable and as set forth in this Section 5.04, with respect to any disclosures shall only apply for the first time that specific information is to be disclosed, and shall not apply to the subsequent disclosure of substantially similar information that has previously been disclosed unless there have been material changes in the disclosure since the date of the previous disclosure.

Section 5.05. Security Interest.

Until all Obligations are paid and performed in full (other than contingent indemnity obligations for which no claim has been made), each Obligor shall grant in favor of the Purchaser a valid, continuing, perfected Lien on and security interest in the Collateral described in the Security Documents, subject as to priority only to the obligations arising in connection with the Term Loan Agreement as provided pursuant to the Intercreditor Agreement.

Section 5.06. Further Assurances; Creation/Acquisition of Subsidiaries; Additional Collateral.

(a) Without limiting the obligations of the Company in the Guaranty and Security Agreement, the Foreign Security Documents or in the other Transaction Documents, the Company hereby agrees to take such action and execute, acknowledge and deliver, and cause each of its Subsidiaries to take such action and execute, acknowledge and deliver, at its sole cost and expense, such agreements, instruments or other documents as the Purchaser may reasonably request from time to time in order to (i) carry out more effectively the purposes of this Agreement and the other Transaction Documents, (ii) maintain and protect the Purchaser's Liens on and security interests in (subject to the terms of the Intercreditor Agreement) the Collateral or any other property of any Obligor intended to be Collateral hereunder free and clear of Liens (other than Permitted Liens), (iii) establish and maintain the validity and effectiveness of any of the Transaction Documents, including, without limitation, making all filings and registrations as contemplated pursuant to the Transaction Documents, and (iv) better assure, convey, grant, assign, transfer and confirm unto the Purchaser the rights now or hereafter intended to be granted to it under this Agreement or any other Transaction Document. In furtherance of the foregoing, to the maximum extent permitted by Applicable Law, the Company (i) authorizes the Purchaser to execute any such agreements, instruments or other documents in each Obligor's name and to file such agreements, instruments or other documents in any appropriate filing office if any Obligor refuses or fails to execute or deliver any of the above reasonably requested agreements, instruments or documents within ten (10) days of the Purchaser's request to do so and (ii) authorizes the Purchaser to file any financing statement required hereunder or under any other Transaction Document, and any continuation statement or amendment with respect thereto, in any appropriate filing office without the signature of such Obligor.

(b) The Company and the Purchaser shall cooperate and provide assistance as reasonably requested by the other party hereto, at the expense of such other party hereto (except as otherwise set forth herein), in connection with any litigation, arbitration, investigation or other proceeding (whether threatened, existing, initiated or contemplated prior to, on or after the date hereof) to which the other party hereto, any of its Affiliates or controlling persons or any of their respective officers, directors, equityholders, controlling persons, managers, agents or employees is or may become a party or is or may become otherwise directly or indirectly affected or as to which any such Persons have a direct or indirect interest, in each case relating to any Transaction Document, the transactions contemplated herein or therein or the Revenue Interests but in all cases excluding any litigation brought by the Company or its Affiliates against the Purchaser or brought by the Purchaser (for itself or on behalf of any Indemnified Party) against the Company.

(c) In the event the Company or any of its Subsidiaries creates or acquires any Subsidiary (other than an Excluded Subsidiary) or if any Subsidiary of the Company elects to become an Obligor (or otherwise ceases to be an Excluded Subsidiary), the Company shall provide five (5) days prior written notice to the Purchaser of the creation or acquisition of such new Subsidiary or the election of such Subsidiary to become an Obligor and promptly (and in any event no later than thirty (30) days after the creation or acquisition thereof, or after such Subsidiary ceases to be an Excluded Subsidiary, or such longer period as the Purchaser may

agree in its sole discretion), take all such action as may be reasonably required by the Purchaser to cause such Subsidiary to become a Subsidiary Guarantor hereunder, including without limitation by (i) executing and delivering a Guaranty (or a joinder thereto), (ii) causing such Subsidiary to become a "Subsidiary Party" under the Intercompany Subordination Agreement, (iii) solely with respect to Domestic Subsidiaries, becoming a party to the applicable Security Documents, (iv) solely with respect to Foreign Subsidiaries, causing such Foreign Subsidiary to take such actions and execute and delivery such Foreign Security Documents as are reasonably required to grant to the Purchaser a valid, continuing, perfected Lien on, and security interest in, all of such Foreign Subsidiary's properties and assets constituting Collateral, and (v) delivering such proof of corporate action, incumbency of officers, opinions of counsel and other documents as reasonably requested by the Purchaser.

(d) With respect to any Collateral acquired after the Closing Date by any Obligor that is not already subject to the Lien created by any of the Transaction Documents or specifically excluded from the requirement to be subject to such Lien in the Transaction Documents, the Company shall promptly (and in any event no later than thirty (30) days after the acquisition thereof, or such longer period as the Purchaser may agree in its sole discretion) (i) execute and deliver to the Purchaser such amendments or supplements to the relevant Transaction Documents or such other documents as the Purchaser shall deem necessary or advisable to grant for its benefit, a Lien on such property subject to no Liens other than Permitted Liens, and (ii) take all actions necessary to cause such Lien to be duly perfected in accordance with all applicable requirements of Applicable Law, including the filing of financing statements in such jurisdictions as may be reasonably requested by the Purchaser. The Company shall, and shall cause each other Obligor to, otherwise take such actions and execute and/or deliver to the Purchaser such documents as the Purchaser shall reasonably require to confirm the validity, perfection and priority of the Lien of the Security Documents on such after-acquired properties.

Section 5.07. Put Option; Call Option.

(a) Put Option. Upon the occurrence of a Put Option Event, the Purchaser shall have the right, but not the obligation (the "Put Option"), to require the Company to repurchase from the Purchaser all, but not less than all, of the right to receive Revenue Interest Payments at the applicable Buy-Out Price therefor. In the event that the Purchaser elects to exercise the Put Option, the Purchaser shall deliver written notice to the Company specifying the closing date for the payment of such Buy-Out Price which date shall be ten (10) days from such notice date (the "Put Option Closing Date"). On the Put Option Closing Date, the Company shall repurchase from the Purchaser the right to receive Revenue Interest Payments at the Buy-Out Price then applicable to the Put Option, in cash, the payment of which shall be made by wire transfer of immediately available funds to the account designated by the Purchaser. Notwithstanding anything to the contrary contained herein, immediately upon the occurrence of a Bankruptcy Event, the Purchaser shall be deemed to have automatically and simultaneously elected to have the Company repurchase from the Purchaser the right to receive Revenue Interest Payments for the Buy-Out Price applicable to the Put Option in cash and such Buy-Out Price shall be immediately due and payable without any further action or notice by any party. For the avoidance of doubt, the Purchaser's election not to exercise the Put Option with respect to a given Put Option Event will not preclude the Purchaser from exercising the Put Option with respect to a continuing or subsequent Put Option Event.

(b) Call Option. At any time after the Closing Date, the Company shall have the right, but not the obligation (the "Call Option"), exercisable upon two (2) Business Days' written notice to the Purchaser, to repurchase, all, but not less than all, of the right to receive Revenue Interest Payments from the Purchaser at a repurchase price equal to the Buy-Out Price then applicable to the Call Option; provided that such written notice delivered by the Company may state that such notice is conditioned upon the effectiveness of other credit facilities or the receipt

of the proceeds from the issuance of other Indebtedness, or the occurrence of some other financing, in which case such notice may be revoked by the Company (by notice to the Purchaser prior to the specified effective date of the Call Option) if such condition is not satisfied; provided, further that, no Call Option shall qualify as a Change of Control Call Option unless the Buy-Out Price payable in connection therewith is paid in full in cash no earlier than the date on which the related Change of Control is consummated and no later than two (2) Business days following such date of consummation. In order to exercise the Call Option, the Company shall deliver written notice to the Purchaser of its election to so repurchase the right to receive Revenue Interest Payments not less than two (2) Business days prior to the proposed closing date (the "Call Closing Date"). On the Call Closing Date, the Company shall repurchase from the Purchaser the right to receive Revenue Interest Payments at the applicable Buy-Out Price, the payment of which shall be made by wire transfer of immediately available funds to the account designated by the Purchaser.

(c) Purchaser Remedies. Upon the exercise of the Put Option, unless payment of the applicable Buy-Out Price has been made when due, the Purchaser may exercise all rights and remedies available to the Purchaser as a creditor hereunder and under the other Transaction Documents and Applicable Law (which exercise may be determined in its sole discretion and which such exercise shall not constitute an election of remedies), including enforcement of the Liens created thereby, subject to the terms of the Intercreditor Agreement. For the avoidance of doubt the applicable Buy-Out Price shall be due and payable (in the case of an exercise of the Put Option or the Call Option, as set forth in this Section 5.07) at any time the Put Option or the Call Option, as the case may be, is exercised or the Obligations are otherwise accelerated hereunder for any reason, whether due to acceleration pursuant to the terms of this Agreement, by operation of law or otherwise (including where bankruptcy filings or the exercise of any bankruptcy right or power, whether in any plan of reorganization or otherwise, results or would result in a payment, discharge, modification or other treatment of the Revenue Interests that would otherwise evade, avoid, or otherwise disappoint the expectations of the Purchaser in receiving the full benefit of their bargained-for applicable Buy-Out Price). Subject to the terms of the Intercreditor Agreement, the Company and the Purchaser acknowledge and agree that no portion of any Buy-Out Price shall constitute unmatured interest, whether under Section 502(b)(2) of the United States Bankruptcy Code or otherwise, but instead is reasonably calculated to ensure that the Purchaser receives the benefit of its bargain under the terms of this Agreement. Subject to the terms of the Intercreditor Agreement, the Company acknowledges and agrees that the Purchaser shall be entitled to recover the full amount of the applicable Buy-Out Price in each and every circumstance such amount is due pursuant to or in connection with this Agreement, including in the case of any Bankruptcy Event, so that the Purchaser shall receive the benefit of its bargain hereunder and otherwise receive full recovery as agreed under every possible circumstance, and, to the fullest extent permitted by Applicable Law, the Company hereby waives any defense to payment, whether such defense may be based in public policy, ambiguity, or otherwise. Subject to the terms of the Intercreditor Agreement, the Company further acknowledges and agrees, and, to the fullest extent permitted by Applicable Law, waives any argument to the contrary, that payment of such amounts does not constitute a penalty or an otherwise unenforceable or invalid obligation. Any damages that the Purchaser may suffer or incur resulting from or arising in connection with any breach hereof or thereof by the Company shall constitute secured obligations owing to the Purchaser.

(d) Right of Set-off; Sharing of Set-off if any amount payable hereunder is not paid as and when due, the Company irrevocably authorizes the Purchaser to proceed, to the fullest extent permitted by Applicable Law, subject to the Intercreditor Agreement, without prior notice, by right of set-off, counterclaim or otherwise, against any assets of the Company in any currency that may at any time be in the possession of the Purchaser or any of its Affiliates, to the full extent of all amounts payable to the Purchaser hereunder; provided, however, that the Purchaser shall notify the Company of the exercise of such right promptly following such exercise.

(e) Rights Not Exclusive. The rights provided for herein are cumulative and are not exclusive of any other rights, powers, privileges or remedies provided by this Agreement or Applicable Law.

(f) Obligations of the Purchaser. In connection with the consummation of a repurchase of the right to receive Revenue Interest Payments pursuant to the Put Option or the Call Option, the Purchaser agrees that it will, at the cost and expense of the Company, concurrently with receipt by the Purchaser of payment in full of the Buy-Out Price (i) execute and deliver to the Company such UCC termination statements and other documents as may be necessary to release the Purchaser's Lien on the Collateral and otherwise give effect to such repurchase and (ii) take such other actions or provide such other assistance as may be necessary to give effect to such repurchase.

Section 5.08. Intellectual Property; Regulatory Approvals.

(a) The Company shall, at its sole expense, either directly or by causing any Subsidiary or Licensee (subject to all restrictions and limitations contained in any applicable license agreement) to do so, use commercially reasonable efforts (including taking legal action to specifically enforce the applicable terms of any License to which any Specified Product or Product Asset may be subject) to prepare, execute, deliver and file any and all agreements, documents or instruments and make all required payments which are necessary to diligently maintain the Material Patents. The Company shall use commercially reasonable efforts to ensure that all patent applications corresponding to the Material Patents are diligently prosecuted with the intent to protect all Specified Products, except where any lapse or abandonment of such patent applications occurs as part of the Company's normal prosecution practices.

(b) The Company shall use commercially reasonable efforts to diligently defend or assert all Intellectual Property owned by or licensed to the Company and relating to any Specified Product against infringement or interference by any other Persons, including acts related to an ANDA directed to any Specified Product, and against any claims of invalidity or unenforceability (including, without limitation, by bringing any legal action for infringement or defending any claim of invalidity or action of a Third Party for declaratory judgment of non-infringement or non-enforceability), except where the failure to do so would not reasonably be expected to result in a Material Adverse Effect. The Company shall not, and shall use its commercially reasonable efforts to cause any Licensee (subject to all restrictions and limitations contained in any applicable license agreement) not to, disclaim or abandon, or fail to take any action necessary to prevent the disclaimer or abandonment of, the Material Patents, except where the failure to do so would not reasonably be expected to result in a Material Adverse Effect.

(c) In the event that the Company becomes aware that any Specified Products infringes or violates any Intellectual Property, or is alleged to infringe or violate any Intellectual Property, that is owned or controlled by a Third Party, the Company shall use commercially reasonable efforts to attempt to (i) invalidate such Intellectual Property or assert that it Specified Product does not infringe any Intellectual Property or (ii) secure the right to use such Intellectual Property on behalf of itself and any affected Licensee, as applicable, except where the failure to do so would not reasonably be expected to result in a Material Adverse Effect, and shall pay all reasonable costs and amounts associated with invalidating such Intellectual Property or obtaining any such license, without any reduction in the Revenue Interests.

(d) The Company shall directly, or through a Subsidiary or Licensee (subject to all restrictions and limitations contained in any applicable license agreement), take any and all actions and prepare, execute, deliver and file any and all agreements, documents or instruments to secure and maintain, all applicable Regulatory Approvals, except where the failure to do so would not reasonably be expected to result in a Material Adverse Effect. The Company shall

provide notice to the Purchaser of any Regulatory Approvals in the United States, Japan or the EU5 Countries received in respect of any Specified Product after the Closing Date promptly after receipt thereof.

(e) Neither the Company nor any of its Subsidiaries shall enter into any License with respect to any Specified Product or any Product Intellectual Property that does not qualify as a Permitted License.

Section 5.09. Use of Proceeds.

The Company shall use the proceeds of the Purchase Price for general corporate purposes and to pay fees and expenses in connection with this Agreement. Without limiting the foregoing, no part of the proceeds of the Purchase Price shall be used, whether directly or indirectly, for any purpose that entails a violation of any of the Regulations of the Board of Governors of the Federal Reserve System, including Regulation T, Regulation U and Regulation X. The Company and each of its Subsidiaries shall ensure that at any time during the term of this Agreement no proceeds of the Purchase Price shall be on-lent or made otherwise available, directly or indirectly, to any Subsidiary or Affiliate of the Company incorporated in Switzerland and/or having its registered office in Switzerland and/or qualifying as a Swiss resident pursuant to art 9 of the Swiss Withholding Tax Act, or, will otherwise be used or made available, directly or indirectly in each case in a manner which would constitute a "use of proceeds in Switzerland" (*Mittelverwendung in der Schweiz*) as interpreted by the Swiss Federal Tax Administration for purposes of Swiss Withholding Tax, unless and until a written confirmation or countersigned tax ruling application from the Swiss Federal Tax Administration has been obtained (in form and substance satisfactory to the Purchaser) confirming that such use of proceeds is permitted without payments under this Agreement becoming subject to Swiss Withholding Tax.

Section 5.10. Protective Covenants.

(a) The Company shall not, and shall not permit any of its Subsidiaries to, without the prior written consent of the Purchaser:

(i) forgive, release or compromise any material amount owed to the Company or any Subsidiary that relates to the Revenue Interests, other than in order to, in its reasonable commercial business judgment, resolve a dispute regarding the amount due;

(ii) waive, amend, cancel or terminate, exercise or fail to exercise, any of its rights constituting or relating to the Revenue Interests in any material respect (including any rights under any Material Contract), except where such waiver, amendment, cancellation, termination, exercise or failure to exercise could not reasonably be likely to result in a Material Adverse Effect;

(iii) create, incur, assume or suffer to exist any Indebtedness, except for Permitted Indebtedness;

(iv) make or permit to exist any Investment, except for Permitted Investments;

(v) declare or make, directly or indirectly, any Restricted Payment, except

that:

(A) each Subsidiary may make Restricted Payments to any Obligor;

(B) the Company and each Subsidiary may declare and make dividend payments or other distributions payable solely in the Qualified Equity Interests of such Person; and

(C) the Company or any of its Subsidiaries may make, create, incur or consummate Permitted Distributions, Permitted Transaction or Permitted Equity Derivatives.

(vi) engage in any material line of business substantially different from those lines of business conducted by the Company and its Subsidiaries on the Closing Date or a business substantially related or incidental thereto, and reasonable extensions thereof;

(vii) amend, modify or change its Organization Documents in a manner materially adverse to the rights or remedies of the Purchaser under the Transaction Documents;

(viii) create, incur, assume or suffer to exist any Lien upon any property or assets of any kind (real or personal, tangible or intangible) of the Company and its Subsidiaries, or agree to do or suffer to exist any of the foregoing, except for Permitted Liens;

(ix) Transfer (i) any Specified Product or related Product Assets, or (ii) subject to compliance with Section 5.17, any other Collateral other than Permitted Transfers;

(x) make or cause any of its Subsidiaries to make (or exercise any option with respect thereto), directly or indirectly, any payment, prepayment, repurchase or redemption for cash of any Indebtedness under any Permitted Convertible Indebtedness (or any indenture or similar or other instruments relating thereto) unless, at the time of and immediately after giving effect thereto, the Company shall have on deposit in one or more Collateral Accounts an aggregate amount of cash and Cash Equivalents that would be sufficient to pay the Buy-Out Price then in effect if, immediately after giving effect thereto, the Company was to exercise a Call Option (other than a Change of Control Call Option); provided that (a) upon the 1x Return Date, this covenant shall automatically terminate without need of notice or any other action by any party hereto and shall be of no further force or effect, and (b) any term or provision hereof to the contrary notwithstanding, so long as in effect, nothing in this Section 5.10(a)(x) shall prohibit or otherwise restrict (i) any required payment or repayment (including in respect of principal or interest) made in respect of any Permitted Convertible Indebtedness on the Convertible Indebtedness Scheduled Maturity Date applicable thereto, (ii) any Permitted Convertible Redemption or other Permitted Transaction, (iii) the making of any scheduled cash interest payments in respect of any Permitted Convertible Indebtedness, (iv) the making of any required cash payments of accrued but unpaid interest upon repurchase or redemption of any Permitted Convertible Indebtedness, (v) the making of any cash payments in lieu of any fractional share issuable upon conversion of any Permitted Convertible Indebtedness, (vi) the making of any required cash payments of any amounts due upon the scheduled maturity of any Permitted Convertible Indebtedness using Equity Cash Proceeds, or (vii) the paying of any ordinary course fees or other expenses incurred in connection with any Permitted Convertible Indebtedness;

(xi) change its fiscal year end (other than, in the case of any Subsidiary, to conform to the Company's fiscal year end); or

(xii) maintain cash in any bank account located in Japan or the Netherlands that would be in excess of the amount of cash that would be appropriate for (i) the continued operations in the ordinary course of business in Japan or the Netherlands, as applicable, and (ii) such other business needs in Japan or the Netherlands (including, for the avoidance of doubt, as a result of the Intercompany Reorganization), as applicable, as reasonably determined by a Responsible Officer of the Company consistent with prudent cash management practices, and not with an intent to hinder the security interests available under the Transaction Documents.

(b) The Company shall not, and shall not permit any of its Subsidiaries to, take any action or engage in any transaction (or series of actions or transactions), whether by reorganization, sale of assets, merger, dissolution, amendment of organizational documents or otherwise, the primary purpose of which is to evade, avoid or seek to avoid the performance or observance of the covenants, agreements or obligations of the Company under the Transaction Documents (including under the Security Documents).

Section 5.11. Insurance.

The Company shall, and shall cause each of its Subsidiaries to, maintain, with financially sound and reputable insurance companies (in any event not materially less financially sound or reputable than its current insurance companies), insurance in such amounts and against such risks as are customarily maintained by companies engaged in the same or similar businesses operating in the same or similar locations, and with coverage amounts substantially the same as currently maintained by the Company and such Subsidiaries. The Company will furnish to the Purchaser certificates evidencing all such insurance policies required to be maintained pursuant to this Section and, subject to Section 5.19, endorsements naming the Purchaser, as lender loss payee (in the case of property/casualty insurance and business interruption insurance) and additional insured (in the case of liability insurance), as applicable, and providing that such insurance policies shall not be terminated or cancelled nor shall any such policy be materially changed in a manner adverse to the insured Person without at least thirty (30) days' prior written notice to the Company and the Purchaser (or ten (10) days' prior written notice in the case of cancellation due to non-payment). Receipt of notice of cancellation or modification of any such insurance policies or reduction of coverage or amounts thereunder shall entitle the Purchaser to renew any such policies, cause the coverage and amounts thereof to be maintained at levels required under this Section or otherwise to obtain similar insurance in place of such policies, in each case at the expense of the Company (payable on demand).

Section 5.12. Taxes.

(a) Tax Returns. The Company and its Subsidiaries shall timely file all federal income and all other material Tax Returns required to be filed by it and will pay all material Taxes levied or imposed upon them or their property, income or assets when due and payable.

(b) Intended Tax Treatment. The Purchaser and the Company agree that (i) the transactions contemplated by this Agreement are intended to constitute and shall be treated by the parties as a debt instrument for U.S. federal and applicable state and local income tax purposes (the "Intended Tax Treatment"), and (ii) the yield on such debt instrument shall be determined assuming that the Revenue Interest Period will end when the Purchasers have received the Return Cap (and, as applicable, that the Buy-Out Price will be determined pursuant to clause (b) of the definition thereof). None of the Purchasers or the Company shall take any Tax position inconsistent with the foregoing unless otherwise required by a determination within

the meaning of Section 1313(a) of the Code. UPON WRITTEN REQUEST BY THE PURCHASER TO THE COMPANY'S CHIEF FINANCIAL OFFICER, THE COMPANY WILL PROMPTLY MAKE AVAILABLE TO THE PURCHASER THE ISSUE PRICE, THE AMOUNT OF ORIGINAL ISSUE DISCOUNT, THE ISSUE DATE, THE YIELD TO MATURITY OF SUCH DEBT INSTRUMENT, THE COMPARABLE YIELD AND PROJECTED PAYMENT SCHEDULE.

Section 5.13. Material Contracts.

(a) Each of the Company and its Subsidiaries shall comply with all terms and conditions of, and fulfill all of its obligations under, all Material Contracts, except as could reasonably be expected not to have a Material Adverse Effect. Neither the Company nor any of its Subsidiaries shall, without the prior consent of the Purchaser (which consent shall not be unreasonably withheld, conditioned or delayed), amend, modify, restate, cancel, supplement, terminate or waive any provision of any Material Contract, or grant any consent thereunder, or agree to do any of the foregoing, in each case which could reasonably be expected to have a Material Adverse Effect on the Revenue Interests (including, without limitation, timing, amount or duration thereof) or to have a Material Adverse Effect.

(b) The Company shall not, and shall not permit any of its Subsidiaries to, enter into any Manufacturing Agreement (other than the Manufacturing Agreements listed on Schedule 5.13(b) of the Disclosure Letter and all amendments, restatements, extensions, supplements or other modifications thereto) relating to active pharmaceutical ingredients or finished products relating to Arikayce after the Closing Date (i) under which a default or of which a termination could interfere with the Purchaser's right to sell or lease, assign, license out, convey, transfer or grant options to purchase any Collateral, (ii) that cannot be collaterally assigned to secure the Obligations, (iii) that cannot be assigned to a purchaser in a foreclosure sale of all or any portion of the Collateral (subject to assumption by the purchaser of all obligations under such Material Contract) in the event of any exercise of rights or remedies under the Transaction Documents, (iv) that contains provisions that restrict or penalize the granting of a security interest in or Lien on such Material Contract or the assignment of such Material Contract upon the sale or other disposition of all or a portion of a product to which such Material Contract relates, or (v) that does not permit the disclosure of information to be provided thereunder to the Purchaser, to any purchaser or prospective purchaser in a foreclosure sale of all or any portion of the Collateral, to any assignee or prospective assignee of the Company or any of its Subsidiaries or to any company in the business of purchasing or financing financial assets, in each case without using its commercially reasonable efforts to ensure such Manufacturing Agreement does not contain the terms listed in clauses (i) to (v) in this Section 5.13(b).

(c) Upon the occurrence of a breach of any Material Contract by any other party thereto, the Company shall seek to enforce all of its (and cause its Subsidiaries to seek to enforce all of their) rights and remedies thereunder if such breach could reasonably be expected to result in a Material Adverse Effect on the Revenue Interests (including, without limitation, timing, amount or duration thereof).

Section 5.14. Benefit Plans and Arrangements.

Except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, none of the Company or any Subsidiary will (i) allow any "employee benefit plan," as defined in section 3(3) of ERISA, that provides retirement benefits, is sponsored by the Company or any Subsidiary, or any of their ERISA Affiliates and is intended to be tax qualified under section 401 of the Code to cease to be tax qualified, or (ii) allow any Benefit Plan

that is sponsored, maintained, contributed to or required to be contributed to by the Company or any Subsidiary to fail to comply in all respects with its terms and Applicable Law.

Section 5.15. Compliance with Sanctions and Anti-Money Laundering Laws.

(a) No Obligor will, nor will any Obligor permit any of its Subsidiaries or controlled Affiliates to, directly or indirectly, knowingly enter into any documents or contracts with any Sanctioned Person.

(b) Each Obligor shall notify the Purchaser in writing promptly (but in any event within five (5) Business Days after) a Responsible Officer of any Obligor becomes aware that any Obligor or any Subsidiary or Affiliate of any Obligor is a Sanctioned Person or that any Obligor or any Subsidiary or Affiliate of any Obligor or any of their respective directors, officers or employees (i) is convicted on, (ii) pleads *nobo contendere* to, (iii) is indicted on, or (iv) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering.

(c) No Obligor will, nor will any Obligor permit any of its Subsidiaries or Affiliates to, directly or indirectly, (i) conduct any prohibited business or engage in any prohibited investment, activity, transaction or deal with any Sanctioned Person, including the making or receiving of any contribution of funds, goods or services to or for the benefit of any Sanctioned Person, (ii) deal in, or otherwise engage in any investment, activity, transaction or dealing relating to, any property or interests in property blocked pursuant to Sanctions; or (iii) engage in or conspire to engage in any investment, activity, transaction or dealing that evades or avoids or violates, or has the purpose of evading or avoiding, or attempts to violate, any of prohibitions under Sanctions or Anti-Money Laundering Laws.

(d) the Company will not, directly or, to the Knowledge of the Company, indirectly (including through an agent or any other Person), use any of the proceeds of any the Purchase Price, or lend, contribute or otherwise make available such proceeds of the Purchase Price to any Subsidiary, joint venture partner or other Person, (i) for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation in any respect of the FCPA, UKBA or any other applicable anti-corruption laws, (ii) in violation in any respect of any Anti-Money Laundering Laws, (iii) in violation of Sanctions or (iv) in violation in any material respect of Export or Import Laws.

(e) the Company shall not, and shall not permit any of its Subsidiaries to, directly or, to the Knowledge of the Company indirectly, fund all or part of any repayment of the Purchase Price or other payments under this Agreement out of proceeds derived from criminal activity or activity or transactions in violation in any respect of the FCPA, UKBA, or any applicable anticorruption laws, Export or Import Laws, Anti-Money Laundering Laws or Sanctions, or that would otherwise cause any Person to be in violation in any respect of the FCPA, UKBA, or any applicable anti-corruption laws, Export or Import Laws, Anti-Money Laundering Laws or Sanctions.

Section 5.16. Transactions with Affiliates.

The Company shall not, and shall not permit any of its Subsidiaries to, engage in any other transactions with any of its Affiliates, including any sale, lease, license or other Transfer of assets to, or purchase, lease, license or other acquisition of any assets from any of its Affiliates, except:

(a) transactions between or among Obligors;

(b) compensation and indemnification of, and other employment or service agreements and arrangements with, directors, officers, employees, consultants and individuals independent contractors of the Company or any of its Subsidiaries; or

(c) any other transaction of any Obligor or any of its Subsidiaries that is (i) on fair and reasonable terms that are no less favorable (including the amount of cash or other consideration receivable or payable by any Obligor or Subsidiary in connection therewith) to any Obligor or Subsidiary than it could obtain in an arm's-length transaction with a Third Party, and (ii) of the kind which would be entered into by a prudent Person in the position of such Obligor or Subsidiary with a Third Party.

Section 5.17. Fiscal Unity.

No Obligor incorporated under Dutch law shall create or become a member of a fiscal unity (*fiscale eenheid*) for Dutch corporate income tax or value added tax purposes (unless such fiscal unity should consist solely of Obligors), unless a fiscal unity for value added tax purposes is imposed by the Dutch tax authorities.

Section 5.18. Operating Accounts; Control Agreements.

In the case of any Obligor, promptly following the establishment of any new Collateral Account at or with any bank or other depository or financial institution located in the United States, such Obligor shall (i) provide to the Purchaser at least ten (10) Business Days' prior written notice of such new Collateral Account and (ii) subject such account to a Control Agreement or other appropriate instrument that is reasonably acceptable to the Purchaser. For each Collateral Account that each Obligor at any time maintains in the United States, such Obligor shall within thirty (30) days of establishing such Collateral Account, cause the applicable bank or other depository or financial institution located in the United States, at or with which any Collateral Account is maintained to execute and deliver, and such Obligor shall execute and deliver, to the Purchaser, a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect the Purchaser's Lien in such Collateral Account in accordance with the terms hereunder and the Intercreditor Agreement, which Control Agreement may not be terminated without the prior written consent of the Purchaser. The provisions of the previous two (2) sentences shall not apply to any Excluded Account; provided, that in the event that any Excluded Account ceases to be an Excluded Account it shall be subject to the requirements under the provisions of the previous two (2) sentences as if such account was opened on the day it ceased to be an Excluded Account. Notwithstanding the foregoing, the Obligors shall have until the date that is ninety (90) days (or such longer period as the Purchaser may agree in its sole discretion) following (i) the Closing Date to comply with the provisions of this Section 5.18 with regards to Collateral Accounts (other than Excluded Accounts) of the Obligors in existence on the Closing Date (or opened during such 90-day period (or such longer period as the Purchaser may agree in its sole discretion)) and (ii) the closing date of any Acquisition or other Investment to comply with the provisions of this Section 5.18 with regards to Collateral Accounts (other than Excluded Accounts) of the Obligors acquired in connection with such Acquisition or other Investment.

Section 5.19. Post-Closing Obligations.

Notwithstanding anything to the contrary in this Agreement, the Company will, and will cause each of its Subsidiaries, as applicable, to take each of the actions set forth on Schedule 5.19 of the Disclosure Letter within the time period prescribed therefor on such schedule (or such longer period as the Purchaser may agree in its sole discretion), which shall include, among other things, that:

(a) the Obligors shall have until the date that is thirty (30) days following the Closing Date (or such longer period as the Purchaser may agree in its sole discretion) to comply with the provisions of Section 5.11 and the applicable provisions of the Intercreditor Agreement with regards to naming the Intercreditor Agent, on behalf of the Purchaser, as additional insured or loss payee, on any products liability or general liability insurance in the United States regarding Collateral in effect on the Closing Date;

(b) the Obligors shall have until the date that is ninety (90) days following the Closing Date (or such longer period as the Purchaser may agree in its sole discretion) to comply with the provisions of Section 5.19 with regards to Collateral Accounts of the Obligors in existence on the Closing Date or opened during such 90-day period;

(c) the Obligors shall have until the date that is thirty (30) days following the Closing Date (or such longer period as the Purchaser may agree in its sole discretion) to comply with the provisions of the Guaranty and Security Agreement and the Intercreditor Agreement with regards to the location of the primary Books of any Obligor or any of its Subsidiaries or the location of any material portion of the Collateral on the Closing Date or during such 30-day period;

(d) the Obligors shall have until the date that is:

(i) 45 days following the Closing Date (or such longer period as the Purchaser may agree in its sole discretion) to deliver (v) the Dutch Security Documents, (w) the opinion of Loyens & Loeff N.V., Dutch counsel to the Purchaser, the Term Lenders, the Term Loan Agent and the Intercreditor Agent, in form and substance reasonably satisfactory to the Purchaser, (x) the Irish Security Documents, (y) the opinion of Matheson LLP, Irish counsel to the Purchaser, the Term Lenders, the Term Loan Agent and the Intercreditor Agent, in form and substance reasonably satisfactory to the Purchaser and (z) the Swiss Security Documents, together with all customary closing deliverables and legal opinions related thereto; and

(ii) 60 days following the Closing Date (or such longer period as the Purchaser may agree in its sole discretion) to deliver the Japanese Security Documents, together with all customary closing deliverables and legal opinions related thereto, except with respect to the Japanese Equity Pledge, which shall be delivered on the Closing Date; and

(e) the applicable Subsidiaries shall have until the date that is thirty (30) days following the Closing Date (or such longer period as the Purchaser may agree in its sole discretion) to cause such Subsidiaries to become a party to the Intercompany Subordination Agreement to the extent permitted under Applicable Law.

All representations and warranties and covenants contained in this Agreement and the other Transaction Documents shall be deemed modified to the extent necessary to take the actions set forth on Schedule 5.19 of the Disclosure Letter within the time periods set forth therein, rather than elsewhere provided in the Transaction Documents, such that to the extent any such action set forth in Schedule 5.19 of the Disclosure Letter is not overdue, the applicable

Obligor shall not be in breach of any representation or warranty or covenant contained in this Agreement or any other Transaction Document applicable to such action for the period from the Closing Date until the date on which such action is required to be fulfilled as set forth on Schedule 5.19 of the Disclosure Letter.

Article VI.

TERMINATION

Section 6.01. Termination Date.

Except as provided in this Section 6.01 and in Section 6.02, this Agreement shall terminate upon expiration of the Revenue Interest Period (the "Term"). If any Reimbursable Expenses payments are required to be made by one of the parties hereunder after that date, this Agreement shall remain in full force and effect until any and all such payments have been made in full, and (except as provided in Section 6.02) solely for that purpose. In addition, this Agreement shall sooner terminate if the Purchaser shall have exercised the Put Option in accordance with Section 5.07(a) or the Company shall have exercised the Call Option in accordance with Section 5.07(b), in either case upon the payment of the in full in cash of the relevant Buy-Out Price and any other Obligations (other than contingent indemnity obligations for which no claim has been made).

Section 6.02. Effect of Termination.

In the event of the termination of this Agreement pursuant to Section 6.01, this Agreement shall forthwith have no further force or effect without any liability on the part of any party hereto or its Affiliates, directors, officers, stockholders, partners, managers or members other than the provisions of this Section 6.02, Section 5.04, and Article VII hereof, which shall survive any termination indefinitely, and Section 5.01(b) and Section 5.01(c), which shall survive for two (2) years after any termination. Nothing contained in this Section 6.02 shall relieve any party from liability for any breach of this Agreement.

Article VII.

MISCELLANEOUS

Section 7.01. Limitations on Damages.

Notwithstanding anything to the contrary in this Agreement, in no event shall either party be liable for special, indirect, incidental, punitive or consequential damages of the other party, whether or not caused by or resulting from the actions of such party or the breach of its covenants, agreements, representations or warranties hereunder, even if such party has been advised of the possibility of such damages; provided, that nothing contained in this Section 7.01 shall limit the Company's indemnification obligations hereunder to the extent such special, indirect, consequential or punitive damages are included in any third party claim in connection with which such Indemnified Party is entitled to indemnification hereunder. In connection with the foregoing, the parties hereto acknowledge and agree that (i) the Purchaser's damages, if any, for any such action or claim will typically include losses for payments that the Purchaser were

entitled to receive in respect of their ownership of the right to receive Revenue Interest Payments but did not receive timely or at all due to such indemnifiable event and (ii) the Purchaser shall be entitled to make claims for all such missing or delayed Revenue Interest Payments as losses hereunder, and such missing or delayed Revenue Interest Payments shall not be deemed special, indirect, incidental, punitive or consequential damages.

Section 7.02. Notices.

All notices, consents, waivers and communications hereunder or under any Transaction Document given by any party to the other shall be in writing and delivered personally, by a recognized overnight courier, by dispatching the same by certified or registered mail, return receipt requested, with postage prepaid, or by email, in each case addressed (with a copy by email):

If to the Purchaser to:

OrbiMed Royalty & Credit Opportunities IV, LP
c/o OrbiMed Advisors LLC
601 Lexington Avenue
54th Floor
New York, NY 10022
Attention: Matthew Rizzo; OrbiMed Credit Reporting
Email: [***]; [***]

With a copy (with shall not constitute notice) to:

Morrison & Foerster LLP
250 West 55th Street New York, NY 10019
Attention: Mark Wojciechowski, Esq.
Email: [***]

If to the Company to:

c/o Insmed Incorporated
700 US Highway 202/206
Bridgewater, New Jersey 08807
Attention: Chief Financial Officer
Email: [***]

With a copy (with shall not constitute notice) to:

Covington & Burling LLP
620 Eighth Avenue
New York, New York 10018-1000
Attention: Peter Schwartz
Telephone: +1 212-841-1268
Email: [***]

or to such other address or addresses as the Purchaser or the Company may from time to time designate by notice as provided herein, except that notices of changes of address shall be effective only upon receipt. All such notices, consents, waivers and communications if mailed and properly addressed with postage prepaid or if properly addressed and sent by pre-paid courier service, shall be deemed given when received; any notice, if transmitted by email, shall be deemed given upon the earlier of (x) confirmation of receipt by the recipient and (y) the opening of business on the next Business Day for the recipient. Unless otherwise indicated, all references to the time of a day in a Transaction Document shall refer to New York City time.

Section 7.03. Successors and Assigns.

(a) The provisions of this Agreement and the other Transaction Documents shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns. The Company shall not be entitled to assign any of its obligations or rights under the Transaction Documents without the prior written consent of the Purchaser. The Purchaser may assign any of its rights under the Transaction Documents without restriction to any Eligible Assignee (or, if a Put Option Event or an "Event of Default" (as defined in the Term Loan Agreement) has occurred and is continuing, to any Person); provided, that the Purchaser shall provide the Company with written notice of any assignment; provided, further, that for purposes of Section 2.05 and Section 7.03(b) (and for purposes of the defined terms used therein), "Purchaser" shall be deemed to include any assignee thereof.

(b) The Company shall maintain a copy of each assignment delivered to it pursuant to Section 7.03(a) and a register for the recordation of the names and addresses of, and the amounts owing to, each Purchaser pursuant to the Obligations and the terms hereof (the "Register"). The Obligations pursuant to this Agreement are intended to be registered obligations for U.S. federal income tax purposes, and the right, title and interest of the Purchaser and its assignees in and to such Obligations, shall be transferable only upon notation of such transfer in the Register. The entries in the Register shall be conclusive absent manifest error, and the Company, its Subsidiaries, and the Purchaser shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as the Purchaser hereunder for all purposes of this Agreement. The Register shall be available for inspection by the Purchaser, at any reasonable time and from time to time upon reasonable prior notice.

Section 7.04. Indemnification.

(a) The Company hereby indemnifies and holds the Purchaser and its respective Affiliates and any of their respective partners, directors, managers, members, officers, employees and agents (each, an "Indemnified Party") harmless from and against any and all (i) liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs and expenses that may be imposed on, incurred by, or asserted against any Indemnified Party as a result of any breach of representations, warranties or covenants under this Agreement or any other Transaction Document by the Company any of its Subsidiaries and (ii) Indemnified Liabilities, in all cases, arising, in whole or in part, out of or relating to any claim, notice, suit or proceeding commenced or threatened in writing (including, without limitation, by electronic means) by any Person (including any Governmental Authority); provided the Company shall not have any obligation to any Indemnified Party hereunder with respect to any Indemnified Liabilities (i) to the extent a court of competent jurisdiction determines by final and nonappealable judgment that such Indemnified Liabilities result from the gross negligence or willful misconduct of such Indemnified Party, (ii) that result from a claim against by the Company against an Indemnified Party for any material breach in bad faith of any such Indemnified Party's obligations under this Agreement, if the Company has obtained a final and nonappealable judgment in its favor on such claim as determined by a court of competent jurisdiction or (iii) that result from a claim not

involving an act or omission of the Company or any of its Subsidiaries and that is brought by an Indemnified Party against another Indemnified Party.

(b) A claim by an Indemnified Party under this Section 7.04 for any matter in respect of which such Indemnified Party seeks indemnification hereunder may be made by delivering, in good faith, a written notice of demand to the indemnifying party, which notice shall contain (i) a description and the amount of any Indemnified Liabilities incurred or suffered or reasonably expected to be incurred or suffered by the Indemnified Party, (ii) a statement that the Indemnified Party is entitled to indemnification under this Section 7.04 for such Indemnified Liabilities and a reasonable explanation of the basis therefor, and (iii) a demand for payment in the amount of such Indemnified Liabilities. Within thirty (30) days after receipt by the indemnifying party of any such notice, the indemnifying party may deliver to the Indemnified Party that delivered the notice a written response in which the indemnifying party (i) agrees that the Indemnified Party is entitled to the full amount of the Indemnified Liabilities claimed in the notice from the Indemnified Party; (ii) agrees that the Indemnified Party is entitled to part, but not all, of the amount of the Indemnified Liabilities claimed in the notice from the Indemnified Party; or (iii) indicates that the indemnifying party disputes the entire amount of the Indemnified Liabilities claimed in the notice from the Indemnified Party. If the Indemnified Party does not receive such a response from the indemnifying party within such thirty (30)-day period, then the indemnifying party shall be conclusively deemed to have agreed that the Indemnified Party is entitled to the full amount. If the indemnifying party and the Indemnified Party are unable to resolve any dispute relating to any amount of the Indemnified Liabilities claimed in the notice from the Indemnified Party within thirty (30) days after the delivery of the response to such notice from the indemnifying party, then the parties shall be entitled to resort to any legal remedy available to such party to resolve such dispute that is provided for in this Agreement, subject to all the terms, conditions and limitations of this Agreement.

Section 7.05. No Implied Representations and Warranties; Survival of Representations and Warranties.

Each party acknowledges and agrees that, other than the representations and warranties specifically contained in any of the Transaction Documents, there are no representations or warranties of either party or any other Person either expressed or implied with respect to the Revenue Interests or the transactions contemplated hereby. Without limiting the foregoing, the Purchaser acknowledges and agrees that the Purchaser and its Affiliates, together with their representatives, have made their own investigation of each Specified Product and are not relying on any implied warranties or upon any representation or warranty whatsoever as to the future amount or potential amount of the Revenue Interests or as to the creditworthiness of the Company. All representations and warranties by the parties contained in this Agreement shall survive the execution, delivery and acceptance thereof by the parties and the closing of the transactions described in this Agreement and continue in effect until payment of all amounts due to the Purchaser under the Transaction Documents and the termination of this Agreement pursuant to its terms.

Section 7.06. Independent Nature of Relationship.

(a) The relationship between the Company and its Subsidiaries, on the one hand, and the Purchaser, on the other, is solely that of seller and purchaser, and for U.S. federal income Tax purposes, that of debtor and creditor, and neither the Purchaser, on the one hand, nor the Company and its Subsidiaries, on the other, has any fiduciary or other special relationship with the other or any of their respective Affiliates. Nothing contained herein or in any other

Transaction Document shall be deemed to constitute the Company and its Subsidiaries and the Purchaser as a partnership, an association, a joint venture or other kind of entity or legal form for any purposes, including for any Tax purposes.

(b) No officer or employee or agent of the Purchaser will be located at the premises of the Company or any of its Affiliates, except in connection with an audit performed pursuant to Section 5.01 or in connection with the enforcement of remedies as contemplated by the Transaction Documents. No officer, manager or employee of the Purchaser shall engage in any commercial activity with the Company or any of its Affiliates other than as contemplated herein and in the other Transaction Documents.

Section 7.07. Entire Agreement.

This Agreement, together with the Exhibits hereto (which are incorporated herein by reference), and the other Transaction Documents constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all prior agreements, understandings and negotiations, both written and oral, between the parties with respect to the subject matter of this Agreement. No representation, inducement, promise, understanding, condition or warranty not set forth herein (or in the Exhibits or other Transaction Documents) has been made or relied upon by either party hereto. None of this Agreement, nor any provision hereof, is intended to confer upon any Person other than the parties hereto any rights or remedies hereunder.

Section 7.08. Amendments; No Waivers.

(a) This Agreement, the other Transaction Documents or any term or provision hereof or thereof may not be amended, changed or modified except with the written consent of the Company and the Purchaser. No waiver of any right hereunder shall be effective unless such waiver is signed in writing by the party against whom such waiver is sought to be enforced.

(b) No failure or delay by either party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by law.

Section 7.09. Interpretation.

When a reference is made in this Agreement to Articles, Sections, Schedules or Exhibits, such reference shall be to an Article, Section or Exhibit to this Agreement or a Schedule to the Disclosure Letter, in each case unless otherwise indicated. The words “include”, “includes” and “including” when used herein shall be deemed in each case to be followed by the words “without limitation”. Neither party hereto shall be or be deemed to be the drafter of this Agreement for the purposes of construing this Agreement against one party or the other.

Section 7.10. Headings and Captions.

The headings and captions in this Agreement or any other Transaction Document are for convenience and reference purposes only and shall not be considered a part of or affect the construction or interpretation of any provision of this Agreement or such Transaction Document.

Section 7.11. Counterparts; Effectiveness; Electronic Signature.

This Agreement may be executed in two or more counterparts, each of which shall be an original, but all of which together shall constitute one and the same instrument. This Agreement shall become effective when each party hereto shall have received a counterpart hereof signed by the other parties hereto. Any counterpart may be executed by facsimile or pdf signature and such facsimile or pdf signature shall be deemed an original. The words 'execution', 'signed', 'signature', 'delivery' and words of like import in or relating to any document to be signed in connection with this Agreement or any other Transaction Document and the transactions contemplated hereby shall be deemed to include Electronic Signatures, deliveries or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature, physical delivery thereof or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any Applicable Law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar State laws based on the Uniform Electronic Transactions Act; provided, that nothing herein shall require any Person to accept electronic signatures in any form or format without its prior written consent. Without limiting the generality of the foregoing, the parties hereto hereby (a) agree that, for all purposes, including in connection with any workout, restructuring, enforcement of remedies, bankruptcy proceedings or litigation among the Purchaser and the Obligors, electronic images of this Agreement or any other Transaction Document (in each case, including with respect to any signature pages thereto) shall have the same legal effect, validity and enforceability as any paper original, and (b) waive any argument, defense or right to contest the validity or enforceability of the Transaction Documents based solely on the lack of paper original copies of any Transaction Documents, including with respect to any signature pages thereto.

Section 7.12. Severability.

If any provision of this Agreement is held to be invalid or unenforceable, the remaining provisions shall nevertheless be given full force and effect.

Section 7.13. Expenses.

The Company will pay all of its own fees and expenses in connection with entering into and consummating the transactions contemplated by this Agreement.

Section 7.14. Governing Law; Jurisdiction.

(a) Each Transaction Document (except as may otherwise expressly stated therein) shall be governed by, and construed, interpreted and enforced in accordance with, the laws of the state of New York, without giving effect to the principles of conflicts of law thereof.

(b) Any legal action or proceeding with respect to this Agreement or any other Transaction Document may be brought in any state or federal court of competent jurisdiction in the State of New York, County of New York. By execution and delivery of this Agreement, each party hereto hereby irrevocably consents to and accepts, for itself and in respect of its property, generally and unconditionally the non-exclusive jurisdiction of such courts. Each party hereto hereby further irrevocably waives any objection, including any objection to the laying of venue

or based on the grounds of forum non conveniens, which it may now or hereafter have to the bringing of any action or proceeding in such jurisdiction in respect of any Transaction Document.

(c) Each party hereto hereby irrevocably consents to the service of process out of any of the courts referred to in clause (b) of this Section 7.14 in any such suit, action or proceeding by the mailing of copies thereof by registered or certified mail, postage prepaid, to it at its address set forth in this Agreement. Each party hereto hereby irrevocably waives any objection to such service of process and further irrevocably waives and agrees not to plead or claim in any suit, action or proceeding commenced hereunder or under any other Transaction Document that service of process was in any way invalid or ineffective. Nothing herein shall affect the right of a party to serve process on the other party in any other manner permitted by law.

Section 7.15. Waiver of Jury Trial.

EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING, CLAIM OR COUNTERCLAIM ARISING OUT OF OR RELATING TO ANY TRANSACTION DOCUMENT OR THE TRANSACTIONS CONTEMPLATED UNDER ANY TRANSACTION DOCUMENT. THIS WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO ANY TRANSACTION DOCUMENT.

[SIGNATURE PAGE FOLLOWS]

Exhibit 10.26

Pursuant to Item 601(b)(10)(iv) of Regulation S-K, confidential information (indicated by [***]) has been omitted from Exhibit 10.26 because it (i) is not material and (ii) is the type of information the Company both customarily and actually treats as private or confidential.

AMENDED AND RESTATED LOAN AGREEMENT

Dated as of October 31, 2024

among

INSMED INCORPORATED

(as ***Borrower***, and a ***Credit Party***),

THE GUARANTORS SIGNATORY HERETO OR OTHERWISE PARTY HERETO FROM TIME TO TIME

(as additional ***Credit Parties***),

BIOPHARMA CREDIT PLC

(as ***Collateral Agent***),

BPCR LIMITED PARTNERSHIP

(as a ***Lender***)

and

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP

(as a ***Lender***)

TABLE OF CONTENTS

Page

2 LOANS AND TERMS OF PAYMENT 2

2.1 Promise to Pay 2

2.2 Term Loans 2

2.3 Payment of Interest on the Term Loans 5

2.4 Expenses 6

2.5 Requirements of Law; Increased Costs 6

2.6 Taxes; Withholding, Etc. 7

2.7 Additional Consideration 10

2.8 Note Register; Term Loan Notes 10

3 CONDITIONS OF TERM LOANS 11

3.1 Conditions Precedent to the Tranche A Term Loans 11

3.2 Conditions Precedent to the Tranche B Term Loans 13

3.3 [RESERVED] 14

3.4 [RESERVED] 14

3.5 Additional Conditions Precedent to Term Loans 14

3.6 Covenant to Deliver 14

3.7 Procedures for Borrowing 15

4 REPRESENTATIONS AND WARRANTIES 15

4.1 Due Organization, Existence, Power and Authority 15

4.2 Equity Interests 15

4.3 Authorization; No Conflict 15
4.4 Government Consents; Third Party Consents 16
4.5 Binding Obligation 16
4.6 Collateral 16
4.7 Adverse Proceedings, Compliance with Laws and Settlement Agreements 20
4.8 Exchange Act Documents; Financial Statements; Financial Condition; No Material Adverse Change; Books and Records 20
4.9 Solvency 21
4.10 Taxes 21
4.11 Environmental Matters 22
4.12 Material Contracts 22
4.13 Regulatory Compliance 22
4.14 Margin Stock 22
4.15 Subsidiaries; Capitalization 23
4.16 Employee Matters 23
4.17 Full Disclosure 23
4.18 Anti-Corruption Laws; Anti-Money Laundering Laws; Sanctions; Export and Import Laws 23
4.19 Health Care Matters 25
4.20 Regulatory Approvals or Licensures 27
4.21 Supply and Manufacturing 28
4.22 Cybersecurity and Data Protection 28
4.23 Additional Representations and Warranties 30
4.24 Centre of Main Interests and Establishments. 30

4.25 Fiscal Unity. 30

5 AFFIRMATIVE COVENANTS 30
5.1 Maintenance of Existence 30
5.2 Financial Statements, Notices, Reports 31
5.3 Taxes 33
5.4 Insurance 33
5.5 Operating Accounts 33
5.6 Compliance with Laws 34
5.7 Protection of Intellectual Property Rights 34
5.8 Books and Records 36
5.9 Access to Collateral; Audits 36
5.10 Use of Proceeds 36
5.11 Further Assurances 36
5.12 Additional Collateral; Guarantors 36
5.13 Formation or Acquisition of Subsidiaries 38
5.14 Post-Closing Requirements 38
5.15 Environmental 38
5.16 Inventory; Returns; Maintenance of Properties 39
5.17 Regulatory Obligations; Maintenance of Regulatory Approval or Licensure; Licensure and Designation; Manufacturing, Marketing and Distribution 40
5.18 Material Contracts; Collateral Documents 40

6 NEGATIVE COVENANTS 40
6.1 Dispositions 40

6.2 Fundamental Changes; Location of Collateral 40
6.3 Mergers, Acquisitions, Liquidations or Dissolutions 41
6.4 Indebtedness 42
6.5 Encumbrances 42
6.6 No Further Negative Pledges; Negative Pledge 42
6.7 Maintenance of Collateral Accounts 43
6.8 Distributions; Investments 43
6.9 No Restrictions on Subsidiary Distributions 43
6.10 Subordinated Debt; Permitted Convertible Indebtedness 43
6.11 Amendments or Waivers of Organizational Documents 44
6.12 Compliance 44
6.13 Compliance with Sanctions and Anti-Money Laundering Laws 44
6.14 Material Contracts 45
7 EVENTS OF DEFAULT 46
7.1 Payment Default 46
7.2 Covenant Default 46
7.3 Withdrawal Event; Material Adverse Change 47
7.4 Attachment; Levy; Restraint on Business 47
7.5 Insolvency 47
7.6 Other Agreements 48
7.7 Judgments 49
7.8 Misrepresentations 49

7.9 Loan Documents; Collateral 49
7.10 ERISA Event 49
7.11 Intercreditor Agreement 49
8 RIGHTS AND REMEDIES UPON AN EVENT OF DEFAULT 49
8.1 Rights and Remedies 49
8.2 Power of Attorney 51
8.3 Application of Payments and Proceeds Upon Default 51
8.4 Collateral Agent's Liability for Collateral 51
8.5 No Waiver; Remedies Cumulative 51
8.6 Demand Waiver; Makewhole Amount; Prepayment Premium; Exit Fee 52
9 NOTICES 52
10 CHOICE OF LAW, VENUE, AND JURY TRIAL WAIVER 53
11 GENERAL PROVISIONS 54
11.1 Successors and Assigns 54
11.2 Indemnification 55
11.3 Severability of Provisions 56
11.4 Correction of Loan Documents 56
11.5 Amendments in Writing; Integration 56
11.6 Counterparts 56
11.7 Survival; Termination Prior to Term Loan Maturity Date 56
11.8 Confidentiality 57

11.9 Attorneys' Fees, Costs and Expenses 58
11.10 Right of Set-Off 58
11.11 Marshalling; Payments Set Aside 58
11.12 Electronic Execution of Documents 58
11.13 Captions 58
11.14 Construction of Agreement 58
11.15 Third Parties 58
11.16 No Advisory or Fiduciary Duty 58
11.17 Credit Parties' Agent 59
11.18 Reaffirmation of Loan Documents; Confirmation of Liens 59
11.19 Effect of Amendment and Restatement 59

12 COLLATERAL AGENT 60
12.1 Appointment and Authority 60
12.2 Rights as a Lender 60
12.4 Exculpatory Provisions 61
12.5 Reliance by Collateral Agent 62
12.6 Delegation of Duties 62
12.7 Resignation of Collateral Agent 62
12.8 Non-Reliance on Collateral Agent and Other Lenders 63
12.9 Collateral and Guaranty Matters 63
12.10 Reimbursement by Lenders 64
12.11 Parallel Liability. 64

12.12 Notices and Items to Lenders 65

13 DEFINITIONS 66

13.1 Definitions 66

Exhibit A: Loan Advance Request Form

Exhibit B-1: Form of Tranche A Term Loan Note

Exhibit B-2: Form of Tranche B Term Loan Note

Exhibit C: Form of Security Agreement

Exhibit D: Commitments; Notice Addresses

Exhibit E: Form of Compliance Certificate

Exhibit F: Intercompany Reorganization

AMENDED AND RESTATED LOAN AGREEMENT

THIS AMENDED AND RESTATED LOAN AGREEMENT (this "**Agreement**"), dated as of October 31, 2024 (the "**Effective Date**") by and among INSMED INCORPORATED, a Virginia corporation (as "**Borrower**" and a Credit Party), the Guarantors signatory hereto or otherwise party hereto from time to time, as additional Credit Parties, BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales with company number 10443190 (as the "**Collateral Agent**"), BPCR LIMITED PARTNERSHIP, a limited partnership established under the laws of England and Wales with registration number LP020944 (as a "**Lender**") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP, a Cayman Islands exempted limited partnership acting by its general partner, BioPharma Credit Investments V GP LLC (as a "**Lender**"), provides the terms on which each Lender shall make, and Borrower shall repay, the Credit Extensions (as hereinafter defined). Subject to the terms and conditions herein, this Agreement amends and restates in its entirety, and replaces, the terms of (and obligations outstanding under) that certain Loan Agreement, dated as of October 19, 2022, as amended by that certain First Amendment, Consent and Waiver dated as of June 30, 2023 (collectively, the "**Prior Loan Agreement**"). As described in greater detail in Section 11.19 hereof, the parties hereto agree that the Prior Loan Agreement is hereby amended, restated and superseded in its entirety by this Agreement, and the parties hereto further agree as follows:

1 ACCOUNTING AND OTHER TERMS

Except as otherwise expressly provided herein, all accounting terms not otherwise defined in this Agreement shall have the meanings assigned to them in conformity with GAAP. Calculations and determinations must be made following GAAP. If at any time any change in GAAP would affect the computation of any financial requirement set forth in any Loan Document (including for purposes of measuring compliance with any provision of Section 6), and either Borrower or the Collateral Agent shall so request, the Collateral Agent and Borrower shall negotiate in good faith to amend such requirement to preserve the original intent thereof in light of such change in GAAP; provided, that, until so amended, (x) such requirement shall continue to be computed in accordance with GAAP prior to such change therein and (y) all financial statements, Compliance Certificates and similar documents provided, delivered or submitted hereunder shall be provided, delivered or submitted together with a reconciliation between the calculations and amounts set forth therein before and after giving effect to such change in GAAP. Notwithstanding any other provision contained herein, all terms of an accounting or financial nature used herein shall be construed, and all computations of amounts referred to herein, including in Section 5 and Section 6 shall be made, without giving effect to any (a) election under ASC 825-10 (or any other Financial Accounting Standards Board Accounting Standards Codification ("**ASC**") or Financial Accounting Standard or Applicable Accounting Standard (including IFRS 9) having a similar result or effect) to value any Indebtedness or other liabilities of any Credit Party or any Subsidiary of any Credit Party at "fair value" and (b) any treatment of Indebtedness in respect of convertible debt instruments under ASC 470-20 (or any other ASC or Financial Accounting Standard or Applicable Accounting Standard having a similar result or effect) to value any such Indebtedness in a reduced or bifurcated manner as described therein, and such Indebtedness shall at all times be valued at the full stated principal amount thereof. Notwithstanding anything to the contrary above or in the definition of "Capital Lease Obligations", all obligations of any Person that are or would have been treated as operating leases for purposes of GAAP prior to the effectiveness of ASC 842 shall continue to be accounted for as operating leases for all purposes hereunder or under any other Loan Documents (whether or not such operating lease obligations were in effect on such date) notwithstanding the fact that such obligations are required in accordance with ASC 842 (on a prospective or retroactive basis or otherwise) to be treated as Capital Leases. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to "Dollars" or "$" are United States Dollars, unless otherwise noted.

For purposes of Sections 5 and 6 and solely with respect to the amount of any Indebtedness, Investment or other transaction made or consummated in a currency other than Dollars, no Default or Event of Default shall be deemed to have occurred after the time such Indebtedness, Investment or other transaction is incurred, made or consummated (so long as such Indebtedness, Investment or other transaction, at the time incurred, made or

consummated, was permitted hereunder) solely as a result of changes in rates of currency exchange occurring over time.

2 LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay.

Borrower hereby unconditionally promises to pay each Lender the outstanding principal amount of the Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.

(a) Availability.

(i) Each Lender has made a term loan to Borrower on the Tranche A Closing Date in an aggregate original principal amount equal to the sum of such Lender's Tranche A Term Loan Commitment, *plus* paid-in-kind interest thereon accrued and capitalized prior to the Effective Date pursuant to the Prior Loan Agreement (each, a "T**ranche A Term Loan**" and, collectively, the "**Tranche A Term Loans**").

(ii) Subject to the terms and conditions of this Agreement (including Sections 3.2, 3.5, 3.6 and 3.7), Borrower agrees to request in accordance with Section 3.7, and each Lender severally agrees to make, a term loan to Borrower on the Tranche B Closing Date in an original principal amount equal to such Lender's Tranche B Term Loan Commitment (individually, a "**Tranche B Term Loan**," and collectively, the "**Tranche B Term Loans**").

(iii) After repayment or prepayment (in whole or in part), no Term Loan (or any portion thereof) may be re-borrowed.

(b) Repayment.

(i) With respect to each Tranche A Term Loan and subject to any acceleration of the Term Loan Maturity Date pursuant to the terms of the definition thereof, Borrower shall make eight (8) equal quarterly payments of principal of each such Tranche A Term Loan commencing on January 3, 2028 and continuing on each Payment Date through the Term Loan Maturity Date.

(ii) With respect to each Tranche B Term Loan and subject to any acceleration of the Term Loan Maturity Date pursuant to the terms of the definition thereof, Borrower shall make eight (8) equal quarterly payments of principal of each such Tranche B Term Loan commencing on January 3, 2028 and continuing on each Payment Date through the Term Loan Maturity Date.

(iii) The Term Loans, including all unpaid principal thereunder (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any and all other outstanding amounts payable under the Loan Documents), is due and payable in full on the Term Loan Maturity Date.

(iv) The Term Loans may be prepaid only in accordance with Section 2.2(c), except as provided in Section 8.1 or the proviso in the definition of Term Loan Maturity Date.

(c) Prepayment of Term Loans.

(i) Borrower shall have the option, at any time after the Tranche A Closing Date, to prepay, in part (in multiples of not less than $50,000,000) or in whole, outstanding principal amounts under the Term Loans advanced by Lenders under this Agreement; provided that (A) Borrower provides written notice to the Collateral Agent of its election (which shall be irrevocable unless the Collateral Agent otherwise consents in writing) to prepay, in part (in multiples of not less than $50,000,000) or in whole, the Term Loans at least five (5) Business Days prior to such prepayment (which notice shall include the amount of the outstanding principal amount of the Term Loans to be prepaid), and (B) the prepayment of such principal amount shall be accompanied by any and all accrued and unpaid interest thereon through the

date of prepayment, any and all amounts payable in connection with such prepayment pursuant to Section 2.2(e) and Section 2.2(f) (as applicable) and, in the case of a prepayment in whole and not in part, any and all other amounts payable or accrued and not yet paid under this Agreement and the other Loan Documents (including pursuant to Section 2.4). The Collateral Agent will promptly notify each Lender of its receipt of such notice, and the amount of such Lender's Applicable Percentage of such prepayment. Notwithstanding anything in this Section 2.2(c)(i) to the contrary, Borrower may rescind any notice of prepayment under this Section 2.2(c)(i) if such prepayment would have resulted from a refinancing of the Term Loans or other contingent transaction, which refinancing or transaction shall not be consummated or shall otherwise be delayed (in which case, a new notice shall be required to be sent in connection with any subsequent prepayment).

(ii) Borrower shall promptly, and in any event no later than ten (10) Business Days prior (or immediately if known fewer than ten (10) Business Days prior) to the consummation of such Change in Control, notify the Collateral Agent in writing of the occurrence (or anticipated occurrence) of a Change in Control, which notice shall include reasonable detail as to the nature, timing and other circumstances of such Change in Control (such notice, a "**Change in Control Notice**"). Borrower shall prepay in full all of the Term Loans advanced by Lenders under this Agreement, immediately upon (and concurrent with) the consummation of such Change in Control, in an amount equal to the sum of (A) all unpaid principal and any and all accrued and unpaid interest thereon through the date of prepayment, and (B) any and all amounts payable with respect to the prepayment under this Section 2.2(c)(ii) pursuant to Section 2.2(e) and Section 2.2(f) (as applicable), together with any and all other amounts payable or accrued and not yet paid under this Agreement and the other Loan Documents (including pursuant to Section 2.4). The Collateral Agent will promptly notify each Lender of its receipt of the Change in Control Notice, and the amount of such Lender's Applicable Percentage of such prepayment.

(iii) Prior to any prepayment, repurchase, redemption or similar action, of the Permitted Convertible Indebtedness in accordance with its terms (the "**Convertible Indebtedness Redemption**") (which occurs prior to the Term Loan Maturity Date), Borrower shall promptly, and in any event no later than fifteen (15) days prior to the consummation of such Convertible Indebtedness Redemption, notify the Collateral Agent in writing of the occurrence of such Convertible Indebtedness Redemption, which notice shall include reasonable detail as to the nature, timing and other circumstances of such Convertible Indebtedness Redemption (such notice, a "**Convertible Indebtedness Redemption Notice**"). Borrower shall prepay in full all of the Term Loans advanced by Lenders under this Agreement, no later than ten (10) days prior to the Convertible Indebtedness Redemption in an amount equal to the sum of (A) all unpaid and outstanding principal and any and all accrued and unpaid interest with respect to the Term Loans, and (B) any applicable amounts payable with respect to the prepayment under this Section 2.2(c)(iii) pursuant to Section 2.2(e) and Section 2.2(f) (as applicable) and all other amounts payable or accrued and not yet paid under this Agreement and the other Loan Documents (including pursuant to Section 2.4). The Collateral Agent will promptly notify each Lender of its receipt of the Convertible Indebtedness Redemption Notice, and the amount of such Lender's Applicable Percentage of such prepayment. Notwithstanding the foregoing, none of the following shall be deemed to be a Convertible Indebtedness Redemption: (w) the conversion to Equity Interests by holders of Permitted Convertible Indebtedness (including any cash payment upon conversion) or required payment of any interest with respect to any Permitted Convertible Indebtedness, in each case, in accordance with the terms of the indenture or other documentation governing such Permitted Convertible Indebtedness; (x) any Permitted Convertible Redemption, (y) the exchange of existing Permitted Convertible Indebtedness for or redemption of existing Permitted Convertible Indebtedness with (1) new Permitted Convertible Indebtedness (the "**Refinancing Convertible Debt**") (or the cash proceeds from the issuance of such Refinancing Convertible Debt) to the extent such Refinancing Convertible Debt is permitted to be issued under the terms of this Agreement and to the extent that such new Refinancing Convertible Debt bears interest at a rate *per annum* not to exceed the greater of [***] percent ([***]%) and such rate as is customary in the market at such time, as determined by the Borrower in its reasonable commercial judgment, (2) Equity Interests, (3) the cash proceeds, if any, received pursuant to the exercise, early unwind or termination of any Permitted Equity Derivative entered into in connection with such existing Permitted Convertible Indebtedness, or (4) cash in respect of accrued and unpaid interest on such exchanged existing Permitted Convertible Indebtedness, or (z) delivery of Equity Interests and cash in lieu of fractional shares or in respect of accrued and unpaid interest to any holder of Permitted Convertible Indebtedness to induce such holder to convert Permitted Convertible Indebtedness in accordance with the terms of the indenture governing such Permitted Convertible Indebtedness (any such transaction described in clause (w), (x), (y) or (z) above, a "**Permitted Transaction**" and collectively, the "**Permitted Transactions**").

(d) Prepayment Application. Any prepayment of the Term Loans pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date (together with the accompanying Makewhole Amount,

Prepayment Premium and Exit Fee that is payable pursuant to Section 2.2(e) and Section 2.2(f) as applicable) shall be paid to Lenders in accordance with their respective Applicable Percentages for application to the Obligations in the following order: (i) first, to due and unpaid Lender Expenses; (ii) second, to due and unpaid Additional Consideration; (iii) third, to accrued and unpaid interest at the Default Rate incurred pursuant to Section 2.3(b), with respect to past due amounts, if any; (iv) fourth, without duplication of amounts paid pursuant to clause (iii) above, to accrued and unpaid interest at the Term Loan Rate; (v) fifth, to the Exit Fee; (vi) sixth, to the Prepayment Premium; (vii) seventh, to the Makewhole Amount, if applicable; (viii) eighth, to the outstanding principal amount of the Term Loans being prepaid; and (ix) ninth, to any remaining amounts then due and payable under this Agreement and the other Loan Documents.

(e) Makewhole Amount.

(i) Any prepayment of the Tranche A Term Loans by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date, in each case occurring prior to the 3rd-year anniversary of the Tranche B Closing Date shall, in any such case, be accompanied by payment of an amount equal to the Tranche A Makewhole Amount.

(ii) Any prepayment of the Tranche B Term Loans by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date, in each case occurring prior to the 3rd-year anniversary of the Tranche B Closing Date shall, in any such case, be accompanied by payment of an amount equal to the Tranche B Makewhole Amount.

(f) Prepayment Premium; Exit Fee.

(i) Any prepayment of the Tranche A Term Loans by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date, shall, in any such case, be accompanied by payment of an amount equal to the Tranche A Prepayment Premium.

(ii) Any prepayment of the Tranche B Term Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date, shall, in any such case, be accompanied by payment of an amount equal to the Tranche B Prepayment Premium.

(iii) Except as a result of the acceleration of the maturity of the Term Loans pursuant to the proviso in the definition of Term Loan Maturity Date, no Prepayment Premium shall be due and owing for any payment of principal of the Term Loans made on the Term Loan Maturity Date.

(iv) Any prepayment or repayment of the Tranche A Term Loans by Borrower (A) pursuant to Section 2.2(c), (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date or (C) pursuant to Section 2.2(b) or otherwise (including, for the avoidance of doubt, on the Term Loan Maturity Date), shall, in any such case, be accompanied by payment of an amount equal to the Tranche A Exit Fee.

(v) Any prepayment or repayment of the Tranche B Term Loans by Borrower (A) pursuant to Section 2.2(c), (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date or (C) pursuant to Section 2.2(b) or otherwise (including, for the avoidance of doubt, on the Term Loan Maturity Date), shall, in any such case, be accompanied by payment of an amount equal to the Tranche B Exit Fee.

(vi) Any and all Exit Fees payable hereunder are in addition to, and not creditable against, any other fee, cost or expenses payable under the Loan Documents (including, for the avoidance of doubt, any Makewhole Amount or Prepayment Premium).

(g) Any Makewhole Amount, Prepayment Premium or Exit Fee payable as a result of any prepayment of the Term Loans pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date, shall, in any such case, be presumed to be the liquidated damages sustained by each applicable Lender as the result of the early redemption and repayment of such Term Loan Notes and Borrower agrees that it is reasonable under the circumstances currently existing. BORROWER EXPRESSLY WAIVES (TO THE FULLEST EXTENT IT MAY

LAWFULLY DO SO) THE PROVISIONS OF ANY PRESENT OR FUTURE REQUIREMENTS OF LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF ANY MAKEWHOLE AMOUNT, PREPAYMENT PREMIUM OR EXIT FEE IN CONNECTION WITH ANY SUCH PREPAYMENT OR ACCELERATION OR OTHERWISE. Borrower expressly agrees that (to the fullest extent it may lawfully do so) that: (i) each Makewhole Amount, Prepayment Premium and Exit Fee is reasonable and is the product of an arm's-length transaction among sophisticated business people, ably represented by counsel; (ii) each Makewhole Amount, Prepayment Premium and Exit Fee shall be payable notwithstanding the then-prevailing market rates at the time payment thereof is made; (iii) there has been a course of conduct among Lenders and Borrower giving specific consideration in this transaction for such agreement to pay each Makewhole Amount, Prepayment Premium and Exit Fee; and (iv) Borrower shall be estopped hereafter from claiming differently than as agreed to in this Section 2.2(g) and Section 8.6. Borrower expressly acknowledges that its agreement to pay the Makewhole Amount, Prepayment Premium and Exit Fee, as the case may be, to applicable Lenders as herein described is a material inducement to such Lenders to make any Credit Extension. Without affecting any of any Lender's rights or remedies hereunder or in respect hereof, if Borrower fails to pay the applicable Makewhole Amount, Prepayment Premium or Exit Fee when due, then the amount thereof shall thereafter bear interest until paid in full at the Default Rate.

2.3 Payment of Interest on the Term Loans.

(a) Interest Rate.

(i) Subject to Section 2.3(b) below, from and after the Effective Date, the principal amount outstanding under each Term Loan shall accrue interest at a fixed rate equal to nine and six tenths percent (9.60%) *per annum* (the "**Term Loan Rate**"), which interest shall be payable quarterly in arrears in accordance with this Section 2.3.

(ii) Interest shall accrue on each Term Loan commencing on, and including, the day on which such Term Loan is made, and shall accrue on such Term Loan, or any portion thereof, through and including the day on which such Term Loan or such portion is paid.

(iii) Interest is due and payable quarterly on each Interest Date, as calculated by the Collateral Agent (which calculations shall be deemed correct absent manifest error, provided that the Collateral Agent shall provide evidence of such calculation upon Borrower's written request), commencing on the first Interest Date occurring after the Effective Date; provided, however, that if any such date is not a Business Day, the applicable interest shall be due and payable on the Business Day immediately preceding such date.

(iv) The parties hereto acknowledge and agree that, (x) pursuant to the Prior Loan Agreement, the accrued, unpaid and uncapitalized interest under the Tranche A Term Loans which is outstanding as of the Effective Date equals $4,217,266.00 in the aggregate and (y) such Obligations are due and payable on the Interest Date immediately following the Effective Date.

(b) Default Rate. In the event Borrower fails to pay any of the Obligations when due (after giving effect to any applicable grace or cure period), or upon the commencement and during the continuance of an Insolvency Proceeding of Borrower, or upon the occurrence and during the continuance of any other Event of Default, immediately (and without notice or demand by any Lender or the Collateral Agent for payment thereof) to Borrower, such past due Obligations shall accrue interest at a rate *per annum* which is three percentage points (3.00%) above the rate that is otherwise applicable thereto (the " **Default Rate**"), and, notwithstanding anything to the contrary in Section 2.3(a) above, such interest shall be payable entirely in cash on demand of any Lender or the Collateral Agent. Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment of any Obligations and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of the Collateral Agent or any Lender.

(c) 360-Day Year. Interest payable under each Term Loan shall be computed on the basis of a year of 360 days, and in each case shall be payable for the actual number of days elapsed.

(d) Minimum interest payments – Swiss Withholding Tax . The rates of interest provided for in this Agreement are minimum interest rates. When entering into this Agreement, the parties hereto have assumed that the interest payable at the rates set out in this Section 2.3 or in other Sections of this Agreement, if any, is not and will not become subject to Swiss Withholding Tax. This notwithstanding, if a Tax deduction is required by law in respect of any interest payable by any Credit Party under a Loan Document and should it be unlawful for any Swiss Guarantor to comply with Section 2.6 for any reason, where this would otherwise be required by the terms of Section 2.6, then (i) the applicable interest rate in relation to that interest payment shall be the interest rate which would have applied to that interest payment as provided for by this Section 2.3 divided by one minus the rate at

which the relevant Tax deduction is required to be made under Swiss domestic tax law and/or applicable double taxation treaties (where the rate at which the relevant Tax deduction is required to be made is for this purpose expressed as a fraction of one) and (b) such Guarantor shall (x) pay the relevant interest at the adjusted rate in accordance with paragraph (i) above and (y) make the Tax deduction on the interest so recalculated, and all references to a rate of interest under the Loan Documents shall be construed accordingly.

(e) Payments. Except as otherwise expressly provided herein, all Term Loan payments and any other payments hereunder by (or on behalf of) Borrower shall be made on the date specified herein to such bank account of each applicable Lender as such Lender (or the Collateral Agent) shall have designated in a written notice to Borrower delivered on or before the Effective Date (which such notice may be updated by such Lender (or the Collateral Agent) by written notice to the Borrower from time to time after the Effective Date). Except as otherwise expressly provided herein, interest is payable quarterly on each Interest Date. Payments of principal or interest received after 11:00 a.m. (New York City time) on such date (or a Payment Date) are considered received at the opening of business on the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. When any payment is due on a day that is not a Business Day, such payment is due on the immediately preceding Business Day. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest made hereunder and pursuant to any other Loan Document, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

2.4 Expenses. Borrower shall pay to or reimburse (or pay directly on behalf of) the Collateral Agent and, as applicable, each Lender, all of such Person's reasonable and documented Lender Expenses incurred through and after the Tranche A Closing Date, promptly after receipt of a written demand therefor by such Lender or the Collateral Agent (with, in the case of any Lender, a copy of such demand to the Collateral Agent), setting forth in reasonable detail such Person's Lender Expenses.

2.5 Requirements of Law; Increased Costs . In the event that any applicable Change in Law:

(a) Does or shall subject any Lender to any Tax of any kind whatsoever with respect to this Agreement, the Term Loans or any other Loan Documents (except, in each case, Indemnified Taxes, Taxes described in clause (b) through (d) of the definition of Excluded Taxes, and Connection Income Taxes);

(b) Does or shall impose, modify or hold applicable any reserve, capital requirement, special deposit, compulsory loan, insurance charge or similar requirements against assets held by, or deposits or other liabilities in or for the account of, advances or loans by, or other credit extended by, or any other acquisition of funds by, any Lender; or

(c) Does or shall impose on any Lender any other condition (other than Taxes, which are addressed in clause (a) above); and the result of any of the foregoing is to increase the cost to such Lender (as determined by such Lender in good faith using calculation methods customary in the industry) of making, renewing or maintaining the Term Loans or to reduce any amount receivable in respect thereof or to reduce the rate of return on the capital of such Lender or any Person controlling such Lender,

3 then, in any such case, such Lender shall notify Borrower in writing of the event by reason of which it has incurred additional costs or has reduced amounts receivable or rate of return, and submit to Borrower a certificate as to such additional costs or has reduced amounts receivable or rate of return containing the calculation thereof in reasonable detail, which shall be conclusive in the absence of manifest error. Borrower shall promptly, and no later than thirty (30) days of its receipt of the certificate described above, pay to such Lender, subject to the terms of this Section 2.5, any additional amounts necessary to compensate such Lender for such additional cost or reduced amounts receivable or rate of return as reasonably determined by such Lender with respect to this Agreement or the Term Loans made hereunder. The provisions of this Section 2.5 shall survive the termination of this Agreement and the payment of the outstanding Term Loans and all other Obligations. Failure or delay on the part of any such Lender to demand compensation for any increased costs or reduction in amounts received or receivable or reduction in return on capital under this Section 2.5 shall not constitute a waiver of such Lender's right to demand such compensation; provided that Borrower shall not be under any obligation to compensate such Lender under this

Section 2.5 with respect to increased costs or reductions with respect to any period prior to the date that is 180 days prior to the date of the delivery of the notice required pursuant to the foregoing provisions of this paragraph; provided, further, that if the Change in Law giving rise to such increased costs or reductions is retroactive, then the 180-day period referred to above shall be extended to include the period of retroactive effect thereof.

4

4.1 Taxes; Withholding, Etc.

(a) All sums payable by any Credit Party hereunder and under the other Loan Documents shall (except to the extent required by Requirements of Law) be paid free and clear of, and without any deduction or withholding on account of, any Tax imposed, levied, collected, withheld or assessed by any Governmental Authority. In addition, Borrower agrees to pay, and shall indemnify and hold each Lender harmless from, Other Taxes, and as soon as practicable after the date of paying Other Taxes to a Governmental Authority, Borrower shall furnish to each Lender (as applicable, with a copy to the Collateral Agent) the original or a certified copy of a receipt evidencing payment thereof or other evidence reasonably satisfactory to such Lender.

(b) If any Credit Party or any other Person (" **Withholding Agent**") is required by Requirements of Law to make any deduction or withholding on account of any Tax (as determined in the good faith discretion of such Withholding Agent) from any sum paid or payable by any Credit Party to any Lender under any of the Loan Documents: (i) such Withholding Agent shall notify such Lender in writing (with a copy to the Collateral Agent) of any such requirement or any change in any such requirement promptly after such Withholding Agent becomes aware of it; (ii) such Withholding Agent shall make any such withholding or deduction; (iii) such Withholding Agent shall pay any such Tax before the date on which penalties attach thereto, such payment to be made (if the liability to pay is imposed on any Credit Party) for its own account or (if that liability is imposed on such Lender, as the case may be) on behalf of and in the name of such Lender in accordance with Requirements of Law; (iv) if the Tax is an Indemnified Tax, the sum payable by such Credit Party in respect of which the relevant deduction, withholding or payment of Indemnified Tax is required shall be increased to the extent necessary to ensure that, after the making of that deduction, withholding or payment (including any deductions for Indemnified Taxes applicable to additional sums payable under this Section 2.6(b)), such Lender receives on the due date a net sum equal to what it would have received had no such deduction, withholding or payment of Indemnified Tax been required or made; and (v) as soon as practicable after paying any sum from which it is required by Requirements of Law to make any deduction or withholding, Borrower shall (or shall cause such Withholding Agent, if not Borrower, to) deliver to such Lender (with a copy to the Collateral Agent) evidence reasonably satisfactory to such Lender of such deduction, withholding or payment and of the remittance thereof to the relevant taxing or other Governmental Authority.

(c) The Borrower shall indemnify each Lender for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this Section 2.6(c)) paid by such Lender and any liability (including any reasonable expenses) arising therefrom or with respect thereto whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. Any indemnification payment pursuant to this Section 2.6(c) shall be made to the applicable Lender within ten (10) days from written demand therefor.

(d) Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to Borrower, at the time or times reasonably requested by Borrower, such properly completed and executed documentation reasonably requested by Borrower as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, such Lender, if reasonably requested by Borrower, shall deliver such other documentation prescribed by applicable law or reasonably requested by Borrower as will enable Borrower to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Section 2.6(d)(i), (ii) or (iv) below) shall not be required if in such Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender. For avoidance of doubt, for

the purposes of this Section 2.6(d), the term "Lender" shall include each applicable assignee. Without limiting the generality of the foregoing:

(i) If any Lender is organized under the laws of the United States or any state thereof, such Lender shall deliver, and shall cause each applicable assignee thereof to deliver, to Borrower an executed copy of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax.

(ii) If any Lender is a Foreign Lender, such Lender shall deliver, and shall cause each applicable assignee thereof to deliver, to Borrower, on or about the date on which such Foreign Lender becomes a Lender under this Agreement, and at such other times as may be necessary in the determination of Borrower (in the reasonable exercise of its discretion), whichever of the following is applicable:

(1) in the case that such Lender is a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document (including any original issue discount), a properly completed and duly executed copy of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, a properly completed and duly executed copy of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

(2) a completed and duly executed copy of IRS Form W-8ECI;

(3) in the case that such Foreign Lender is claiming an exemption from U.S. federal withholding Tax pursuant to the "portfolio interest exemption" under Section 881(c) of the IRC, it shall provide Borrower with the applicable executed IRS Form W-8BEN-E or IRS Form W-8BEN, as applicable, and a certificate reasonably satisfactory to Borrower to the effect that any interest received by such Foreign Lender is not received by a "bank" on "extension of credit made pursuant to a loan agreement entered into in the ordinary course of its trade or business" within the meaning of 881(c)(3)(A) of the IRC, a "10 percent shareholder" of Borrower within the meaning of Section 871(h)(3)(B) of the IRC, or a "controlled foreign corporation" related to Borrower as described in Section 881(c)(3)(C) of the IRC, or

(4) to the extent that such Foreign Lender is not the beneficial owner, an executed copy of IRS Form W-8IMY, accompanied by a withholding statement and IRS Form W-8ECI, IRS Form W-8BEN-E (or W-8BEN, as applicable), IRS Form W-9 or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a certificate referenced in Section 2.6(d)(ii)(3) above on behalf of each such direct or indirect partner.

(iii) If any Lender is a Foreign Lender it shall, to the extent it is legally entitled to do so, deliver to Borrower (in such number of copies as shall be requested by the recipient) on or about the date on which it becomes a party to this Agreement (and from time to time thereafter upon the reasonable request of Borrower), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with

such supplementary documentation as may be prescribed by applicable law to permit Borrower to determine the withholding or deduction required to be made.

(iv) If a payment made to any Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the IRC, as applicable), such Lender shall deliver to Borrower at the time or times prescribed by law and at such time or times reasonably requested by Borrower such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the IRC) and such additional documentation reasonably requested by Borrower as may be necessary for Borrower to comply with their obligations under FATCA and to determine that Lender has complied with its obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this clause (iv), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

(v) Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or notify the Borrower in writing of its legal inability to do so.

(e) If any party hereto determines, in its discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this Section 2.6 (including by the payment of additional amounts pursuant to this Section 2.6), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made, or additional amounts paid, under this Section 2.6 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this clause (e) in the event that such indemnified party is required to repay such refund to such Governmental Authority and the requirement to repay such refund to such Governmental Authority is not due to the indemnified party's failure to timely provide complete and accurate Internal Revenue Service forms and other documentation required pursuant to Section 2.6(d) or Section 2.8. Notwithstanding anything to the contrary in this clause (e), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this clause (e) if the payment of such amount would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the indemnification payments or additional amounts giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such tax had never been paid. This clause (e) shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

(f) Tax Status of Borrower. Borrower is currently treated as a corporation for U.S. federal income tax purposes. Borrower shall not take any affirmative action (including not making any election under Treasury Regulations Section 301.7701-3(c) (or any successor provision) by way of filing an IRS Form 8832) to change its U.S. entity tax classification without the prior written consent of the Required Lenders.

(g) Tax Reporting Assistance. Borrower shall use best efforts to assist any Lender (i) in the computation of accruals with respect to any "original issue discount" or "market discount" arising with respect to the Term Loans for U.S. federal income tax purposes, and (ii) with its compliance with any associated tax reporting or filing requirements of such Lender or its partners, members or beneficial owners.

4.2 Additional Consideration.

(a) As additional consideration for the obligation of each Lender to fund its Applicable Percentage of the Tranche A Term Loans and the funding of its Applicable Percentage of the Tranche A Term Loans pursuant to Section 2.2(a) and Section 3.7, on the Tranche A Closing Date, Borrower shall pay to each Lender an amount equal to the product of (i) such Lender's Tranche A Term Loan Commitment, multiplied by (ii) 0.02 (each such product, the "**Tranche A Additional Consideration**"). Any and all Tranche A Additional Consideration is

due and payable on the Tranche A Closing Date, fully earned when paid and shall not be refundable for any reason whatsoever and shall be treated as original issue discount with respect to the Tranche A Term Loans for U.S. federal income tax purposes. The Tranche A Additional Consideration payable hereunder shall be due on the Tranche A Closing Date and shall be deducted, as applicable, from the proceeds of the Tranche A Term Loans to be advanced to Borrower pursuant to Section 2.2(a) and Section 3.7.

(b) As additional consideration for the obligation of each Lender to fund its Applicable Percentage of the Tranche B Term Loans and the funding of its Applicable Percentage of the Tranche B Term Loans pursuant to Section 2.2(b) and Section 3.7, on the Tranche B Closing Date, Borrower shall pay to each Lender an amount equal to the product of (i) such Lender's Tranche B Term Loan Commitment, multiplied by (ii) 0.02 (each such product, the "**Tranche B Additional Consideration**"). Any and all Tranche B Additional Consideration is due and payable on the Tranche B Closing Date, fully earned when paid and shall not be refundable for any reason whatsoever and shall be treated as original issue discount with respect to the Tranche B Term Loans for U.S. federal income tax purposes. The Tranche B Additional Consideration payable hereunder shall be due on the Tranche B Closing Date and shall be deducted, as applicable, from the proceeds of the Tranche B Term Loans to be advanced to Borrower pursuant to Section 2.2(b) and Section 3.7.

(c) Any and all Additional Consideration payable hereunder is in addition to, and not creditable against, any other fee, cost or expenses payable under the Loan Documents.

4.3 Note Register; Term Loan Notes.

(a) Note Register. Borrower will maintain at all times at its principal executive office a register that identifies each beneficial owner that is entitled to a payment of principal and stated interest on each Term Loan (the "**Note Register**") and provides for the registration and transfer of Term Loan Notes so that each Term Loan is at all times in "registered form" within the meaning of Section 163(f), 871(h)(2) and 881(c)(2) of the IRC and any related regulations (and any other relevant or successor provisions of the IRC or such regulations). Each Term Loan: (i) shall, pursuant to this clause (a), be registered as to both principal and any stated interest with Borrower or its agent, and (ii) may be transferred or exchanged by any Lender only by surrender of the old instrument at the principal executive office of Borrower (or at the place of payment named in the Term Loan Note, if any), accompanied, if so required by Borrower in the case of a Lender Transfer, by a written instrument of transfer in form reasonably satisfactory to Borrower duly executed by the holder thereof or by such holder's attorney duly authorized in writing, and Borrower will execute and deliver in exchange therefor a new Term Loan Note or Term Loan Notes, in such denomination(s) as may be requested by such holder, of like tenor and in the same aggregate outstanding principal amount as the aggregate outstanding principal amount of the Term Loan Note(s) so surrendered. Any Term Loan Note issued in exchange for any other Term Loan Note or upon transfer thereof shall carry the rights to unpaid interest and interest to accrue that were carried by the Term Loan Note so exchanged or transferred, and neither gain nor loss of interest shall result from any such transfer or exchange. Any transfer tax or governmental charge relating to such transaction shall be paid by the holder requesting the exchange. The entries in the Note Register shall be conclusive and binding for all purposes, including as to the outstanding principal amount of the Term Loan Note and the payment of interest, principal and other sums due hereunder absent manifest error and Borrower, Lenders and any of their respective agents may treat the Person in whose name any Term Loan Note is registered as the sole and exclusive record and beneficial holder and owner of such Term Loan Note for all purposes whatsoever.

(b) Term Loan Notes. Each Lender shall issue to Borrower, and Borrower shall execute and deliver to each Lender to evidence such Lender's Term Loan, a Term Loan Note. All amounts due under the Term Loan Notes shall be repayable as set forth in this Agreement and interest shall accrue on the principal amount of the Term Loans represented by the Term Loan Notes, in each case, in accordance with the terms of this Agreement. All Term Loan Notes shall rank for all purposes *pari passu* with each other.

5 CONDITIONS OF TERM LOANS

5.1 Conditions Precedent to the Tranche A Term Loans. Each Lender's obligation to advance its Applicable Percentage of the Tranche A Term Loan Amount is subject to the satisfaction (or waiver in Lenders' sole discretion in accordance with Section 11.5 hereof) of the following conditions:

(a) the Collateral Agent's and each Lender's receipt:

(i) on the Tranche A Closing Date, of copies of the Loan Agreement, the Disclosure Letter, the Perfection Certificate for Borrower and its Subsidiaries and the Advance Request Form, in each case (x) dated as of the Tranche A Closing Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form and substance reasonably satisfactory to the Collateral Agent; and

(ii) on the Tranche A Closing Date, of copies of the other Loan Documents (including the schedules thereto) (including any notices required pursuant to the Dutch Security Documents), including the Term Loan Notes executed by Borrower and the OrbiMed Intercreditor Agreement, the Intercompany Subordination Agreement, Collateral Documents (but excluding any Control Agreements, Collateral Access Agreements and any other Loan Document described in Schedule 5.14 of the Disclosure Letter to be delivered after the Tranche A Closing Date), in each case (x) dated as of the Tranche A Closing Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form and substance reasonably satisfactory to the Collateral Agent;

(b) the Collateral Agent's receipt of (i) true, correct and complete copies of the Operating Documents (including, in relation to a Dutch Obligor, a recent extract from the Dutch trade register (*handelsregister*) relating to it) of each of Borrower and the Credit Parties (being for any Swiss Guarantor a recently certified excerpt from the relevant commercial register (*Handelsregisterauszug*) and a copy of the up-to-date articles of association (*Statuten*), certified by the relevant commercial register), and (ii) a Secretary's Certificate, dated the Tranche A Closing Date, certifying that the foregoing copies are true, correct and complete (such Secretary's Certificate to be in form and substance reasonably satisfactory to the Collateral Agent);

(c) the Collateral Agent's receipt of a good standing certificate for each Credit Party (where applicable in the subject jurisdiction) (or a letter of status with respect to any Credit Party incorporated in Ireland), certified by a Director or the Secretary of such Credit Party as of a date no earlier than thirty (30) days prior to the Tranche A Closing Date, certified (where available) by the Secretary of State (or the equivalent thereof) of the jurisdiction of incorporation, formation or organization of such Person as of a date no earlier than thirty (30) days prior to the Tranche A Closing Date;

(d) the Collateral Agent's receipt of a Secretary's Certificate in relation to each Credit Party, dated the Tranche A Closing Date, certifying that (i) attached as Exhibit A to such certificate is a true, correct, and complete copy of the Borrowing Resolutions then in full force and effect authorizing and ratifying the execution, delivery, and performance by such Credit Party of the Loan Documents to which it is a party, (ii) the name(s) and title(s) of the officers or directors or other signatories of such Credit Party authorized to execute the Loan Documents to which such Credit Party is a party on behalf of such Credit Party together with a sample of the true signature(s) of such Credit Party(s), and (iii) that the Collateral Agent and each Lender may conclusively rely on such certificate with respect to the authority of such officers unless and until such Credit Party shall have delivered to the Collateral Agent a further certificate canceling or amending such prior certificate;

(e) each Credit Party shall have obtained all Governmental Approvals, if any, and all consents or approvals of other Persons, including the approval or consent of the equityholders of Borrower, if any, in each case that are necessary in connection with the transactions contemplated by the Loan Documents, and each of the foregoing shall be in full force and effect and in form and substance reasonably satisfactory to the Collateral Agent;

(f) the Collateral Agent's receipt on the Tranche A Closing Date of opinions of (i) Covington & Burling LLP, United States counsel to Borrower and the other the Credit Parties, (ii) Hunton Andrews Kurth LLP, Virginia counsel to Borrower and the other the Credit Parties, (iii) Squire Gaikokuho Kyodo Jigyo Horitsu Jimusho, as Japanese counsel to Borrower and the other Credit Parties, (iv) Matheson LLP, Irish counsel to the Lenders and the Collateral Agent, and (v) Walder Wyss Ltd., Swiss counsel to the Lenders and the Collateral Agent, in each case in form and substance reasonably satisfactory to the Collateral Agent;

(g) (i) subject to Section 5.14, the Collateral Agent's receipt on the Tranche A Closing Date of (i) evidence that any products liability and general liability insurance policies maintained regarding any Collateral are in full force and effect and (ii) appropriate evidence showing the Collateral Agent, for the benefit of Lenders and the other Secured Parties, having been named as additional insured or loss payee, as applicable (such evidence to be in form and substance reasonably satisfactory to the Collateral Agent) with respect to any products liability and general liability insurance policies maintained in the United States regarding any Collateral;

(h) the Collateral Agent's receipt prior to the Tranche A Closing Date of Borrower's U.S. tax forms and all documentation and other information required by bank regulatory authorities under applicable "know-your-customer" and anti-money laundering rules and regulations, including the U.S.A. Patriot Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001));

(i) concurrent with the funding of the Term Loan, payment of Lender Expenses then due as specified in Section 2.4 hereof for which Borrower has received an invoice at least one (1) Business Day prior, and payment of the Additional Consideration in accordance with Section 2.7, which such payments shall be deducted from the proceeds of the Term Loan;

(j) the Collateral Agent's and each Lender's receipt of: (i) the OrbiMed Intercreditor Agreement, dated as of the Tranche A Closing Date and executed and delivered by each of Borrower and OrbiMed, (ii) the Royalty Revenue Contract, dated as of the Tranche A Closing Date and executed and delivered by each of Borrower and OrbiMed, and (iii) each other Royalty Revenue Document, dated as of the Tranche A Closing Date and executed and delivered by the parties thereto;

(k) evidence of the payment in full of the Purchase Price (as such term is defined in the Royalty Revenue Contract), any expense reimbursements and any and all other amounts pursuant to the Royalty Revenue Contract prior to or concurrent with the funding of the Term Loan; and

(l) in respect of each Dutch Obligor;

(i) a copy of a resolution of its board of directors approving its execution and the terms of, and the transactions contemplated by, the Loan Documents to which it is a party;

(ii) if applicable, a copy of a resolution of its board of supervisory directors (if any) approving its execution and the terms of, and the transactions contemplated by, the Loan Documents to which it is a party;

(iii) if applicable, copy of a resolution of its general meeting of shareholders approving its execution and the terms of, and the transactions contemplated by, the Loan Documents to which it is a party; and

(iv) if it is required by law or any arrangement binding on it to obtain works council advice in respect of its or any other person's entry into the Loan Documents, a copy of a positive or neutral advice from its (central) works council (and, if such advice is not unconditional, confirmation from the Borrower that (i) the conditions set by the works council are and will be complied with and (ii) such compliance does not and will not constitute a Material Adverse Change) including the request for advice or, a confirmation of its board of directors included in the board resolution that no works council has jurisdiction in respect of any of the transactions contemplated by the Loan Documents to which it is a party.

5.2 Conditions Precedent to the Tranche B Term Loans . Each Lender's obligation to advance its Applicable Percentage of the Tranche B Term Loan Amount is subject to the satisfaction (or waiver in accordance with Section 11.5 hereof) of the following conditions:

(a) the Collateral Agent's and each Lender's receipt, on the Tranche B Closing Date, of each of the Tranche A Term Loan Note and the Tranche B Term Loan Note, executed by Borrower and, if and to the extent any update thereto is necessary between the Tranche A Closing Date and the Tranche B Closing Date, a Disclosure Letter or Perfection Certificate updated in reasonable detail (provided, that in no event may the Disclosure Letter or the Perfection Certificate be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)), in each case (x) dated as of the Tranche B Closing Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form reasonably satisfactory to the Collateral Agent;

(b) the Collateral Agent's receipt of a Secretary's Certificate in relation to each Credit Party, dated the Tranche B Closing Date, certifying that: (i) attached as an Exhibit to such certificate is a true, correct, and complete copy of the Borrowing Resolutions then in full force and effect authorizing the Tranche B Term Loan; (ii) (ii) attached as an Exhibit to such certificate are true, correct and complete copies of the Operating Documents of each Credit Party (being for any Swiss Guarantor a recently certified excerpt from the relevant commercial register (*Handelsregisterauszug*) and a copy of the up-to-date articles of association (*Statuten*), certified by the relevant commercial register) and (iii) the name(s) and title(s) of the officers or directors or other signatories of such Credit Party authorized to execute the Loan Documents to which such Credit Party is a party on behalf of such Credit Party together with a sample of the true signature(s) of such Credit Party(s), and (iii) that the Collateral Agent and each Lender may conclusively rely on such certificate with respect to the authority of such officers;

(c) the Collateral Agent's and each Lender's receipt of a copy of the consent or approval of OrbiMed to this Agreement and the transactions contemplated herein and under the other Loan Documents, dated and in force and effect as of the Tranche B Closing Date and executed and delivered by all parties thereto;

(d) concurrent with the funding of the Tranche B Term Loan, payment of Lender Expenses then due as specified in Section 2.4 hereof for which Borrower has received an invoice at least one (1) Business Day prior, and payment of the Additional Consideration in accordance with Section 2.7(b), which such payments shall be deducted from the proceeds of the Tranche B Term Loan;

(e) no prepayment of the principal amount of any Term Loan has been made pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of any Term Loan pursuant to Section 8.1(a);

(f) the Collateral Agent's receipt of a certificate, dated the Tranche B Closing Date and signed by a Responsible Officer of Parent, confirming: (i) there is no Adverse Proceeding pending or, to the Knowledge of Parent, threatened in writing, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, except as set forth on Schedule 4.7 of the Disclosure Letter delivered in accordance with Section 3.2(a); and (ii) satisfaction of the conditions precedent set forth in this Section 3.2 and in Section 3.5, Section 3.6 and Section 3.7 (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent);

(g) the Collateral Agent's receipt of the following: (i) an Irish law deed of confirmation of security in respect of the Irish law debenture dated 8 December 2022 duly executed by each of Insmed Holdings Limited and Insmed Ireland Limited and dated as of the Tranche B Closing Date; and (ii) an Irish law deed of confirmation of security in respect of the Irish law share charge dated 8 August 2023 duly executed by Insmed Switzerland GmbH and dated as of the Tranche B Closing Date;

(h) the Collateral Agent's receipt of, in respect of each Dutch Obligor:

(i) a copy of a resolution of its board of directors approving its execution and the terms of, and the transactions contemplated by, the Loan Documents to which it is a party;

(ii) if applicable, a copy of a resolution of its board of supervisory directors (if any) approving its execution and the terms of, and the transactions contemplated by, the Loan Documents to which it is a party;

(iii) if applicable, copy of a resolution of its general meeting of shareholders approving its execution and the terms of, and the transactions contemplated by, the Loan Documents to which it is a party; and

(iv) if it is required by law or any arrangement binding on it to obtain works council advice in respect of its or any other person's entry into the Loan Documents, a copy of a positive or neutral advice from its (central) works council (and, if such advice is not unconditional, confirmation from the Company that (x) the conditions set by the works council are and will be complied with and (y) such compliance does not and will not constitute a Material Adverse Change) including the request for advice or, a confirmation of its board of directors included in the board resolution that no works council has jurisdiction in respect of any of the transactions contemplated by the Loan Documents to which it is a party; and

(i) the Collateral Agent's and each Lender's receipt, on the Tranche B Closing Date, of a copy of the Swiss Security Confirmation Agreement (x) dated as of the Tranche B Closing Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form reasonably satisfactory to the Collateral Agent;

(j) the Borrower's receipt of all Term Loan Notes (as defined in the Prior Loan Agreement) issued under the Prior Loan Agreement, duly endorsed for cancellation.

5.3 [RESERVED].

5.4 [RESERVED].

5.5 Additional Conditions Precedent to Term Loans . The obligation of each Lender to advance its Applicable Percentage of each Term Loan is subject to the following additional conditions precedent:

(a) the representations and warranties made by the Credit Parties in Section 4 of this Agreement and in the other Loan Documents are true and correct in all material respects on the Closing Date, unless any such representation or warranty is stated to relate to a specific earlier date, in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (it being understood that any representation or warranty that is qualified as to "materiality," "Material Adverse Change," or similar language shall be true and correct in all respects (as so qualified), in each case, on the Closing Date (both with and without giving effect to the Term Loans) or as of such earlier date, as applicable);

(b) each borrowing by Borrower hereunder shall constitute a representation and warranty by Borrower, as of the applicable Closing Date, that: (i) there is no Adverse Proceeding pending or, to the Knowledge of Borrower, threatened, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, except as set forth on Schedule 4.7 of the Disclosure Letter; (ii) the organizational structure and capital structure of Borrower and each of its Subsidiaries is as described on Schedule 4.15 of the Disclosure Letter as at the applicable Closing Date; and (iii) the conditions precedent set forth in this Section 3.5, in Section 3.1 or Section 3.2, as applicable, and in Section 3.6 and Section 3.7 have been satisfied; and

(c) there shall not have occurred (i) any Material Adverse Change or (ii) any Default or Event of Default.

5.6 Covenant to Deliver. The Credit Parties agree to deliver to the Collateral Agent or each Lender, as applicable, each item required to be delivered to Collateral Agent or each Lender, as applicable, under this Agreement as a condition precedent to any Credit Extension; provided, however, that any such items set forth on Schedule 5.14 of the Disclosure Letter shall be delivered to the Collateral Agent within the time period prescribed therefor on such schedule. The Credit Parties expressly agree that a Credit Extension made prior to the receipt by the Collateral Agent or any Lender, as applicable, of any such item shall not constitute a waiver by the Collateral Agent or any Lender of the Credit Parties' obligation to deliver such item, and the making of any Credit Extension in the absence of any such item required to have been delivered by the date of such Credit Extension shall be in the applicable Lender's sole discretion.

5.7 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of each Term Loan set forth in this Agreement, to obtain any Term Loans, Borrower shall deliver to the Collateral Agent and Lenders by electronic mail or facsimile a completed Advance Request Form for such Term Loan executed by a Responsible Officer of Borrower (which notice shall be irrevocable on and after the date on which such notice is given and Borrower shall be bound to make a borrowing in accordance therewith), in which case each Lender agrees, subject to the satisfaction of the applicable conditions precedent set forth in this Article 3, to advance an amount equal to its Applicable Percentage of the Tranche A Term Loan Amount or the Tranche B Term Loan Amount on the Tranche A Closing Date or the Tranche B Closing Date, as applicable, by wire transfer of same day funds in Dollars, to such account(s) in the United States as may be designated in writing to the Collateral Agent by Borrower at least two (2) Business Days prior to the Tranche A Closing Date or Tranche B Closing Date, as applicable.

6 REPRESENTATIONS AND WARRANTIES

In order to induce each Lender and the Collateral Agent to enter into this Agreement and for each Lender to make the Credit Extensions to be made on the Tranche B Closing Date, each Credit Party, jointly and severally with each other Credit Party, represents and warrants to each Lender and the Collateral Agent that the following statements are true and correct as of the Effective Date and the Tranche B Closing Date (both with and without giving effect to the Term Loans) except as otherwise specified below:

6.1 Due Organization, Existence, Power and Authority . Borrower and each of its Subsidiaries (a) is duly incorporated, organized or formed, and validly existing and, where applicable, in good standing under the laws of its jurisdiction of incorporation, organization or formation identified on Schedule 4.15 of the Disclosure Letter, (b) has all requisite power and authority to (i) own, lease, license and operate its assets and properties and to carry on its business as currently conducted and (ii) execute and deliver the Loan Documents to which it is a party

and to perform its obligations thereunder and otherwise carry out the transactions contemplated thereby, (c) is duly qualified and, where applicable, in good standing under the laws of each jurisdiction where its ownership, lease, license or operation of assets or properties or the conduct of its business requires such qualification, and (d) has all requisite Governmental Approvals to operate its business as currently conducted; except in each case referred to clauses (a) (other than with respect to Borrower and any other Credit Party), (b)(i), (c) or (d) above, to the extent that failure to do so could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

6.2 Equity Interests. All of the outstanding Equity Interests in each Subsidiary of Borrower, the Equity Interests in which are required to be pledged pursuant to the Collateral Documents, have been duly authorized and validly issued, are (where required by Requirements of Law to be) fully paid and, in the case of Equity Interests representing corporate interests, are non-assessable and all such Equity Interests owned directly by Borrower or any other Credit Party are owned free and clear of all Liens except for Permitted Liens. Schedule 4.2 of the Disclosure Letter identifies each Person, the Equity Interests in which are required to be pledged pursuant to the Collateral Documents.

6.3 Authorization; No Conflict. Except as set forth on Schedule 4.3 of the Disclosure Letter, the execution, delivery and performance by each Credit Party of the Loan Documents to which it is a party, and the consummation of the transactions contemplated thereby, (a) have been duly authorized by all necessary corporate or other organizational action and (b) do not and will not (i) contravene the terms of any of such Credit Party's Operating Documents, (ii) conflict with or result in any breach or contravention of, or require any payment to be made under (A) any provision of any security issued by such Person or of any agreement, instrument or other undertaking to which such Credit Party is a party or affecting such Credit Party or the assets or properties of such Credit Party or any of its Subsidiaries or (B) any order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which such Credit Party or any of its properties or assets are subject, (iii) result in the creation of any Lien (other than under or otherwise permitted under the Loan Documents) or (iv) violate any Requirements of Law, except, in the cases of clauses (b)(ii) and (b)(iv) above, to the extent that such conflict, breach, contravention, payment or violation could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

6.4 Government Consents; Third Party Consents. Except as set forth on Schedule 4.4 of the Disclosure Letter, no Governmental Approval or other approval, consent, exemption or authorization, or other action by, or notice to, or filing with, any Governmental Authority or any other Person (including any counterparty to any Company IP Agreement or other Material Contract) is necessary or required in connection with (a) the execution, delivery or performance by, or enforcement against, any Credit Party of this Agreement or any other Loan Document, or for the consummation of the transactions contemplated hereby or thereby, (b) the grant by any Credit Party of the Liens granted by it pursuant to the Collateral Documents, (c) the perfection or maintenance of the Liens created under the Collateral Documents (including the priority thereof) or (d) the exercise by the Collateral Agent or any Lender of its rights under the Loan Documents or the remedies in respect of the Collateral pursuant to the Collateral Documents, except in each case of clause (a) through (d) above, for (i) filings necessary to perfect the Liens on the Collateral granted by the Credit Parties to the Collateral Agent for the benefit of Lenders and the other Secured Parties, (ii) the approvals, consents, exemptions, authorizations, actions, notices and filings which have been duly obtained, taken, given or made and are in full force and effect, (iii) filings under state or federal securities laws, (iv) notices required to be delivered by the Collateral Agent or any Lender in connection with, or the cooperation of any third Person (that is not an Affiliate of any Credit Party) that is required for, any exercise of any of the rights or remedies by the Collateral Agent or any Lender, and (v) those approvals, consents, exemptions, authorizations or other actions, notices or filings, the failure of which to obtain or make could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

6.5 Binding Obligation. This Agreement has been duly executed and delivered by Borrower and each other Credit Party that is a party hereto and each other Loan Document has been duly executed and delivered by each Credit Party that is a party thereto, and in each case constitutes a legal, valid and binding obligation of Borrower or such Credit Party (as applicable), enforceable against Borrower or such Credit Party (as applicable) in accordance with its respective terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally, by general principles of equity.

6.6 Collateral. In connection with this Agreement, Borrower has delivered to the Collateral Agent a completed certificate signed by a Responsible Officer of Borrower (the "**Perfection Certificate**"). Each Credit Party, jointly and severally, represents and warrants to the Collateral Agent and each Lender that:

(a) (i) its exact legal name is that indicated on the Perfection Certificate and on the signature page thereof; (ii) it is an organization or company of the type and is organized or incorporated in the jurisdiction set

forth in the Perfection Certificate; (iii) the Perfection Certificate accurately sets forth its organizational identification number or accurately states that it has none; (iv) the Perfection Certificate accurately sets forth its place of business, or, if more than one, its chief executive office as well as its mailing address (if different than its chief executive office); (v) except as set forth in the Perfection Certificate, it (and each of its predecessors) has not, in the five (5) years prior to the Effective Date and the Tranche B Closing Date, changed its jurisdiction of formation, organizational structure or type, or any organizational number assigned by its jurisdiction; and (vi) all other information set forth on the Perfection Certificate pertaining to it and each of its Subsidiaries is accurate and complete in all material respects.

(b) (i) it has good and valid title to, has the rights it purports to have in, and subject to Permitted Subsidiary Distribution Restrictions, Permitted Negative Pledges and the occurrence of each Closing Date, the power to transfer each item of the Collateral upon which it purports to grant a Lien under any Collateral Document, free and clear of any and all Liens except Permitted Liens and except for such irregularities or defects in title as could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change and (ii) it has no deposit accounts maintained at a bank or other depository or financial institution which are not Excluded Accounts other than the deposit accounts described in the Perfection Certificate delivered to the Collateral Agent in connection herewith.

(c) a true, correct and complete list of each pending, registered, issued or in-licensed Patent (including any Patents that are or are intended to be listed in the FDA's so-called "Orange Book" as covering Product), Copyright and Trademark that relates to any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Product (including any delivery devices, such as nebulizers) in the Territory, and regulatory exclusivities that are listed in the FDA's so-called "Orange Book" as covering Product, and that, individually or when taken together with any other such Patents, Copyrights, Trademarks, or regulatory exclusivities, is material to the business of Borrower and its Subsidiaries, taken as a whole, and that is owned or co-owned by, or exclusively or nonexclusively in-licensed to, any Credit Party or any of its Subsidiaries as of the Effective Date and on the Tranche B Closing Date (collectively, the "**Current Company IP**"), including its name/title, current owner or co-owners (including ownership interest), registration, patent or application number, and registration or application date, in each jurisdiction where issued or filed in the Territory, is set forth on Schedule 4.6(c) of the Disclosure Letter. Except as set forth on Schedule 4.6(c) of the Disclosure Letter:

(i) (A) to the Knowledge of such Credit Party, each item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries is valid, subsisting and enforceable (or will be enforceable upon issuance) and no item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries has in any respect lapsed or expired, been cancelled, held unpatentable, held unenforceable or held invalidated in a final, non-appealable court decision, or become abandoned (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment or naturally upon expiration of patent term), and no circumstance or grounds exist that would lead to any such Current Company IP being held unpatentable, unenforceable or invalid in a final, non-appealable court decision, or reduce the ownership or use of such Current Company IP, by any Credit Party or any of its Subsidiaries, and (B) no written notice has been received challenging the validity, patentability, enforceability, inventorship or ownership (other than from patent and trademark offices through the normal prosecution practices), or relating to any lapse, expiration, invalidation, cancellation, abandonment or unenforceability, of any item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment or naturally upon expiration of patent term);

(ii) (A) each item of Current Company IP that is exclusively or nonexclusively in-licensed from another Person is in force, and no item of Current Company IP that is exclusively or nonexclusively in-licensed by a Credit Party or any of its Subsidiaries has in any respect lapsed or expired, or has been cancelled, held unpatentable, held unenforceable or held invalidated in a final, non-appealable court decision, or has become abandoned (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment of licensor or naturally upon expiration of patent term), and (B) no written notice has been received challenging the validity, patentability, enforceability, inventorship or ownership, or relating to any lapse, expiration, invalidation, cancellation, abandonment or unenforceability, of any item of Current Company IP that is exclusively or nonexclusively in-licensed by a Credit Party or any of its Subsidiaries (other than from patent and trademark offices through the licensor's normal prosecution practices or naturally upon expiration of patent term);

(iii) each Credit Party or any of its Subsidiaries possesses valid title to the Current Company IP for which it is listed as the owner or co-owner, as applicable, on Schedule 4.6(c) of the Disclosure Letter. There are no Liens on any Current Company IP other than Permitted Liens. Except as set forth on Schedule 4.6(c) of the Disclosure Letter, (x) each Person who has or has had any rights in or to owned Current Company IP or any trade secrets owned by any Credit Party or any of its Subsidiaries, including each inventor named on the Patents within such owned Current Company IP filed by any Credit Party or any of its Subsidiaries has executed an agreement assigning his, her or its entire right, title and interest in and to such owned Current Company IP and such trade secrets, and the inventions, improvements, ideas, discoveries, writings, works of authorship, information and other intellectual property embodied, described or claimed therein, to the stated owner thereof, and (y) to the Knowledge of such Credit Party, no such Person has any contractual or other obligation that would preclude or conflict with such assignment or the exploitation of Product in the Territory or entitle such Person to ongoing payments;

(iv) each Credit Party or any of its Subsidiaries possesses an exclusive in-license from PARI Pharma GmbH for the eFlow nebulizer referred to as the Lamira® Nebulizer System, including the control unit with screen, nebulizer handset with aerosol head, nebulizer connection cord and power supply, vibrating membrane, mixing chamber, valve system, and related intellectual property; and

(v) to the Knowledge of such Credit Party, there are no issued patents or published patent applications with pending claims as of the Tranche B Closing Date which if issued and valid, could reasonably be expected to materially adversely affect the exploitation of Product in the United States or Japan.

(d) There are no maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is owned by or exclusively or nonexclusively licensed to any Credit Party or any of its Subsidiaries, nor have any applications or registrations therefor lapsed or become abandoned, been cancelled or expired (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment of the Credit Parties, their respective Subsidiaries or the licensor).

(e) There are no unpaid fees, royalties or indemnification payments under any Company IP Agreement that have become due, or are reasonably expected to become due or overdue, except as would not reasonably be expected to materially adversely affect any Credit Party's or any of its Subsidiary's rights thereunder. Each Company IP Agreement is in full force and effect and, to the Knowledge of such Credit Party, is legal, valid, binding and enforceable in accordance with its respective terms, except as may be limited by bankruptcy, insolvency, reorganization, examinership, moratorium or similar laws relating to or limiting creditors' rights generally or by equitable principles relating to enforceability. No Credit Party or any of its Subsidiaries is in material breach of or material default under any Company IP Agreement to which it is a party or may otherwise be bound, and to the Knowledge of such Credit Party, no circumstances or grounds exist that could give rise to a claim of material breach or right of rescission, termination, non-renewal, revision, or amendment of any of the Company IP Agreements, including the execution, delivery and performance of this Agreement and the other Loan Documents.

(f) No payments by any Credit Party or any of its Subsidiaries are due to any other Person in respect of the Current Company IP, other than pursuant to the Company IP Agreements, the Royalty Revenue Contract, and those fees payable to patent offices in connection with the prosecution and maintenance of the Current Company IP and associated attorney fees.

(g) Except as noted on Schedule 4.6(g) of the Disclosure Letter, no Credit Party is a party to, nor is it bound by, any Excluded License.

(h) No Credit Party or any of its Subsidiaries has undertaken or omitted to undertake any acts, and, to the Knowledge of such Credit Party, no circumstance or grounds exist that would invalidate or reduce, in whole or in part, the enforceability or scope of any Credit Party's or any of its Subsidiary's: (i) right or entitlement to the Current Company IP in any manner that could reasonably be expected to materially adversely affect any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Product in the Territory; or (ii) in the case of Current Company IP owned or co-owned by or exclusively or non-exclusively licensed to any Credit Party or any of its Subsidiaries, other than with respect to Permitted Licenses and except as set forth on Schedule 4.6(h) of the Disclosure Letter, entitlement to own or license and exploit the Current Company IP in any manner.

(i) Except as set forth on Schedule 4.6(i) of the Disclosure Letter, to the Knowledge of such Credit Party, there is no product or other technology of any third party that infringes or could reasonably be expected to infringe a Patent within the Current Company IP.

(j) Except as set forth on Schedule 4.6(j) of the Disclosure Letter, in each case where an issued Patent within the Current Company IP is owned or co-owned by any Credit Party or its Subsidiaries by assignment, the assignment has been duly recorded with the U.S. Patent and Trademark Office and, if applicable, the assignment has been duly recorded or will be recorded promptly with all similar offices and agencies anywhere in the world in which foreign counterparts are registered, filed or issued.

(k) There are no pending or, to the Knowledge of such Credit Party, threatened (in writing) claims against Borrower or any of its Subsidiaries alleging (i) that any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Product in the Territory infringes or violates (or in the past infringed or violated), or form a reasonable basis for a claim of infringement or violation of, any of the rights of any third parties in or to any Intellectual Property ("**Third Party IP**") or constitutes a misappropriation (or in the past constituted a misappropriation) of any Third Party IP, or (ii) that any Current Company IP is invalid, unpatentable or unenforceable (other than from patent and trademark offices through the normal prosecution practices).

(l) To the Knowledge of such Credit Party, the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory has not in the past and does not (i) infringed or infringe or violated or violate, or formed or form a reasonable basis for a claim of infringement or violation of, any of the rights of any third parties in or to any Third Party IP or (ii) constituted or constitute a misappropriation of any Third Party IP.

(m) Except as set forth on Schedule 4.6(m) of the Disclosure Letter, to the Knowledge of such Credit Party, there are no settlements, covenants not to sue, consents, judgments, orders or similar obligations which: (i) restrict the rights of any Credit Party or any of its Subsidiaries to use any Intellectual Property relating to any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Product in the Territory (in order to accommodate any Third Party IP or otherwise), or (ii) permit any third parties to use any Company IP.

(n) Except as set forth on Schedule 4.6(n) of the Disclosure Letter, to the Knowledge of such Credit Party, (i) there is no, nor has there been any, infringement or violation by any Person of any of the Company IP or any of the rights therein, and (ii) there is no, nor has there been any, misappropriation by any Person of any of the Company IP or any of the subject matter thereof.

(o) Each Credit Party and each of its Subsidiaries has taken commercially reasonable measures customary in the life sciences industry, to protect the confidentiality and value of all trade secrets owned by such Credit Party or any of its Subsidiaries, in each case relating to any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory. To the Knowledge of such Credit Party, any disclosure by a Credit Party or any of its Subsidiaries of any such trade secrets to any third party has been pursuant to the terms of a written agreement with such third party, and no Credit Party or any of its Subsidiaries has suffered any material data breach or other incident that has resulted in any loss, unauthorized access, use, disclosure or modification of any such trade secrets.

(p) Except as set forth on Schedule 4.6(p) of the Disclosure Letter, to the Knowledge of such Credit Party, Product made, used or sold under the Patents in the U.S. within the Current Company IP has been marked with the proper patent notice.

(q) Except as set forth on Schedule 4.6(q) of the Disclosure Letter, to the Knowledge of such Credit Party, at the time of any shipment of Product, the units thereof so shipped complied in all material respects with their relevant specifications and were developed and manufactured in accordance with applicable current Good Manufacturing Practices, Good Clinical Practices, Good Laboratory Practices and other applicable Requirements of Law.

(r) With respect to the Current Company IP consisting of Patents, except as set forth on Schedule 4.6(r) of the Disclosure Letter:

(i) to the Knowledge of such Credit Party, all prior art material to such Patents was adequately disclosed, to the extent such disclosure is required, to the relevant patent office or considered by the respective patent offices during prosecution of such Patents;

(ii) subsequent to the issuance of such Patents, no Credit Party nor any Subsidiary nor any of their respective predecessors-in-interest, has filed any disclaimer or made or permitted any other voluntary reduction in the scope of the inventions claimed in such Patents;

(iii) to the Knowledge of such Credit Party, no subject matter designated allowable or allowed by the U.S. Patent and Trademark Office of such Patents is subject to any competing conception claims of allowable or allowed subject matter of any patent applications or patents of any third party and have not been the subject of any interference, and such Patents are not and have not been the subject of any re-examination, opposition or any other post-grant proceedings;

(iv) if any of such Patents is terminally disclaimed to another patent or patent application, all patents and patent applications subject to such terminal disclaimer are included in the Collateral; and

(v) neither any Credit Party nor any Subsidiaries has received a legal opinion, whether preliminary in nature or qualified in any manner, which concludes that a challenge to the validity or enforceability of any such Patents is more likely than not to succeed.

(s) (A) Neither any Credit Party nor any Subsidiary, nor, to the Knowledge of such Credit Party, any of their respective agents or representatives, has engaged in any conduct, or omitted to perform any necessary act, the result of which would invalidate or render unpatentable or unenforceable any such Patent and (B) to the Knowledge of such Credit Party, no prior owner of any such Patent of any Credit Party or any of its Subsidiaries, nor any of such prior owner's agents or representatives, have engaged in any conduct, or omitted to perform any necessary act, the result of which would invalidate or render unpatentable or unenforceable any such Patent.

(t) The Collateral Documents create in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a valid and continuing and, upon the making of the filings and the taking of the actions required under the terms of the Loan Documents (except to the extent not required to be perfected pursuant to the terms of the Loan Documents), perfected Lien on and security interest in the Collateral (in each case, solely to the extent perfection is available under Requirements of Law through the making of such filings and taking of such actions), securing the payment of the Obligations, and having priority over all other Liens on and security interests in the Collateral (except Permitted Liens).

6.7 Adverse Proceedings, Compliance with Laws and Settlement Agreements .

(a) (i) Except as set forth on Schedule 4.7 of the Disclosure Letter, there are no Adverse Proceedings pending or, to the Knowledge of such Credit Party, threatened in writing, at law, in equity, in arbitration or before any Governmental Authority, by or against Borrower or any of its Subsidiaries; and (ii) neither Borrower nor any of its Subsidiaries (A) is in violation of any Requirements of Law, excluding any Requirement of Law which is being contested in good faith by appropriate proceedings, where such violation could reasonably be expected to result in uninsured damages or costs to Borrower or any of its Subsidiaries, individually or together with any other such violation, in an amount in excess of $[***], or (B) is subject to or in default with respect to any final judgments, orders, writs, injunctions, settlement agreements, decrees, rules or regulations of any court or any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign.

(b) Each of Borrower and its Subsidiaries (and, to Borrower's Knowledge, each other party thereto) is in compliance with the terms of all settlement agreements (relating to any Adverse Proceeding) to which Borrower or any Subsidiary is a party.

6.8 Exchange Act Documents; Financial Statements; Financial Condition; No Material Adverse Change; Books and Records .

(a) The Exchange Act Documents filed by Borrower with the SEC since December 31, 2023, when they were filed with the SEC, conformed in all material respects to the requirements of the Exchange Act, and as of the time they were filed with the SEC, none of such documents contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein (excluding any projections and

forward-looking statements, estimates, budgets and general economic or industry data of a general nature), in the light of the circumstances under which they were made, not misleading; provided, that, with respect to projected financial information, Borrower represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time (it being understood that such projections are not a guarantee of financial performance and are subject to uncertainties and contingencies, many of which are beyond the control of Borrower or any Subsidiary, and neither Borrower nor any Subsidiary can give any assurance that such projections will be attained, that actual results may differ in a material manner from such projections and any failure to meet such projections shall not be deemed to be a breach of any representation or covenant herein).

(b) The Borrower's audited annual financial statements as of December 31, 2023 and unaudited quarterly financial statements as of March 31, 2024 and June 30, 2024 (in each case, including the related notes thereto) of Borrower and its Subsidiaries included in the Exchange Act Documents present fairly in all material respects the consolidated financial condition of Borrower and such Subsidiaries and their consolidated results of operations as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified. Such financial statements have been prepared in conformity with GAAP applied on a consistent basis throughout the periods covered thereby, except as otherwise disclosed therein and, in the case of unaudited, interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes.

(c) Borrower acknowledges that its management is responsible for the preparation and fair presentation of the financial statements of Borrower and each of its Subsidiaries delivered to the Collateral Agent pursuant to Section 5.2(a), in each case, in conformance with GAAP. Borrower has, suitable for a company of its size and stage of development, designed, implemented and maintained internal controls relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

(d) Since December 31, 2023, there has not occurred any change or event that has had or could reasonably be expected to have, either alone or in conjunction with any other change(s), event(s) or failure(s), a Material Adverse Change.

(e) Since December 31, 2023, there has not occurred any Transfer by Borrower or any Subsidiary, voluntary or involuntary, of any material part of the business, assets or property of Borrower or any Subsidiary, and no purchase or other acquisition by any of them of any business, assets or property (including any Equity Interests of any other Person) material to Borrower or any Subsidiary, in each case, which is not reflected in the financial statements of Borrower and its Subsidiaries included in the Exchange Act Documents (or in the notes thereto) and has not otherwise been disclosed in writing to the Collateral Agent or Lenders on or prior to the Tranche B Closing Date.

(f) The Books of Borrower and each of its Subsidiaries contain full, true and correct entries of all dealings and transactions in relation to its business and activities in conformity with GAAP and Requirements of Law in all material respects.

6.9 Solvency. The Credit Parties and their Subsidiaries, on a consolidated basis, are Solvent. Without limiting the generality of the foregoing, there has been no proposal made or resolution adopted by any competent corporate body for the dissolution or liquidation of any Credit Party.

6.10 Taxes. All U.S. federal, state, local and foreign income and other material Tax returns and reports (or extensions thereof) of each Credit Party and each of its Subsidiaries required to be filed by any of them have been timely filed and are correct in all material respects, and all income and other material Taxes, assessments, deposits and contributions which are due and payable by any Credit Party or any of its Subsidiaries or levied or imposed upon them or any of their properties, assets or in respect of any of their income, businesses or franchises have been paid when due and payable, except where such payment can be lawfully withheld and the validity or amount thereof is being contested in good faith by appropriate proceedings; provided that no such Tax or any claim for Taxes that have become due and payable shall be required to be paid if, in each case, (i) the applicable Credit Party has set aside on its books adequate reserves therefor in conformity with GAAP, or (ii) the failure to pay such Taxes, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Change. To the Knowledge of such Credit Party, there is no pending or proposed Tax assessment against any Credit Party or any of its Subsidiaries that would, if made, result in a Material Adverse Change.

6.11 Environmental Matters. Neither Borrower nor any of its Subsidiaries nor any of their respective Facilities or operations is subject to any outstanding written order, consent decree or settlement agreement with any Person relating to any Environmental Law, any Environmental Claim, or any Hazardous Materials Activity that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. There are and, to the Knowledge of such Credit Party, have been, no conditions, occurrences, or Hazardous Materials

Activities that would reasonably be expected to form the basis of an Environmental Claim against Borrower or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. To the Knowledge of such Credit Party, no predecessor of Borrower or any of its Subsidiaries has filed any notice under any Environmental Law indicating past or present treatment of Hazardous Materials at any Facility, which would reasonably be expected to form the basis of an Environmental Claim against Borrower or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change (but, for the avoidance of doubt, neither Borrower nor any of its Subsidiaries has, directly or indirectly, undertaken any investigation of or made any inquiries to, or relating to, any of its or its Subsidiaries' predecessors), and neither Borrower's nor any of its Subsidiaries' operations involves the generation, transportation, treatment, storage or disposal of hazardous waste, as defined under 40 C.F.R. Parts 260 – 270 or any foreign or United States state equivalents, which would reasonably be expected to form the basis of an Environmental Claim against Borrower or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. No event or condition has occurred or is occurring with respect to any Credit Party relating to any Environmental Law, any Release of Hazardous Materials, or any Hazardous Materials Activity that, individually or in the aggregate, has resulted in, or could reasonably be expected to result in, a Material Adverse Change.

6.12 Material Contracts. After giving effect to the consummation of the transactions contemplated by this Agreement, except as described on Schedule 4.12 of the Disclosure Letter, each Material Contract is a valid and binding obligation of the applicable Credit Party and, to the Knowledge of such Credit Party, each other party thereto, and is in full force and effect, and neither the applicable Credit Party nor, to the Knowledge of such Credit Party, any other party thereto is in material breach thereof or default thereunder, except where such breach or default (which default has not been cured or waived) could not reasonably be expected to give rise to any cancellation, termination or acceleration right of the applicable counterparty thereto. No Credit Party or any of its Subsidiaries has received any written notice from any party to any Material Contract asserting or to the Knowledge of such Credit Party, threatening to assert, circumstances that could reasonably be expected to result in the cancellation, termination or invalidation of any Material Contract (or any provision thereof) or the acceleration of such Credit Party's or Subsidiary's obligations thereunder.

6.13 Regulatory Compliance. No Credit Party is or is required to be registered as, or is a company "controlled" by, an "investment company" as defined in, or is subject to regulation under, the Investment Company Act of 1940. Except as could not reasonably be expected to result in a Material Adverse Change, each Credit Party has complied with the Federal Fair Labor Standards Act (and any foreign or United States state equivalent). Except as could not, either individually or in the aggregate, reasonably be expected to result in a Material Adverse Change, each Plan is in compliance with the applicable provisions of ERISA, the IRC and other U.S. federal or state or foreign Requirements of Law, respectively. (i) No ERISA Event has occurred or is reasonably expected to occur; (ii) neither any Credit Party nor any ERISA Affiliate has incurred, or reasonably expects to incur, any liability (and no event has occurred which, with the giving of notice under Section 4219 of ERISA, would result in such liability) under Section 4201 *et seq*. of ERISA with respect to a Multiemployer Plan; and (iii) neither any Credit Party nor any ERISA Affiliate has engaged in a transaction that would be subject to Section 4069 or 4212(c) of ERISA, except, with respect to each of clauses (i), (ii) and (iii) above, as could not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

6.14 Margin Stock. No Credit Party is engaged principally, or as one of its important activities, in extending credit for the purpose of, whether immediate or ultimate, purchasing or carrying Margin Stock. No Credit Party owns any Margin Stock. No Credit Party or any of its Subsidiaries has taken or permitted to be taken any action that might cause any Loan Document to violate Regulation T, U or X of the Federal Reserve Board.

6.15 Subsidiaries; Capitalization. Schedule 4.15 of the Disclosure Letter includes a complete and accurate list of Borrower and each of its Subsidiaries, setting forth (a) its name and jurisdiction of incorporation, organization or formation, (b) in the case of each Credit Party (other than the Borrower), the number of authorized and issued shares (or equivalent) of each class (where applicable) of its Equity Interests outstanding, and (c) the percentage of its outstanding shares of each class owned (directly or indirectly) by Borrower or any of its Subsidiaries and the certificate numbers(s) for the same (if any) and in the case of Insmed Godo Kaisha the percentage of its membership interest owned (directly or indirectly) by Borrower or any of its Subsidiaries, and (d) the number and effect, if exercised, of all of its outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto. Except as set forth on Schedule 4.15 of the Disclosure Letter, each Credit Party is a Registered Organization.

6.16 Employee Matters. Neither Borrower nor any of its Subsidiaries is engaged in any unfair labor practice that could reasonably be expected to result in a Material Adverse Change. There is (a) no unfair labor practice complaint pending against Borrower or any of its Subsidiaries or, to the Knowledge of such Credit Party, threatened in writing against any of them in each case before the National Labor Relations Board, and no grievance

or arbitration proceeding arising out of or under any collective bargaining agreement that is pending against Borrower or any of its Subsidiaries or, to the Knowledge of such Credit Party, threatened in writing against any of them, (b) no strike or work stoppage in existence or, to the Knowledge of such Credit Party, threatened in writing involving Borrower or any of its Subsidiaries, and (c) to the Knowledge of such Credit Party, no union representation question existing with respect to the employees of Borrower or any of its Subsidiaries and, to the Knowledge of such Credit Party, no union organization activity that is taking place that in each case specified in any of clauses (a), (b) and (c) above, individually or taken together with any other matter specified in clause (a), (b) or (c) above, could reasonably be expected to result in a Material Adverse Change.

6.17 Full Disclosure. None of the documents, certificates or written statements (excluding any projections and forward-looking statements, estimates, budgets and general economic or industry data of a general nature) furnished or otherwise made available to the Collateral Agent or any Lender by or on behalf of any Credit Party for use in connection with the transactions contemplated hereby (in each case, taken as a whole and as modified or supplemented by other information so furnished promptly after the same becomes available) contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained herein or therein, as of the time when made or delivered, not misleading in light of the circumstances in which the same were made; provided, that, with respect to projected financial information, Borrower represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time (it being understood that such projections are not a guarantee of financial performance and are subject to uncertainties and contingencies, many of which are beyond the control of Borrower or any Subsidiary, and neither Borrower nor any Subsidiary can give any assurance that such projections will be attained, that actual results may differ in a material manner from such projections and any failure to meet such projections shall not be deemed to be a breach of any representation or covenant herein). To the Knowledge of Borrower, there are no facts (other than matters of a general economic or industry nature) that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change and that have not been disclosed herein or in such other documents, certificates and written statements furnished or made available to the Collateral Agent or any Lender for use in connection with the transactions contemplated hereby.

6.18 Anti-Corruption Laws; Anti-Money Laundering Laws; Sanctions; Export and Import Laws .

(a) None of Borrower, its Subsidiaries, their directors or officers, or, to the Knowledge of such Credit Party, any agent or employee of Borrower or any Subsidiary of Borrower has, at any time in the last three (3) years, (i) used any corporate funds of Borrower or any Subsidiary of Borrower for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity, (ii) made any direct or, to the Knowledge of such Credit Party, indirect unlawful payment to any foreign or domestic government official or employee from corporate funds of Borrower or any Subsidiary of Borrower, (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "**FCPA**"), the U.K. Bribery Act 2010 (" **UKBA**") or any other applicable anti-corruption laws or (iv) made any bribe, improper rebate, payoff, influence payment, kickback or other unlawful payment, and no part of the proceeds of any Credit Extension will be used, directly or, to the Knowledge of such Credit Party, indirectly, for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation of the FCPA, UKBA or any other applicable anti-corruption laws. No action, suit or proceeding by or before any Governmental Authority or any arbitrator involving Borrower or any of its Subsidiaries with respect to the FCPA, UKBA or any other applicable anti-corruption laws is pending or to the Knowledge of such Credit Party, threatened in writing nor is there a basis for such action, suit or proceeding.

(b) (i) The operations of Borrower and its Subsidiaries are and have been conducted at all times in the last five (5) years with applicable financial recordkeeping and reporting requirements of the Bank Secrecy Act of 1970 (as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001) and the anti-money laundering laws, rules and regulations of each jurisdiction (foreign or domestic) in which Borrower or any of its Subsidiaries is subject to such jurisdiction's Requirements of Law (collectively, the "**Anti-Money Laundering Laws**") and (ii) no action, suit or proceeding by or before any Governmental Authority or any arbitrator involving Borrower or any of its Subsidiaries with respect to the Anti-Money Laundering Laws is pending or to the Knowledge of such Credit Party, threatened in writing.

(c) None of Borrower, its Subsidiaries, or, their directors, officers or, to the Knowledge of such Credit Party, any employee or agent of Borrower or any Subsidiary of Borrower is, or is fifty percent (50.0%) or more owned or otherwise controlled by individuals or entities that are, the target or subject of any economic, trade or financial sanctions or restrictive measures administered and enforced by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**"), the U.S. Department of State, the United Nations Security Council, the European Union and each member state thereof, or Switzerland (the Swiss State Secretariat for Economic

Affairs of Switzerland (SECO) or the Swiss Directorate of International Law (DIL)) or His Majesty's Treasury of the United Kingdom (collectively " **Sanctions**"). Neither Borrower nor any of its Subsidiaries: (i) has assets located in, or otherwise directly or indirectly derives revenues from or engages in, investments, dealings, activities, or transactions in or with, any Sanctioned Country; or (ii) directly or indirectly derives revenues from, conducts any business or engages in investments, dealings, activities, or transactions with, any Sanctioned Person, including the making or receiving of any contribution of funds, goods or services to or for the benefit of any Sanctioned Person. Borrower will not, directly or indirectly (including through an agent or any other Person), use the proceeds of any Term Loans, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other Person, for (i) the purpose of financing the activities of any Person that is the target or subject of Sanctions or in any country or territory that at the time of such funding, is the subject of Sanctions, (ii) in any Sanctioned Country, or (iii) any purpose that could cause any Person to be in violation of Sanctions. No action, suit or proceeding by or before any Governmental Authority or any arbitrator involving Borrower or any of its Subsidiaries with respect to Sanctions is pending or to the Knowledge of such Credit Party, threatened in writing, nor is there a basis for such action, suit or proceeding.

(d) Borrower will not, directly or, to the Knowledge of such Credit Party, indirectly (including through an agent or any other Person), use any of the proceeds of any Credit Extension, or lend, contribute or otherwise make available such proceeds of any Credit Extension to any Subsidiary, joint venture partner or other Person, (i) for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation of the FCPA, UKBA or any other applicable anti-corruption laws, (ii) in violation of any Anti-Money Laundering Laws, or (iii) in violation of Sanctions.

(e) Borrower, its Subsidiaries, their respective officers and directors, and to the Knowledge of Borrower, their respective agents and employees, are in compliance in all respects with Sanctions. Borrower and its Subsidiaries have instituted and maintain policies and procedures reasonably designed to ensure compliance with Sanctions, Anti-Money Laundering Laws, Export and Import Laws, and applicable anti-corruption laws, including the FCPA and UKBA.

(f) Borrower and its Subsidiaries are in compliance in all material respects with applicable Export and Import Laws.

6.19 Health Care Matters.

(a) *Compliance with Health Care Laws*. Except as set forth on Schedule 4.19(a) of the Disclosure Letter, each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries and each officer, Affiliate, and employee acting on behalf of such Credit Party or any of its Subsidiaries, is in compliance in all material respects with all Health Care Laws applicable to such Credit Party or Subsidiary.

(b) *Compliance with Regulatory Requirements*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, are in compliance with applicable FDA Laws including the Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) (the " **FDCA**"), the Public Health Service Act (21 U.S.C. § 262 through § 263) (the "**PHSA**") and regulations promulgated thereunder relating to Orphan Drug designation, Fast Track, Breakthrough Therapy, Priority Review, and Qualified Infectious Disease Product designations, and Limited Population Pathway for Antibacterial and Antifungal Drugs; and are otherwise in compliance in all material respects with all applicable FDA Laws including the FDCA, the PHSA and regulations promulgated thereunder; EU Laws including the EU Community Code on medicinal products (Directive 2001/83/EC), the EMA Regulation (Regulation (EC) No 726/2004), the Manufacturing Directive (Commission Directive 2003/94/EC), the Clinical Trials Regulation (Regulation (EU) No 536/2014), and related implementing legislation of individual EU Member States and related guidance at EU level and national level in individual EU Member States; Japanese Laws including the Law on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics ("**PMDL**"); FDA Laws, EU Laws and Japanese Laws and related regulations relating to research, development, testing, manufacture, approval, licensure, clearance, authorization, designation, post-approval (or post-licensure, post-authorization, or post-clearance, as applicable) monitoring and commitments, reporting (including post-marketing safety reports for combination products), manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory. Any Product distributed or sold in the Territory at all times during the past five (5) years has been (i) manufactured and developed in all material respects in accordance with current Good Manufacturing Practices, Good Clinical Practices, and Good Laboratory Practices (as applicable), and (ii) if and to the extent such Product is required to be approved or licensed by the relevant Governmental Authority pursuant to FDA Laws, EU Laws, Japanese Laws, or other foreign law equivalents, in order to be legally marketed in the Territory for such Product's intended uses, such Product has been approved or licensed for such intended uses, meets in all material respects any additional

conditions of approval, clearance, authorization, or licensure by the competent Governmental Authority, and no inquiries regarding material issues have been initiated by any competent Governmental Authority, except in each case referred to in sub-clauses (i) or (ii) above, to the extent that any failure to ensure the foregoing could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

(c) *Applicability of Controlled Substances Act*. Product does not contain a controlled substance (as that term is defined under the Controlled Substances Act (21 U.S.C. § 801 et seq.)).

(d) *Material Statements*. Within the past four (4) years, neither any Credit Party, nor, to the Knowledge of such Credit Party, any Subsidiary or any officer or employee or Affiliate of any Credit Party or Subsidiary in its capacity as a Subsidiary or as an officer, employee or Affiliate of a Credit Party or Subsidiary (as applicable), nor, to the Knowledge of such Credit Party, any agent of any Credit Party or Subsidiary, (i) has made an untrue statement of a material fact or a fraudulent statement to any Governmental Authority under any Health Care Law, (ii) has failed to disclose a material fact to any Governmental Authority under any Health Care Law, or (iii) has otherwise committed an act, made a statement or failed to make a statement that, at the time such statement or disclosure was made (or, in the case of such failure, should have been made) or such act was committed, could reasonably be expected to constitute a material violation of any Health Care Law.

(e) *Proceedings; Audits*. Except as has been set forth on Schedule 4.19(e) of the Disclosure Letter, there is no Adverse Proceeding pending or, to the Knowledge of such Credit Party, threatened in writing, against any Credit Party or any of its Subsidiaries relating to any allegations of non-compliance with any Health Care Laws, FDA Laws, EU Laws, or Japanese Laws.

(f) *Recalls, Safety Notices, Etc*. Within the last five (5) years, except as has been set forth on Schedule 4.19(f) of the Disclosure Letter, neither any Credit Party nor any of its Subsidiaries has initiated or otherwise engaged in any recalls, field notifications, safety warnings, “dear doctor” letters, investigator notices, safety alerts or other material notices of action, including as a result of any Risk Evaluation and Mitigation Strategy (or foreign equivalent) proposed or enforced by the FDA, the European Commission, the EMA, the competent authorities of the EU Member States, the MHRA, the PMDA, the MHLW, or any other equivalent foreign Governmental Authority relating to an alleged lack of safety or regulatory compliance of Product. To the Knowledge of such Credit Party, there is no reasonable expectation that there are grounds for imposition of a clinical hold, as described in 21 C.F.R. § 312.42, or a withdrawal of an Investigational Device Exemption, as defined in 21 C.F.R. § 812.30, in each case of Product.

(g) *Preclinical Studies / Clinical Trials*. All pre-clinical and clinical studies relating to Product conducted by or on behalf of any Credit Party or any of its Subsidiaries have been, or are being, conducted in compliance with all applicable Requirements of Law, including the applicable requirements of FDA Laws, EU Laws, Japanese Laws, Good Laboratory Practices, Good Clinical Practices, regulations under the Common Rule, including regulations under 45 C.F.R. part 46, and the Animal Welfare Act and applicable experimental protocols, procedures and controls, United States state equivalents and equivalent foreign laws and applicable regulations. Except as set forth on Schedule 4.19(g) of the Disclosure Letter, during the past five (5) years, no clinical trial conducted by or on behalf of any Credit Party or any of its Subsidiaries has been terminated or suspended by any Regulatory Agency and neither any Credit Party nor any of its Subsidiaries has received any notice that the FDA (or foreign equivalent), any other Governmental Authority or any institutional review board, ethics committee or safety monitoring committee has recommended, initiated or, to the Knowledge of such Credit Party threatened to initiate any action to suspend or terminate any clinical trial conducted by or on behalf of any Credit Party or any of its Subsidiaries or to otherwise restrict the preclinical research on or clinical study of Product.

(h) *Advertising / Promotion*. For the past five (5) years, each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, officers, employees and agents has advertised, promoted, marketed and distributed Product in the Territory in compliance in all material respects with FDA Laws, EU Laws, Japanese Laws, and other applicable Requirements of Law. Except as set forth on Schedule 4.19(h) of the Disclosure Letter, for the past five (5) years, neither any Credit Party nor, to the Knowledge of such Credit Party, any of its Subsidiaries, officers, employees or agents has received any written notice (including any notice under 21 C.F.R. § 316.36) of or is subject to any civil, criminal or administrative action, suit, demand, claim, complaint, hearing, investigation, demand letter, warning letter, untitled letter, proceeding or request for information from the FDA (or foreign equivalents) or any other Governmental Authority concerning noncompliance with any FDA Laws, EU Laws, Japanese Laws, or other Requirements of Law with regard to advertising, promoting, marketing or distributing Product in the Territory.

(i) *Recordkeeping / Reporting*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, has maintained records relating to any aspect of the research, development, testing, manufacture, recall, production, handling, labeling, packaging, storage, supply, promotion, distribution, marketing,

commercialization, import, export and sale of Product in the Territory in compliance in all material respects with FDA Laws, EU Laws, Japanese Laws, Health Care Laws and other applicable Requirements of Law, and each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, has submitted to the FDA (or foreign equivalents) and other Governmental Authorities in a timely manner all material notices and annual or other reports required to be made, including adverse experience reports, annual reports (including annual reports specific to holders of Orphan Drug designation), and safety reports (including post-marketing safety reports for combination products) required to be made for Product.

(j) *Prohibited Transactions; No Whistleblowers*. Except as set forth on Schedule 4.19(j) of the Disclosure Letter, within the past five (5) years, to the Knowledge of such Credit Party, neither any Credit Party, any Subsidiary, any officer or employee or Affiliate of a Credit Party or Subsidiary, nor any other Person acting on behalf of any Credit Party or any Subsidiary, directly or indirectly: (i) has offered or paid any remuneration, in cash or in kind, to, or made any financial arrangements with, any past, present or potential patient, supplier, physician or contractor, in order to illegally obtain business or payments from such Person in material violation of any Health Care Law; (ii) has given or made, or is party to any illegal agreement to give or make, any illegal gift or gratuitous payment of any kind, nature or description (whether in money, property or services) to any past, present or potential patient, supplier, physician or contractor, or any other Person in material violation of any Health Care Law; (iii) has given or made, or is party to any agreement to give or make on behalf of any Credit Party or any of its Subsidiaries, any contribution, payment or gift of funds or property to, or for the private use of, any governmental official, employee or agent where either the contribution, payment or gift or the purpose of such contribution, payment or gift is or was a material violation of the laws of any Governmental Authority having jurisdiction over such payment, contribution or gift; (iv) has established or maintained any unrecorded fund or asset for any purpose or made any materially misleading, false or artificial entries on any of its books or records for any reason; or (v) has made, or is party to any agreement to make, any payment to any Person with the intention or understanding that any part of such payment would be in material violation of any Health Care Law. To the Knowledge of such Credit Party, there are no actions pending or threatened (in writing) against any Credit Party or any of its Subsidiaries or any of their respective Affiliates under any foreign, federal or United States state healthcare whistleblower statute, including under the False Claims Act of 1863 (31 U.S.C. § 3729 et seq.).

(k) *Exclusion*. Except as set forth on Schedule 4.19(k) of the Disclosure Letter, neither any Credit Party nor, to the Knowledge of such Credit Party, any Subsidiary or any officer, employee or Affiliate of a Credit Party or Subsidiary having authority to act on behalf of any Credit Party or any Subsidiary, is or, to the Knowledge of such Credit Party, has been threatened in writing to be: (i) excluded from any Governmental Payor Program pursuant to 42 U.S.C. § 1320a-7b and related regulations, to the extent applicable; (ii) "suspended" or "debarred" from selling any products to the U.S. government or its agencies pursuant to the Federal Acquisition Regulation relating to debarment and suspension applicable to federal government agencies generally (42 C.F.R. Subpart 9.4), or other U.S. Requirements of Law; (iii) debarred, disqualified, suspended or excluded from participation in Medicare, Medicaid or any other Governmental Payor Program or is listed on the General Services Administration list of excluded parties, to the extent applicable; (iv) debarred by the FDA (or foreign equivalent); or (v) a party to any other action or proceeding by any Governmental Authority that would prohibit the applicable Credit Party or Subsidiary from distributing or selling Product in the Territory or providing any services to any governmental or other purchaser pursuant to any Health Care Laws.

(l) *Health Information*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, to the extent applicable, has implemented written policies and procedures as well as training that is reasonable and customary in the pharmaceutical industry, satisfies the requirements of all applicable Requirements of Law (including HIPAA, Section 5 of the FTC Act, CCPA, CMIA, GDPR and APPI, as applicable) and is otherwise designed to assure continued compliance and to detect non-compliance. Neither any Credit Party nor, to the Knowledge of such Credit Party, any Subsidiary that is not a Credit Party, is a "covered entity" or "business associate" as defined in HIPAA (45 C.F.R. § 160.103).

(m) *Corporate Integrity Agreement*. Neither any Credit Party or Subsidiary or any of their respective Affiliates, nor to the Knowledge of such Credit Party, any of their respective officers, directors, managing employees or agents (as those terms are defined in 42 C.F.R. § 1001.1001), is a party to or has any ongoing reporting or disclosure obligations under, or is otherwise subject to, any corporate integrity agreement, monitoring agreement, deferred prosecution agreement, consent decree, settlement order or other similar agreements, or any order, in each case imposed by any U.S. Governmental Authority, concerning compliance with any laws, rules or regulations, issued under or in connection with a Governmental Payor Program.

6.20 Regulatory Approvals or Licensures.

(a) Except as set forth on Schedule 4.20(a) of the Disclosure Letter, each Credit Party and each Subsidiary involved in any research, development, manufacture, production, use, commercialization,

marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory has all Regulatory Approvals or Licensures material to the conduct of its business and operations.

(b) Each Credit Party, each Subsidiary and, to the Knowledge of such Credit Party, each licensee of a Credit Party or a Subsidiary of any Intellectual Property relating to Product, is in compliance with, and at all times during the past five (5) years, has complied with all applicable foreign, federal, state and local laws, rules and regulations governing any aspect of the research, development, testing, approval, licensure, clearance, authorization, post-approval (or post-licensure, post-authorization, or post-clearance, as applicable) monitoring and commitments, reporting (including post-marketing safety reports for combination products), manufacture, production, packaging, labeling, use, commercialization, designation, exclusivity, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory, including all such regulations promulgated by each applicable Regulatory Agency (including the FDA, the European Commission, the EMA, the competent authorities of the EU Member States and the MHRA, the PMDA, the MHLW, or any other applicable foreign equivalents), except where any instance of failure to comply with any such laws, rules or regulations could not, whether individually or taken together with any other such failures, reasonably be expected to result in a Material Adverse Change. Except as set forth on Schedule 4.20(b) of the Disclosure Letter, within the last five (5) years, no Credit Party or its Subsidiaries has received any written notice from any Regulatory Agency citing action or inaction by any Credit Party or any of its Subsidiaries that would constitute a violation of any applicable foreign, federal, state or local laws, rules or regulations, including a Warning Letter or Untitled Letter from FDA and equivalent EU, Japanese, and other foreign communications.

6.21 Supply and Manufacturing.

(a) Except as set forth on Schedule 4.21(a) of the Disclosure Letter, to the Knowledge of such Credit Party, Product at all times during the past five (5) years has been manufactured in sufficient quantities and of a sufficient quality to satisfy demand of Product in the Territory, without the occurrence of any event or any series of related events causing inventory of Product to have become exhausted prior to satisfying such demand. To the Knowledge of such Credit Party, no event or circumstance (or series of related events or circumstances) has occurred that has caused or could reasonably be expected to cause inventory of Product to become exhausted in any calendar year prior to satisfying the sales demand (if any) of Product in the Territory in such calendar year.

(b) Except as set forth on Schedule 4.21(b) of the Disclosure Letter, to the Knowledge of such Credit Party, no event or circumstance (or series of related events or circumstances) has occurred or, in the reasonable business judgment of Borrower, is reasonably likely to occur, that would cause or could reasonably be expected to cause Product (A) to not be manufactured in any calendar year in sufficient quantities to satisfy or exceed the greater of (i) the net sales amount for such calendar year set forth in the Product Revenue Forecast and (ii) the expected needs of patients with the disease or condition for which Product was designated as an Orphan Drug for such calendar year, as reasonably determined by a Responsible Officer of the Borrower in good faith (provided such calendar year occurs during the full term of Orphan Drug exclusive approval granted under 21 C.F.R. § 316.34); or (B) to not be manufactured in a manner that supports Orphan Drug designation under EU Law or Japanese Law, as applicable.

(c) Except as set forth on Schedule 4.21(c) of the Disclosure Letter, to the Knowledge of such Credit Party, (i) no manufacturer (including a contract manufacturer) or producer of Product has been during the last five (5) years or is currently subject to a material Regulatory Agency shutdown, restriction or import or export prohibition, (ii) no manufacturer (including a contract manufacturer) or producer of Product has received in the past five (5) years or is currently subject to (1) a FDA Form 483 or (2) other written Regulatory Agency notice of inspectional observations, Warning Letter, Untitled Letter or request to make changes to Product that could reasonably be expected to impact Product, in either case of sub-clause (1) or (2) above with respect to any facility manufacturing or producing Product for import, distribution or sale or lease in the Territory, and (iii) with respect to each such FDA Form 483 received or other written Regulatory Agency notice (if any), to the Knowledge of such Credit Party all deficiencies relating to Good Manufacturing Practice requirements documented therein, and any disputes regarding any such deficiencies, have been corrected or otherwise resolved.

(d) Except as disclosed in Schedule 4.21(d) of the Disclosure Letter, no Credit Party or any of its Subsidiaries has received any written or, to the Knowledge of such Credit Party, other notice from any party to any Manufacturing Agreement containing any indication by or intent or threat in writing of, such party to reduce or cease, in any material respect, the supply of Product or any active pharmaceutical ingredient, prodrug, or proprietary technology for administration incorporated therein in the Territory or any other raw materials or other component materials needed to fulfill its contractual obligations related to Product in any Manufacturing Agreement through calendar year 2027 (or such earlier date in accordance with the terms and conditions of such Manufacturing Agreement, as applicable).

6.22 Cybersecurity and Data Protection.

(a) Except as set forth in Schedule 4.22(a) of the Disclosure Letter, to the Knowledge of such Credit Party, the information technology systems used in the business of each of Borrower and its Subsidiaries (collectively, "**Systems**") operate and perform in all material respects as required to permit each of Borrower and its Subsidiaries to conduct their respective businesses as presently conducted in the Territory. Borrower and each of its Subsidiaries has implemented and shall maintain reasonable and appropriate security controls and safeguards to protect the confidentiality, integrity, and availability of Sensitive Information and to protect the Systems. To the Knowledge of such Credit Party, no System contains any material ransomware, disabling codes or instructions, spyware, Trojan horses, worms, viruses or other software routines that are designed or intended to delete, destroy, disable, disrupt, impair, interfere with, perform unauthorized modifications to, or provide unauthorized access to any data, files, software, system, network, or other device. Borrower and its Subsidiaries have and maintain back-up systems, consistent with the industry in which Borrower and each of its Subsidiaries operate and the size and condition of Borrower and each of its Subsidiaries, designed to provide continuing availability of the material functionality provided by the Systems in the event of any malfunction of, or other event interrupting access to or the functionality of, such Systems. Borrower and each of its Subsidiaries use commercially reasonable efforts to maintain System security, including promptly implementing material security patches that are generally available for the Systems.

(b) Except as set forth on Schedule 4.22(b) of the Disclosure Letter, Borrower and each of its Subsidiaries has implemented and maintains a commercially reasonable, enterprise-wide privacy and information security program ("**Security Program**") with plans, policies, and procedures for privacy and physical and cyber security (including for disaster recovery, business continuity, encryption, data back-up, Systems access controls, workstation use and security, incident detection and incident response), that includes commercially reasonable and appropriate administrative, technical and physical safeguards designed to protect the integrity and availability of the Systems, consistent with the industry in which Borrower and each of its Subsidiaries operate and the size and condition of Borrower and its Subsidiaries, and designed to protect against (i) any unauthorized, accidental, or unlawful access to or acquisition, use, disclosure, transmission, retention, processing, loss, destruction, corruption or modification of Personal Data that would require notification to any affected individuals or any Governmental Authority under any applicable Data Protection Laws (each, a "**Personal Data Breach**"), (ii) any unauthorized, accidental, or unlawful access to or acquisition, use, disclosure, transmission, loss, destruction, corruption or modification of Sensitive Information that is not Personal Data, and (iii) any security incidents that would result in unauthorized, accidental, or unlawful access to or acquisition, use, control, disruption, destruction, or modification of any of the Systems (including cyber-attacks) that could reasonably be expected to result in a material and adverse effect on the operation of Borrower's or any of its Subsidiaries' business operations as currently conducted (sub-clauses (i) through (iii), collectively, "**Security Incidents**").

(c) Borrower and each of its Subsidiaries has conducted commercially reasonable privacy and security audits and penetration tests at reasonable intervals on all Systems that maintain, store, access, or process Sensitive Information, in each case consistent with the industry in which Borrower and each of its Subsidiaries operate and the size and condition of Borrower and each of its Subsidiaries. Borrower and each of its Subsidiaries has taken commercially reasonable steps to address and remediate all material privacy or data security issues identified as "critical," "high risk," or similar level of risk rating that are raised in any such audits or penetration tests (including any third-party audits of the Systems).

(d) Borrower and each of its Subsidiaries has conducted commercially reasonable privacy and data security diligence, consistent with generally accepted practices within the industry in which Borrower and each of its Subsidiaries operates and in compliance with applicable Data Protection Laws, on all service providers (including clinical trial investigators, contract research organizations, contract laboratories, contract manufacturers, suppliers, clinical data management organizations, back-office service providers, vendors and contractors) that (i) collect, create, receive, access, maintain, store, or otherwise process Sensitive Information for or on behalf of Borrower or any of its Subsidiaries, or (ii) access or maintain the Systems. Except as set forth on Schedule 4.22(d) of the Disclosure Letter, neither Borrower nor any of its Subsidiaries has, in the past five (5) years, received notice from any such service provider that the service provider experienced a Security Incident impacting Borrower's or any of its Subsidiaries' Sensitive Information.

(e) Except as set forth on Schedule 4.22(e) of the Disclosure Letter, to the Knowledge of Borrower neither Borrower nor any of its Subsidiaries, has in the past five (5) years suffered any (i) Personal Data Breaches or (ii) any other Security Incidents that, individually or together with any other such breaches or incidents, could reasonably be expected to have a material and adverse effect on Borrower's or any of its Subsidiaries' business operations, such as a material disruption of development, manufacturing or commercialization programs relating to Product.

(f) Borrower and each of its Subsidiaries is in material compliance with the requirements of (i) their respective Security Programs, (ii) their respective contractual obligations regarding the privacy, the security and the notification of breaches of Personal Data, including customer, consumer, patient, clinical trial participant and employee information, (iii) their respective contractual non-disclosure obligations, (iv) their respective publicly available privacy notices and policies, and (v) all applicable Data Protection Laws.

(g) Except as set forth on Schedule 4.22(g) of the Disclosure Letter, in the past five (5) years: (i) neither Borrower nor any of its Subsidiaries has received any written third party claims or, to the Knowledge of Borrower, any threat (in writing) of a third party claim, related to any Personal Data Breaches or other Security Incidents; and (ii) neither Borrower nor any of its Subsidiaries has received any written notice of any claims or investigations (including investigations by any Governmental Authority) relating to any Personal Data Breaches or other Security Incidents, except, in each case of sub-clauses (i) and (ii) above as could not reasonably be expected to be material to Borrower and its Subsidiaries, taken as a whole.

(h) In the past five (5) years, Borrower and each of its Subsidiaries has maintained all database registrations required under applicable Data Protection Laws material to the Borrower and its Subsidiaries.

6.23 Additional Representations and Warranties.

(a) Except as set forth on Schedule 4.23(a) of the Disclosure Letter, after giving effect to consummation of the transactions contemplated by this Agreement, there is no Indebtedness for borrowed money (i) owed to Borrower or any of its Subsidiaries, or (ii) owed by Borrower or any of its Subsidiaries.

(b) Except as set forth on Schedule 4.23(b) of the Disclosure Letter, neither Borrower nor any of its Subsidiaries are party to, or otherwise bound by, any Hedging Agreements.

6.24 Centre of Main Interests and Establishments.

For the purposes of Regulation (EU) 2015/848 of 20 May 2015 on insolvency proceedings (recast) (the "Regulation"), each Credit Party's centre of main interest (as that term is used in Article 3(1) of the Regulation) is situated in its jurisdiction of incorporation and it has no "establishment" (as that term is used in Article 2(10) of the Regulation) in any other jurisdiction.

6.25 Fiscal Unity.

No Credit Party incorporated under Dutch law is or has been a member of a fiscal unity (*fiscale eenheid*) for Dutch corporate income tax or value added tax purposes (unless such fiscal unity consists solely of Credit Parties).

7 AFFIRMATIVE COVENANTS

Each Credit Party covenants and agrees that, until payment in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), each Credit Party shall, and shall cause each of its Subsidiaries to:

7.1 Maintenance of Existence. (a) Preserve, renew and maintain in full force and effect its and all its Subsidiaries' legal existence under the Requirements of Law in their respective jurisdictions of organization, incorporation or formation other than as otherwise expressly permitted hereunder; (b) take all commercially reasonable action to maintain all rights, privileges (including its good standing (where applicable in the subject jurisdiction)), permits, licenses and franchises necessary or desirable for it and all of its Subsidiaries in the ordinary course of its business, except in the case of clause (a) (other than with respect to Borrower) and clause (b) above, (i) to the extent that failure to do so could not reasonably be expected to result in a Material Adverse Change or (ii) pursuant to a transaction permitted by this Agreement; and (c) comply with all Requirements of Law of any Governmental Authority to which it is subject, except where the failure to do so could not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change.

7.2 Financial Statements, Notices, Reports. Deliver to the Collateral Agent:

(a) Financial Statements.

(i) Annual Financial Statements. As soon as available, but in any event within ninety (90) days after the end of each fiscal year of Borrower, beginning with the fiscal year ending December 31, 2024, a consolidated balance sheet of Borrower and its Subsidiaries as of the end of such fiscal year, and the related consolidated statements of income, cash flows and stockholders' equity for such fiscal year, in each case certified by a Responsible Officer of Borrower, all prepared in accordance with GAAP, with such consolidated financial statements to be audited and accompanied by (i) a report and opinion of Borrower's independent certified public accounting firm of recognized national standing (which report and opinion shall be prepared in accordance with GAAP and shall not be subject to any qualification as to "going concern" or scope of audit, other than such consolidated financial statements for the fiscal year ending December 31, 2026 and then solely in respect of the Term Loans maturing on the Term Loan Maturity Date), stating that such financial statements fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Borrower and its Subsidiaries as of the dates and for the periods specified in accordance with GAAP, and (ii) if and only if Borrower is required to comply with the internal control provisions pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 requiring an attestation report of such independent certified public accounting firm, an attestation report of such independent certified public accounting firm as to Borrower's internal controls pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 attesting to management's assessment that such internal controls meet the requirements of the Sarbanes-Oxley Act of 2002;

(ii) Quarterly Financial Statements. As soon as available, but in any event within forty-five (45) days after the end of each of the first three (3) fiscal quarters of each fiscal year of Borrower, beginning with the fiscal quarter ending March 31, 2025, a consolidated balance sheet of Borrower and its Subsidiaries as of the end of such fiscal quarter, and the related consolidated statements of income and cash flows and for such fiscal quarter and (in respect of the second and third fiscal quarters of such fiscal year) for the then-elapsed portion of Borrower's fiscal year, all prepared in accordance with GAAP, subject to normal year-end audit adjustments and the absence of disclosures normally made in footnotes, but not subject to any qualification or statement as to "going concern," other than such consolidated financial statements for the fiscal quarters occurring during the twelve (12) calendar months preceding the Term Loan Maturity Date and then solely in respect of the Term Loans maturing on the Term Loan Maturity Date; provided, however, that Borrower shall be deemed to have made such delivery of such consolidated financial statements if such consolidated financial statements shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC). Such consolidated financial statements shall be certified by a Responsible Officer of Borrower as, to his or her knowledge, fairly presenting, in all material respects, the consolidated financial condition, results of operations and cash flows of Borrower and its Subsidiaries as of the dates and for the periods specified in accordance with GAAP consistently applied, and on a basis consistent with the audited consolidated financial statements referred to under Section 5.2(a)(i), subject to normal year-end audit adjustments and the absence of footnotes;

(iii) Quarterly Compliance Certificate. Upon delivery (or within five (5) Business Days following any deemed delivery) of financial statements pursuant to Section 5.2(a)(i) or Section 5.2(a)(ii), a duly completed Compliance Certificate signed by a Responsible Officer of Borrower, certifying, among other things, that (A) such financial statements fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Borrower and its Subsidiaries as of the applicable dates and for the applicable periods in accordance with GAAP consistently applied, not subject to any qualification or statement as to "going concern" or "scope of audit" other than as expressly permitted under sub-clauses (i) and (ii) above, and (B) no Event of Default or Default has occurred or, if such an Event of Default or Default has occurred, specifying the nature and extent thereof and any corrective action taken or proposed to be taken with respect thereto; and

(iv) Other Information. As promptly as practicable (and in any event within five (5) Business Days) after the reasonable request of the Collateral Agent, such additional information regarding the operations, properties, business, liabilities or condition (financial or otherwise) of Borrower and its Subsidiaries (including with respect to the Collateral), or compliance with the terms of this Agreement or any other Loan Documents.

(v) FDA Approval Date . As promptly as practicable following the occurrence thereof, written notice with reasonable detail that the FDA Approval Date has occurred.

(b) Notice of Defaults or Events of Default, ERISA Events, Withdrawal Events and Material Adverse Changes . Written notice as promptly as practicable (and in any event within five (5) Business Days) after a Responsible Officer of any Credit Party shall have obtained knowledge thereof, of (i) the receipt by Borrower or any of its Subsidiaries of a Withdrawal Recommendation Notice, or (ii) the occurrence of, or the occurrence of any event

which could reasonably be expected to result in, any (w) Default or Event of Default, (x) ERISA Event, (y), Withdrawal Event or (z) Material Adverse Change.

(c) Legal Action Notice. Promptly (and in any event within five (5) Business Days) upon any Credit Party's receipt or otherwise obtaining Knowledge thereof, written notice of: (i) correspondence received from any securities regulatory or exchange to the authority of which Borrower or any Subsidiary of Borrower is or may become subject from time to time (in any applicable U.S. or foreign jurisdiction) concerning any investigation or possible investigation or other material inquiry by such agency regarding financial or other operational results of Borrower or any such Subsidiary; or (ii) any legal action, litigation, investigation or proceeding pending or threatened in writing against Borrower or any of its Subsidiaries (A) that could reasonably be expected to result in uninsured damages or costs to Borrower or any of its Subsidiaries, individually or together with any other such action, litigation, investigation or proceeding, in an amount in excess of $[***], or (B) that alleges violations of any Health Care Laws, FDA Laws, EU Laws, Japanese Laws, Data Protection Laws or any other applicable statutes, rules, regulations, standards, guidelines, policies and orders, or applicable foreign equivalents, administered or issued by any U.S. or foreign Governmental Authority which, individually or together with any other such allegations, could reasonably be expected to result in a Material Adverse Change; and in each case of sub-clause (i) or (ii) above, provide such additional information (including a description in reasonable detail regarding any material development) as the Collateral Agent may reasonably request in relation thereto.

(d) Accounting Changes. Written notice as promptly as practicable (and in any event within five (5) Business Days) after any material change in accounting policies or financial reporting practices by Borrower or any Subsidiary.

Notwithstanding the foregoing, any documents, materials, notices or other information, that Borrower, any Credit Party or any Subsidiary of Borrower is required to deliver under Sections 5.2(a)(i), (a)(ii), (a)(v), (c) or (d) above shall be deemed to have been made if such item shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC), provided, however, that in the case of any notice required to be delivered under Section 5.2(c) above, such notice shall be deemed to have been so made with respect to additional information the Collateral Agent may reasonably request only if it includes such additional information.

(e) Assignment Notice. Prompt written notice of any Credit Party's obtaining Knowledge of any assignment of any of Borrower's or OrbiMed's obligations or rights under the Royalty Revenue Contract or any other Royalty Revenue Document to which Borrower or any of its Subsidiaries is a party, or any acquisition of any interest in OrbiMed's rights under the Royalty Revenue Contract or any other Royalty Revenue Document to which Borrower or any of its Subsidiaries is a party.

(f) Material Statements and Reports.

(i) Promptly after entering into the same, copies of any amendments, restatements, amendment and restatements, supplements, modifications, consents, approvals or waivers to or otherwise in respect of the Royalty Revenue Documents (including a description in reasonable detail regarding any fees or payments made in connection therewith);

(ii) Promptly after the furnishing thereof, copies of any statement or report furnished to OrbiMed pursuant to Section 5.01 or Section 5.02 of the Royalty Revenue Contract;

(iii) Upon request by the Collateral Agent, copies of any material statement or report furnished to any holder of debt securities of Borrower or any Subsidiary pursuant to the terms of any indenture, loan or credit or similar agreement;

(iv) At the time of delivery of each quarterly Compliance Certificate pursuant to Section 5.2(a)(iii), copies of any notices or other correspondence furnished to any party to the Purchase Agreement during the applicable fiscal quarter pursuant to Section 7.12 of the Purchase Agreement; and

(v) At the time of delivery of each quarterly Compliance Certificate pursuant to Section 5.2(a)(iii), copies of any notice or other correspondence received from any party to the Purchase Agreement during the applicable fiscal quarter and relating to any material disputes or material objection regarding the compliance by (or on behalf of) Borrower with the covenants set forth in Section 7.9 of the Purchase Agreement.

7.3 **Taxes**. Timely file all required U.S. federal and material state, local and foreign income and other material Tax returns and reports or extensions therefor and timely pay all U.S. federal and material state, local and foreign Taxes, assessments, deposits and contributions imposed upon it or any of its properties or assets or in respect of any of its income, businesses or franchises before any penalty or fine accrue thereon; provided, however, that no such Tax or any claim for Taxes that have become due and payable and have or may become a Lien on any Collateral shall be required to be paid if (a) it can be lawfully withheld and it is being contested in good faith, so long as adequate reserves therefor have been set aside on its books and maintained in conformity with GAAP, and (b) solely in the case of a Tax or claim that has or may become a Lien against any Collateral, such contest proceedings conclusively operate to stay the sale or forfeiture of any portion of any Collateral to satisfy such Tax or claim.

7.4 **Insurance**. Maintain with financially sound and reputable independent insurance companies or underwriters, insurance with respect to its properties and business against loss or damage of the kinds customarily insured against by Persons of comparable size engaged in the same or similar business, of such types and in such amounts (after giving effect to any self-insurance reasonable and customary for similarly situated Persons of comparable size engaged in the same or similar businesses as Borrower and its Subsidiaries) as are customarily carried under similar circumstances by such other Persons. Subject to the timing requirements of Section 5.14 (solely with respect to any such policies in effect as of the Tranche A Closing Date), any products liability or general liability insurance maintained in the United States regarding Collateral shall name the Collateral Agent, on behalf of the Lenders and the other Secured Parties, as additional insured or loss payee, as applicable (the additional insured clauses or endorsements for which, in form and substance reasonably satisfactory to the Collateral Agent). So long as no Event of Default shall have occurred and be continuing, Borrower and its Subsidiaries may retain all or any portion of the proceeds of any insurance of Borrower and its Subsidiaries (and each Lender shall promptly remit to Borrower any proceeds received by it with respect to any such insurance).

7.5 **Operating Accounts**.

(a) In the case of any Credit Party, promptly following the establishment of any new Collateral Account at or with any bank or other depository or financial institution located in the United States, subject such account to a Control Agreement or other appropriate instrument that is reasonably acceptable to the Collateral Agent. For each Collateral Account that each Credit Party at any time maintains in the United States, such Credit Party shall, within thirty (30) days of establishing such Collateral Account, cause the applicable bank or other depository or financial institution located in the United States, at or with which any Collateral Account is maintained to execute and deliver, and such Credit Party shall execute and deliver, to the Collateral Agent, a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect the Collateral Agent's Lien, for the benefit of Lenders and the other Secured Parties, in such Collateral Account in accordance with the terms hereunder, which Control Agreement may not be terminated without the prior written consent of the Collateral Agent. The provisions of the previous two (2) sentences shall not apply to (1) accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of any Credit Party's employees, (2) zero balance accounts, provided that, within two (2) Business Days of any deposit made into any such zero balance account, such deposit is swept in full to an account subject to a Control Agreement, (3) accounts (including trust accounts) used exclusively for escrow, customs, insurance or fiduciary purposes, (4) merchant accounts, (5) accounts used exclusively for compliance with any Requirements of Law to the extent such Requirements of Law prohibit the granting of a Lien thereon, (6) accounts which constitute cash collateral in respect of a Permitted Lien and (7) any other account established and maintained in the ordinary course of business or in furtherance of a *bona fide* general corporate purpose, and designated as an Excluded Account by a Responsible Officer of Borrower in writing delivered to the Collateral Agent, the cash balance of which such account, together with all other such accounts excluded under this sub-clause 7, do not exceed $[***] in the aggregate at any time (all such accounts in sub-clauses (1) through (7) above, collectively, the "**Excluded Accounts**"). Notwithstanding the foregoing, the Credit Parties shall have until the date that is ninety (90) days (or such longer period as the Collateral Agent may agree in its sole discretion) following (i) the Tranche A Closing Date to comply with the provisions of this Section 5.5 with regards to Collateral Accounts (other than Excluded Accounts) of the Credit Parties in existence on the Tranche A Closing Date (or opened during such 90-day period (or such longer period as the Collateral Agent may agree in its sole discretion)) and (ii) the closing date of any Acquisition or other Investment to comply with the provisions of this Section 5.5 with regards to Collateral Accounts (other than Excluded Accounts) of the Credit Parties acquired in connection with such Acquisition or other Investment.

(b) [Reserved.]

7.6 **Compliance with Laws**.

(a) Comply in all respects with the Requirements of Law and all orders, writs, injunctions, decrees and judgments applicable to it or to its business or its assets or properties (including Environmental Laws,

ERISA, Anti-Money Laundering Laws, OFAC, FCPA, UKBA, Health Care Laws, FDA Laws, EU Laws, Japanese Laws, Data Protection Laws and the Federal Fair Labor Standards Act and any foreign or United States state equivalents), including in connection with governing the research, development, testing, approval, clearance, authorization, exclusivity, licensure, designation, post-approval (or post-licensure, post-authorization, or post-clearance, as applicable) monitoring requirements or commitments, reporting (including post-marketing safety reports for combination products), manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory, except, in each case, if the failure to comply therewith could not, individually or taken together with any other such failures, reasonably be expected to result in a Material Adverse Change.

(b) Borrower and its Subsidiaries have instituted and shall maintain policies and procedures reasonably designed to ensure compliance with Sanctions, Anti-Money Laundering Laws, Export and Import Laws and applicable anti-corruption laws, including the FCPA and UKBA.

7.7 Protection of Intellectual Property Rights.

(a) Except as expressly permitted under clause (b) below, use commercially reasonable efforts to: (i) protect, defend and maintain the validity and enforceability of the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory, including defending any future or current oppositions, interference proceedings, reissue proceedings, reexamination proceedings, *inter partes* review proceedings, derivation proceedings, post grant review proceedings, cancellation proceedings, injunctions, lawsuits, hearings, investigations, complaints, arbitrations, mediations, demands, International Trade Commission investigations, decrees, or any other disputes, disagreements, or claims, challenging the legality, validity, patentability, enforceability, inventorship or ownership of such Company IP; (ii) maintain the confidential nature of any material trade secrets and trade secret rights which are used in the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory; and (iii) not allow any Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory to be abandoned, disclaimed, forfeited or dedicated to the public by a Credit Party or any of its Subsidiaries (other than through the abandonment of Current Company IP in the exercise of the Credit Parties' normal prosecution practices and reasonable business judgment, e.g., the abandonment of a continuation application that is no longer needed to maintain the pendency of another patent application) or any Company IP Agreement to be terminated, as applicable, without the Collateral Agent's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed); provided, however, that with respect to any such Company IP that is not owned by a Credit Party or any of its Subsidiaries, the obligations in sub-clauses (i) and (iii) above shall apply only to the extent a Credit Party or any of its Subsidiaries have the right to take such actions or to cause any licensee or other third party to take such actions pursuant to applicable agreements or contractual rights.

(b) Except as a Credit Party may otherwise determine in its reasonable business judgment, (i) use commercially reasonable efforts, at its (or its Subsidiary's) sole expense, either directly or indirectly, with respect to any licensee or licensor under the terms of any Credit Party's (or any of its Subsidiary's) agreement with the respective licensee or licensor, as applicable, to take any actions (including taking legal action to specifically enforce the applicable terms of any license agreement) and prepare, execute, deliver and file agreements, documents or instruments which are necessary to (A) prosecute and maintain the Company IP material to any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory and (B) diligently defend or assert the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory against material infringement, misappropriation, violation or interference by any other Persons and, in the case of Copyrights, Trademarks and Patents within such material Company IP, against any claims of invalidity, unpatentability or unenforceability (including by bringing any legal action for infringement, dilution, violation, derivation or defending any counterclaim of invalidity or action of a non-Affiliate third party for declaratory judgment of non-infringement or non-interference); and (ii) use commercially reasonable efforts to cause any licensee or licensor of any material Company IP not to, and such Credit Party shall not, disclaim, forfeit, dedicate to the public or abandon, or fail to take any action necessary to prevent the disclaimer, forfeiture or abandonment of such Company IP material to any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory (other than through the lapse, expiration or abandonment of Current Company IP in the exercise of the Credit Parties' normal prosecution practices and reasonable business judgment, *e.g.*, the abandonment of a continuation application that is no longer needed to maintain the pendency of another patent application); except, that sub-clauses (i) and (ii) above shall apply only to the extent a Credit Party or any of its Subsidiaries have the right to take such actions or to cause any licensor, licensee or other third party to take such

actions pursuant to applicable agreements or contractual rights, and taking such actions would not otherwise breach, terminate or otherwise violate the terms of the applicable agreements. Each Credit Party agrees to (1) notify the Collateral Agent in writing, promptly (and in any event within five (5) Business Days), of, and (2) keep the Collateral Agent reasonably informed regarding, (x) any infringement or violation any of the rights of any Credit Party or its Subsidiary in or to any material Company IP, or any misappropriation by any Person of any material Company IP or any of the subject matter thereof, and (y) any Product that infringes or violates any Third Party IP or constitutes a misappropriation of any Third Party IP.

(c) Save as contemplated by any Permitted License, use commercially reasonable efforts to protect, defend and maintain market and data exclusivity for the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory through the Term Loan Maturity Date, and use commercially reasonable efforts to not allow for the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of an equivalent or bioequivalent version of Product in the Territory before the Term Loan Maturity Date, in each case if such equivalent or bioequivalent version infringes or violates, or could reasonably be expected to infringe or violate, any of the rights of any Credit Party or its Subsidiary in or to any material Company IP, unless, in any such case, the Borrower has determined to do so in the exercise of its reasonable business judgement. Borrower agrees to promptly notify the Collateral Agent in writing of the commencement of any material opposition, interference proceeding, reissue proceeding, reexamination proceeding, *inter partes* review proceeding, post-grant review proceeding, derivation proceeding, cancellation proceeding, injunction, lawsuit, hearing, investigation, complaint, arbitration, mediation, demand, International Trade Commission investigation, decree, or any other dispute, disagreement, or claim, in each case challenging the legality, validity, patentability, enforceability, inventorship or ownership of any material Company IP (including any claim in any Patent within the Company IP that is material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Product in the Territory).

7.8 Books and Records. Maintain proper Books, in which entries that are full, true and correct in all material respects and are in conformity with GAAP consistently applied shall be made of all material financial transactions and matters involving the assets, properties and business of such Credit Party (or such Subsidiary).

7.9 Access to Collateral; Audits. Allow the Collateral Agent, or its agents or representatives, at any time after the occurrence and during the continuance of an Event of Default, during normal business hours and upon reasonable advance notice, to visit and inspect any of the Collateral or to inspect and copy and (at the sole discretion of the Collateral Agent) audit any Credit Party's Books. The foregoing inspections and audits, if any, shall be at the relevant Credit Party's expense.

7.10 Use of Proceeds. (a) Use the proceeds of the Term Loans solely to fund its general corporate and working capital requirements; and (b) not use the proceeds of the Term Loans, directly or indirectly, for the purpose of purchasing or carrying any Margin Stock, for the purpose of reducing or retiring any Indebtedness that was originally incurred to purchase or carry any Margin Stock, for the purpose of extending credit to any other Person for the purpose of purchasing or carrying any Margin Stock or for any other purpose that might cause any Term Loan to be considered a "purpose credit" within the meaning of Regulation T, U or X of the Federal Reserve Board; and (c) shall ensure that at any time during the term of this Agreement no proceeds of any Term Loan shall be on-lent or made otherwise available, directly or indirectly, to any member of the Group incorporated in Switzerland and/or having its registered office in Switzerland and/or qualifying as a Swiss resident pursuant to art 9 of the Swiss Withholding Tax Act, or, will otherwise be used or made available, directly or indirectly in each case in a manner which would constitute a "use of proceeds in Switzerland" (*Mittelverwendung in der Schweiz*) as interpreted by the Swiss Federal Tax Administration for purposes of Swiss Withholding Tax, unless and until a written confirmation or countersigned tax ruling application from the Swiss Federal Tax Administration has been obtained (in form and substance satisfactory to the Collateral Agent) confirming that such use of proceeds is permitted without payments under any Loan Document becoming subject to Swiss Withholding Tax. If requested by the Collateral Agent, Borrower shall complete and sign Part I of a copy of Federal Reserve Form G-3 referred to in Regulation U and deliver such copy to the Collateral Agent.

7.11 Further Assurances. Promptly upon the reasonable written request of the Collateral Agent, execute, acknowledge and deliver such further documents and do such other acts and things in order to effectuate or carry out more effectively the purposes of this Agreement and the other Loan Documents at its expense, including after the Tranche A Closing Date taking such steps as are reasonably deemed necessary or desirable by the Collateral Agent to maintain, protect and enforce its Lien, for the benefit of Lenders and the other Secured Parties,

on Collateral securing the Obligations created under the Collateral Documents and the other Loan Documents in accordance with the terms of the Collateral Documents and the other Loan Documents, subject to Permitted Liens.

7.12 Additional Collateral; Guarantors.

(a) From and after the Tranche A Closing Date, except as otherwise approved in writing by the Collateral Agent, each Credit Party (other than Borrower) shall, and Borrower and each other Credit Party shall cause each of its Subsidiaries (other than Excluded Subsidiaries), and Borrower may at its election cause any Excluded Subsidiaries (and the Collateral Agent and Lenders shall cooperate with any such election), to guarantee the Obligations (and to execute and deliver to the Collateral Agent a joinder to the Security Agreement (in the form attached thereto) and a joinder to the Intercompany Subordination Agreement), and each Credit Party (other than Borrower) shall, and Borrower and each other Credit Party shall cause each of its Subsidiaries (other than Excluded Subsidiaries) to, grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon (subject to Permitted Liens), and pledge to the Collateral Agent for the benefit of Lenders and the other Secured Parties, all of such Credit Party's or Subsidiary's properties and assets constituting Collateral, whether now existing or hereafter acquired or existing (including in connection with an Asset Acquisition), to secure such guaranty (and to execute and deliver to the Collateral Agent a joinder or pledge amendment to the Security Agreement (in the form(s) attached thereto), and a joinder to the Intercompany Subordination Agreement, as applicable); provided, that Borrower's and each such other Credit Party's obligations to take the foregoing actions with respect to any assets acquired as part of an Asset Acquisition and to cause any Subsidiaries incorporated, organized, formed or acquired (including by Stock Acquisition) after the Tranche A Closing Date, including all such Subsidiary's properties and assets (including in connection with an Asset Acquisition), to take the foregoing actions shall, in each case, be subject to the timing requirements of Section 5.13 or Section 5.14, as and only to the extent applicable. Additionally, from and after the Tranche A Closing Date, Borrower and each other Credit Party shall, and shall cause each of its Subsidiaries (other than Excluded Subsidiaries) to, grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon (subject to Permitted Liens, the limitations set forth herein and the limitations set forth in the other Loan Documents), and pledge to the Collateral Agent for the benefit of Lenders and the other Secured Parties, all of Borrower's and each such other Credit Party's or Subsidiary's properties and assets constituting Collateral, whether now existing or hereafter acquired or existing (including in connection with an Asset Acquisition), to secure the payment and performance in full of all of the Obligations (and to execute and deliver to the Collateral Agent a joinder or pledge amendment to the Security Agreement (in the form(s) attached thereto) and a joinder to the Intercompany Subordination Agreement, as applicable); provided, that Borrower and each such Credit Party's obligations to take the foregoing actions with respect to any assets acquired as part of an Asset Acquisition and to cause any Subsidiaries incorporated, organized, formed or acquired (including by Stock Acquisition) after the Tranche A Closing Date, including all such Subsidiary's properties and assets (including in connection with an Asset Acquisition), to take the foregoing actions shall, in each case, be subject to the timing requirements of Section 5.13 or Section 5.14, as and only to the extent applicable. Furthermore, except as otherwise approved in writing by the Collateral Agent, from and after the Tranche A Closing Date, Borrower and each other Credit Party shall, and shall cause each of its Subsidiaries (other than Excluded Subsidiaries) to, grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon (subject to Permitted Liens, the limitations set forth herein and the limitations set forth in the other Loan Documents), and pledge to the Collateral Agent for the benefit of Lenders and the other Secured Parties, all of the Equity Interests (other than Excluded Equity Interests) in each of its Subsidiaries (other than Excluded Subsidiaries) (and to execute and deliver to the Collateral Agent a joinder or pledge amendment to the Security Agreement (in the form(s) attached thereto) and a joinder to the Intercompany Subordination Agreement, as applicable). In connection with each pledge of certificated Equity Interests required under the Loan Documents, the Credit Parties shall deliver, or cause to be delivered, to the Collateral Agent, in addition to a pledge amendment to the Security Agreement (in the form attached thereto), such certificate(s) together with stock powers or assignments, as applicable, properly endorsed for transfer to the Collateral Agent or duly executed in blank, in each case reasonably satisfactory to the Collateral Agent. In connection with each pledge of uncertificated Equity Interests required under the Loan Documents, Borrower and the other Credit Parties shall deliver, or cause to be delivered, to the Collateral Agent, in addition to a pledge amendment to the Security Agreement (in the form attached thereto), an executed uncertificated stock control agreement among the issuer, the registered owner and the Collateral Agent, substantially in the form attached to the Security Agreement.

(b) In the event any Credit Party acquires any fee title to real estate in the U.S. with a fair market value (reasonably determined in good faith by a Responsible Officer of such Credit Party) in excess of $[***], unless otherwise agreed by the Collateral Agent, such Person shall execute or deliver, or cause to be executed or delivered, to the Collateral Agent, (i) within sixty (60) days after such acquisition, an appraisal complying with the Financial Institutions Reform, Recovery and Enforcement Act of 1989, (ii) within forty-five (45) days after receipt of notice from the Collateral Agent that such real estate is located in a Special Flood Hazard Area, Federal Flood Insurance, (iii) within sixty (60) days after such acquisition, a fully executed Mortgage, in form and substance reasonably satisfactory to the Collateral Agent, together with an A.L.T.A. lender's title insurance policy

issued by a title insurer reasonably satisfactory to the Collateral Agent, in form and substance (including any endorsements) and in an amount reasonably satisfactory to the Collateral Agent insuring that the Mortgage is a valid and enforceable first priority Lien on the respective property, free and clear of all defects, encumbrances and Liens (other than Permitted Liens), (iv) simultaneously with such acquisition, then-current A.L.T.A. surveys, certified to the Collateral Agent by a licensed surveyor sufficient to allow the issuer of the lender's title insurance policy to issue such policy without a survey exception and (v) within sixty (60) days after such acquisition, an environmental site assessment prepared by a qualified firm reasonably acceptable to the Collateral Agent, in form and substance reasonably satisfactory to the Collateral Agent.

(c) [Reserved]

(d) Notwithstanding anything to the contrary herein, in no event shall any Credit Party or any Subsidiary be required to enter into or deliver any foreign law-governed documents, file or record any documents or agreements (including any agreements relating to Intellectual Property) with any foreign Governmental Authority or take any other actions under foreign law with respect to Collateral held in any jurisdiction other than the United States, Switzerland, The Netherlands, Ireland and Japan or the jurisdiction of such Credit Party or Subsidiary, or, solely upon the occurrence and during the continuance of an Event of Default and by written notice to the Credit Parties, as the Collateral Agent may in its sole discretion otherwise require.

(e) In relation to any Credit Party that is incorporated in Ireland, a guarantee provided by such Credit Party under the terms of this Agreement does not apply to any liability to the extent that it would result in the guarantee constituting unlawful financial assistance within the meaning of section 82 of the Irish Companies Act, 2014.

7.13 Formation or Acquisition of Subsidiaries. If any Credit Party or any of its Subsidiaries at any time after the Tranche A Closing Date incorporates, organizes, forms or acquires (including by a Stock Acquisition) a Subsidiary (including by division), including any Intercompany Reorganization Subsidiary, other than an Excluded Subsidiary (a "**New Subsidiary**") or if any Credit Party makes an Asset Acquisition (including pursuant to the Intercompany Reorganization), such Credit Party shall (x) notify the Collateral Agent in writing no later than five (5) days prior to such incorporation, organization, formation or acquisition or Asset Acquisition (to the extent such incorporation, organization, formation or acquisition or Asset Acquisition will result in an entity becoming a Credit Party under the terms hereof) or the election of an Excluded Subsidiary to become a Credit Party, and (y) as promptly as practicable but in no event later than thirty (30) days (or such longer period as Collateral Agent may agree in its sole discretion) after such incorporation, organization, formation or acquisition or Asset Acquisition or if an Excluded Subsidiary elects to become a Credit Party: (a) without limiting the generality of clause (c) below, such Credit Party or Excluded Subsidiary, as applicable, will cause such New Subsidiary, Credit Party or Excluded Subsidiary, as applicable, to the extent required or applicable to execute and deliver to the Collateral Agent a joinder to the Security Agreement (in the form attached thereto), a joinder to the Intercompany Subordination Agreement and any relevant IP Agreement or other Collateral Documents, as applicable; (b) such Credit Party or Excluded Subsidiary, as applicable, will deliver (or cause to be delivered) to the Collateral Agent (i) true, correct and complete copies of the Operating Documents of such New Subsidiary or Excluded Subsidiary, as applicable, (ii) a Secretary's Certificate, certifying that the copies of the Operating Documents of such New Subsidiary or Excluded Subsidiary, as applicable, are true, correct and complete (such Secretary's Certificate to be in form and substance reasonably satisfactory to the Collateral Agent) and (iii) a good standing certificate for such New Subsidiary or Excluded Subsidiary, as applicable, certified by the Secretary of State (or the equivalent thereof) of its jurisdiction of organization, incorporation or formation (where applicable in the subject jurisdiction); and (c) such Credit Party or Excluded Subsidiary, as applicable, will cause such New Subsidiary or Excluded Subsidiary, as applicable, to satisfy all requirements contained in this Agreement (including Section 5.12) and each other Loan Document if and to the extent applicable to such New Subsidiary or Excluded Subsidiary, as applicable. The parties hereto agree that any New Subsidiary or Excluded Subsidiary, as applicable, shall constitute a Credit Party for all purposes hereunder as of the date of the execution and delivery of any joinder contemplated by clause (a) above or the date such New Subsidiary or Excluded Subsidiary, as applicable, provides any guarantee of the Obligations as contemplated by Section 5.12. Any document, agreement or instrument executed or issued pursuant to this Section 5.13 shall be a Loan Document.

7.14 Post-Closing Requirements. Borrower will, and will cause each of its Subsidiaries, as applicable, to take each of the actions set forth on Schedule 5.14 of the Disclosure Letter within the time period prescribed therefor on such schedule (or such longer period as the Collateral Agent may agree in its sole discretion), which shall include, among other things, that notwithstanding anything to the contrary in Section 3.2, the applicable

Credit Parties shall have until the date that is thirty (30) days following the Effective Date to deliver executed copies of the Japanese Security Documents further described on Schedule 5.14 of the Disclosure Letter.

(i) All representations and warranties and covenants contained in this Agreement and the other Loan Documents shall be deemed modified to the extent necessary to take the actions set forth on Schedule 5.14 of the Disclosure Letter within the time periods set forth therein, rather than elsewhere provided in the Loan Documents, such that to the extent any such action set forth in Schedule 5.14 of the Disclosure Letter is not overdue, the applicable Credit Party shall not be in breach of any representation or warranty or covenant contained in this Agreement or any other Loan Document applicable to such action for the period from the Tranche B Closing Date until the date on which such action is required to be fulfilled as set forth on Schedule 5.14 of the Disclosure Letter.

7.15 Environmental.

(a) Deliver to the Collateral Agent:

(i) as soon as practicable following receipt thereof, copies of all environmental audits, investigations, analyses and reports of any kind or character, whether prepared by personnel of Borrower or any of its Subsidiaries or by independent consultants, governmental authorities or any other Persons, with respect to significant environmental matters at any Facility or with respect to any Environmental Claims that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change;

(ii) promptly upon a Responsible Officer of any Credit Party or any of its Subsidiaries obtaining knowledge of the occurrence thereof, written notice describing in reasonable detail (A) any Release required to be reported to any federal, state, local or foreign governmental or regulatory agency under any applicable Environmental Laws that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, (B) any remedial action taken by (or on behalf of) any Credit Party or any other Person in response to (x) any Hazardous Materials Activities, the existence of which, individually or in the aggregate, could reasonably be expected to result in one or more Environmental Claims resulting in a Material Adverse Change, or (y) any Environmental Claims that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, and (C) any Credit Party's discovery of any occurrence or condition on any real property adjoining or in the vicinity of any Facility that could cause such Facility or any part thereof to be subject to any material restrictions on the ownership, occupancy, transferability or use thereof under any Environmental Laws, provided, that with respect to real property adjoining or in the vicinity of any Facility, Borrower shall have no duty to affirmatively investigate or make any efforts to become or stay informed regarding any such adjoining or nearby properties;

(iii) as soon as practicable following the sending or receipt thereof by any Credit Party, a copy of any and all written communications with respect to (A) any Environmental Claims that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, (B) any Release required to be reported to any federal, state, local or foreign governmental or regulatory agency that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, and (C) any request for information from any Governmental Authority that suggests such Governmental Authority is investigating whether any Credit Party or any of its Subsidiaries may be potentially responsible for any Hazardous Materials Activity that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change; and

(iv) prompt written notice describing in reasonable detail (A) any proposed acquisition of stock, assets, or property by Borrower or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to affect the ability of Borrower or any of its Subsidiaries to maintain in full force and effect all material Governmental Approvals required under any Environmental Laws for their respective operations, and (B) any proposed action to be taken by Borrower or any of its Subsidiaries to modify current operations, in each case of sub-clause (A) and (B) above, that, individually or taken together with any other such proposed acquisitions or actions, expose Borrower or any of its Subsidiaries to, or result in, Environmental Claims that could reasonably be expected to result in a Material Adverse Change.

(b) Each Credit Party shall, and shall cause each of its Subsidiaries to, promptly take any and all actions reasonably necessary to (i) cure any violation of applicable Environmental Laws by Borrower or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse

Change, and (ii) make an appropriate response to any Environmental Claim against Borrower or any of its Subsidiaries and discharge any obligations it may have to any Person thereunder where failure to do so, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change.

7.16 Inventory; Returns; Maintenance of Properties. Keep all Inventory which constitutes Product in good and marketable condition, free from material defects and otherwise keep all Inventory which constitutes Product in compliance with all applicable FDA Laws, EU Laws, Japanese Laws, and all other foreign equivalents, as applicable, except where the failure to do so could not reasonably be expected to result in a Material Adverse Change. Returns and allowances between a Credit Party and its Account Debtors shall follow such Credit Party's customary practices. Each Credit Party will, and will cause each of its Subsidiaries to, maintain or cause to be maintained in good repair, working order and condition, ordinary wear and tear, casualty and condemnation excepted, all material tangible properties used or useful in its respective business, and from time to time will make or cause to be made all commercially reasonable repairs, renewals and replacements thereof except where failure to do so could not reasonably be expected to result in a Material Adverse Change.

7.17 Regulatory Obligations; Maintenance of Regulatory Approval or Licensure; Licensure and Designation; Manufacturing, Marketing and Distribution.

(a) (i) Comply in all material respects with Governmental Authority post-marketing approval, authorization, clearance, or licensure requirements and commitments and monitoring for Product in the Territory, as applicable; (ii) maintain all Regulatory Approvals or Licensures required or otherwise material to manufacture, market and distribute Product in the Territory; (iii) with respect to each calendar year commencing with calendar year 2022, use commercially reasonable efforts to maintain manufacturing capacity to sell Product in the U.S. in sufficient quantities to satisfy or exceed either (x) the net sales amount for such calendar year set forth in the Product Revenue Forecast or (y) the expected needs of patients with the disease or condition for which Product was designated as an Orphan Drug for such calendar year, as reasonably determined by a Responsible Officer of Borrower in good faith (provided such calendar year occurs during the full term of Orphan Drug exclusive approval granted under 21 C.F.R. § 316.34); unless, however, that, with respect to any such calendar year, if the net sales amount for such calendar year set forth in the Product Revenue Forecast would not be sufficient to meet reasonably anticipated demand for such calendar year, in which case, maintain manufacturing capacity to sell Product in the U.S. in sufficient quantities to satisfy or exceed the needs of patients with the disease or condition for which Product was designated as an Orphan Drug for such calendar year, except where the failure to do so could not reasonably be expected to result in a Material Adverse Change; and (iv) manufacture Product in a manner that supports Orphan Drug designation under EU Law or Japanese Law, as applicable.

(b) Deliver to the Collateral Agent, as promptly as practicable after a Responsible Officer of Borrower shall have obtained knowledge thereof, written notice describing in reasonable detail any instance where the Credit Party or any of its Subsidiaries has a reasonable expectation that there are grounds for imposition of a clinical hold, as described in 21 C.F.R. § 312.42, or withdrawal of an Investigational Device Exemption, as defined in 21 C.F.R. § 812.30, in each case with respect to Product.

7.18 Material Contracts; Collateral Documents. Comply (a) with all of its covenants, agreements, undertakings and obligations arising under, and fulfill all of its obligations under, each Material Contract to which it is a party, except as could not reasonably be expected to have a Material Adverse Change, and (b) in all respects with all of its covenants, agreements, undertakings and obligations arising under, and fulfill all of its obligations under, each Collateral Document to which it is a party.

8 NEGATIVE COVENANTS

Each Credit Party covenants and agrees that, until payment in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), such Credit Party shall not, and shall cause each of its Subsidiaries not to:

8.1 Dispositions. Convey, sell, lease, transfer, exchange, assign, covenant not to sue, enter into a coexistence agreement, exclusively or nonexclusively license out, or otherwise dispose of (including any sale-leaseback or any transfer of assets pursuant to a plan of division), directly or indirectly and whether in one or a series of transactions (collectively, "**Transfer**"), all or any part of its properties or assets constituting Collateral (including, for the avoidance of doubt, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party) or any Company IP that does not constitute Collateral under the Loan Documents but is related to any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of

Product in the Territory; except, in each case of this Section 6.1, for Permitted Transfers not otherwise expressly prohibited under Section 6.6(b).

8.2 Fundamental Changes; Location of Collateral.

(a) Without at least ten (10) days' prior written notice to the Collateral Agent (or, solely with respect to the Intercompany Reorganization, at least two (2) Business Days' prior written notice to the Collateral Agent), solely in the case of a Credit Party: (i) change its jurisdiction of organization, incorporation or formation, (ii) change its organizational structure or type, (iii) change its legal name, or (iv) change any organizational number (if any) assigned by its jurisdiction of organization, incorporation or formation.

(b) Maintain its primary Books at or deliver any Collateral with a fair market value (reasonably determined in good faith by a Responsible Officer of Borrower), individually or together with any other Collateral, in excess of $[***] to, one or more mortgaged or leased locations or one or more warehouses, processors or bailees, as applicable, unless, subject to the timing requirements of Section 5.14 (solely with respect to such locations, warehouses, processors or bailees where such Books or Collateral is located on the Tranche A Closing Date or during the 60-day period following the Tranche A Closing Date), such Credit Party uses commercially reasonable efforts to obtain a Collateral Access Agreement for such mortgaged or leased location or such warehouse, processor or bailee governing such Books or such Collateral (as applicable), in form and substance reasonably satisfactory to the Collateral Agent, to the extent such Collateral is located in the United States. Notwithstanding anything to the contrary herein, such obligation to deliver Collateral Access Agreements will not apply to any inventory or assets while in transit.

(c) Establish or maintain any bank account other than the bank accounts set forth on Schedule 6.2(c) of the Disclosure Letter (which bank accounts constitute all of the deposit accounts, securities accounts or other similar accounts maintained by any Credit Party on the Tranche B Closing Date), unless (i) in the case of any bank account that is not an Excluded Account, the Collateral Agent is provided at least ten (10) Business Days' written notice from such Credit Party prior to the establishment or maintenance of such account and (ii) to the extent such account is established or maintained in the United States, such account is made subject to a Control Agreement in accordance with Section 5.5 hereof.

(d) Maintain cash in any bank account located in Japan or the Netherlands that would be in excess of the amount of cash that would be appropriate for (i) the continued operations in the ordinary course of business in Japan or the Netherlands, as applicable, and (ii) such other business needs in Japan or the Netherlands (including, for the avoidance of doubt, as a result of the Intercompany Reorganization), as applicable, as reasonably determined by a Responsible Officer of the Borrower consistent with prudent cash management practices, and not with an intent to hinder the security interests available under the Loan Documents.

(e) Take any action or engage in any transaction (or series of actions or transactions), whether by reorganization, sale of assets, merger, dissolution, amendment of Operating Documents or otherwise (including, for the avoidance of doubt, the Intercompany Reorganization), the primary purpose of which is to evade, avoid or seek to avoid the performance or observance of any of the covenants, agreements or obligations of any Credit Party under the Loan Documents (including under the Collateral Documents).

8.3 Mergers, Acquisitions, Liquidations or Dissolutions.

(a) Merge, divide itself into two (2) or more entities, consolidate, liquidate or dissolve, or permit any of its Subsidiaries to merge, divide itself into two (2) or more entities, consolidate, liquidate or dissolve with or into any other Person, except that:

(i) (x) any Subsidiary of Borrower may merge or consolidate with or into a Credit Party, provided that the Credit Party is the surviving entity and (y) any Subsidiary of Borrower may liquidate or dissolve, provided that prior to or concurrent with such liquidation or dissolution, the remaining assets of such Subsidiary shall be distributed to another Subsidiary, provided, further, that if the liquidating or dissolving Subsidiary is a Credit Party, the assets of such Subsidiary shall be distributed to an existing or newly-formed Credit Party,

(ii) any Subsidiary of Borrower may merge or consolidate with any other Subsidiary of Borrower, provided that if any party to such merger or consolidation is a Credit Party then either (x) such Credit Party is the surviving entity or (y) the surviving or resulting entity executes and delivers to the Collateral Agent a joinder to the Security Agreement in the form attached thereto, a joinder to the Intercompany Subordination Agreement and any relevant IP Agreement or other Collateral Documents, as

applicable, and otherwise satisfies the requirements of Section 5.13 substantially contemporaneously with completion of such merger or consolidation;

(iii) any Subsidiary of Borrower may divide itself into two (2) or more entities or be dissolved or liquidated, provided that if such Subsidiary is a Credit Party, the properties and assets of such Subsidiary are allocated or distributed to an existing or newly-formed Credit Party;

(iv) any Subsidiary that is not a Credit Party may be dissolved or liquidated; provided that (x) all of its assets and business are transferred to a Credit Party and (y) neither such dissolution or liquidation nor such transfer could reasonably be expected to result in a Material Adverse Change; and

(v) any Permitted Acquisition or Permitted Investment may be structured as a merger or consolidation.

(b) make, or permit any of its Subsidiaries to make, Acquisitions outside the ordinary course of business, including any purchase of all or substantially all of the assets of, or any division or line of business of, any other Person, other than Permitted Acquisitions or Permitted Investments. For the avoidance of doubt, nothing in this Section 6.3 shall prohibit the completion of the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such merger, division, consolidation, liquidation or dissolution is described in Exhibit F hereto) or any Credit Party or its Subsidiaries from entering into in-licensing agreements; provided that, in each case of this clause (b), no Indebtedness not otherwise permitted hereunder is incurred or assumed in connection therewith.

8.4 Indebtedness. Directly or indirectly, create, incur, assume or guaranty, or otherwise become or remain directly or indirectly liable with respect to, any Indebtedness (including any Indebtedness consisting of obligations evidenced by a bond, debenture, note or other similar instrument) that is not Permitted Indebtedness; provided, however, that the accrual of interest, the accretion of accreted value and the payment of interest in the form of additional Indebtedness shall not be deemed to be an incurrence of Indebtedness for purposes of this Section 6.4.

8.5 Encumbrances. Except for Permitted Liens, (i) create, incur, allow, or suffer to exist any Lien on any Collateral (including, for the avoidance of doubt, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party), or (ii) permit (other than pursuant to the terms of the Loan Documents) any material portion of the Collateral (including, for the avoidance of doubt, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party) not to be subject to the first priority security interest granted in the Loan Documents or otherwise pursuant to the Collateral Documents, in each case of this clause (ii), other than as a direct result of any action by the Collateral Agent or any Lender or failure of the Collateral Agent or any Lender to perform an obligation thereof under the Loan Documents.

8.6 No Further Negative Pledges; Negative Pledge.

(a) No Credit Party nor any of its Subsidiaries shall enter into any agreement, document or instrument directly or indirectly prohibiting (or having the effect of prohibiting) or limiting the ability of such Credit Party or Subsidiary to create, incur, assume or suffer to exist any Lien upon any Collateral, whether now owned or hereafter acquired, in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, with respect to the Obligations or under the Loan Documents, in each case of this Section 6.6, other than Permitted Negative Pledges.

(b) Notwithstanding Section 6.1 and except pursuant to the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such transfer, Indebtedness or other transaction is described in Exhibit F hereto), no Credit Party will Transfer, or create, incur, allow or suffer to exist any Lien on, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party, except for: (i) Permitted Liens; (ii) transfers between or among Credit Parties, provided that any and all steps as may be reasonably required to be taken in order to create and maintain a first priority security interest in and Lien upon such Equity Interests in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, are taken contemporaneously with the completion of any such transfer; and (iii) sales, assignments, transfers, exchanges or other dispositions to qualify directors if required by Requirements of Law or otherwise permitted under this Agreement, provided that such sale, assignment, transfer, exchange or other disposition shall be for the minimum number of Equity Interests as are necessary for such qualification under Requirements of Law.

8.7 Maintenance of Collateral Accounts. Maintain any Collateral Account except in accordance with the terms of Section 5.5 hereof.

8.8 Distributions; Investments.

(a) Pay any dividends or make any distribution or payment on, or redeem, retire or repurchase any of its Equity Interests, except, in each case of this Section 6.8, for Permitted Distributions, Permitted Transactions and Permitted Equity Derivatives.

(b) Directly or indirectly make any Investment other than Permitted Acquisitions and Permitted Investments.

For the avoidance of doubt, nothing in this Section 6.8 shall prohibit any Credit Party or its Subsidiaries from entering into in-licensing agreements; provided, however, that, in each case, no Indebtedness that is not Permitted Indebtedness is incurred or assumed in connection therewith.

8.9 No Restrictions on Subsidiary Distributions. No Credit Party nor any of its Subsidiaries shall enter into any agreement, document or instrument directly or indirectly prohibiting (or having the effect of prohibiting) or limiting the ability of any Subsidiary of Borrower to (a) pay dividends or make any other distributions on any of such Subsidiary's Equity Interests owned by Borrower or any other Subsidiary of Borrower, (b) repay or prepay any Indebtedness owed by such Subsidiary to Borrower or any other Subsidiary of Borrower, (c) make loans or advances to Borrower or any other Subsidiary of Borrower, or (d) transfer, lease or license any Collateral to Borrower or any other Subsidiary of Borrower, except, in each case of this Section 6.9, for Permitted Subsidiary Distribution Restrictions.

8.10 Subordinated Debt; Permitted Convertible Indebtedness. Notwithstanding anything to the contrary in this Agreement:

(a) Make or permit any voluntary or optional prepayment or repayment of the outstanding principal amount of any Subordinated Debt other than in accordance with the express terms of a subordination, intercreditor or other similar agreement relating to such Subordinated Debt, if any, that is in form and substance reasonably satisfactory to the Collateral Agent;

(b) Make or permit any payment of interest (including accrued and unpaid interest) in cash on or in respect of any Subordinated Debt at any time that a Default or Event of Default shall have occurred and be continuing other than in accordance with the express terms of a subordination, intercreditor or other similar agreement relating to such Subordinated Debt, if any, that is in form and substance reasonably satisfactory to the Collateral Agent; or

(c) Amend, restate, supplement or otherwise modify any terms, conditions or other provisions of any Subordinated Debt, or any agreement, instrument or other document relating thereto, in any manner which would contravene in any respect any of the foregoing or adversely affect the payment or priority subordination thereof (as applicable) to Obligations owed to Lenders, in each case except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt, if any, is subject, without the prior written consent of the Collateral Agent (in its sole discretion).

(d) For the avoidance of doubt, no Credit Party shall, and each Credit Party shall cause each of its Subsidiaries not to, directly or indirectly, create, incur, assume or guaranty, or otherwise become directly or indirectly liable with respect to, any Subordinated Debt except as otherwise expressly permitted hereunder.

(e) Make or permit any voluntary or optional prepayment or repayment of the outstanding amount of any Indebtedness under the Royalty Revenue Contract or other Royalty Revenue Documents (including any principal or interest), exercise or consummate any Call Option (as defined in the Royalty Revenue Contract) or amend, restate, supplement or otherwise modify any terms, conditions or other provisions of such Indebtedness or the Royalty Revenue Contract or other Royalty Revenue Documents in any manner which would contravene in any respect any of the foregoing or adversely affect the payment or priority subordination thereof (as applicable) to Obligations owed to Lenders, in each case other than to the extent permitted by the express terms of the OrbiMed Intercreditor Agreement.

(f) Make or cause any of its Subsidiaries to make (or exercise any option with respect thereto), directly or indirectly, any payment, prepayment, repurchase or redemption for cash of any Indebtedness

under the 2028 Convertible Notes (or the indenture relating thereto) or any Permitted Convertible Indebtedness unless and until all of the Obligations are paid in full; provided, however, that nothing in this Section 6.10(f) shall prohibit or otherwise restrict (i) any Permitted Convertible Redemption or other Permitted Transaction, (ii) scheduled cash interest payments, (iii) required cash payments of accrued but unpaid interest upon repurchase or redemption thereof, (iv) cash payments in lieu of any fractional share issuable upon conversion thereof, (v) required cash payments of any amounts due upon the scheduled maturity thereof using Equity Cash Proceeds, or (vi) any ordinary course fees or other expenses in connection therewith.

8.11 Amendments or Waivers of Organizational Documents. Amend, restate, supplement or otherwise modify, or waive, any provision of its Operating Documents in a manner that would reasonably be expected to result in a Material Adverse Change.

8.12 Compliance.

(a) Become an "investment company" under the Investment Company Act of 1940, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose;

(b) With respect to any ERISA Affiliate, cause or suffer to exist (i) any event that would result in the imposition of a Lien under ERISA on any assets or properties of any Credit Party or a Subsidiary of a Credit Party with respect to any Plan or (ii) any other ERISA Event that, in the case of clauses (i) and (ii) above, could reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change.

(c) Permit the occurrence of any other event with respect to any present pension, profit sharing or deferred compensation plan which could reasonably be expected to result in a Material Adverse Change.

8.13 Compliance with Sanctions and Anti-Money Laundering Laws .

(a) The Collateral Agent and each Lender hereby notifies each Credit Party that pursuant to the requirements of Sanctions and Anti-Money Laundering Laws, and such Person's policies and practices, the Collateral Agent and each Lender is required to obtain, verify and record certain information and documentation that identifies each Credit Party and its principals, which information includes the name and address of each Credit Party and its principals and such other information that will allow the Collateral Agent and each Lender to identify such party in accordance with Sanctions and Anti-Money Laundering Laws.

(b) No Credit Party will, nor will any Credit Party permit any of its Subsidiaries or controlled Affiliates to, directly or indirectly, knowingly enter into any documents or contracts with any Sanctioned Person.

(c) Each Credit Party shall notify the Collateral Agent and each Lender in writing promptly (but in any event within five (5) Business Days after) a Responsible Officer of any Credit Party becomes aware that any Credit Party or any Subsidiary or Affiliate of any Credit Party is a Sanctioned Person or that any Credit Party or any Subsidiary or Affiliate of any Credit Party or any of their respective directors, officers or employees (i) is convicted on, (ii) pleads *nolo contendere* to, (iii) is indicted on, or (iv) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering.

(d) No Credit Party will, nor will any Credit Party permit any of its Subsidiaries or Affiliates to, directly or indirectly, (i) conduct any prohibited business or engage in any prohibited investment, activity, transaction or deal with any Sanctioned Person, including the making or receiving of any contribution of funds, goods or services to or for the benefit of any Sanctioned Person, (ii) deal in, or otherwise engage in any investment, activity, transaction or dealing relating to, any property or interests in property blocked pursuant to Sanctions, or (iii) engage in or conspire to engage in any investment, activity, transaction or dealing that evades or avoids or violates, or has the purpose of evading or avoiding, or attempts to violate, any of prohibitions under Sanctions or Anti-Money Laundering Laws.

(e) Borrower will not, directly or, to the Knowledge of Borrower, indirectly (including through an agent or any other Person), use any of the proceeds of any Credit Extension, or lend, contribute or otherwise make available such proceeds of any Credit Extension to any Subsidiary, joint venture partner or other Person, (i) for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation in any respect of the FCPA, UKBA or any other applicable anti-corruption laws, (ii) in

violation in any respect of any Anti-Money Laundering Laws, (iii) in violation of Sanctions or (iv) in violation in any material respect of Export or Import Laws.

(f) Borrower shall not, and shall not permit any of its Subsidiaries to, directly or, to the Knowledge of Borrower, indirectly, fund all or part of any repayment of the Credit Extensions or other payments under this Agreement out of proceeds derived from criminal activity or activity or transactions in violation in any respect of the FCPA, UKBA, or any applicable anti- corruption laws, Export or Import Laws, Anti-Money Laundering Laws or Sanctions, or that would otherwise cause any Person (including any Person participating in the Credit Extensions, whether as agent, lender, sponsor, underwriter, advisor, investor, or otherwise) to be in violation in any respect of the FCPA, UKBA, or any applicable anti-corruption laws, Export or Import Laws, Anti-Money Laundering Laws or Sanctions.

8.14 Material Contracts.

(a) Waive, amend, cancel or terminate, exercise or fail to exercise, any material rights constituting or relating to any of the Material Contracts or (b) breach, default under, or take any action or fail to take any action that, with the passage of time or the giving of notice or both, would constitute a default or event of default under any of the Material Contracts, in each case of this Section 6.14, which, individually or taken together with any other such waivers, amendments, cancellations, terminations, exercises or failures, could reasonably be expected to have a Material Adverse Change.

(b) From and after the Tranche A Closing Date, enter into any Manufacturing Agreement (excluding, for the avoidance of doubt, any Manufacturing Agreement listed on Schedule 12.1 of the Disclosure Letter and all amendments, restatements, extensions, supplements or other modifications thereto) relating to active pharmaceutical ingredients or finished products relating to ARIKAYCE® (i) under which a default or of which a termination could interfere with the Collateral Agent's or any Lender's right to sell or lease, assign, license out, convey, transfer or grant options to purchase any Collateral, (ii) that cannot be collaterally assigned to secure the Obligations, (iii) that cannot be assigned to a purchaser in a foreclosure sale of all or any portion of the Collateral (subject to assumption by the purchaser of all obligations under such Material Contract) in the event of any exercise of rights or remedies under the Loan Documents, (iv) that contains provisions that restrict or penalize the granting of a security interest in or Lien on such Material Contract or the assignment of such Material Contract upon the sale or other disposition of all or a portion of a product to which such Material Contract relates, or (v) that does not permit the disclosure of information to be provided thereunder to the Collateral Agent and Lenders, to any purchaser or prospective purchaser in a foreclosure sale of all or any portion of the Collateral, to any assignee or prospective assignee of Borrower or any of its Subsidiaries or to any company in the business of purchasing or financing financial assets, in each case without using its commercially reasonable efforts to ensure such Manufacturing Agreement does not contain the terms listed in sub-clauses (i) to (v) above.

(c) Without limitation to any other provision herein or in any other Loan Document, until all of the Obligations have been paid, performed or discharged in full and Borrower has no further right to obtain any Credit Extension hereunder, make, and such Credit Party shall cause its Affiliates not to make, any payment (whether of principal, interest or otherwise) on account of the Obligations (as such term is defined in the Royalty Revenue Contract) of the Purchaser, other than (i) any payments due and payable to OrbiMed pursuant to the Royalty Revenue Documents as in effect on the date of this Agreement and taking into account any modification thereto permitted under Section 5.2 of the OrbiMed Intercreditor Agreement, but excluding in all cases, for the avoidance of doubt, any advance payment, prepayment or similar payment that Borrower has the right, but not the obligation, to make pursuant to the Royalty Revenue Documents or that Borrower agrees to make pursuant to any amendment, restatement, amendment and restatement, supplement or modification thereto or any approval, consent or waiver in respect thereof, (ii) any indemnity payment due and payable to OrbiMed pursuant to the Royalty Revenue Documents as in effect on the date of this Agreement, (iii) any payment of any underpayment due and payable to OrbiMed pursuant to the Royalty Revenue Documents as in effect on the date of this Agreement or any payment of out-of-pocket expenses of OrbiMed by Borrower or any of its Subsidiaries pursuant to the Royalty Revenue Documents as in effect on the date of this Agreement, or (iv) any reimbursement of documented costs reasonably incurred by OrbiMed related to perfection and enforcement and due and payable to OrbiMed pursuant to the Royalty Revenue Documents as in effect on the date of this Agreement, except, in each case of in each case of sub-clauses (i) through (iv) above so long as any such payment or reimbursement is not in contravention of any other term or condition set forth in this Agreement or any other Loan Document.

8.15 Fiscal Unity. With respect to a Credit Party incorporated under Dutch law, create or become a member of a fiscal unity (*fiscale eenheid*) for Dutch corporate income tax or value added tax purposes (unless such

fiscal unity should consist solely of Credit Parties), unless a fiscal unity for value added tax purposes is imposed by the Dutch tax authorities.

9 EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an " **Event of Default**") under this Agreement:

9.1 Payment Default. Any Credit Party fails to (a) make any payment of any principal of the Term Loans when and as the same shall become due and payable, whether at the due date thereof (including pursuant to Section 2.2(c)) or at a date fixed for prepayment (whether voluntary or mandatory) thereof or by acceleration thereof or otherwise, or (b) within five (5) Business Days after the same becomes due and payable, any payment of interest or premium pursuant to Section 2.2, including any applicable Additional Consideration, Makewhole Amount, Prepayment Premium, Exit Fee, or any other Obligations (which such five (5) Business Day cure period shall not apply to any such payments due on the Term Loan Maturity Date or such earlier date pursuant to Section 2.2(c)(ii) or Section 2.2(c)(iii) hereof or the date of acceleration pursuant to Section 8.1(a) hereof). A failure to pay any such interest, premium or Obligations pursuant to the foregoing clause (b) prior to the end of such five (5) Business Day-period shall not constitute an Event of Default (unless such payment is due on the Term Loan Maturity Date or such earlier date pursuant to Section 2.2(c)(ii) or Section 2.2(c)(iii) hereof or the date of acceleration pursuant to Section 8.1(a) hereof).

9.2 Covenant Default.

(a) The Credit Parties: (i) fail or neglect to perform any obligation in Sections 5.3, 5.4, 5.5, 5.10, 5.13, 5.14 or 5.17(a) or (ii) violate or breach any covenant or agreement in Section 6; or

(b) The Credit Parties fail or neglect to perform any obligation in Section 5.2, 5.6, 5.7 or 5.17(b), such failure or neglect is capable of being cured and continues for ten (10) days, after the earlier of the date on which (i) a Responsible Officer of any Credit Party becomes aware of such failure or neglect and (ii) written notice thereof shall have been given to Borrower by the Collateral Agent or any Lender. Cure periods provided under this Section 7.2(b) shall not apply, among other things, to any of the covenants referenced in clause (a) above.

(c) The Credit Parties fail or neglect to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents on its part to be performed, kept or observed and such failure or neglect is capable of being cured and continues for twenty (20) days, after the earlier of the date on which (i) a Responsible Officer of any Credit Party becomes aware of such failure or neglect and (ii) written notice thereof shall have been given to Borrower by the Collateral Agent or any Lender. Cure periods provided under this Section 7.2(c) shall not apply, among other things, to any of the covenants referenced in clause (a) or (b) above.

9.3 Withdrawal Event; Material Adverse Change. A (a) Withdrawal Event occurs with respect to ARIKAYCE® in the United States, or (b) a Material Adverse Change occurs; provided, however, that, notwithstanding anything in this Agreement to the contrary, if any of the formations, transfers, contributions, Indebtedness, transactions or arrangements described in Exhibit F hereto could reasonably be expected to result in a Material Adverse Change, the parties hereto agree to cooperate in good faith to modify any such formation, transfer, contribution, Indebtedness, transaction or arrangement in a commercially reasonable manner in order to resolve or cure any such Material Adverse Change; provided, further, that if the parties hereto cannot mutually agree on such resolution or cure within twenty (20) days (or, if such Material Adverse Change cannot in a diligent manner be resolved or cured within such 20-day period, such longer period as the parties hereto mutually agree) after any party hereto notifies the other parties hereto in writing of the occurrence of such Material Adverse Change, such Material Adverse Change shall be deemed an Event of Default hereunder and nothing herein shall preclude, prevent, bar or impede the Collateral Agent or any Lender from exercising any and all of its rights and remedies hereunder with respect to such Material Adverse Change.

9.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of any Credit Party or of any entity under the control of any Credit Party (including a Subsidiary) in excess of $[***] on deposit or otherwise maintained with the Collateral Agent, or (ii) a notice of lien or levy is filed against any of material portion of Collateral by any Governmental Authority, and the same under sub-clauses (i) or (ii) above is not, within thirty (30) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); or

(b) (i) Any material portion of Collateral is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower and its Subsidiaries from conducting any material part of their business, taken as a whole.

9.5 Insolvency.

(a) An involuntary proceeding shall be commenced or an involuntary petition shall be filed in a court of competent jurisdiction seeking: (i) relief in respect of any Credit Party, or of a substantial part of the property of any Credit Party, under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership, examinership or similar law; (ii) the appointment of a receiver, trustee, custodian, sequestrator, conservator, examiner or similar official for any Credit Party or for a substantial part of the property or assets of any Credit Party; or (iii) the winding-up or liquidation of any Credit Party, and such proceeding or petition shall continue undismissed or unstayed for sixty (60) days or an order or decree approving or ordering any of the foregoing shall be entered; or

(b) Any Credit Party shall: (i) voluntarily commence any proceeding or file any petition seeking relief under Title 11 of the United States Code, as now constituted or hereafter amended, or any other existing or future federal, state or foreign bankruptcy, insolvency, receivership, examinership, relief of debtors or similar law; (ii) consent to the institution of, or fail to contest in a timely and appropriate manner, any proceeding or the filing of any petition described in clause (a) above; (iii) apply for or consent to the appointment of a receiver, interim receiver, receiver and manager, administrative receiver, trustee, custodian, sequestrator, conservator, examiner or similar official for any Credit Party or for any portion of the property or assets of any Credit Party; (iv) file an answer admitting the material allegations of a petition filed against it in any such proceeding; (v) make a general assignment for the benefit of creditors, or enter into a composition, compromise, assignment or arrangement with any of its creditors (whether by way of a voluntary arrangement, schedule of arrangement, deed of compromise or otherwise); (vi) become unable, admit in writing its inability or fail generally to pay its debts as they become due; (vii) take any action for the purpose of effecting any of the foregoing; or (viii) wind up or liquidate (except as otherwise expressly permitted hereunder);

(c) Any Credit Party shall be generally not paying its debts as such debts become due or shall admit in writing its inability to pay its debts generally;

(d) A receiver, interim receiver, receiver and manager, trustee, administrator, administrative receiver, custodian, examiner or other similar official is appointed, either voluntarily or involuntarily, to or in respect of any Credit Party or the whole or any part of the property, assets or undertaking of any Credit Party;

(e) There shall be commenced against any Credit Party a case, proceeding or other action seeking issuance of a warrant of attachment, execution, distraint or similar process against (i) all or a substantial portion of its assets or (ii) a material portion of the Collateral, which results in the entry of an order for any such relief which shall not have been vacated, discharged, stayed, satisfied or bonded pending appeal within sixty (60)days from the entry thereof;

(f) Any Credit Party or any Subsidiary shall be insolvent as defined in any statute of the Bankruptcy Code or in the fraudulent conveyance or fraudulent transfer statutes of the Commonwealth of Virginia or other applicable jurisdiction of organization; or

(g) An affirmative vote by the applicable Board of Directors to commence any case, proceeding or other action described in clause (a) above or any other action by any Credit Party or any Subsidiary to otherwise cause, consent to, approve or acquiesce in any of the acts described in clauses (a) through (f) above.

(h) Without limiting the generality of clauses (a) through (g) above, in relation to any Credit Party incorporated in Switzerland and/or having its registered office in Switzerland, the (insolvency) terms referred to above shall include any steps and actions under Swiss law which are analogous to those described above, in particular, without limitation of the scope of clauses (a) through (g) above, in respect of the following proceedings: "*Drohende Zahlungsunfähigkeit* (threat of illiquidity/insolvency) within the meaning of art. 725 and 820 of the Swiss Code of Obligations, " *Zahlungsunfähigkeit*" (inability to pay its debts), "*Zahlungseinstellung*" (suspending making payments), "*hälftiger Kapitalverlust*" or "*Überschuldung*" within the meaning of art. 725a, 725b and art. 820 of the Swiss Code of Obligations (half of the share capital and the legal reserves not covered; over-indebtedness, i.e. liabilities not covered by the assets), duty of filing of the balance sheet with the judge due to over-indebtedness or insolvency pursuant to art. 725b and art. 820 of the Swiss Code of Obligations, "*Nachlassverfahren*" (composition with creditors) including in particular "*Nachlassstundung*" (moratorium) and proceedings regarding "*Nachlassvertrag*" (composition agreements) and "*Notstundung*" (emergency moratorium), "*Fälligkeitsaufschub*" (postponement of maturity of indebtedness), "*Konkursaufschub / Gesellschaftsrechtliches*

Moratorium" (postponement of the opening of bankruptcy; moratorium proceedings) pursuant to art. 725, 725a, 725b and 820 CO, notification of the courts under these provisions and actions for "*Auflösung* / *Liquidation*" (dissolution/liquidation).

9.6 Other Agreements.

(a) Any Credit Party fails to pay any Indebtedness (including any Indebtedness represented by any Loan Note and excluding the Indebtedness represented by this Agreement and the other Loan Documents), in each case (i) within any applicable grace period after such payment is due and payable (including at final maturity) or after the acceleration of any such Indebtedness by the holder(s) thereof because of a breach or default, and (ii) if the total amount of such Indebtedness unpaid or accelerated exceeds, individually or together with any other such unpaid or accelerated amounts, $[***].

(b) (i) A Put Option (as defined in the Royalty Revenue Contract) or a Change in Control Purchase Option (as defined in the Royalty Revenue Contract) or a Call Option (as defined in the Royalty Revenue Contract) (including a Change of Control Call Option (as defined in the Royalty Revenue Contract)), has been exercised under the terms of the Royalty Revenue Contract or other Royalty Revenue Document, (ii) upon the occurrence of a Put Option Event (as defined in the Royalty Revenue Contract) or any other event that would give OrbiMed the right to require Borrower to pay the Buy-Out Price (as defined in the Royalty Revenue Contract), or (iii) upon any prepayment, payment, repurchase, redemption, conversion, exchange or similar action of any Permitted Convertible Indebtedness not expressly permitted under this Agreement.

9.7 Judgments. One or more final, non-appealable judgments, orders, or decrees for the payment of money in an amount in excess of $[***] (but excluding any final judgments, orders, or decrees for the payment of money that are covered by independent third-party insurance as to which liability has not been denied by such insurance carrier or by an indemnification claim against a solvent and unaffiliated Person that is not a Credit Party as to which such Person has not denied liability for such claim), shall be rendered against one or more Credit Parties and the same are not, within thirty (30) days after the entry thereof, discharged or execution thereof stayed or bonded pending appeal, or such judgments are not discharged prior to the expiration of any such stay.

9.8 Misrepresentations. Any Credit Party or any Person acting for any Credit Party makes or is deemed to make any representation or warranty now or later in, or pursuant to, this Agreement or any other Loan Document, and such representation or warranty is incorrect in any material respect (or, to the extent any such representation or warranty is qualified by materiality or Material Adverse Change, in any respect) when made or deemed to be made.

9.9 Loan Documents; Collateral. Any material provision of any Loan Document shall for any reason cease to be valid and binding on or enforceable against any Credit Party, or any Credit Party shall so state in writing or bring an action to limit its obligations or liabilities thereunder; or any Collateral Document shall for any reason (other than pursuant to the terms thereof) cease to create a valid security interest in any material portion of the Collateral purported to be covered thereby or such security interest shall for any reason (other than pursuant to the terms of the Loan Documents) cease to be a perfected and first priority security interest in any material portion of the Collateral subject thereto, subject only to Permitted Liens, in each case, other than as a direct result of any action by the Collateral Agent or any Lender or failure of the Collateral Agent or any Lender to perform an obligation thereof under the Loan Documents.

9.10 ERISA Event. An ERISA Event occurs that, individually or taken together with any other ERISA Events, results or could reasonably be expected to result in a Material Adverse Change, or the imposition of a Lien under Section 303(k) of ERISA on any Collateral that could reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change.

9.11 Intercreditor Agreement. A material default or breach occurs under the OrbiMed Intercreditor Agreement, the Intercompany Subordination Agreement or any other subordination, intercreditor or other similar agreement with respect to any Permitted Indebtedness that constitutes Subordinated Debt or Permitted Convertible Indebtedness, or any creditor party to such an agreement with the Collateral Agent (or Lenders) and any Credit Party breaches any of the terms of such agreement in any material respect; provided, that material defaults or breaches for the purposes of this Section 7.11 shall include breaches of any payment, enforcement or subordination provisions or

restrictions set forth in such agreement. For the avoidance of doubt, default or breaches by any Secured Party shall not constitute an Event of Default hereunder.

10 RIGHTS AND REMEDIES UPON AN EVENT OF DEFAULT

10.1 Rights and Remedies. While an Event of Default occurs and continues, the Collateral Agent may, or at the request of the Required Lenders, will, without notice or demand:

(a) declare all Obligations (including, for the avoidance of doubt, any and all amounts payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable) immediately due and payable (but if an Event of Default described in Section 7.5 occurs, all Obligations, including any and all amounts payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, are automatically and immediately due and payable without any notice, demand or other action by the Collateral Agent or any Lender), whereupon all Obligations for principal, interest, premium or otherwise (including, for the avoidance of doubt, any and all amounts payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable) shall become due and payable by Borrower without presentment for payment, demand, notice of protest or other demand or notice of any kind, which are all expressly waived by the Credit Parties hereby;

(b) stop advancing money or extending credit for Borrower's benefit under this Agreement;

(c) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that the Collateral Agent considers advisable, notify any Person owing Borrower money of the Collateral Agent's security interest, for the benefit of the Lenders and the other Secured Parties, in such funds, and verify the amount of the Collateral Accounts;

(d) make any payments and do any acts it considers necessary or reasonable to protect the Collateral or the Collateral Agent's security interest, for the benefit of Lenders and the other Secured Parties, in the Collateral. Borrower shall assemble the Collateral if the Collateral Agent or the Required Lenders requests and make it available as the Collateral Agent designates or the Required Lenders designate. The Collateral Agent or its agents or representatives may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien that appears to be prior or superior to its security interest, for the benefit of Lenders and the other Secured Parties, and pay all expenses incurred. Borrower grants the Collateral Agent an irrevocable, royalty-free license or other right to enter, use, operate and occupy (and for its agents or representatives to enter, use, operate and occupy), without charge, any such premises to exercise any of the Collateral Agent's or any Lender's rights or remedies under this Section 8.1 (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, advertise for sale, sell, assign, license out, convey, transfer or grant options to purchase any Collateral);

(e) apply to the Obligations (i) any balances and deposits of Borrower it holds, (ii) any amount held by the Collateral Agent owing to or for the credit or the account of Borrower or (iii) any balance from any Collateral Account of any Credit Party or instruct the bank at which any such Collateral Account is maintained to pay the balance of any such Collateral Account to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct;

(f) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. With respect to any and all Intellectual Property owned or held by any Credit Party and included in Collateral, each Credit Party hereby grants to the Collateral Agent, for the benefit of Lenders and the other Secured Parties: (i) an irrevocable, non-exclusive, assignable, royalty-free license or other right to use (and for its agents or representatives to use), without charge, including the right to sublicense, use and practice, any and all such Intellectual Property in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, advertise for sale, sell, assign, license out, convey, transfer or grant options to purchase any Collateral, and access to all media in which any of the licensed items may be recorded or stored and to all Software and programs used for the compilation or printout thereof; and (ii) in connection with the Collateral Agent's exercise of its rights or remedies under this Section 8.1 (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, sell, assign, license out, convey, transfer or grant options to purchase any Collateral), each Credit Party's rights under all licenses and all franchise Contracts inure to the benefit of all Secured Parties;

(g) place a "hold" on any account maintained with the Collateral Agent or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(h) demand and receive possession of the Books of any Credit Party regarding Collateral; and

(i) exercise all rights and remedies available to the Collateral Agent or any Lender under the Collateral Documents or any other Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Each of the Collateral Agent and Lender agrees that in connection with any foreclosure or other exercise of rights under this Agreement or any other Loan Document with respect to any Intellectual Property included in the Collateral, the rights of the licensees under any license of such Intellectual Property will not be terminated, limited or otherwise adversely affected so long as no default exists thereunder in a way that would permit the licensor to terminate such license (commonly termed a non-disturbance). Without limitation to any other provision herein or in any other Loan Document, while an Event of Default occurs and continues, at the Collateral Agent's or the Required Lenders' request, representatives from Borrower and the Collateral Agent shall promptly meet (in person or telephonically) to discuss in good faith how to collect, receive, appropriate and realize upon Borrower's rights and interests in, to and under any Company IP Agreement, including in connection with any foreclosure or other exercise of the Collateral Agent's or any Lender's rights with respect thereto. If Borrower and the Collateral Agent do not mutually agree with respect thereto within ten (10) Business Days after such request by the Collateral Agent (or such later date as agreed by the Collateral Agent), then the Collateral Agent may request Borrower to, and Borrower (promptly following the receipt of such request) shall, use reasonable best efforts to obtain the written consent of any counterparty to the exercise by the Collateral Agent or any Lender of any and all rights and remedies under this Agreement or any other Loan Document with respect to any Company IP Agreement, in form and substance reasonably satisfactory to the Collateral Agent.

10.2 Power of Attorney. Borrower hereby irrevocably appoints the Collateral Agent and any Related Party thereof as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's name on any checks or other forms of payment or security; (b) sign Borrower's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Collateral Accounts directly with depository banks where the Collateral Accounts are maintained, for amounts and on terms the Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's products liability or general liability insurance policies maintained in any jurisdiction regarding Collateral; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of the Collateral Agent or a third party as the Code permits. Borrower hereby appoints the Collateral Agent and any Related Party thereof as its lawful attorney-in-fact to file or record any documents necessary to perfect or continue the perfection of the Collateral Agent's security interest, for the benefit of Lenders and the other Secured Parties, in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) have been satisfied in full and no Lender is under any further obligation to make Credit Extensions hereunder. The foregoing appointment of the Collateral Agent and any Related Party thereof as Borrower's attorney in fact, and all of the Collateral Agent's (or such Related Party's) rights and powers, coupled with an interest, are irrevocable until all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) have been fully repaid and performed and each Lender's obligation to provide Credit Extensions terminates.

10.3 Application of Payments and Proceeds Upon Default. If an Event of Default has occurred and is continuing, the Collateral Agent shall apply any funds in its possession, whether from Borrower account balances, payments, proceeds realized as the result of any collection of Collateral Accounts or disposition of any other Collateral, or otherwise, to the Obligations in such order as the Collateral Agent shall determine in its sole discretion. Subject to the OrbiMed Intercreditor Agreement, any surplus shall be paid to Borrower or other Persons legally entitled thereto; Borrower shall remain liable to Lenders for any deficiency. If the Collateral Agent or any Lender directly or indirectly enters into a deferred payment or other credit transaction with any purchaser at any sale of Collateral, the Collateral Agent or such Lender, as applicable, shall have the option, exercisable at any time, of either reducing the Obligations by the principal amount of the purchase price or deferring the reduction of the Obligations until the actual receipt by the applicable Lender(s) of cash therefor.

10.4 Collateral Agent's Liability for Collateral. So long as the Collateral Agent complies with Requirements of Law regarding the safekeeping of the Collateral in the possession or under the control of the Collateral Agent, the Collateral Agent shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; or (c) any act or default of any other Person. In no event shall the Collateral

Agent or any Lender have any liability for any diminution in the value of the Collateral for any reason. Borrower bears all risk of loss, damage or destruction of the Collateral.

10.5 No Waiver; Remedies Cumulative. The Collateral Agent's or any Lender's failure, at any time or times, to require strict performance by Borrower or any other Person of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of the Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Each of the Collateral Agent's and Lender's rights and remedies under this Agreement and the other Loan Documents are cumulative. Each of the Collateral Agent and Lenders has all rights and remedies provided under the Code, by law, or in equity. The exercise by the Collateral Agent or any Lender of one right or remedy is not an election and shall not preclude the Collateral Agent or any Lender from exercising any other remedy under this Agreement or other remedy available at law or in equity, and the waiver by the Collateral Agent or any Lender of any Event of Default is not a continuing waiver. The Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

10.6 Demand Waiver; Makewhole Amount; Prepayment Premium; Exit Fee. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by the Collateral Agent on which Borrower is liable. Borrower acknowledges and agrees that if the maturity of all Obligations shall be accelerated pursuant to Section 8.1(a) by reason of the occurrence of an Event of Default, the applicable Makewhole Amount, Prepayment Premium and Exit Fee that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, shall become due and payable by Borrower upon such acceleration, whether such acceleration is automatic or is effected by the Collateral Agent's or any Lender's declaration thereof, as provided in Section 8.1(a), and shall also become due and payable in the event the Obligations are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure or by any other similar means, and Borrower shall pay the applicable Makewhole Amount, Prepayment Premium and Exit Fee that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, as compensation to Lenders for the loss of its investment opportunity and not as a penalty, and Borrower waives any right to object thereto in any voluntary or involuntary bankruptcy, insolvency or similar proceeding or otherwise.

11 NOTICES

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by electronic mail or facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address (if any) indicated below. Any party to this Agreement may change its mailing or electronic mail address or facsimile number by giving all other parties hereto written notice thereof in accordance with the terms of this Section 9.

If to Borrower or any other Credit Party:

c/o Insmed Incorporated
700 US Highway 202/206
Bridgewater, New Jersey 08807
Attn: Chief Financial Officer
Email: [***]

with copies to (which shall not constitute notice) to:

Covington & Burling LLP
620 Eighth Avenue
New York, New York 10018-1000
Attn: Peter Schwartz
Tel: +1 212-841-1268
Email: [***]

If to Collateral Agent: BioPharma Credit PLC
c/o Company Matters Ltd.
Central Square
29 Wellington Street
Leeds
LS1 4DL
United Kingdom
Attn: Company Secretary
Tel: +44 01 392 477 500
Email: [***]

with copies (which shall not constitute notice) to:

Pharmakon Advisors, LP
110 East 59th Street, #2800
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: +1 (212) 883-2296
Email: [***]

and

Akin Gump Strauss Hauer & Feld LLP
One Bryant Park
New York, NY 10036-6745
Attn: Geoffrey E. Secol
Phone: +1 (212) 872-8081
Email: [***]

If to any Lender: To the address of such Lender set forth on Exhibit D attached hereto.

with copies (which shall not constitute notice) to:

Pharmakon Advisors, LP
110 East 59th Street, #2800
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: +1 (212) 883-2296
Email: [***]

and

Akin Gump Strauss Hauer & Feld LLP
One Bryant Park
New York, NY 10036-6745
Attn: Geoffrey E. Secol
Phone: (212) 872-8081
Email: [***]

12 CHOICE OF LAW, VENUE, AND JURY TRIAL WAIVER

THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ANY PRINCIPLES OF CONFLICTS OF LAW THAT COULD REQUIRE THE APPLICATION OF THE LAW OF ANY OTHER JURISDICTION, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL APPLY TO THAT EXTENT. Except as contemplated by the immediately succeeding paragraph, each party hereto submits to the exclusive jurisdiction of the courts of the State of New York sitting in New York County, and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, and agrees that all claims in respect of any such action, litigation or proceeding may be heard and determined in such New York State court or, to the fullest extent permitted by Requirements of Law, in such Federal court; provided, however, that nothing in this Agreement shall be deemed to operate to preclude the Collateral Agent or any Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of the Collateral Agent or any Lender. Each Credit Party expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and each Credit Party hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or *forum non conveniens* and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Each Credit Party hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to such party at the address set forth in (or otherwise provided in accordance with the terms of) Section 9 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of such party's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY REQUIREMENTS OF LAW, EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ITS RIGHT TO A JURY TRIAL IN ANY CLAIM, SUIT, ACTION OR PROCEEDING WITH RESPECT TO, OR DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH, THIS AGREEMENT, ANY OTHER LOAN DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREIN AND THEREIN OR RELATED HERETO OR THERETO (WHETHER FOUNDED IN CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO OTHER PARTY AND NO RELATED PARTY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 10 AND (C) HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

13 GENERAL PROVISIONS

13.1 Successors and Assigns.

(a) This Agreement binds and is for the benefit of the parties hereto and their respective successors and permitted assigns.

(b) No Credit Party may transfer, pledge or assign this Agreement or any other Loan Document or any rights or obligations hereunder or thereunder without the prior written consent of each Lender. Subject to Section 11.1(d), any Lender may at any time sell, transfer, assign or pledge this Agreement or any other Loan Document or any of its rights or obligations hereunder or thereunder, or grant a participation in all or any part of, or any interest in, such Lender's obligations, rights or benefits under this Agreement and the other Loan Documents, including with respect to any Term Loan (or any portion thereof), to any other Lender, any Affiliate of any Lender or any third Person without Borrower's consent (any such sale, transfer, assignment, pledge or grant of a

participation, a "**Lender Transfer**") including, for the avoidance of doubt, in furtherance of, as contemplated under or otherwise in connection with any Lender's credit facility (including any exercise of rights or remedies thereunder or any actions as a result of any such exercise); provided, however, that no Lender may make a Lender Transfer to a Disqualified Assignee without Borrower's prior written consent except after the occurrence and during the continuance of an Event of Default (in which case such consent is not required); provided, further, that no Lender may make a Lender Transfer to a Non-Public Lender. From and after the effective date specified in each sale, transfer, or assignment, the assignee thereunder shall be a party to this Agreement and, to the extent of the interest assigned, have the rights and obligations of a Lender under this Agreement.

(c) In the case of a Lender Transfer in the form of a participation granted by any Lender to any third party, (i) such Lender's obligations under this Agreement shall remain unchanged, (ii) such Lender shall remain solely responsible to the other parties hereto for the performance of its obligations hereunder, (iii) Borrower shall continue to deal solely and directly with such Lender in connection with such Lender's rights and obligations under this Agreement and (iv) any agreement or instrument pursuant to which such Lender sells such participation shall provide that such Lender shall retain the sole right to enforce this Agreement and to approve any amendment, restatement, supplement or other modification hereto, in each case subject to the terms and conditions of this Agreement. Borrower agrees that each participant shall be entitled to the benefits of Sections 2.5 and 2.6 (subject to the requirements and limitations therein, including the requirements under Section 2.6(d) (it being understood that the documentation required under Section 2.6(d) shall be delivered to the applicable Lender)) to the same extent as if it were a Person that had acquired its interest by assignment pursuant to clause (b) above; provided that, with respect to any participation, such participant shall not be entitled to receive any greater payment under Sections 2.5 or 2.6 than the applicable Lender (i.e., the party that participated the interest) would have been entitled to receive, except to the extent of any entitlement to receive a greater payment resulting from a Change in Law that occurs after such participant acquired the applicable participation.

(d) Borrower shall record any Lender Transfer in the Note Register. Each Lender shall provide Borrower and the Collateral Agent with written notice of a Lender Transfer delivered no later than five (5) Business Days prior to the date on which such Lender Transfer is consummated. If any Lender sells a participation in any Term Loan or any other obligation under a Loan Document, such Lender shall, acting solely for this purpose as a non-fiduciary agent of Borrower, maintain a register on which it enters the name and address of each participant and principal amounts (and stated interest) of each participant's interest in the Term Loans or other obligations under the Loan Documents (the "**Participant Register**"); provided, however, that such Lender shall have no obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans or its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan, letter of credit or other obligation is in "registered form" within the meaning of Section 163(f), 871(h)(2) and 881(c)(2) of the IRC and any related regulations (and any other relevant or successor provisions of the IRC or such regulations) (in which case the Participant Register shall be available for inspection by Borrower upon reasonable prior written notice). The entries in the Participant Register shall be conclusive absent manifest error, and the Collateral Agent and each Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary.

(e) Any attempted transfer, pledge or assignment of this Agreement or any other Loan Document or any rights or obligations hereunder or thereunder in violation of this Section 11.1 shall be null and void and neither Borrower nor any transfer agent shall give any effect in the Note Register to such attempted transfer.

13.2 Indemnification.

(a) Borrower agrees to indemnify and hold harmless each of the Collateral Agent, the Intercreditor Agent, Lenders and its and their respective Affiliates (and its or their respective successors and assigns) and each manager, member, partner, controlling Person, director, officer, employee, agent or sub-agent, advisor and affiliate thereof (each such Person, an "**Indemnified Person**") from and against any and all Indemnified Liabilities; provided, however, that Borrower shall have no obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities to the extent such Indemnified Liabilities (i) are determined by a court of competent jurisdiction by final and nonappealable judgment to have resulted from the gross negligence or willful misconduct of such Indemnified Person (or the gross negligence or willful misconduct of such Indemnified Person's affiliates or controlling Persons or any of their respective managers, members, partners, controlling Persons, directors, officers, employees, agents or sub-agents, advisors or affiliates), (ii) result from a claim brought by Borrower against an Indemnified Person for material breach in bad faith of any of such Indemnified Person's obligations hereunder or under any other Loan Document, if Borrower has obtained a final and nonappealable judgment in its favor on such claim as determined by a court of competent jurisdiction, or (z) result from a claim not involving an act or omission of Borrower or any of its Subsidiaries that is brought by an Indemnified Person against another Indemnified Person (other than against the Collateral Agent or the Intercreditor Agent in their capacities as such). This Section 11.2(a)

shall not apply with respect to Taxes other than any Taxes that represent liabilities, obligations, losses, damages, penalties, claims, costs, expenses and disbursements arising from any non-Tax claim.

(b) To the extent permitted by Requirements of Law, no party to this Agreement shall assert, and each party to this Agreement hereby waives, any claim against any other party hereto (and its or their successors and assigns), and each manager, member, partner, controlling Person, director, officer, employee, agent or sub-agent, advisor and affiliate thereof, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) (whether or not the claim therefor is based on contract, tort or duty imposed by any applicable legal requirement) arising out of, in connection with, arising out of, as a result of, or in any way related to, this Agreement or any Loan Document or any agreement or instrument contemplated hereby or thereby or referred to herein or therein, the transactions contemplated hereby or thereby, any Credit Extension or the use of the proceeds thereof or any act or omission or event occurring in connection therewith, and each party to this Agreement hereby waives, releases and agrees not to sue upon any such claim or any such damages, whether or not accrued and whether or not known or suspected to exist in its favor.

(c) Any action taken by any Credit Party under or with respect to any Loan Document, even if required under any Loan Document or at the request of the Collateral Agent, the Intercreditor Agent or any Lender, shall be at the expense of such Credit Party, and neither the Collateral Agent, the Intercreditor Agent nor any Secured Party shall be required under any Loan Document to reimburse any Credit Party or any Subsidiary of any Credit Party therefor except as expressly provided therein. In addition, and without limiting the generality of Section 2.4, Borrower agrees to pay or reimburse upon demand each of the Collateral Agent, the Intercreditor Agent and Lenders (and their respective successors and assigns) and each of their respective Related Parties, if applicable, for any and all fees, expenses and disbursements of the kind or nature described in clause (b) of the definition of "Lender Expenses" incurred by it.

13.3 Severability of Provisions. In case any provision in or obligation hereunder or under any other Loan Document shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

13.4 Correction of Loan Documents. The Collateral Agent or Required Lenders may correct patent errors and fill in any blanks in the Loan Documents consistent with the agreement of the parties hereto so long as the Collateral Agent or Required Lenders, as applicable, provides the Credit Parties and the other parties hereto with written notice of such correction and allows the Credit Parties at least ten (10) days to object to such correction in writing delivered to the Collateral Agent and each Lender. In the event of such objection, such correction shall not be made except by an amendment to this Agreement in accordance with Section 11.5.

13.5 Amendments in Writing; Integration.

(a) No amendment, restatement or modification of or supplement to any provision of this Agreement or any other Loan Document, or waiver, discharge or termination of any obligation hereunder or thereunder, no approval or consent hereunder or thereunder (including any consent to any departure by Borrower or any other Credit Party herefrom or therefrom), shall in any event be effective unless the same shall be in writing and signed by Borrower (on its own behalf and on behalf of each other Credit Party) and the Required Lenders; provided, however, that no such amendment, restatement, modification, supplement, waiver, discharge, termination, approval or consent shall, unless in writing and signed by the Collateral Agent and the Required Lenders, affect the rights or duties of, or any amounts payable to, the Collateral Agent under this Agreement or any other Loan Document. Any such waiver, approval or consent granted shall be limited to the specific circumstance expressly described in it, and shall not apply to any subsequent or other circumstance, whether similar or dissimilar, or give rise to, or evidence, any obligation or commitment to grant any further waiver, approval or consent.

(b) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations among the parties hereto about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

13.6 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

13.7 Survival; Termination Prior to Term Loan Maturity Date . All covenants, representations and warranties made in this Agreement continue in full force until this Agreement has terminated pursuant to this Section 11.7 and all Obligations (other than contingent indemnification obligations to the extent no claim giving rise

thereto has been asserted and any other obligations which, by their terms, are to survive the termination of this Agreement) have been paid in full and satisfied in accordance with the terms of this Agreement. The obligation of Borrower or any other the Credit Parties in Section 11.2 to indemnify Indemnified Persons shall survive until the statute of limitations with respect to such claim or cause of action shall have run. So long as all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted and any other obligations which, by their terms, are to survive the termination of this Agreement and for which no claim has been made) have been paid in full and satisfied in accordance with the terms of this Agreement, this Agreement shall be terminated (a) prior to the Term Loan Maturity Date by Borrower, effective five (5) Business Days (or such shorter period as the Collateral Agent may agree in its sole discretion) after all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted and any other obligations which, by their terms, are to survive the termination of this Agreement and for which no claim has been made) have been paid in full and written notice of termination is delivered to the Collateral Agent and the Lenders or (b) if no such notice is delivered, automatically on the Term Loan Maturity Date following the payment in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted and any other obligations which, by their terms, are to survive the termination of this Agreement and for which no claim has been made).

13.8 Confidentiality. Any information regarding the Credit Parties and their Subsidiaries and their businesses provided to the Collateral Agent or any Lender by or on behalf of any Credit Party pursuant to the Loan Documents shall be deemed "Confidential Information"; provided, however, that Confidential Information does not include information that is either: (i) in the public domain or in the possession of the Collateral Agent, any Lender or any of their respective Affiliates or when disclosed to the Collateral Agent, any Lender or any of their respective Affiliates, or becomes part of the public domain after disclosure to the Collateral Agent, any Lender or any of their respective Affiliates, in each case, other than as a result of a breach by the Collateral Agent, any Lender or any of their respective Affiliates of the obligations under this Section 11.8; or (ii) disclosed to the Collateral Agent, any Lender or any of their respective Affiliates by a third party if the Collateral Agent, such Lender or such Affiliate, as applicable, does not know (following reasonable inquiry) that the third party is prohibited from disclosing the information. Neither the Collateral Agent nor any Lender shall disclose any Confidential Information to a third party or use Confidential Information for any purpose other than the administration of the Loan Documents, the exercise of its rights or remedies under the Loan Documents or the performance of its duties or obligations under the Loan Documents. The foregoing in this Section 11.8 notwithstanding, the Collateral Agent and each Lender may disclose Confidential Information: (a) to any of its Subsidiaries or Affiliates; (b) to prospective transferees, purchasers or participants of any interest in the Term Loans (including, for the avoidance of doubt, in connection with any proposed Lender Transfer), provided that no such disclosure to any Disqualified Assignees shall be permitted hereunder without Borrower's prior written consent (which consent shall not be required after the occurrence and during the continuance of an Event of Default); (c) as required by law, regulation, subpoena, or other order, provided, that (x) prior to any disclosure under this clause (c), the Collateral Agent or such Lender, as applicable, agrees to endeavor to provide Borrower with prior written notice thereof, and with respect to any law, regulation, subpoena or other order, to the extent that the Collateral Agent or such Lender is permitted to provide such prior notice to Borrower pursuant to the terms hereof, and (y) any disclosure under this clause (c) shall be limited solely to that portion of the Confidential Information as may be specifically compelled by such law, regulation, subpoena or other order; (d) as the Collateral Agent or any Lender otherwise deems necessary or prudent under Sanctions, Anti-Money Laundering Laws, the FCPA, UKBA or other applicable anti-corruption laws, or Export and Import Laws, provided, that prior to any disclosure under this clause (d), the Collateral Agent or such Lender, as applicable, agrees to endeavor to provide Borrower with prior written notice thereof to the extent practicable, and with respect to any law, regulation, subpoena or other order, to the extent that the Collateral Agent or such Lender is permitted to provide such prior notice to Borrower; (e) to the extent requested by regulators having jurisdiction over the Collateral Agent or such Lender or as otherwise required in connection with the Collateral Agent's or such Lender's examination or audit by such regulators; (f) to third-party service providers of the Collateral Agent or such Lender; and (g) to any of the Collateral Agent's or such Lender's Related Parties; provided, however, that the third parties to which Confidential Information is disclosed pursuant to clauses (a), (b), (f) and g) are bound by obligations of confidentiality and non-use that are no less restrictive than those contained herein.

The provisions of this Section 11.8 shall survive the termination of this Agreement.

13.9 Attorneys' Fees, Costs and Expenses . In any action or proceeding between, on the one hand, any Credit Party and, on the other hand, the Collateral Agent or any Lender, arising out of or relating to the Loan Documents other than in connection with the enforcement against any Credit Party of this Agreement or any other

Loan Document, the prevailing party shall be entitled to recover its reasonable attorneys' fees and other costs and expenses incurred, in addition to any other relief to which it may be entitled.

13.10 Right of Set-Off. In addition to any rights now or hereafter granted under Requirements of Law and not by way of limitation of any such rights, upon the occurrence of an Event of Default and at any time thereafter during the continuance of any Event of Default, each Lender is hereby authorized by each Credit Party at any time or from time to time, without prior notice to any Credit Party, any such notice being hereby expressly waived by Borrower (on its own behalf and on behalf of each other Credit Party), to set off and to appropriate and to apply any and all deposits (general or special, including Indebtedness evidenced by certificates of deposit, whether matured or unmatured, but not including trust accounts) and any other Indebtedness at any time held or owing by such Lender to or for the credit or the account of any Credit Party against and on account of the obligations and liabilities of any Credit Party to such Lender hereunder and under the other Loan Documents, including all claims of any nature or description arising out of or connected hereto or with any other Loan Document, irrespective of whether or not (a) the Collateral Agent or such Lender shall have made any demand hereunder or (b) the principal of or the interest on the Term Loans or any other amounts due hereunder shall have become due and payable pursuant to Section 2 and although such obligations and liabilities, or any of them, may be contingent or unmatured. Each Lender agrees promptly to notify Borrower and the Collateral Agent after any such set off and application made by such Lender; provided, that the failure to give such notice shall not affect the validity of such set off and application.

13.11 Marshalling; Payments Set Aside. Neither the Collateral Agent nor any Lender shall be under any obligation to marshal any assets in favor of any Credit Party or any other Person or against or in payment of any or all of the Obligations. To the extent that any Credit Party makes a payment or payments to any Lender, or the Collateral Agent or any Lender enforces any Liens or exercises its rights of setoff, and such payment or payments or the proceeds of such enforcement or setoff or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside or required to be repaid to a trustee, receiver, examiner or any other party under any bankruptcy law, any other state or federal law, common law or any equitable cause, then, to the extent of such recovery, the obligation or part thereof originally intended to be satisfied, and all Liens, rights and remedies therefor or related thereto, shall be revived and continued in full force and effect as if such payment or payments had not been made or such enforcement or setoff had not occurred.

13.12 Electronic Execution of Documents. The words "execution," "signed," "signature," and words of like import in this Agreement and the other Loan Documents shall be deemed to include electronic signatures or electronic records, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any Requirements of Law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

13.13 Captions. Section headings herein are included herein for convenience of reference only and shall not constitute a part hereof for any other purpose or be given any substantive effect.

13.14 Construction of Agreement. The parties hereto mutually acknowledge that they and their respective attorneys have participated in the preparation and negotiation of this Agreement. In cases of uncertainty, this Agreement shall be construed without regard to which of the parties hereto caused the uncertainty to exist.

13.15 Third Parties. Nothing in this Agreement, whether express or implied, is intended to: (a) except as expressly provided in Section 11.2(a), confer any benefits, rights or remedies under or by reason of this Agreement on any Persons other than the express parties to it and their respective successors and permitted assigns; (b) relieve or discharge the obligation or liability of any Person not an express party to this Agreement; or (c) give any Person not an express party to this Agreement any right of subrogation or action against any party to this Agreement.

13.16 No Advisory or Fiduciary Duty. The Collateral Agent and each Lender may have economic interests that conflict with those of the Credit Parties. Each Credit Party agrees that nothing in the Loan Documents or otherwise will be deemed to create an advisory, fiduciary or agency relationship or fiduciary or other implied duty between any Lender or the Collateral Agent, on the one hand, and such Credit Party, its Subsidiaries, and any of their respective stockholders or affiliates, on the other hand. Each Credit Party acknowledges and agrees that (i) the transactions contemplated by the Loan Documents are arm's-length commercial transactions between each Lender and the Collateral Agent, on the one hand, and such Credit Party, its Subsidiaries and their respective affiliates, on the other hand, (ii) in connection therewith and with the process leading to such transaction, the Collateral Agent and each Lender is acting solely as a principal and not the advisor, agent or fiduciary of such Credit Party, its Subsidiaries or their respective affiliates, management, stockholders, creditors or any other Person, (iii) neither the Collateral Agent nor any Lender has assumed an advisory or fiduciary responsibility in favor of any Credit Party, its

Subsidiaries or their respective affiliates with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Collateral Agent or any Lender or any of their respective affiliates has advised or is currently advising such Credit Party, its Subsidiaries or their respective affiliates on other matters) or any other obligation to such Credit Party, its Subsidiaries or their respective affiliates except the obligations expressly set forth in the Loan Documents, and (iv) each Credit Party, its Subsidiaries and their respective affiliates have consulted their own legal and financial advisors to the extent each deemed appropriate. Each Credit Party further acknowledges and agrees that it is responsible for making its own independent judgment with respect to such transactions and the process leading thereto. Each Credit Party agrees that it will not claim that the Collateral Agent or any Lender has rendered advisory services of any nature or respect, or owes a fiduciary or similar duty to such Credit Party, its Subsidiaries or their respective affiliates in connection with such transaction or the process leading thereto.

13.17 Credit Parties' Agent. Each of the Credit Parties hereby irrevocably appoints Borrower, as its agent, attorney-in-fact and legal representative for all purposes, including requesting disbursement of the Term Loans and receiving account statements and other notices and communications to Credit Parties (or any of them) from the Collateral Agent or the Lenders, executing amendments, waivers or other modifications of or supplements to Loan Documents and executing or designating new Loan Documents. The Collateral Agent or the Lenders may rely, and shall be fully protected in relying, on any request for the Term Loans, disbursement instruction, report, information or any other notice or communication made or given by Borrower and any amendment, waiver or other modification of or supplement to a Loan Document or the execution or designation of new Loan Documents executed or made by Borrower, whether in its own name or on behalf of one or more of the other Credit Parties, and the Collateral Agent or the Lenders shall not have any obligation to make any inquiry or request any confirmation from or on behalf of any other Credit Party as to the binding effect on it of any such request, instruction, report, information, other notice, communication, amendment, supplement, waiver, other modification, execution or designation, nor shall the joint and several character of the Credit Parties' obligations hereunder be affected thereby.

13.18 Reaffirmation of Loan Documents; Confirmation of Liens. Except to the extent that any Loan Document (as defined in the Prior Loan Agreement) is being explicitly terminated, replaced or amended and restated in connection with the amendment and restatement being implemented hereby, each such Loan Document shall continue to be in full force and effect and is hereby ratified and confirmed in all respects, except that, from and after the Effective Date, each reference in any such Loan Document to the "Loan Agreement," "thereunder," "thereof" or words of like import shall be deemed to mean references to this Loan Agreement. As of the Effective Date, Borrower and each other Credit Party hereby (a) reaffirm each of its covenants, agreements and obligations contained in any such Loan Document, (b) reaffirm each guarantee, pledge and grant of a security interest made in favor of the Collateral Agent under or in connection with the Prior Loan Agreement and any Loan Documents entered into in connection therewith and (c) agree that notwithstanding the amendment and restatement of the Prior Loan Agreement, such guarantees, pledges and grants of security interest in favor of the Collateral Agent shall continue in full force and effect.

13.19 Effect of Amendment and Restatement.

(a) On the Effective Date, the Prior Loan Agreement shall be amended, restated and superseded in its entirety. The parties hereto acknowledge and agree that (i) this Loan Agreement and the other documents entered into in connection herewith do not constitute a novation, payment and reborrowing, or termination of the "Obligations" (as defined in the Prior Loan Agreement) under the Prior Loan Agreement, as in effect prior to the Effective Date but rather a substitution of certain of the terms contained therein, as set forth herein and (ii) such "Obligations" are in all respects continuing after the Effective Date (as amended and restated hereby) as indebtedness and obligations outstanding under this Loan Agreement, enforceable with only the terms thereof being modified as provided by this Agreement and shall be deemed to be Obligations governed by this Agreement. On and after the Effective Date, the rights and obligations of the parties hereto shall be governed by this Loan Agreement, except that the rights and obligations of the parties hereto with respect to the period prior to the Effective Date shall be governed by the provisions of the Prior Loan Agreement as it existed prior to such amendment and restatement.

(b) In connection with the amendment and restatement of the Prior Loan Agreement, Borrower and each other Credit Party release, waive and discharge any claims or causes of action which it may have against the Collateral Agent, and each of the Lenders (as each such term is defined in the Prior Loan Agreement) and any of the other holders of the Obligations (as defined in the Prior Loan Agreement) arising under the Prior Loan Agreement or any of the other Loan Documents (as defined in the Prior Loan Agreement) executed in

connection with the Prior Loan Agreement (the " **Prior Loan Documents**"), whether on the Original Effective Date or at any time thereafter but prior to the Effective Date, or relating to any of their performance thereunder.

(c) On and after the Effective Date, all references to the Prior Loan Agreement or the "Loan Agreement" in any and all of the Prior Loan Documents shall be deemed to include references to this Agreement, as amended, restated, supplemented or otherwise modified from time to time.

14 COLLATERAL AGENT

14.1 Appointment and Authority. Each Lender hereby irrevocably appoints BioPharma Credit PLC to act on its behalf as the Collateral Agent hereunder and under the other Loan Documents and authorizes the Collateral Agent to take such actions on its behalf and to exercise such powers as are delegated to the Collateral Agent by the terms hereof or thereof, together with such actions and powers as are reasonably incidental thereto. Except for the first two (2) sentences of Section 12.7 and the first sentence and penultimate paragraph of Section 12.9, the provisions of this Section 12 are solely for the benefit of the Collateral Agent and Lenders, and neither Borrower nor any other Credit Party shall have rights as a third party beneficiary of any of such provisions. Subject to Section 12.9 and Section 11.5, any action required or permitted to be taken by the Collateral Agent hereunder shall be taken with the prior approval of the Required Lenders.

14.2 Rights as a Lender. The Person serving as the Collateral Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Collateral Agent and the term "Lender" or "Lenders" shall, unless otherwise expressly indicated or unless the context otherwise requires, include the Person serving as the Collateral Agent hereunder in its individual capacity. Such Person and its Affiliates may lend money to, own securities of, act as the financial advisor or in any other advisory capacity for and generally engage in any kind of business with Borrower or any Subsidiary or other Affiliate thereof as if such Person were not the Collateral Agent hereunder and without any duty to account therefor to any Lender.

14.3 Swiss Collateral Document. Without limiting any other rights of the Collateral Agent under this Agreement, in relation to the Swiss Security Documents:

(a) the Collateral Agent holds:

(i) any security interest constituted by such Swiss Security Document (but only in relation to an assignment or any other non-accessory (*nicht akzessorische*) security interest);

(ii) the benefit of this clause (a); and

(iii) any proceeds of such security interest,

as fiduciary (*treuhänderisch*) in its own name but for the account of all relevant Secured Parties which have the benefit of such security interest in accordance with this Agreement and the respective Swiss Security Documents;

(b) each present and future Secured Party hereby authorizes the Collateral Agent:

(i) acting for itself and in the name and for the account of such Secured Party to accept as its direct representative (*direkter Stellvertreter*) any Swiss law pledge or any other Swiss law accessory (*akzessorische*) security interest made or expressed to be made to such Secured Party in relation to the Swiss Security Documents, to hold, administer and, if necessary, enforce any such security interest on behalf of each relevant Secured Party which has the benefit of such security interest;

(ii) to agree as its direct representative (*direkter Stellvertreter*) to amendments and alterations to any Swiss Security Document which creates a pledge or any other Swiss law accessory (*akzessorische*) security interest;

(iii) to effect as its direct representative (*direkter Stellvertreter*) any release of a security interest created under a Swiss Security Document in accordance with this Agreement; and

(iv) to exercise as its direct representative (*direkter Stellvertreter*) such other rights granted to the Collateral Agent hereunder or under the relevant Swiss Security Document.

(c) the Collateral Agent, when acting in its capacity as creditor of the Parallel Liability, holds:

(i) any Swiss law pledge or any other Swiss law accessory (*akzessorische*) security interest;

(ii) any proceeds of such security interest; and

(iii) the benefit of this paragraph and of the Parallel Liability, as creditor in its own right but for the benefit of the Secured Parties in accordance with this Agreement;

(d) each present and future Secured Party hereby authorizes the Collateral Agent, including when acting in its capacity as creditor of the Parallel Liability, to appoint a security agent under the OrbiMed Intercreditor Agreement:

(i) acting for itself and in the name and for the account of such Secured Party and the Collateral Agent to accept as its direct representative (*direkter Stellvertreter*) any Swiss law pledge or any other Swiss law accessory (*akzessorische*) security interest made or expressed to be made to such Secured Party and the Collateral Agent in relation to the Swiss Security Documents, to hold, administer and, if necessary, enforce any such security interest on behalf of each relevant Secured Party and the Collateral Agent which has the benefit of such security interest;

(ii) to agree as its direct representative (*direkter Stellvertreter*) to amendments and alterations to any Swiss Security Document which creates a pledge or any other Swiss law accessory (*akzessorische*) security interest;

(iii) to effect as the direct representative (*direkter Stellvertreter*) of each Secured Party and the Collateral Agent any release of a security interest created under a Swiss Security Document in accordance with this Agreement and the OrbiMed Intercreditor Agreement; and

(iv) to exercise as the direct representative (*direkter Stellvertreter*) of each Secured Party and the Collateral Agent such other rights granted to the Collateral Agent hereunder and under the OrbiMed Intercreditor Agreement or under the relevant Swiss Security Document.

14.4 Exculpatory Provisions.

(a) The Collateral Agent shall not have any duties or obligations to the Lenders except those expressly set forth herein and in the other Loan Documents to which it is a party. Without limiting the generality of the foregoing, with respect to the Lenders, the Collateral Agent:

(i) shall not be subject to any fiduciary or other implied duties, regardless of whether a Default or Event of Default has occurred and is continuing;

(ii) shall not have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents to which it is a party that the Collateral Agent is required to exercise as directed in writing by the Required Lenders (or such other number or percentage of the Lenders as shall be expressly provided for herein or in such other Loan Documents), provided that the Collateral Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Collateral Agent to liability or that is contrary to any Loan Document or Requirements of Law; and

(iii) shall not, except as expressly set forth herein and in the other Loan Documents to which it is a party, have any duty to disclose, and shall not be liable for the failure to disclose, any information relating to any Credit Party or any of its Affiliates that is communicated to or obtained by the Person serving as the Collateral Agent or any of its Affiliates in any capacity.

(b) The Collateral Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Required Lenders (or such other number or percentage of the Lenders as shall be necessary, or as the Collateral Agent shall believe in good faith shall be necessary, under the circumstances as provided in Section 11.5) or (ii) in the absence of its own gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and nonappealable judgment. The Collateral Agent shall be deemed not to

have knowledge of any Default or Event of Default unless and until notice describing such Default or Event of Default is given to the Collateral Agent in writing by Borrower or a Lender.

(c) The Collateral Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any Default or Event of Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Section 3 or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Collateral Agent.

14.5 Reliance by Collateral Agent. The Collateral Agent shall be entitled to rely upon, and shall not incur any liability for relying upon, any notice, request, certificate, consent, statement, instrument, document or other writing (including any electronic message, internet or intranet website posting or other distribution) believed by it to be genuine and to have been signed, sent or otherwise authenticated by the proper Person. The Collateral Agent also may rely upon any statement made to it orally or by telephone and believed by it to have been made by the proper Person, and shall not incur any liability for relying thereon. The Collateral Agent may consult with legal counsel (who may be counsel for Borrower), independent accountants, manufacturing consultants and other experts selected by it, and shall not be liable for any action taken or not taken by it in accordance with the advice of any such counsel, accountants, consultants or experts.

14.6 Delegation of Duties. The Collateral Agent may perform any and all of its duties and exercise its rights and powers hereunder or under any other Loan Document by or through any one or more sub-agents appointed by the Collateral Agent. The Collateral Agent and any such sub-agent may perform any and all of its duties and exercise its rights and powers by or through their respective Related Parties. The exculpatory provisions of this Section 12 shall apply to any such sub-agent and to the Related Parties of the Collateral Agent and any such sub-agent. The Collateral Agent shall not be responsible for the negligence or misconduct of any sub-agent except to the extent that a court of competent jurisdiction determines in a final and nonappealable judgment that the Collateral Agent acted with gross negligence or willful misconduct in the selection of such sub-agent.

14.7 Resignation of Collateral Agent. The Collateral Agent may at any time give notice of its resignation to the Lenders and Borrower. Upon the receipt of any such notice of resignation, the Required Lenders shall have the right, with the Borrower's prior written consent so long as no Event of Default has occurred and is continuing, to appoint a successor; provided, however, that Borrower's consent shall not be required to the extent the successor is an Affiliate of the Collateral Agent or any Lender (provided that such Collateral Agent shall consult with the Borrower regarding such appointment prior to the effectiveness thereof). If no successor shall have been so appointed by the Required Lenders and shall have accepted such appointment within thirty (30) days after the retiring Collateral Agent gives notice of its resignation, then the retiring Collateral Agent may, on behalf of the Lenders, appoint a successor Collateral Agent that is a Related Party of the Collateral Agent or any Lender; provided that, whether or not a successor has been appointed or has accepted such appointment, such resignation shall become effective upon delivery of the notice thereof. Upon the acceptance of a successor's appointment as Collateral Agent hereunder, such successor shall succeed to and become vested with all of the rights, powers, privileges and duties of the retiring (or retired) Collateral Agent, and the retiring Collateral Agent shall be discharged from all of its duties and obligations under the Loan Documents (if not already discharged therefrom as provided above in this Section 12.7), other than its obligations under Section 11.8. After the retiring Collateral Agent's resignation, the provisions of this Section 12 and Section 10 shall continue in effect for the benefit of such retiring Collateral Agent, its sub-agents and their respective Related Parties in respect of any actions taken or omitted to be taken by any of them while the retiring Collateral Agent was acting as Collateral Agent. Upon any resignation by the Collateral Agent, all payments, communications and determinations provided to be made by, to or through the Collateral Agent shall instead be made by, to or through each Lender directly, until such time as a Person accepts an appointment as Collateral Agent in accordance with this Section 12.7.

14.8 Non-Reliance on Collateral Agent and Other Lenders . Each Lender acknowledges that it has, independently and without reliance upon the Collateral Agent or any other Lender or any of their respective Related Parties and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Agreement and make Credit Extensions hereunder. Each Lender also acknowledges that it will, independently and without reliance upon the Collateral Agent or any other Lender or any of their respective Related Parties and based on such documents and information as it shall from time to time deem appropriate,

continue to make its own decisions in taking or not taking action under or based upon this Agreement, any other Loan Document or any related agreement or any document furnished hereunder or thereunder.

14.9 Collateral and Guaranty Matters. Each Lender agrees that any action taken by the Collateral Agent or the Required Lenders in accordance with the provisions of this Agreement or of the other Loan Documents, and the exercise by the Collateral Agent or Required Lenders of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of the Lenders. Without limiting the generality of the foregoing, the Lenders irrevocably authorize and instruct the Collateral Agent, and the Collateral Agent agrees:

(a) to release any Lien on any property granted to or held by the Collateral Agent under any Collateral Document (i) upon payment and satisfaction in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) in accordance with the terms of this Agreement, (ii) that is sold, transferred, disposed or to be sold, transferred, disposed as part of or in connection with any sale, transfer or other disposition (other than any sale to a Credit Party) permitted hereunder, (iii) subject to Section 11.5, if approved, authorized or ratified in writing by the Required Lenders, or (iv) to the extent such property is owned by a Guarantor, upon the release of such Guarantor from its obligations under the Loan Documents pursuant to clause (c) below;

(b) to subordinate any Lien on any property granted to or held by the Collateral Agent under any Loan Document to the holder of any Lien on such property that is permitted by clauses (d), (i), (j), (m), (n) and (r) of the definition of "Permitted Liens" (solely with respect to modifications, replacements, extensions or renewals of Liens permitted under clauses (d), (i), (j), (m) and (n) of the definition of "Permitted Liens");

(c) to release any Guarantor from its obligations under each Collateral Document if such Person ceases to be a Subsidiary (or becomes an Excluded Subsidiary) as a result of a transaction permitted hereunder or upon payment and satisfaction in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) in accordance with this Agreement;

(d) to enter into non-disturbance and similar agreements in connection with the licensing of Intellectual Property permitted pursuant to the terms of this Agreement; and

(e) to enter into any subordination, intercreditor or other similar agreement with respect to any Permitted Indebtedness that constitutes Subordinated Debt.

Without prejudice to the obligation to fulfill the foregoing, upon request by the Collateral Agent at any time, the Required Lenders will confirm in writing the Collateral Agent's authority to release or subordinate its interest in particular types or items of property, or to release any Guarantor from its obligations under each Collateral Document pursuant to this Section 12.9.

In each case as specified in this Section 12.9, the Collateral Agent will (and each Lender irrevocably authorizes and instructs the Collateral Agent to), at Borrower's expense, (A) deliver to Borrower any Collateral that is in the Collateral Agent's possession in connection with the release of the Collateral Agent's Lien thereon, and (B) execute and deliver to the applicable Credit Party such documents as such Credit Party may reasonably request (i) to evidence the release or subordination of such item of Collateral from the Liens and security interests granted under the Collateral Documents, (ii) to enter into non-disturbance or similar agreements in connection with the licensing of Intellectual Property, (iii) to enter into any subordination, intercreditor or other similar agreement with respect to any Permitted Indebtedness that constitutes Subordinated Debt or (iv) to evidence the release of any Guarantor (as applicable) from its obligations under each Collateral Document, in each case in accordance with the terms of the Loan Documents and this Section 12.9 and in form and substance reasonably acceptable to the Collateral Agent.

Without limiting the generality of Section 12.10 below, the Collateral Agent shall deliver to the Lenders notice of any action taken by it under this Section 12.9 promptly after the taking thereof; provided that delivery of or failure to deliver any such notice shall not affect the Collateral Agent's rights, powers, privileges and protections under this Section 12.

14.10 Reimbursement by Lenders. To the extent that Borrower for any reason fails to indefeasibly pay any amount required under Section 2.4 to be paid by it to the Collateral Agent (or any sub-agent thereof) or any Related Party of any of the foregoing, each Lender severally agrees to pay to the Collateral Agent (or any such sub-

agent) or such Related Party, as the case may be, such Lender's *pro rata* share (based upon the percentages as used in determining the Required Lenders as of the time that the applicable unreimbursed expense or indemnity payment is sought) of such unpaid amount; provided that the unreimbursed expense or indemnified loss, damage, liability or related expense, as the case may be, was incurred by or asserted against the Collateral Agent (or any such sub-agent) in its capacity as such or against any Related Party of any of the foregoing acting for the Collateral Agent (or any sub-agent) in connection with such capacity.

14.11 Parallel Liability.

(a) Each Credit Party irrevocably and unconditionally undertakes to pay to the Collateral Agent an amount equal to the aggregate amount of its Corresponding Liabilities (as these may exist from time to time).

(b) The parties hereto agree that:

(i) a Credit Party's Parallel Liability is due and payable at the same time as, for the same amount of and in the same currency as its Corresponding Liabilities;

(ii) a Credit Party's Parallel Liability is decreased to the extent that its Corresponding Liabilities have been irrevocably paid or discharged and its Corresponding Liabilities are decreased to the extent that its Parallel Liability has been irrevocably paid or discharged;

(iii) a Credit Party's Parallel Liability is independent and separate from, and without prejudice to, its Corresponding Liabilities, and constitutes a single obligation of that Credit Party to the Collateral Agent (even though that Credit Party may owe more than one Corresponding Liability to the Secured Parties under the Loan Documents) and an independent and separate claim of the Collateral Agent to receive payment of that Parallel Liability (in its capacity as the independent and separate creditor of that Parallel Liability and not as a co-creditor in respect of the Corresponding Liabilities);

(iv) for purposes of this Section 12.11, the Collateral Agent acts in its own name and not as agent, representative or trustee of the Secured Parties and accordingly holds neither its claim resulting from a Parallel Liability nor any Lien securing a Parallel Liability on trust; and

(v) a Credit Party's Parallel Liability will never exceed its Corresponding Liabilities.

(c) For purposes of this Section 12.11:

(i) "**Corresponding Liabilities**" means Obligations excluding each Parallel Liability.

(ii) "**Parallel Liability**" means a Credit Party's undertaking pursuant to this Section 12.11.

(d) This Section 12.11 shall apply only in respect of any Corresponding Liabilities relating to, arising out of or in connection with, the Japanese Security Documents or the Dutch Security Documents or any of the Collateral (as such term is defined in such Japanese Security Documents or Dutch Security Documents, as applicable).

14.12 Notices and Items to Lenders. The Collateral Agent shall deliver to the Lenders each notice, report, statement, approval, direction, consent, exemption, authorization, waiver, certificate, filing or other item received by it pursuant to this Agreement or any other Loan Document (including any item received by it pursuant to Section 3 or set forth on Schedule 5.14 of the Disclosure Letter); provided, that any delivery of or failure to deliver any such notice, report, statement, approval, direction, consent, exemption, authorization, waiver, certificate, filing or item shall not otherwise alter or effect the rights of the Lenders or the Collateral Agent under this Agreement or any other Loan Document or the validity of such item. In addition, to the extent the Collateral Agent or the Required Lenders deliver any notices, approvals, authorizations, directions, consents or waivers to Borrower pursuant to this Agreement or any other Loan Document, the Collateral Agent or the Required Lenders, as applicable, will also deliver such notice, approval, authorization, direction, consent or waiver to the other Lenders on or about the same time such notice, approval, authorization, direction, consent or waiver is provided to Borrower; provided, that the delivery of or failure to deliver such notice, approval, authorization, direction, consent or waiver to the other Lenders shall not in any way effect the obligations of Borrower, or the rights of the Collateral Agent or

the Required Lenders, in respect of such notice, approval, authorization, direction, consent or waiver or the validity thereof.

14.13 Dutch Terms. In this Agreement, where it relates to a Person incorporated or established in the Netherlands and unless a contrary intention appears, a reference to:

(a) "authorization", where applicable, includes without limitation:

(i) any action required to comply with the Dutch Works Council Act (*Wet op de ondernemingsraden*); and

(ii) obtaining a positive or neutral advice (*advies*) from the competent works council(s);

(b) financial assistance means any act contemplated by section 2:98(c) of the Dutch CC;

(c) a security interest includes any mortgage (*hypotheek*), pledge (*pandrecht*), retention-of-title arrangement (*recht van retentie*), right to reclaim goods (*recht van reclame*), right of retention (*recht van retentive*), privilege (*voorrecht*) and, in general, any right in rem (*beperkt recht*) created for the purpose of granting security (*goederenrechtelijk zekerheidsrecht*);

(d) a director in relation to a Dutch Person, means a managing director (*bestuurder*) and board of directors means its managing board (*bestuur*);

(e) gross negligence means *grove schuld*;

(f) moratorium includes *surséance van betaling* and a moratorium declared includes *surséance verleend*;

(g) willful misconduct means *opzet*;

(h) a winding-up, administration or dissolution (and any of those terms) includes a Dutch entity being declared bankrupt (*failliet verklaard*) or dissolved (*ontbonden*);

(i) any step or procedure taken in connection with a insolvency proceeding includes a Dutch entity having filed a notice under Section 36 of the Dutch Tax Collection Act (*Invorderingswet 1990*);

(j) a receiver or trustee in bankruptcy includes a trustee in bankruptcy (*curator*);

(k) an administrator includes a *bewindvoerder*; a *herstructureringsdeskundige* or an *observatory*;

(l) an attachment includes a *beslag* and attaching or taking possession of (any of those terms) includes serving an attachment order (*beslag leggen*); and

(m) works council means each works council (*ondernemingsraad*) or central or group works council (*centrale of groeps ondernemingsraad*) having jurisdiction over that Person.

15 DEFINITIONS

15.1 Definitions. For the purposes of and as used in the Loan Documents: (a) references to any Person include its successors and assigns and, in the case of any Governmental Authority, any Person succeeding to its functions and capacities; (b) except as the context otherwise requires (including to the extent otherwise expressly provided in any Loan Document), (i) references to any law, statute, treaty, order, policy, rule or regulation include any amendments, supplements and successors thereto and (ii) references to any contract, agreement, consent, waiver, instrument or other document include any amendments, restatements, amendments and restatements, supplements or modifications thereto or thereof from time to time to the extent permitted by the provisions thereof; (c) the word "shall" is mandatory; (d) the word "may" is permissive; (e) the word "or" has the inclusive meaning represented by the phrase "and/or"; (f) the words "include", "includes" and "including" are not limiting; (g) the singular includes the plural and the plural includes the singular; (h) numbers denoting amounts that are set off in parentheses are negative unless the context dictates otherwise; (i) each authorization herein shall be deemed

irrevocable and coupled with an interest; (j) all accounting terms shall be interpreted, and all determinations relating thereto shall be made, in accordance with GAAP; (k) references to any time of day shall be to New York time; (l) the words “herein”, “hereof”, “hereby”, “hereto” and “hereunder” refer to this Agreement as a whole; and (m) unless otherwise expressly provided, references to specific sections, articles, clauses, sub-clauses, annexes and exhibits are to this Agreement and references to specific schedules are to the Disclosure Letter. The provisions of this Section 13.1 shall survive the termination of this Agreement. As used in this Agreement, the following capitalized terms have the following meanings:

“**2028 Convertible Notes**” means the 0.75% Convertible Senior Notes due June 1, 2028 issued by Borrower pursuant to that certain Second Supplemental Indenture, dated as of May 13, 2021, by and between Borrower and Wells Fargo Bank, National Association.

“**Account**” means any “account” as defined in the Code with such additions to such term as may hereafter be made, and includes all accounts receivable, book debts, and other sums owing to Credit Parties.

“**Account Debtor**” means any “account debtor” as defined in the Code with such additions to such term as may hereafter be made.

“**Acquisition**” means (a) any Stock Acquisition, or (b) any Asset Acquisition.

“**Additional Consideration**” means, individually or collectively, as the context dictates, the Tranche A Additional Consideration or the Tranche B Additional Consideration.

“**Advance Request Form**” means a Loan Advance Request Form in substantially the form attached hereto as Exhibit A.

“**Adverse Proceeding**” means any action, suit, proceeding, hearing (whether administrative, judicial or otherwise), governmental investigation or arbitration (whether or not purportedly on behalf of any Credit Party or any of its Subsidiaries) at law or in equity, or before or by any Governmental Authority, domestic or foreign (including any Environmental Claims), whether pending or, to the Knowledge of such Credit Party, threatened against or adversely affecting any Credit Party or any of its Subsidiaries or any property of the Borrower or any of its Subsidiaries.

“**Affiliate**” means, with respect to any Person, each other Person that owns or controls, directly or indirectly, such Person, any other Person that controls or is controlled by or is under common control with such Person, and each of that Person’s senior executive officers, directors, partners and, for any Person that is a limited liability company or limited liability partnership, that Person’s managers and members. As used in this definition, “control” means (a) direct or indirect beneficial ownership of at least fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in a Person or (b) the power to direct or cause the direction of the management of such Person by contract or otherwise. In no event shall the Collateral Agent, the Intercreditor Agent or any Lender be deemed to be an Affiliate of Borrower or any of its Subsidiaries.

“**Agreement**” is defined in the preamble hereof.

“**Anti-Money Laundering Laws**” is defined in Section 4.18(b).

“**APPI**” means the Japanese Act on the Protection of Personal Information (Act No. 57 of 2003 as amended in 2015), as amended by the Amended Act on the Protection of Personal Information (Act No. 57 of 2003 as amended in 2020), and including all related guidelines issued by the Japanese Personal Information Protection Commission or other relevant Governmental Authority.

“**Applicable Percentage**” means, with respect to each Lender at any time of determination, (a) with respect to the Tranche A Term Loans, the percentage equal to a fraction, the numerator of which is the outstanding principal amount of such Lender’s portion of the Tranche A Term Loans at such time, and the denominator of which is the

aggregate outstanding principal amount of the Tranche A Term Loans at such time; and (b) with respect to the Tranche B Term Loans, (i) on or prior to the Tranche B Closing Date, the percentage equal to a fraction, the numerator of which is the amount of such Lender's Tranche B Term Loan Commitment at such time and the denominator of which is the aggregate Tranche B Term Loan Commitments at such time or (ii) thereafter, the percentage equal to a fraction, the numerator of which is the outstanding principal amount of such Lender's portion of the Tranche B Term Loans at such time, and the denominator of which is the aggregate outstanding principal amount of the Tranche B Term Loans at such time.

"**ARIKAYCE**®" is defined in the definition of Product.

"**ASC**" is defined in Section 1.

"**Asset Acquisition**" means, with respect to Borrower or any of its Subsidiaries, any purchase, exclusive or nonexclusive in-license or other acquisition of any properties or assets of any other Person (other than assets used and acquired in the ordinary course of business consistent with past practice for consideration that does not include any Contingent Obligation or other contingent consideration), including any purchase or other acquisition of any business unit, line of business or division of such Person. Notwithstanding the foregoing, "Asset Acquisition" does not include any in-license or any collaboration, co-promotion or co-marketing arrangement pursuant to which Borrower or any Subsidiary acquires rights to research, develop, use, make, promote, sell, lease or market the products of another Person.

"**Bankruptcy Code**" means Title 11 of the United States Code entitled "Bankruptcy," as now and hereafter in effect, or any successor statute (and any foreign equivalent).

"**Board of Directors**" means, with respect to any Person, (i) in the case of any corporation, the board of directors of such Person, (ii) in the case of any limited liability company, the board of managers of such Person, or if there is none, the Board of Directors of the managing member of such Person, (iii) in the case of any partnership or exempted limited partnership, the Board of Directors of the general partner of such Person and (iv) in any other case, the functional equivalent of the foregoing.

"**Board of Governors**" means the Board of Governors of the United States Federal Reserve System, or any successor thereto.

"**Books**" means all books and records including ledgers, records regarding a Credit Party's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"**Borrower**" is defined in the preamble hereof.

"**Borrowing Resolutions**" means, with respect to any Credit Party, those resolutions adopted by such Credit Party's Board of Directors and delivered by such Credit Party to the Collateral Agent pursuant to Section 3.1(d) or Section 3.2(b), as applicable, approving the Loan Documents to which such Credit Party is a party and the transactions contemplated thereby (including the Term Loans).

"**Brensocatib**" is defined in the definition of Product.

"**Business Day**" means any day that is not a Saturday or a Sunday or a day on which banks are authorized or required to be closed in New York, New York or London, England.

"**Capital Lease**" means, as applied to any Person, any lease of, or other arrangement conveying the right to use, any property by that Person as lessee that has been or should be accounted for as a capital lease on a balance sheet of such Person prepared in accordance with GAAP (subject to Section 1 hereof).

"**Capital Lease Obligations**" means, at any time, with respect to any Capital Lease, any lease entered into as part of any sale leaseback transaction of any Person or any synthetic lease, the amount of all obligations of such Person that is (or that would be, if such synthetic lease or other lease were accounted for as a Capital Lease) capitalized on a balance sheet of such Person prepared in accordance with GAAP.

"**Cash Equivalents**" means:

(a) securities issued or directly and fully guaranteed or insured by the United States government or any agency or instrumentality of the United States government or by the government of any other member country of the Organisation for Economic Co-operation and Development ("OECD") (provided that the full faith and credit of the United States or such other member country of OECD, as applicable, is pledged in support of those securities) or any agency or instrumentality of the OECD, in each case, having maturities of not more than two (2) years from the date of acquisition;

(b) certificates of deposit, time deposits with maturities of one year or less from the date of acquisition, bankers' acceptances with maturities not exceeding one year and overnight bank deposits and demand deposits, in each case, with any commercial bank having (i) capital and surplus in excess of $500,000,000 in the case of U.S. banks or (ii) capital and surplus in excess of $100,000,000 (or the U.S. dollar equivalent as of the date of determination) in the case of non-U.S. banks or a rating for its long-term unsecured and noncredit enhanced debt obligations of "A" or higher by Standard & Poor's Rating Services or Fitch Ratings Ltd or "A2" or higher by Moody's Investors Service Limited;

(c) commercial paper or marketable short-term money market or readily marketable direct obligations and similar securities having a credit rating of either A-1 or higher by Standard & Poor's Rating Service or F1 or higher by Fitch Ratings Ltd or P-1 or higher Moody's Investors Service Limited, and, in each case, maturing within two (2) years after the date of acquisition;

(d) repurchase obligations with a term of not more than seven (7) days for underlying securities of the types described in clauses (a) and (c) above entered into with any financial institution meeting the qualifications specified in clause (b) above;

(e) investment funds investing ninety-five percent (95.0%) of their assets in securities of the types described in clauses (a) through (d) above and clause (f) below;

(f) investments in money market funds which have a credit rating of either A-1 or higher by Standard & Poor's Rating Service or F1 or higher by Fitch Ratings Ltd or P-1 or higher by Moody's Investors Service Limited (or, if at any time none of Fitch Ratings Ltd, Moody's Investors Service Limited or Standard & Poor's Rating Service shall be rating such obligations, an equivalent rating from another rating agency) and that have portfolio assets of at least $1,000,000,000; and

(g) other investments in accordance with the Borrower's investment policy as of the Tranche B Closing Date or otherwise approved in writing by the Collateral Agent (such approval not to be unreasonably withheld, conditioned or delayed).

"**CCPA**" means the provisions and implementing regulations of the California Consumer Privacy Act, as amended and codified at Cal. Civ. Code § 1798.100 *et seq*.

"**Change in Control**" means: (a) a transaction or series of transactions (including any merger or consolidation involving Borrower) whereby any "person" or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act, but excluding any employee benefit plan of such Person or its Subsidiaries, and any Person acting in its capacity as trustee, agent or other fiduciary or administrator of any such plan) is or becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of a more than fifty percent (50.0%) of any class of outstanding Equity Interests of Borrower ordinarily entitled to vote in the election of directors (or compatible voting Equity Interests), or (ii) obtains the power (whether or not exercised) to elect a

majority of directors of Borrower; (b) a sale, directly or indirectly, of all or substantially all of the consolidated assets of Borrower and its Subsidiaries in one transaction or a series of transactions (whether by way of merger, stock purchase, asset purchase or otherwise); or (c) a merger or consolidation involving Borrower in which Borrower is not the surviving Person or in which Persons holding more than fifty percent (50.0%) of the power to elect a majority of directors of Borrower immediately prior to such merger or consolidation do not continue to hold at least fifty percent (50.0%) of such power immediately after such merger or consolidation.

"**Change in Control Notice**" is defined in Section 2.2(c)(ii).

"**Change in Law**" means the occurrence, after the date of this Agreement, of any of the following: (a) the adoption or taking into effect of any law, treaty, order, policy, rule or regulation, (b) any change in any law, treaty, order, policy, rule or regulation or in the administration, published interpretation or application thereof by any Governmental Authority or (c) the making or issuance of any request, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided that notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall be deemed to be a "Change in Law", regardless of the date enacted, adopted or issued.

"**Closing Date**" means the Tranche A Closing Date or the Tranche B Closing Date, as applicable.

"**CMIA**" means the California Confidentiality of Medical Information Act, Cal. Civ. Code pt. 2.6 § 56 *et seq*.

"**Code**" means the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles of the Code, the definition of such term contained in Article 9 of the Code shall govern; provided, further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, the Collateral Agent's Lien, for the benefit of Lenders and the other Secured Parties, on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"**Collateral**" means, collectively, "Collateral", as such term is defined in the Security Agreement, "Collateral," as such term is defined in the Dutch Security Documents, "Secured Assets," as such term is defined in the Irish Collateral Documents and "Pledged Portfolio," as such term is defined in the Japanese Equity Pledge, any tangible or intangible assets, equity or other property pledged or assigned for security purposes, as the case may be, under the Swiss Security Documents, any tangible or intangible assets, equity or other property pledged under the English Security Documents, and any and all other assets and properties of whatever kind and nature subject or purported to be subject from time to time to a Lien under any Collateral Document, but in any event excluding all Excluded Property.

"**Collateral Access Agreement**" means an agreement, in form and substance reasonably satisfactory to the Collateral Agent and to which the Collateral Agent is a party, pursuant to which a mortgagee or lessor of real property on which Collateral is stored or otherwise located, or a warehouseman, processor or other bailee of Inventory or other property owned by any Credit Party, acknowledges the Liens and security interests of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, and waives (or, if approved by the Collateral Agent in its sole discretion, subordinates) any Liens or security interests held by such Person on any such Collateral, and, in the case of any such agreement with a mortgagee or lessor, permits the Collateral Agent and any Lender (and its representatives and designees) reasonable access to any Collateral stored or otherwise located thereon.

"**Collateral Account**" means any Deposit Account of a Credit Party maintained with a bank or other depository or financial institution located in the United States, any Securities Account of a Credit Party maintained with a securities intermediary located in the United States, or any Commodity Account of a Credit Party maintained with a commodity intermediary located in the United States, in each case, other than an Excluded Account.

"**Collateral Agent**" is defined in the preamble hereof.

"**Collateral Documents**" means the Security Agreement, the Japanese Security Documents, the Swiss Security Documents, the Irish Collateral Documents, the Dutch Security Documents, the English Security Documents, the Control Agreements, the IP Agreements, any Mortgages and all other instruments, documents and agreements delivered by any Credit Party pursuant or incidental to this Agreement or any of the other Loan Documents, in each case, in order to grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, or perfect a Lien on any Collateral as security for the Obligations, and all amendments, restatements, modifications or supplements thereof or thereto.

"**Commodity Account**" means any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"**Common Rule**" means the U.S. Federal Policy for the Protection of Human Subjects, codified at 45 C.F.R. part 46, and any foreign (or United States state) equivalents.

"**Company IP**" means any and all of the following, as they exist in and throughout the Territory: (a) Current Company IP; (b) improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications with respect to any Current Company IP, any patent issued with respect to any of the Current Company IP, including any patent right claiming the apparatus, system, component or composition of matter of, or the method of making or using, the Product in the Territory, any reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent and all foreign and international counterparts of any of the foregoing, and any confirmation patent or registration patent or patent of addition based on any such patent; (c) trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how, operating manuals, confidential or proprietary information, research in progress, algorithms, data, databases, data collections, designs, processes, procedures, methods, protocols, materials, formulae, drawings, schematics, blueprints, flow charts, models, strategies, prototypes, techniques, and the results of experimentation and testing, including samples, in each case, as specifically related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory; and (d) to the extent not described in clauses (a), (b) or (c) above, any and all IP Ancillary Rights specifically relating to any of the foregoing (other than all income, royalties, proceeds and liabilities at any time due and payable or asserted under or with respect to any of the foregoing), including, for the avoidance of doubt, all rights to sue or recover at law or in equity for any past, present or future infringement, misappropriation, dilution, violation or other impairment thereof, and, in each case, all rights to obtain any other intellectual property right ancillary to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights.

"**Company IP Agreement**" means each material contract or agreement, pursuant to which Borrower or any of its Subsidiaries has the legal right to exploit Current Company IP or other Intellectual Property that is owned by another Person and material to the business of Borrower and its Subsidiaries, to research, develop, manufacture, produce, use, supply, commercialize, market, import, store, transport, offer for sale or lease, distribute or sell or lease Product, including: (a) the License Agreement, dated as of April 25, 2008, between Borrower (as successor in interest to Transave, Inc.) and PARI Pharma GmbH, as amended by Amendment No. 1 to License Agreement effective June 24, 2009, Assignment and Amendment No. 2 to License Agreement effective December 22, 2010, Amendment No. 3 to License Agreement effective March 6, 2012, Amendment No. 4 to License Agreement effective May 21, 2012, Amendment No. 5 to License Agreement effective October 5, 2015, Amendment No. 6 to License Agreement effective October 9, 2015, Amendment No. 7 to License Agreement effective July 21, 2017 and Amendment No. 8 to License Agreement effective December 19, 2018; (b) the Commercialization Agreement, dated as of July 8, 2014, between Borrower and PARI Pharma GmbH, as amended by Amendment No. 1 to

Commercialization Agreement effective as of July 21, 2017 and Amendment No. 2 to Commercialization Agreement effective July 20, 2018; (c) the Technology Transfer Agreement, dated as of October 20, 2017, between Borrower and Patheon UK Limited; (d) the Amendment to Technology Transfer Agreement and Manufacturing and Supply Agreement, dated as of March 11, 2021, between Borrower and Patheon UK Limited; (e) the Master Agreement for Pharmaceutical Development and Technology Transfer Services, effective May 23, 2018, between Borrower and Patheon Inc.; (f) the License Agreement, dated as of October 4, 2016, between Borrower and AstraZeneca AB; (g) the Contract Manufacturing Agreement, dated February 7, 2014, between Borrower and Resilience Biotechnologies Inc. (as successor in interest to Therapure Biopharma Inc.), as amended by the Amending Agreement dated March 13, 2014; (h) the API Supply Agreement, dated as of November 11, 2015, between ACS Dobfar, Interchem Corporation and Borrower, as amended; and (h) the Master Services Agreement between Insmed Incorporated and Esteve Quimica, S.A., dated as of January 23, 2018, as amended.

"**Competitor**" means, at any time of determination, any Person (and each other Person that owns or controls, directly or indirectly, such Person, or that controls or is controlled by or is under common control with such Person) that is directly and primarily engaged in the same, substantially the same, or similar line of business as Borrower and its Subsidiaries, taken as a whole, as of such time.

"**Compliance Certificate**" means that certain certificate in the form attached hereto as Exhibit E.

16 "**Connection Income Taxes**" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

"**Contingent Obligation**" means, for any Person, (a) any direct or indirect liability, contingent or not, of that Person for any indebtedness, lease, dividend, letter of credit or other obligation of another Person directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable (other than by endorsements of instruments in the course of collection) and (b) any obligation of that Person to pay an earn-out payment, milestone payment or other contingent payment or contingent compensation (including purchase price adjustments, royalties and milestone payments payable upon achievement of levels of net sales) to a counterparty incurred or created in connection with an Acquisition, Transfer, Investment or otherwise in connection with any license, collaboration, development or similar agreement, in each instance where such contingent payment or compensation becomes due and payable upon the occurrence of an event or the performance of an act (and not solely with the passage of time). The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the amount required to be shown as liability on the balance sheet of such Person in accordance with GAAP (or, if not required to be so shown, the maximum reasonably anticipated amount reasonably determined by a Responsible Officer of such Person in good faith); but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement. Notwithstanding anything to the contrary in the foregoing, Permitted Equity Derivatives shall not constitute a Contingent Obligation.

"**Control Agreement**" means, with respect to any Credit Party, any control agreement entered into among such Credit Party, the Collateral Agent and, in the case of a Deposit Account, the bank or other depository or financial institution located in the United States at which such Credit Party maintains such Deposit Account, or, in the case of a Securities Account or a Commodity Account, the securities intermediary or commodity intermediary located in the United States at which such Credit Party maintain such Securities Account or Commodities Account, in either case, pursuant to which the Collateral Agent obtains control (within the meaning of the Code), or otherwise has a perfected first priority security interest (subject to any Permitted Liens), over such Collateral Account.

17 "**Convertible Indebtedness Redemption**" is defined in Section 2.2(c)(iii).

18 "**Convertible Indebtedness Redemption Notice**" is defined in Section 2.2(c)(iii).

"**Copyrights**" means any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret (and all related IP Ancillary Rights).

19 "**CPRA**" means the California Privacy Rights Act.

"**Credit Extension**" means any Term Loan or any other extension of credit by any Lender for Borrower's benefit pursuant to this Agreement.

"**Credit Party**" means Borrower and each Guarantor.

"**CRR**" means Regulation (EU) no. 575/2013 of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending regulation (EU) No. 648/2012.

"**Current Company IP**" is defined in Section 4.6(c).

"**Data Protection Laws**" means any and all applicable foreign or domestic (including U.S. federal, state and local), statutes, ordinances, orders, rules, regulations, judgments, Governmental Approvals, or any other requirements of Governmental Authorities relating to the privacy, security, notification of breaches or confidentiality of Personal Data, including, to the extent applicable to the Borrower or any of its Subsidiaries, HIPAA, Section 5 of the FTC Act and other consumer protection laws, GDPR, APPI, CCPA, CPRA and other comprehensive state privacy laws, CMIA and other U.S. state medical information privacy laws and genetic testing laws.

"**Default**" means any breach of or default under any term, provision, condition, covenant or agreement contained in this Agreement or any other Loan Document or any other event, in each case that, with the giving of notice or the lapse of time or both, would constitute an Event of Default.

"**Default Rate**" is defined in Section 2.3(b).

"**Deposit Account**" means any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"**Disclosure Letter**" means the disclosure letter, dated the Tranche B Closing Date, delivered by the Credit Parties to the Collateral Agent pursuant to Section 3.2(a).

"**Disqualified Assignee**" means (a) any Competitor, or (b) any Person listed on Schedule 13.1 of the Disclosure Letter.

"**Disqualified Equity Interest**" means any Equity Interest that, by its terms (or by the terms of any security or other Equity Interests into which it is convertible or for which it is exchangeable) or upon the happening of any event or condition: (a) matures or is mandatorily redeemable, pursuant to a sinking fund obligation or otherwise (except if redeemable or convertible into other Equity Interest that would not constitute a Disqualified Equity Interest or as a result of a change of control, asset sale or similar event so long as any and all rights of the holders thereof upon the occurrence of a change of control, asset sale or similar event shall be subject to the prior repayment in full in cash of the Term Loans and the satisfaction in full of all other Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) in accordance with the terms of this Agreement); (b) is redeemable at the option of the holder thereof, in whole or in part (except if redeemable or convertible into other Equity Interest that would not constitute a Disqualified Equity Interest or as a result of a change of control, asset sale or similar event so long as any rights of the holders thereof upon the occurrence of a change of control, asset sale or similar event shall be subject to the prior repayment in full in cash of the Term Loans and the satisfaction in full of all other Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto have been asserted) in accordance with this Agreement); (c) provides for the scheduled

payments of dividends or distributions in cash; or (d) is convertible into or exchangeable for (i) Indebtedness which is not Permitted Indebtedness or (ii) any other Equity Interest that would constitute a Disqualified Equity Interest; in each case described in clauses (a) through (d) above, prior to the date that is 120 days after the Term Loan Maturity Date; provided that, if any such Equity Interest is issued pursuant to any plan for the benefit of any employee, director, manager or consultant of the Borrower or its Subsidiaries or by any such plan to such employee, director, manager or consultant, such Equity Interest shall not constitute a "Disqualified Equity Interest" solely because it may be required to be repurchased by the Borrower or its Subsidiaries in order to satisfy applicable statutory or regulatory obligations or as a result of the termination, death or disability of such employee, director, manager or consultant.

"**Dollars**," "**dollars**" or use of the sign "**$**" means only lawful money of the United States and not any other currency, regardless of whether that currency uses the "$" sign to denote its currency or may be readily converted into lawful money of the United States.

"**Domestic Subsidiary**" means, with respect to any Credit Party, a Subsidiary of such Credit Party that is incorporated or organized under the laws of the United States.

"**Dutch CC**" means the Dutch Civil Code (*Burgerlijk Wetboek*).

"**Dutch Obligor**" means a Credit Party incorporated under Netherlands law.

"**Dutch Security Documents**" means

(a) the Dutch law governed deed of pledge of receivables, moveable assets and IP security assets between (i) Insmed Netherlands B.V. as a pledgor, (ii) Insmed Netherlands Holdings B.V., as a pledgor and (ii) the Collateral Agent as pledgee; and

(b) the Dutch law governed deed of pledge of shares in the capital of Insmed Netherlands B.V. between Insmed Ireland Limited as pledgor, the Collateral Agent as pledgee and Insmed Netherlands B.V. as company.

"**Effective Date**" is defined in the preamble hereof.

"**ENCORE Event**" means the occurrence of a statistically significant improvement in the change from baseline to Month 13 in the respiratory symptom score and the proportion of subjects achieving durable culture conversion at Month 15 between the ARIKAYCE® treatment group and the placebo control group.

"**English Security Documents**" means:

(a) the English law governed debenture dated 22 February 2024 between (i) Insmed Innovation UK Ltd. as chargor and (ii) the Collateral Agent; and

(b) the English law governed share charge dated 22 February 2024 between (i) Insmed Incorporated as chargor and (ii) the Collateral Agent.

"**Environmental Claim**" means any investigation, notice, notice of violation, claim, action, suit, proceeding, demand, abatement order or other order or directive (conditional or otherwise), by any Governmental Authority or any other Person, arising (i) pursuant to or in connection with any actual or alleged violation of any Environmental Law; (ii) in connection with any Hazardous Material or any actual or alleged Hazardous Materials Activity; or (iii) in connection with any actual or alleged damage, injury, threat or harm to health, safety, natural resources or the environment.

"**Environmental Laws**" means any and all current or future, foreign or domestic, statutes, ordinances, orders, rules, regulations, judgments, Governmental Approvals, or any other requirements of Governmental Authorities relating to (i) environmental matters, including those relating to any Hazardous Materials Activity; (ii)

the generation, use, storage, transportation or disposal of Hazardous Materials; or (iii) occupational safety and health, industrial hygiene, land use or the protection of human, plant or animal health or welfare, in each case, in any manner applicable to any Credit Party or any of its Subsidiaries or any Facility.

"**Equity Cash Proceeds**" means, with respect to any issuance of Equity Interests after the Tranche A Closing Date, the amount in excess of $[***] in cash proceeds (net of reasonable costs associated therewith) actually received by Borrower from all such issuances, which have not been previously used to redeem Permitted Convertible Indebtedness.

"**Equity Interests**" means, with respect to any Person, collectively, any and all shares, interests, participations or other equivalents (however designated) of capital stock of a corporation, any and all equivalent ownership interests in such Person (other than a corporation), including partnership interests and membership interests, and any and all warrants, rights or options to purchase or other arrangements or rights to acquire (by purchase, conversion, dividend, distribution or otherwise) any of the foregoing (and all other rights, powers, privileges, interests, claims and other property in any manner arising therefrom or relating thereto); provided, however, that any Permitted Convertible Indebtedness or other Indebtedness convertible into Equity Interests (or into any combination of cash and Equity Interests based on the value of such Equity Interests) shall not constitute Equity Interests unless and until (and solely to the extent) so converted into Equity Interests.

"**ERISA**" means the Employee Retirement Income Security Act of 1974, and the regulations promulgated thereunder.

"**ERISA Affiliate**" means, with respect to any Person, any trade or business (whether or not incorporated) that, together with such Person, is treated as a single employer under Section 414(b) or (c) of the IRC or, solely for purposes of Section 302 of ERISA or Section 412 of the IRC, Section 414(m) or (o) of the IRC.

"**ERISA Event**" means (a) any "reportable event," as defined in Section 4043 of ERISA or the regulations issued thereunder, with respect to a Plan (other than an event for which the 30-day notice period is waived by regulation); (b) with respect to a Plan, the failure by Borrower or its Subsidiaries or their ERISA Affiliates to satisfy the minimum funding standard of Section 412 of the IRC and Section 302 of ERISA, whether or not waived; (c) the failure by Borrower or its Subsidiaries or their ERISA Affiliates to make by its due date a required installment under Section 430(j) of the IRC with respect to any Plan or to make any required contribution to a Multiemployer Plan; (d) the filing pursuant to Section 412(c) of the IRC or Section 302(c) of ERISA of an application for a waiver of the minimum funding standard with respect to any Plan; (e) the incurrence by Borrower or any of its ERISA Affiliates of any liability under Title IV of ERISA with respect to the termination of any Plan; (f) the receipt by Borrower or its Subsidiaries or any of their respective ERISA Affiliates from the Pension Benefit Guaranty Corporation (referred to and defined in ERISA) or a plan administrator of any notice relating to the intention to terminate any Plan under Section 4041 or any Multiemployer Plan under 4041A of ERISA or to appoint a trustee to administer any Plan under Section 4042 of ERISA, or the occurrence of any event or condition which could reasonably be expected to constitute grounds under ERISA for the termination of, or the appointment of a trustee to administer, any Plan under Section 4041 Section or 4042 of ERISA; (g) the incurrence by Borrower or its Subsidiaries or any of their respective ERISA Affiliates of any liability with respect to the withdrawal from any Plan pursuant to Section 4063 of ERISA or Multiemployer Plan; (h) the receipt by Borrower or its Subsidiaries or any of their respective ERISA Affiliates of any notice, concerning the imposition of Withdrawal Liability or a determination that a Multiemployer Plan is, or is expected to be, insolvent, within the meaning of Section 4245 of ERISA; (i) the "substantial cessation of operations" by Borrower or its Subsidiaries or their ERISA Affiliates within the meaning of Section 4062(e) of ERISA with respect to a Plan; or (j) the occurrence of a nonexempt prohibited transaction (within the meaning of Section 4975 of the IRC or Section 406 of ERISA) with respect to a Plan which could reasonably be expected to result in a material liability to Borrower or its Subsidiaries.

"**EU Laws**" means all applicable statutes, rules and regulations implemented administered or enforced by the European Commission, the European Medicines Agency ("**EMA**") or the competent authorities of the EU Member States including, but not limited to, the EU Community Code on medicinal products (Directive 2001/83/EC), the EMA Regulation (Regulation (EC) No 726/2004), the Manufacturing Directive (Commission Directive

2003/94/EC), the Clinical Trials Regulation (Regulation (EU) No 536/2014), and related implementing legislation of individual EU Member States and related guidance at EU level and national level in individual EU Member States.

"**Event of Default**" is defined in Section 7.

"**Exchange Act**" means the Securities Exchange Act of 1934.

"**Exchange Act Documents**" means any and all documents filed by Borrower with the SEC pursuant to the Exchange Act.

"**Excluded Accounts**" is defined in Section 5.5.

"**Excluded Equity Interests**" means, collectively: (i) any Equity Interests in any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) are validly prohibited by Requirements of Law; (ii) any Equity Interests in any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party and such consent, approval or waiver has not been obtained by Borrower following Borrower's commercially reasonable efforts to obtain the same; (iii) any Equity Interests in any Subsidiary that is a non-Wholly-Owned Subsidiary that the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Borrower or an Affiliate of Borrower) the right to terminate its obligations under, the Operating Documents or the joint venture agreement or shareholder agreement with respect to, or any other contract with such third party relating to such non-Wholly-Owned Subsidiary, including any contract evidencing Indebtedness of such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Document, joint venture agreement, shareholder agreement or other contract is in effect; (iv) all or a portion of the Equity Interests in a Foreign Subsidiary the pledge of which would, as a result of a change in Requirements of Law following the date hereof, be reasonably be expected to result in an income inclusion for Borrower under Section 956 of the IRC (or a successor or similar provision) or Treasury Regulations promulgated thereunder that causes a material adverse tax consequence to Borrower and its Subsidiaries, taken as a whole; and (v) any Equity Interests in any other Subsidiary with respect to which, Borrower and the Collateral Agent reasonably determine by mutual agreement that the cost (including the Tax costs) of granting the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a security interest in and Lien upon, and pledging to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, such Equity Interests, to secure the Obligations (and any guaranty thereof) are excessive, relative to the value to be afforded to the Secured Parties thereby.

20 "**Excluded License**" means an exclusive or non-exclusive license or exclusive or non-exclusive sublicense, to a Person other than a Subsidiary of Borrower, of any Intellectual Property within the U.S., Japan, France, Germany, Italy, Spain or the United Kingdom covering Product that conveys to the licensee or sublicensee exclusive rights to practice all or substantially all rights to such Intellectual Property in the U.S., Japan, France, Germany, Italy, Spain or the United Kingdom, for which the consideration (i) does not consist of the type based upon (x) future development or commercialization of Product in the U.S., Japan, France, Germany, Italy, Spain or the United Kingdom (such as earn-out payments, milestone (whether financial, regulatory or otherwise in nature) payments or royalties based on net sales) or (y) performance of services by Borrower or any of its Subsidiaries (such as transition services), and (ii) consists only of upfront advances or initial license fees or similar initial payments, with no anticipated subsequent payments or only *de minimis* payments to Borrower or any of its Subsidiaries.

"**Excluded Property**" has the meaning set forth for such term in the Security Agreement.

"**Excluded Subsidiaries**" means, collectively: (i) any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests in such Subsidiary to secure the Obligations (and any guaranty thereof) are validly prohibited by Requirements of Law (for the avoidance of doubt, not including the Operating Documents of such Subsidiary, except to the extent covered in sub-clause (ii) or (iii) below); (ii) any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests in such Subsidiary to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party (other than Borrower or an Affiliate of Borrower) and any such consent, approval or waiver has not been obtained, directly or indirectly, by Borrower following Borrower's direct and indirect commercially reasonable efforts to obtain the same; (iii) any Subsidiary that is a non-Wholly-Owned Subsidiary, with respect to which, the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, the properties and assets of such non-Wholly-Owned Subsidiary, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Borrower or an Affiliate of Borrower) the right to terminate its obligations under, such non-Wholly-Owned Subsidiary's Operating Documents or the joint venture agreement or shareholder agreement with respect thereto or any other contract with such third party relating to such non-Wholly-Owned Subsidiary, including any contract evidencing Indebtedness of such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Document, joint venture agreement, shareholder agreement or other contract is in effect; (iv) any Subsidiary that owns properties and assets with an aggregate fair market value (as reasonably determined in good faith by a Responsible Officer of Borrower) of less than $[***]; (v) each of (A) Celtrix Pharmaceuticals, Inc., (B) any Foreign Subsidiary organized under the laws of France, the United Kingdom, Italy or Germany and existing as of the Tranche A Closing Date, and (C) any other Subsidiary not organized in Japan, Ireland, the Netherlands, Switzerland and the United States, unless, in each case of sub-clauses (A), (B) and (C) above, such Subsidiary at any time (w) owns, co-owns or otherwise maintains any material Company IP, (x) licenses any Company IP from any third party, (y) enters into any Material Contract or otherwise becomes a party thereto or bound thereby or (z) otherwise engages in any business operations material to any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Product in the Territory (in which case the parties hereto agree that any such Subsidiary shall constitute a Credit Party for all purposes under the Loan Documents as of the date of such ownership, co-ownership, maintenance, license, entry or becoming so bound, or engagement); and (vi) any other Subsidiary with respect to which, Borrower and the Collateral Agent reasonably determine by mutual agreement that the cost (including Tax costs) of granting the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a security interest in and Lien upon, and pledging to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests of such Subsidiary to secure the Obligations (and any guaranty thereof) are excessive relative to the value to be afforded to the Secured Parties thereby. Notwithstanding the foregoing or any other provision of this Agreement, no Subsidiary existing as of the Tranche A Closing Date or organized, formed or acquired, directly or indirectly, by any Credit Party from and after the Tranche A Closing Date (including any Intercompany Reorganization Subsidiary), that at any time (A) owns, co-owns or otherwise maintains any material Company IP, (B) licenses any Company IP from any third party, (C) enters into any Material Contract or otherwise becomes a party thereto or bound thereby or (D) otherwise engages in any business operations material to any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Product in the U.S., Japan, France, Germany, Italy, Spain or the United Kingdom shall be (or shall be deemed to be) an

Excluded Subsidiary for any purpose under the Loan Documents without the prior written consent of the Collateral Agent or the Required Lenders.

21 "**Excluded Taxes**" means any of the following Taxes imposed on or with respect to Lender or required to be withheld or deducted from a payment to Lender, (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed as a result of Lender being organized under the laws of, or having its principal office or its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes, (b) U.S. federal withholding Taxes imposed on amounts payable to or for the account of Lender with respect to any Obligation pursuant to a law in effect on the date on which (i) Lender acquires such interest in any Obligation or (ii) Lender changes its lending office, except in each case to the extent that, pursuant to Section 2.6, amounts with respect to such Taxes were payable either to Lender's assignor immediately before Lender became a party hereto or to Lender immediately before it changed its lending office, (c) Taxes attributable to Lender's failure to comply with Section 2.6(d), and (d) any withholding Taxes imposed under FATCA.

"**Exit Fee**" means the Tranche A Exit Fee or the Tranche B Exit Fee, individually or collectively, as applicable.

"**Export and Import Laws**" means any applicable law, regulation, order or directive that applies to the import, export, re-export, transfer, disclosure or provision of goods, software, technology or technical assistance including, without limitation, restrictions or controls administered pursuant to the U.S. Export Administration Regulations, 15 C.F.R. Parts 730-774, administered by the U.S. Department of Commerce, Bureau of Industry and Security; U.S. Customs regulations; and similar import and export laws, regulations, orders and directives of other jurisdictions to the extent applicable.

"**Facility**" means, with respect to any Credit Party, any real property (including all buildings, fixtures or other improvements located thereon) now, hereafter or heretofore owned, leased, operated or used by such Credit Party or any of its Subsidiaries or any of their respective predecessors or Affiliates.

"**FATCA**" means Sections 1471 through 1474 of the IRC, as of the date of this Agreement (including, for the avoidance of doubt, any agreements between the governments of the United States and the jurisdiction in which the applicable Lender is resident implementing such provisions), or any amended or successor version that is substantively comparable and not materially more onerous to comply with, and any current or future regulations promulgated thereunder or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the IRC, any intergovernmental agreement entered into in connection with the implementation of the foregoing sections of the IRC and any fiscal or regulatory legislation, regulations, rules or practices adopted pursuant to, or official interpretations implementing such Sections of the IRC or intergovernmental agreements.

"**FCPA**" is defined in Section 4.18(a).

"**FDA**" means the United States Food and Drug Administration (and any United States state equivalent).

"**FDA Approval Date**" means the date on which the FDA has granted approval (including accelerated approval) of an NDA for brensocatib in any form for the treatment of bronchiectasis, or an indication that is substantially the same.

"**FDA Laws**" means all applicable statutes (including the FDCA and PHSA), rules and regulations implemented, administered, or enforced by the FDA (and any United States state equivalents), and as interpreted through applicable guidance documents by the FDA.

"**FDCA**" is defined in Section 4.19(b).

"**Federal Reserve Board**" means the Board of Governors of the Federal Reserve System.

"**First Amendment Effective Date**" means June 30, 2023.

22 "**Foreign Lender**" means a Lender that is not a "United States person" as defined in Section 7701(a)(30) of the IRC.

23 "**Foreign Subsidiary**" means, with respect to any Credit Party, any Subsidiary of such Credit Party that is not a Domestic Subsidiary.

"**GAAP**" means with respect to Borrower and its Subsidiaries, generally accepted accounting principles in the United States as set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession, which are applicable to the circumstances as of the date of determination, consistently applied.

"**GDPR**" means, collectively, (i) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (the "**EU GDPR**") and (ii) the EU GDPR as it forms part of the laws of the United Kingdom by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (the "**UK GDPR**").

24 "**Good Clinical Practices**" means the standards set forth in 21 C.F.R. Parts 50, 54, 56, 312, 314 and 316 (and any foreign equivalents), and as interpreted through applicable guidance documents by FDA (and foreign equivalents).

25 "**Good Laboratory Practices**" means the standards set forth in 21 C.F.R. Part 58 (and any foreign equivalent), and as interpreted through applicable guidance documents by FDA (and foreign equivalents).

26 "**Good Manufacturing Practices**" means the good manufacturing practice and quality system standards set forth in 21 C.F.R. Parts 4, 210, 211, 600, 610, and 820 (and any foreign equivalents), and as interpreted through applicable guidance documents by FDA (and foreign equivalents).

"**Governmental Approval**" means any consent, authorization, approval, licensure, clearance, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"**Governmental Authority**" means any nation or government, any state or other political subdivision thereof, any agency (including Regulatory Agencies, data protection authorities, and agencies acting as supervisory governmental organizations on issues of privacy protection), government department, authority (including state attorneys general), instrumentality, regulatory body, ministry, commission, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"**Governmental Payor Programs**" means all governmental third party payor programs in which any Credit Party or its Subsidiaries participates, including Medicare, Medicaid, TRICARE or any other U.S. federal or state health care programs.

"**Guarantor**" means, at any time, any Person that is, pursuant to the terms of any Loan Document, a guarantor of any of the Obligations at that time.

"**Hazardous Materials**" means any chemical, material or substance, exposure to which is prohibited, limited or regulated by any Governmental Authority or which may or could pose a hazard to the health and safety of the owners, occupants or any Persons in the vicinity of any Facility or to the indoor or outdoor environment.

"**Hazardous Materials Activity**" means any past, current, proposed or threatened activity, event or occurrence involving any Hazardous Materials, including the use, manufacture, possession, storage, holding, presence, existence, location, Release, threatened Release, discharge, placement, generation, transportation, processing, construction, treatment, abatement, removal, remediation, disposal, disposition or handling of any Hazardous Materials, and any corrective action or response action with respect to any of the foregoing.

"**Health Care Laws**" means, collectively: (a) applicable federal, state or local laws, rules, regulations, codes, orders, ordinances, statutes and requirements issued under or in connection with Medicare, Medicaid or any other Government Payor Program; (b) applicable federal and state laws and regulations governing the privacy, security, notification of breaches regarding and other confidentiality of health information, including HIPAA and Section 5 of the FTC Act; (c) applicable federal, state and local fraud and abuse laws of any Governmental Authority, including the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7(b)), the civil False Claims Act (31 U.S.C. § 3729 et seq.), Sections 1320a-7 and 1320a-7a of Title 42 of the United States Code and the regulations promulgated pursuant to such statutes; (d) the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173) and the regulations promulgated thereunder; (e) the Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h); (f) any applicable reporting and disclosure requirements, including any arising under Section 603 of the Veteran's Health Care Act (Quarterly and Annual Non-Federal Average Manufacturer Price and Federal Ceiling Price), Best Price, Federal Supply Schedule Contract Prices and Tricare Retail Pharmacy Refunds, and Medicare Part D; (g) applicable federal, state or local laws, rules, regulations, ordinances, statutes and requirements relating to (x) the regulation of managed care, third party payors and Persons bearing the financial risk for the provision or arrangement of health care services, (y) billings to insurance companies, health maintenance organizations and other Managed Care Plans or otherwise relating to insurance fraud and (z) any insurance, health maintenance organization or managed care Requirements of Law; (h) regulations for the protection of human research subjects (including 45 C.F.R. part 46); and (i) any other applicable Requirements of Law, including any EU, Japanese or other foreign equivalents, relating to any aspect of the research, development, testing, approval, exclusivity, licensure, clearance, authorization, designation, post-authorization (or post-licensure, post-clearance, or post-approval, as applicable) monitoring or commitments, reporting (including post-marketing safety reports for combination products), manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale or lease, distribution or sale or lease of or payment for Product.

"**Hedging Agreement**" means any interest rate, currency, commodity or equity swap, collar, cap, floor or forward rate agreement, or other agreement or arrangement designed to protect a Person against fluctuations in interest rates, currency exchange rates or commodity or equity prices or values (including any option with respect to any of the foregoing and any combination of the foregoing agreements or arrangements), and any confirmation execution in connection with any such agreement or arrangement. Notwithstanding anything to the contrary in the foregoing, any Permitted Equity Derivative shall not constitute a Hedging Agreement.

"**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996, as amended and supplemented by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, any and all rules or regulations promulgated from time to time thereunder, and any U.S. state or federal laws with regard to the security, privacy, or notification of breaches of the confidentiality of health information which are not preempted pursuant to 45 C.F.R. Part 160, Subpart B.

27 "**IFRS**" means international accounting standards within the meaning of IAS Regulation 1606/2002 to the extent applicable to the relevant financial statements.

"**Indebtedness**" means, with respect to any Person, without duplication: (a) all indebtedness for advanced or borrowed money of, or credit extended to, such Person; (b) all obligations issued, undertaken or assumed by such Person as the deferred purchase price of assets, properties, services or rights (other than (i) accrued expenses and trade payables entered into in the ordinary course of business which are not more than one hundred and eighty (180) days past due or subject to a bona fide dispute, (ii) obligations to pay for services provided by employees and individual independent contractors in the ordinary course of business which are not more than one hundred and twenty (120) days past due or subject to a bona fide dispute, (iii) liabilities associated with customer prepayments and deposits, and (iv) prepaid or deferred revenue arising in the ordinary course of business), including (A) any obligation or liability to pay deferred purchase price or other similar deferred consideration for such assets, properties, services or rights where such deferred purchase price or consideration becomes due and payable solely upon the passage of time, and (B) any obligation described in clause (b) of the definition of "Contingent Obligation;" (c) the face amount of all letters of credit issued for the account of such Person and, without duplication, all drafts drawn thereunder and all reimbursement or payment obligations with respect to letters of credit, surety bonds, performance bonds and other similar instruments issued by such Person; (d) all obligations of such Person evidenced by notes, bonds, debentures or other debt securities or similar instruments (including debt securities convertible into Equity Interests, including Permitted Convertible Indebtedness), including obligations so evidenced incurred in connection with the acquisition of properties, assets or businesses; (e) all indebtedness of such Person created or arising under any conditional sale or other title retention agreement or incurred as financing, in either case with respect to property acquired by such Person (even though the rights and remedies of the seller or bank under such agreement in the event of default are limited to repossession or sale of such property); (f) all Capital Lease Obligations of such Person; (g) the principal balance outstanding under any synthetic lease, off-balance sheet loan or similar off balance sheet financing product by such Person; (h) Disqualified Equity Interests; (i) all indebtedness referred to in clauses (a) through (g) above of other Persons secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien upon or in assets or properties (including accounts and contracts rights) owned by such Person, even though such Person has not assumed or become liable for the payment of such indebtedness of such other Persons; and (j) all Contingent Obligations of such Person described in clause (a) of the definition thereof. For the avoidance of doubt, "Indebtedness" shall include Permitted Convertible Indebtedness, but shall not include any Permitted Equity Derivative.

28 "**Indemnified Liabilities**" means, collectively, any and all liabilities, obligations, losses, damages (including natural resource damages), penalties, claims, actions, judgments, suits, costs, reasonable and documented out-of-pocket fees, expenses and disbursements of any kind or nature whatsoever (including the reasonable and documented fees, expenses and disbursements of counsel for Indemnified Persons (it being agreed that such legal counsel fees and expenses shall be limited to one primary legal counsel, one local legal counsel in each applicable jurisdiction and one intellectual property legal counsel (as and to the extent applicable) for the Indemnified Persons)) incurred by any Indemnified Person or asserted against any Indemnified Person by any Person (including Borrower) relating to or arising out of or in connection with, or as a result of, this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby (including any Lender's agreement to make Credit Extensions or the use or intended use of the proceeds thereof, or any enforcement of any of the Loan Documents (including any sale of, collection from, or other realization upon any of the Collateral or the enforcement of any guaranty of the Obligations)), including (i) the execution or delivery of this Agreement, any other Loan Document or any agreement or instrument contemplated hereby or thereby, the performance by the parties hereto of their respective obligations hereunder or thereunder or the consummation of the transactions contemplated hereby or thereby, (ii) any Term Loan or the use or proposed use of the proceeds therefrom, (iii) any actual or alleged presence or release of Hazardous Materials on or from any property owned or operated by Borrower or any of its Subsidiaries, or any liability relating to any Environmental Law, any Release of Hazardous Materials or any Hazardous Materials Activity, (iv) any actual or prospective claim, suit, litigation, investigation, hearing or proceeding relating to any of the foregoing, whether based on contract, tort or any other theory, whether brought by, commenced or threatened in writing by any Person (including Borrower or any of its affiliates), and regardless of whether any Indemnified

Person is or is designated as a party or a potential party thereto, and (v) the enforcement of the indemnity hereunder, in each case whether direct, indirect or consequential and whether based on any federal, state or foreign laws, statutes, rules or regulations, on common law or equitable cause or on contract or otherwise, that may be imposed on, incurred by, or asserted against any such Indemnified Person, in any manner.

"**Indemnified Person**" is defined in Section 11.2(a).

29 "**Indemnified Taxes**" means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of any Credit Party under any Loan Document and (b) to the extent not otherwise described in clause (a) above, Other Taxes.

"**Insolvency Proceeding**" means, with respect to any Person, any proceeding by or against such Person under the Bankruptcy Code, or any other domestic or foreign bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, examinership or other relief; provided, however, that, solely with respect to any Person incorporated, organized or formed in any jurisdiction other than the United States, "Insolvency Proceeding" shall not include any winding-up petition against such Credit Party which is frivolous or vexatious and is discharged or dismissed within thirty (30) days of the commencement thereof or any step or procedure in connection with any transaction otherwise permitted under this Agreement.

"**Intellectual Property**" means all:

(a) Copyrights, Trademarks, and Patents;

(b) trade secrets and trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals;

(c) (i) all computer programs, including source code and object code versions, (ii) all data, databases and compilations of data, whether machine readable or otherwise, and (iii) all documentation, training materials and configurations related to any of the foregoing (collectively, "**Software**");

(d) all right, title and interest arising under any contract or Requirements of Law in or relating to Internet Domain Names;

(e) design rights;

(f) IP Ancillary Rights (including all IP Ancillary Rights related to any of the foregoing); and

(g) all other intellectual property or industrial property rights.

30 "**Intercompany Reorganization**" means any and all entity formations, asset transfers, capital contributions, Indebtedness, licensing and supply transactions and any other arrangements solely between or among Borrower and its wholly-owned Subsidiaries or Borrower's wholly-owned Subsidiaries, to effect the reorganization of the organizational structure or capital structure of Borrower and its Subsidiaries for the purpose of optimizing the overall economic performance and efficiency of Borrower and its Subsidiaries as a whole, to occur and be consummated: (a) on or before March 31, 2023 as to the agreements and transactions described on Exhibit F hereto; and (b) thereafter; provided, however, that in each case under clause (b) above, such formation, transfer, contribution, Indebtedness, transaction or arrangement has been approved by the Collateral Agent or the Required Lenders prior to the consummation thereof, such approval not to be unreasonably withheld or delayed.

31 "**Intercompany Reorganization Subsidiary**" means any direct or indirect wholly-owned Subsidiary of the Borrower that is formed pursuant to the Intercompany Reorganization.

32 "**Intercompany Subordination Agreement**" means that certain New York law-governed intercompany subordination agreement, dated as of the Tranche A Closing Date, among Borrower, its Subsidiaries party thereto from time to time, OrbiMed and the Collateral Agent (for the benefit of Lenders and the other Secured Parties).

33 "**Intercreditor Agent**" has the meaning set forth for such term in the OrbiMed Intercreditor Agreement.

"**Interest Date**" means the last day of each calendar quarter, commencing with the last day of the calendar quarter during which the Effective Date occurs.

"**Interest Period**" means, as to each Term Loan: (a) the period commencing on (and including) the Effective Date and ending on (and including) the first Interest Date occurring from and after the Effective Date, provided, however, that if such Interest Date is not a Business Day, such Interest Period shall end on the immediately preceding Business Day; and (b) thereafter, each period beginning on (and including) the first day following the end of the preceding Interest Period and ending on the earlier of (and including) (i) the next Interest Date, provided, however, that if such Interest Date is not a Business Day, such Interest Period shall end on the immediately preceding Business Day, and (ii) the Term Loan Maturity Date.

"**Internet Domain Name**" means all right, title and interest (and all related IP Ancillary Rights) arising under any contract or Requirements of Law in or relating to Internet domain names.

"**Inventory**" means all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes all merchandise (including Product), materials (including raw materials), parts, components (including component materials and component raw materials), supplies, packing and shipping materials, work in process and finished products, technology (including software, systems, and solutions), and all elements needed to fulfill obligations related to Product under any Manufacturing Agreements including such inventory as is temporarily out of a Credit Party's or Subsidiary's custody or possession or in transit (prior to title having transferred) and including any returned goods and any documents of title representing any of the above.

"**Investment**" means (a) any beneficial ownership interest in any Person (including Equity Interests), (b) any Acquisition or (c) the making of any advance, loan, extension of credit or capital contribution in or to, any Person. The amount of an Investment shall be the amount actually invested (which, in the case of any Investment by a Credit Party or any of its Subsidiaries constituting the contribution of an asset or property, shall be based on the good faith estimate of the fair market value of such asset or property at the time such Investment is made as reasonably determined by a Responsible Officer of such Credit Party), less the amount of cash received or returned for such Investment, without adjustment for subsequent increases or decreases in the value of such Investment or write-ups, write-downs or write-offs with respect thereto; provided that in no event shall such amount be less than zero.

"**IP Agreements**" means, collectively, (a) those certain IP Security Agreement(s) entered into by and between Borrower and the Collateral Agent, dated as of the Tranche A Closing Date, and (b) any IP Security Agreement entered into by and between any relevant Credit Party and the Collateral Agent after the Tranche A Closing Date in accordance with the Loan Documents.

"**IP Ancillary Rights**" means, with respect to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals, all income, royalties, proceeds and liabilities at any time due or payable or asserted under or with respect to any of the foregoing or otherwise with respect thereto, including all rights to sue or recover at law or in equity for any past,

present or future infringement, misappropriation, dilution, violation or other impairment thereof, and, in each case, all rights to obtain any other intellectual property right ancillary to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights.

"**IP Security Agreement**" means "IP Security Agreement", as such term is defined in the Security Agreement.

"**IRC**" means the Internal Revenue Code of 1986, as amended, or any successor statute.

"**Irish Collateral Documents**" means:

(a) the Irish law debenture entered into by (i) BioPharma Credit, PLC (as collateral agent), and (ii) Insmed Holdings Limited and Insmed Ireland Limited (as chargors); and

(b) the Irish law share charge entered into by (i) BioPharma Credit, PLC (as collateral agent), and (ii) Insmed Incorporated (as chargor) in relation to the shares in Insmed Holdings Limited.

"**Irish Companies Act**" means the companies Act 2014 of Ireland (as amended).

"**IRS**" means the United States Internal Revenue Service or any successor agency.

"**Japanese Equity Pledge**" means the Japanese law membership interest pledge agreement dated on or about the Tranche B Closing Date and entered into by (i) the Collateral Agent, (ii) Insmed Netherlands Holdings B.V., and (iii) Insmed Godo Kaisha in relation to the membership interests in Insmed Godo Kaisha.

34 "**Japanese Laws**" means all applicable statutes, rules and regulations implemented administered or enforced by Japan's Pharmaceuticals and Medical Devices Agency ("**PMDA**"), Ministry of Health, Labour and Welfare (" **MHLW**"), and other relevant agencies, including the PMDL.

35 "**Japanese Security Documents**" means the Japanese Equity Pledge, and any other documents designated as a Japanese Security Documents by the Collateral Agent and the Borrower (or that is specified in such document as being a Japanese Security Documents).

"**Knowledge**" means, with respect to any Person, the actual knowledge, after reasonable investigation, of the Responsible Officers of such Person.

"**Lender**" means each Person signatory hereto as a "Lender" and its successors and assigns.

"**Lender Expenses**" means, collectively:

(a) all reasonable and documented out-of-pocket fees and expenses of the Collateral Agent, the Intercreditor Agent and, as applicable, each Lender (and their respective successors and assigns) and their respective Related Parties (including the reasonable and documented out-of-pocket fees, expenses and disbursements of any legal counsel (it being agreed that such legal counsel fees, expenses and disbursements shall be limited to one primary legal counsel, one local legal counsel in each applicable jurisdiction and one intellectual property legal counsel (as and to the extent applicable) for the Collateral Agent, the Intercreditor Agent, Lenders and Related Parties, taken as a whole)), manufacturing consultants or intellectual property experts (it being agreed that such consultant or expert fees, expenses and disbursements shall be limited to one such consultant and one such expert for the Collateral Agent, the Intercreditor Agent, Lenders and such Related Parties, taken as a whole) therefor, (i) incurred in connection with developing, preparing, negotiating, syndicating, executing and delivering, and interpreting, investigating and administering, the Loan Documents (or any term or provision thereof), any commitment, proposal letter, letter of intent or term sheet therefor or any other document prepared in connection therewith, (ii) incurred in connection with the consummation and administration of any transaction contemplated

therein, (iii) incurred in connection with the performance of any obligation or agreement contemplated therein, (iv) incurred in connection with any modification or amendment of any term or provision of, or any supplement to, or the termination (in whole or in part) of, any Loan Document, (v) incurred in connection with internal audit reviews and Collateral audits, or (vi) otherwise incurred with respect to the Credit Parties in connection with the Loan Documents, including any filing or recording fees and expenses; and

(b) all reasonable and documented out-of-pocket costs and expenses incurred by the Collateral Agent, the Intercreditor Agent and each Lender (and their respective successors and assigns) and their respective Related Parties (including the reasonable and documented out-of-pocket fees, expenses and disbursements of any legal counsel therefor for the Collateral Agent, the Intercreditor Agent, Lenders and such Related Parties taken as a whole) in connection with (i) any refinancing or restructuring of the credit arrangements provided hereunder in the nature of a "work-out," (ii) the enforcement or protection or preservation of any right or remedy under any Loan Document, any Obligation, with respect to any of the Collateral or any other related right or remedy, or (iii) the commencement, defense, conduct of, intervention in, or the taking of any other action with respect to, any proceeding (including any Insolvency Proceeding) related to any Credit Party or any Subsidiary of any Credit Party in respect of any Loan Document or Obligation, or otherwise in connection with any Loan Document or Obligation (or the response to and preparation for any subpoena or request for document production relating thereto).

"**Lender Transfer**" is defined in Section 11.1(b).

"**Lien**" means a claim, mortgage, deed of trust, levy, charge, pledge, security interest or other encumbrance of any kind or assignment for security purposes, whether voluntarily incurred or arising by operation of law or otherwise against any property or assets.

"**Loan Documents**" means, collectively, this Agreement, the Disclosure Letter, the Term Loan Notes, the Security Agreement, the Dutch Security Documents, the English Security Documents, the Irish Collateral Documents, the Swiss Security Documents, the Japanese Security Documents, the OrbiMed Intercreditor Agreement, the Intercompany Subordination Agreement, the IP Agreements, the Perfection Certificate, any Control Agreement, any Collateral Access Agreement, any other Collateral Document, any guaranties executed by a Guarantor in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties in connection with this Agreement, and any other present or future agreement between or among a Credit Party, the Collateral Agent and any Lender in connection with this Agreement, including in each case, for the avoidance of doubt, any annexes, exhibits or schedules thereto, and any related ancillary documents, agreements, waivers or consents.

"**Loan Note**" is defined in the First Amendment to Loan Agreement, dated as of the First Amendment Effective Date, by and among Borrower (on its own behalf and on behalf of each other Credit Party), Lenders and the Collateral Agent.

"**Makewhole Amount**" means the Tranche A Makewhole Amount or the Tranche B Makewhole Amount, individually or collectively, as applicable.

"**Managed Care Plans**" means all health maintenance organizations, preferred provider organizations, individual practice associations, competitive medical plans and similar arrangements.

"**Manufacturing Agreement**" means any contract or agreement entered into on or prior to the Effective Date by any Credit Party or any of its Subsidiaries with third parties for (i) the clinical or commercial manufacture or in-bound supply in the Territory of Product for any indication, or (ii) for the commercial manufacture or in-bound supply of any active pharmaceutical ingredient, prodrug, or medical device component material incorporated therein that was included in the NDA for Product (with the Manufacturing Agreements in effect as of the Effective Date being set forth in Schedule 12.1 of the Disclosure Letter), and (b) any future contract or agreement entered into after the Effective Date by any Credit Party or any of its Subsidiaries with third parties for (i) the clinical or commercial manufacture or in-bound supply in the Territory of Product for any indication or (ii) for the commercial manufacture or in-bound supply of any active pharmaceutical ingredient, prodrug, or medical device component material incorporated therein.

"**Margin Stock**" means "margin stock" within the meaning of Regulations U and X of the Federal Reserve Board as now and from time to time hereafter in effect.

36 "**Material Adverse Change**" means any material adverse change in or material adverse effect on: (a) the business, operations, condition (financial or otherwise), properties or assets (including all or any portion of the Collateral), liabilities (actual or contingent), operations or performance of the Credit Parties, taken as a whole, since December 31, 2021; (b) without limiting the generality of clause (a) above, (i) any of the rights or remedies of the Credit Parties, taken as a whole, in or related to the research, development, exclusivity, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory or (ii) the period of regulatory exclusivity granted by the FDA (or foreign equivalent) for Product (including Orphan Drug exclusivity); (c) any ability of the Credit Parties, taken as a whole, to fulfill the payment or performance obligations under this Agreement or any other Loan Document; (d) any ability of the Credit Parties, taken as a whole, to fulfill the payment or performance obligations under the Royalty Revenue Contract or any other Royalty Revenue Document; (e) the binding nature or validity of, or the ability of the Collateral Agent, the Intercreditor Agent or any Lender to enforce, the Loan Documents or any of its rights or remedies under the Loan Documents; or (f) the validity, perfection (except to the extent expressly permitted under the Loan Documents) or priority of Liens in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, or the Intercreditor Agreement, as gratuitous bailee and non-fiduciary agent for the benefit of OrbiMed, (except to the extent expressly permitted under the OrbiMed Intercreditor Agreement or resulting solely from any actions or inactions on the part of the Collateral Agent or the Intercreditor Agent despite timely receipt of information regarding Borrower and its Subsidiaries as required by this Agreement).

"**Material Contract**" means any contract or other arrangement to which any Credit Party or any of its Subsidiaries is a party (other than the Loan Documents) or by which any of its assets or properties are bound, in each case, relating to any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory, for which the breach of, default or nonperformance under, cancellation or termination of or the failure to renew could reasonably be expected to result in a Material Adverse Change under clause (a), (b), (c), (e) or (f) of the definition thereof. For the avoidance of doubt, each Manufacturing Agreement and each Company IP Agreement is deemed to be a Material Contract for all purposes hereunder and the Royalty Revenue Contract and each other Royalty Revenue Document is deemed to be a Material Contract for all purposes hereunder.

"**Medicaid**" means the health care assistance program established by Title XIX of the SSA (42 U.S.C. 1396 et seq.).

"**Medicare**" means the health insurance program for the aged and disabled established by Title XVIII of the SSA (42 U.S.C. 1395 et seq.).

"**Mortgage**" means any deed of trust, leasehold deed of trust, mortgage, leasehold mortgage, deed to secure debt, leasehold deed to secure debt or other document creating a Lien on real estate or any interest in real estate.

"**Multiemployer Plan**" means a multiemployer plan within the meaning of Section 4001(a)(3) or Section 3(37) of ERISA (a) to which Borrower or its Subsidiaries or their respective ERISA Affiliates is then making or accruing an obligation to make contributions; (b) to which Borrower or its Subsidiaries or their respective ERISA Affiliates has within the preceding five (5) plan years made contributions; or (c) with respect to which Borrower or its Subsidiaries could incur material liability.

"**NDA**" means a new drug application, submitted to the FDA pursuant to 21 U.S.C. § 355 seeking authorization to market a new drug in the United States, or any foreign equivalent.

"**Non-Public Lender**" means: (i) until interpretation of "public" as referred to in the CRR by the relevant authority or authorities, an entity that provides repayable funds to a Dutch Obligor for a minimum initial amount of EUR 100,000 (or its equivalent in another currency) or an entity otherwise qualifying as not forming part of the public; and (ii) following the publication of an interpretation of "public" as referred to in the CRR by the relevant authority or authorities, such amount or such criterion as a result of which such entity shall qualify as not forming part of the public.

"**Note Register**" is defined in Section 2.8.

"**Obligations**" means, collectively, the Credit Parties' obligations to pay when due any and all debts, principal, interest, Lender Expenses, the Additional Consideration, the Makewhole Amount, the Prepayment Premium, the Exit Fee and any other fees, expenses, indemnities and amounts any Credit Party owes any Lender or the Collateral Agent now or later, under this Agreement or any other Loan Document, including interest accruing after Insolvency Proceedings begin (whether or not allowed), and to perform Borrower's duties under the Loan Documents.

"**OFAC**" is defined in Section 4.18(c).

"**Operating Documents**" means, collectively with respect to any Person, such Person's formation and constitutional documents and, (a) if such Person is a corporation, its bylaws (or similar organizational regulations), (b) if such Person is an exempted company or a company limited by shares, its memorandum and articles of association (or similar organizational regulations), (c) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (d) if such Person is a partnership, its partnership agreement (or similar agreement), in each case including all amendments, restatements, supplements and modifications thereto.

"**OrbiMed**" means, collectively, OrbiMed Royalty & Credit Opportunities IV, LP and its Affiliates.

"**OrbiMed Intercreditor Agreement**" means that certain New York law-governed intercreditor agreement, dated as of the Tranche A Closing Date, among Borrower, OrbiMed and the Collateral Agent (for the benefit of Lenders and the other Secured Parties).

"**ordinary course of business**" means, in respect of any transaction involving any Person, the ordinary course of such Person's business, undertaken by such Person in good faith and not for purposes of evading any covenant, prepayment obligation or restriction in any Loan Document.

37 "**Orphan Drug**" means a drug or biologic that meets the definition for "orphan drug" provided in 21 C.F.R. § 316.3(b)(10) that has been granted an orphan drug designation by the Secretary of U.S. Department of Health and Human Services under 21 U.S.C. § 360bb, and any foreign equivalents.

38 "**Other Connection Taxes**" means, with respect to any Lender, Taxes imposed as a result of a present or former connection between such Lender and the jurisdiction imposing such Tax (other than connections arising solely from such Lender having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Term Loan or Loan Document).

39 "**Other Taxes**" means all present or future stamp, court or documentary, intangible, recording, excise, filing, value added Taxes, mortgage or property Taxes, charges or similar levies or similar Taxes that arise from any payment made hereunder, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to a Lender Transfer.

"**Participant Register**" is defined in Section 11.1(d).

"**Patents**" means all patents and patent applications (including any improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications), any patent issued with respect to any of the foregoing patent applications, any reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign and international counterparts of any of the foregoing. For the avoidance of doubt, patents and patent applications under this definition include individual patent claims and include all patents and patent applications filed with the U.S. Patent and Trademark Office or which could be nationalized in the United States.

"**Payment Date**" means, with respect to the Term Loans and as the context dictates: (a) the first Interest Date occurring in the calendar quarter during which the Effective Date occurs; (b) thereafter, each succeeding Interest Date; and (c) the Term Loan Maturity Date; provided, however, that if any Payment Date would otherwise fall on a day that is not a Business Day, such Payment Date shall be the immediately preceding Business Day.

"**PCI Cap**" means an amount equal to the sum of (a) $[***] *plus* (b) such amount of proceeds that will be used solely to repay or retire existing Permitted Convertible Indebtedness and is placed into an escrow account solely dedicated to such use *plus*, (c) so long as (i) no Default or Event of Default has occurred and is continuing, (ii) no Material Adverse Change or Withdrawal Event has occurred and (iii) the ENCORE Event has occurred, $[***].

"**Perfection Certificate**" is defined in Section 4.6.

"**Permitted Acquisition**" means any Acquisition, so long as:

(a) no Default or Event of Default shall have occurred and be continuing as of, or could reasonably be expected to result from, the consummation of such Acquisition;

(b) the properties or assets being acquired or licensed, or the Person whose Equity Interests are being acquired, are useful in or engaged in, as applicable, (i) the same, similar or related line of business as that then-conducted by Borrower and its Subsidiaries, or (ii) a line of business that is related or ancillary to or in furtherance of a line of business as that then-conducted by Borrower and its Subsidiaries;

(c) in the case of any Asset Acquisition, any and all assets are being acquired or licensed in such Acquisition by a Credit Party and, within the timeframes expressly set forth in Section 5.12 with respect to all such assets constituting Collateral, such Credit Party shall have executed and delivered or authorized, as applicable, any and all joinders, security agreements, financing statements and any other documentation, and made such other deliveries, required by Section 5.12 or reasonably requested by the Collateral Agent in order to include such newly acquired or licensed assets within the Collateral, in each case to the extent required by Section 5.12;

(d) in the case of any Stock Acquisition, any and all Equity Interests are being acquired in such Acquisition by a Credit Party and, such Credit Party shall have complied with its obligations under Section 5.13, in each case to the extent such Equity Interests are subject thereto; and

(e) any Indebtedness or Liens assumed in connection with such Acquisition are otherwise permitted under Section 6.4 or 6.5, respectively.

40 "**Permitted Convertible Indebtedness**" means Indebtedness of the Borrower or any Subsidiary of Borrower that is a Credit Party having a feature which entitles the holder thereof in certain circumstances to convert or exchange all or a portion of such Indebtedness into Equity Interests in Borrower or such Subsidiary (or other securities or property following a merger event or other change of the common stock of Borrower or such Subsidiary), cash or any combination of cash and such Equity Interests (or such other securities or property) based

on the market price of such Equity Interests (or such other securities or property); provided, however, that (a) such Indebtedness shall be unsecured, (b) such Indebtedness shall not be guaranteed by any Subsidiary of Borrower, (c) such Indebtedness shall bear interest at a rate *per annum* not to exceed the greater of [***] percent ([***]%) and such rate as is customary in the market at such time, as determined by the Borrower in its reasonable commercial judgment, (d) such Indebtedness shall not include covenants and defaults (other than covenants and defaults customary for convertible indebtedness but not customary for loans, as determined by Borrower in its good faith judgment) that are, taken as a whole, more restrictive on the Credit Parties than the provisions of this Agreement (as determined by Borrower in its good faith judgment), (e) immediately prior to and after giving effect to the incurrence of such Indebtedness, no Default or Event of Default shall have occurred and be continuing or could reasonably be expected to occur as a result therefrom (after giving effect to this Agreement), (f) such Indebtedness shall not (i) mature or be mandatorily redeemable, pursuant to a sinking fund obligation or otherwise, (ii) be redeemable at the option of the holder thereof, in whole or in part or (iii) provide for the scheduled payment of dividends or distributions (other than scheduled cash interest payments) in cash, in each case of the foregoing sub-clauses (i), (ii) and (iii), earlier than twelve (12) months after the Term Loan Maturity Date (it being understood, for the avoidance of doubt, that (w) a redemption right of Borrower or such Subsidiary in respect of such Indebtedness, (x) conversion rights of holders in respect of such Indebtedness, (y) acceleration rights of holders of such Indebtedness upon the occurrence of an event of default specified in the agreement governing such Indebtedness and (z) the obligation to pay customary amounts to holders of such Indebtedness in connection with a "change of control" or "fundamental change", in each case, shall not be considered in connection with the determination of scheduled maturity date for purposes of this clause (f)); (g) immediately after giving effect to the incurrence of any such Indebtedness, the difference of (x) the amount of all Permitted Convertible Indebtedness (including all Indebtedness under the 2028 Convertible Notes and the indenture relating thereto) permitted hereunder and then outstanding *less* (y) the amount of proceeds of such Indebtedness that (1) will be used solely to repay or retire existing Permitted Convertible Indebtedness and (2) is placed into an escrow account solely dedicated to such use, shall not exceed the PCI Cap; and (h) Borrower shall have delivered to the Collateral Agent a certificate of a Responsible Officer of Borrower certifying as to the foregoing clauses (a) through (g) with respect to any such Indebtedness.

"**Permitted Convertible Redemption**" means the payment of the principal amount of any Indebtedness under the 2028 Convertible Notes (or the indenture relating thereto) prior to maturity, with cash, unless the last reported sale price of Borrower's common stock is at least 1.3 times the conversion price of such Indebtedness then in effect for at least twenty (20) Trading Days (whether or not consecutive) during any thirty (30) consecutive Trading Day period ending on the Trading Day prior to the date on which Borrower provides the redemption notice in accordance with the indenture governing such Indebtedness.

"**Permitted Distributions**" means, in each case subject to Section 6.8 if applicable:

(a) dividends, distributions or other payments by any Wholly-Owned Subsidiary of Borrower on its Equity Interests to, or the redemption, retirement or purchase by any Wholly-Owned Subsidiary of Borrower of its Equity Interests from, Borrower or any other Wholly-Owned Subsidiary of Borrower;

(b) dividends, distributions or other payments by any non-Wholly-Owned Subsidiary on its Equity Interests to, or the redemption, retirement or purchase by any non-Wholly-Owned Subsidiary of its Equity Interests from, Borrower or any other Subsidiary or each other owner of such non-Wholly-Owned Subsidiary's Equity Interests based on their relative ownership interests of the relevant class of such Equity Interests;

(c) exchanges, redemptions or conversions by Borrower in whole or in part any of its Equity Interests for or into another class of its Equity Interests or rights to acquire its Equity Interests or with proceeds from substantially concurrent equity contributions or issuances of new Equity Interests;

(d) any such payments arising from (i) the Intercompany Reorganization (but only to the extent pursuant to any distribution described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such payments are described in Exhibit F hereto), (ii) a Permitted Acquisition or (iii) other Permitted Investment, in each case of this clause (d) by Borrower or any of its Subsidiaries;

(e) the payment of dividends by Borrower solely in non-cash pay and non-redeemable capital stock (including, for the avoidance of doubt, dividends and distributions payable solely in Equity Interests);

(f) cash payments in lieu of the issuance of fractional shares arising out of stock dividends, splits or combinations or in connection with the exercise of warrants, options or other securities convertible into or exchangeable for Equity Interests, including the 2028 Convertible Notes and Permitted Convertible Indebtedness;

(g) in connection with any Acquisition or other Investment by Borrower or any of its Subsidiaries, (i) the receipt or acceptance of the return to Borrower or any of its Subsidiaries of Equity Interests of Borrower constituting a portion of the purchase price consideration in settlement of indemnification claims, or as a result of a purchase price adjustment (including earn-outs or similar obligations) and (ii) payments or distributions to equity holders pursuant to appraisal rights required under Requirements of Law;

(h) the distribution of rights pursuant to any shareholder rights plan or the redemption of such rights for nominal consideration in accordance with the terms of any shareholder rights plan;

(i) dividends, distributions or payments on its Equity Interests by any Subsidiary to any Credit Party;

(j) dividends, distributions or payments on its Equity Interests by any Subsidiary that is not a Credit Party to any other Subsidiary that is not a Credit Party;

(k) purchases of Equity Interests of Borrower or its Subsidiaries in connection with the exercise of stock options by way of cashless exercise, or in connection with the satisfaction of withholding tax obligations;

(l) issuance to directors, officers, employees or contractors of Borrower or its Subsidiaries of awards or common stock of Borrower pursuant to awards, of restricted stock, restricted stock units, or other rights to acquire common stock of Borrower, in each case pursuant to plans or agreements approved by Borrower's Board of Directors (or committee thereof) or stockholders;

(m) the repurchase, retirement or other acquisition or retirement for value of Equity Interests of Borrower or any of its Subsidiaries held by any future, present or former employee, consultant, officer or director (or spouse, ex-spouse or estate of any of the foregoing or trust for the benefit of any of the foregoing or any lineal descendants thereof) of Borrower or any of its Subsidiaries pursuant to any management equity plan or stock option plan or any other management or employee benefit plan or agreement, or any stock subscription or shareholder agreement or employment agreement; provided, however, that the aggregate payments made under this clause (m) do not exceed in any calendar year the sum of (i) $[***] *plus* (ii) the amount of any payments received in such calendar year under key-man life insurance policies;

(n) dividends or distributions on its Equity Interests by Borrower or any of its Subsidiaries payable solely in additional shares of its common stock; and

(o) solely in connection with Permitted Convertible Indebtedness and any Refinancing Convertible Debt relating thereto, the Credit Parties or its Subsidiaries may enter into Permitted Equity Derivatives (and may settle, terminate or unwind any such Permitted Equity Derivatives in connection with any refinancing, early conversion or maturity of such Permitted Convertible Indebtedness).

"**Permitted Equity Derivative**" means any call or capped option (or substantively equivalent equity derivative transaction) or call spread transaction relating to the Equity Interests of Borrower or any other Credit Party purchased by Borrower or such Credit Party in connection with the issuance of Permitted Convertible Indebtedness and any Refinancing Convertible Debt relating thereto by Borrower or such other Credit Party, provided, that the purchase price for such call or capped option does not exceed the net cash proceeds received by Borrower or such other Credit Party from the issuance of such Permitted Convertible Indebtedness or Refinancing Convertible Debt.

"**Permitted Indebtedness**" means:

(a) Indebtedness of the Credit Parties to Secured Parties under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Tranche B Closing Date and shown on Schedule 12.2 of the Disclosure Letter;

(c) Permitted Convertible Indebtedness (including, for the avoidance of doubt, all Indebtedness under the 2028 Convertible Notes and the indenture relating thereto); provided that, the difference of (x) the amount of such Permitted Convertible Indebtedness permitted hereunder and then outstanding *less* (y) the amount of proceeds of such Indebtedness that (1) will be used solely to repay or retire existing Permitted Convertible Indebtedness and (2) is placed into an escrow account solely dedicated to such use, shall not at any time exceed the PCI Cap;

(d) (i) (A) Indebtedness incurred to finance the purchase, construction, repair, or improvement of fixed assets and (B) Capital Lease Obligations not covered under clause (d)(ii) of this definition; provided, however, that the aggregate amount of all such Indebtedness does not exceed (x) prior to the occurrence of the FDA Approval Date, $[***] in the aggregate, or (y) on or after the occurrence of the FDA Approval Date, $[***] in the aggregate, in either case at any time outstanding, and (ii) Capital Lease Obligations for new research and operations spaces and related equipment, and for the expansion of existing research and operations spaces and related equipment; provided, however, that such Indebtedness shall only be permitted following the FDA Approval Date and the aggregate amount of all such Indebtedness does not exceed $[***] at any time outstanding;

(e) Indebtedness in connection with trade credit, corporate credit cards, purchasing cards or bank card products, provided, that the aggregate amount of all such Indebtedness that is secured shall not exceed $[***] at any time outstanding;

(f) guarantees of Permitted Indebtedness;

(g) Indebtedness assumed in connection with any Permitted Acquisition, Permitted Transfer or Permitted Investment, so long as such Indebtedness was not incurred in connection with, or in anticipation of, such Permitted Acquisition, Permitted Transfer, Permitted Investment;

(h) Indebtedness of Borrower or any of its Subsidiaries with respect to letters of credit, bank guarantees, bankers' acceptances, warehouse receipts or similar instruments outstanding and to the extent secured, secured solely by cash or Cash Equivalents, in each case entered into in the ordinary course of business;

(i) Indebtedness owed: (i) by a Credit Party to another Credit Party; (ii) by a Subsidiary of Borrower that is not a Credit Party to another Subsidiary of Borrower that is not a Credit Party; (iii) by a Credit Party to a Subsidiary of Borrower that is not a Credit Party; or (iv) by a Subsidiary of Borrower that is not a Credit Party to a Credit Party, not to exceed (x) prior to the occurrence of the FDA Approval Date, $[***] in the aggregate, or (y) on or after the occurrence of the FDA Approval Date, $[***] in the aggregate, in either case at any time outstanding;

(j) Indebtedness consisting of Contingent Obligations described in clause (a) of the definition thereof: (i) of a Credit Party of Permitted Indebtedness of another Credit Party (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder); (ii) of a Subsidiary of Borrower which is not a Credit

Party of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of another Subsidiary of Borrower which is not a Credit Party; (iii) of a Subsidiary of Borrower which is not a Credit Party of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of a Credit Party; or (iv) of a Credit Party of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of a Subsidiary of Borrower which is not a Credit Party not to exceed $[***] in the aggregate at any time outstanding;

(k) Indebtedness consisting of Contingent Obligations described in clause (b) of the definition thereof, not to exceed $[***] in the aggregate at any time outstanding and then due and payable, in each instance (i) incurred in connection with any Permitted Acquisition, Permitted Transfer, Permitted Investment or any in-licensing or any collaboration, co-promotion, co-marketing arrangement, and (ii) only if such Indebtedness is due and payable upon the occurrence of an event or the performance of an act (and not solely with the passage of time);

(l) Indebtedness of any Person that becomes a (direct or indirect) Subsidiary of Borrower (or of any Person not previously a Subsidiary that is merged or consolidated with or into a Subsidiary of Borrower in a transaction permitted hereunder, including pursuant to the Intercompany Reorganization, but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such Indebtedness is described in Exhibit F hereto) after the Tranche B Closing Date; provided, that all such Indebtedness was not made in contemplation of or in connection with such Person becoming a (direct or indirect) Subsidiary of Borrower (or merging or consolidating with or into a Subsidiary of Borrower) or the Permitted Acquisition of related assets;

(m) (i) Indebtedness with respect to workers' compensation claims, payment obligations in connection with health, disability or other types of social security benefits, unemployment or other insurance obligations, reclamation and statutory obligations or (ii) Indebtedness related to employee benefit plans, including annual employee bonuses, accrued wage increases and 401(k) plan matching obligations; in each case, incurred in the ordinary course of business;

(n) Indebtedness in respect of performance bonds, bid bonds, appeal bonds, surety bonds and completion guarantees and similar obligations arising in the ordinary course of business;

(o) Indebtedness in respect of netting services, overdraft protection and other cash management services, in each case in the ordinary course of business;

(p) Indebtedness consisting of the financing of insurance premiums in the ordinary course of business;

(q) Indebtedness consisting of guarantees resulting from endorsement of negotiable instruments for collection by any Credit Party in the ordinary course of business;

(r) unsecured Indebtedness incurred in connection with any items of Permitted Distributions in clause (m) of the definition of "Permitted Distributions";

(s) to the extent constituting Indebtedness, Permitted Equity Derivatives;

(t) other unsecured Indebtedness in an aggregate amount not to exceed $[***] at any one time outstanding;

(u) any Indebtedness arising under a declaration of joint and several liability used for the purpose of section 2:403 of the Dutch CC (and any residual liability (*overblijvende aansprakelijkheid*) under such declaration arising pursuant to section 2:404(2) of the Dutch CC);

(v) Indebtedness in respect of any liability arising as a result of a fiscal unity (*fiscale eenheid*) between Credit Parties incorporated in the Netherlands (or equivalent in any other jurisdiction);

(w) Indebtedness under any (i) unsecured Hedging Agreements entered into for hedging and not speculative purposes, and (ii) Hedging Agreements with respect to interest rates that are secured by cash or Cash Equivalents and entered into for hedging and not speculative purposes; and

(x) subject to the proviso immediately below, extensions, refinancings, renewals, modifications, amendments, restatements and, in the case of any items of Permitted Indebtedness in clause (b) of the definition thereof or Permitted Indebtedness constituting notes governed by an indenture (including Permitted Convertible Indebtedness), exchanges, of any items of Permitted Indebtedness in clauses (a) through (v) above, provided, that in the case of clause (b) above, the principal amount thereof is not increased (other than by any reasonable amount of premium (if any), interest (including post-petition interest), fees, expenses, charges or additional or contingent interest reasonably incurred in connection with the same and the terms thereof); provided, further, that in the case of any Indebtedness permitted under clause (c) above, (x) the maturity thereof is not shortened to before the Term Loan Maturity Date, (y) the difference of (A) the amount of all Permitted Convertible Indebtedness permitted hereunder and then outstanding *less* (B) the amount of proceeds of such Indebtedness that (1) will be used solely to repay or retire existing Permitted Convertible Indebtedness and (2) is placed into an escrow account solely dedicated to such use, does not exceed the PCI Cap, and (z) there is no change to or addition of any direct or indirect obligor with respect thereto unless such new obligor thereto is or shall become a Guarantor hereunder.

Notwithstanding the foregoing or anything in this Agreement to the contrary, except with respect to the Royalty Revenue Contract and the other Royalty Revenue Documents, (x) no direct or indirect synthetic royalty or similar financing transaction involving the sale of revenues or royalties entered into after the Tranche B Closing Date, and (y) except to the extent incurred in connection with any Permitted Acquisitions, Permitted Investments, in-licensing agreements or any collaboration, co-promotion or co-marketing arrangements, no Indebtedness constituting royalty payments or sales milestones based on net sales that is, directly or indirectly, created, incurred, assumed or guaranteed after the Tranche B Closing Date, in each case of clause (x) or (y) above, by a Credit Party or any of its Subsidiaries, shall in any instance be permitted under this Agreement without the prior written consent of the Collateral Agent or the Required Lenders.

"**Permitted Investments**" means:

(a) Investments (including Investments in Subsidiaries) existing on the Tranche B Closing Date and shown on Schedule 12.3 of the Disclosure Letter, including any extensions, renewals or reinvestments thereof;

(b) Investments consisting of cash and Cash Equivalents;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business;

(d) subject to Section 5.5, Investments consisting of deposit accounts or securities accounts;

(e) Investments in connection with (i) the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such Investments are described in Exhibit F hereto), (ii) Permitted Transfers, and (iii) the establishment and maintenance of an Intercompany Reorganization Subsidiary;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors (or a committee thereof);

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of accounts receivable of, or prepaid royalties and other credit extensions or advances, to customers, suppliers or manufacturers who are not Affiliates, in the ordinary course of business or otherwise to support capacity demand; provided that this clause (h) shall not apply to Investments of any Credit Party in any of its Subsidiaries;

(i) joint ventures or strategic alliances consisting of the licensing or development of technology or the providing of technical support;

(j) Investments (i) required in connection with a Permitted Acquisition (including the formation of any Subsidiary for the purpose of effectuating such Permitted Acquisition, the capitalization of such Subsidiary whether by capital contribution or intercompany loans to the extent otherwise permitted by the terms of this Agreement, related Investments in Subsidiaries necessary to consummate such Permitted Acquisition and the receipt of any non-cash consideration in such Permitted Acquisition) and (ii) consisting of earnest money or escrow deposits required in connection with a Permitted Acquisition or other acquisition of properties or assets not otherwise prohibited hereunder;

(k) Investments constituting the formation of any Subsidiary for the purpose of consummating a merger or acquisition transaction permitted by Section 6.3(a)(i) through (iv) hereof, which such transaction is otherwise a Permitted Investment;

(l) Investments of any Person that (i) becomes a Subsidiary of Borrower (or of any Person not previously a Subsidiary of Borrower that is merged or consolidated with or into a Subsidiary of Borrower in a transaction permitted hereunder) after the Tranche B Closing Date, or (ii) are assumed after the Tranche B Closing Date by Borrower or any Subsidiary of Borrower in connection with an acquisition of assets from such Person by Borrower or such Subsidiary, in either case, in a Permitted Acquisition; provided, that in each case, any such Investment (w) does not constitute Indebtedness of such Person, (x) exists at the time such Person becomes a Subsidiary of Borrower (or is merged or consolidated with or into a Subsidiary of Borrower) or such assets are acquired, (y) was not made in contemplation of or in connection with such Person becoming a Subsidiary of Borrower (or merging or consolidating with or into a Subsidiary of Borrower) or such acquisition of assets, and (z) could not reasonably be expected to result in a Default or an Event of Default;

(m) Investments arising as a result of the licensing of Intellectual Property in the ordinary course of business and not prohibited under this Agreement;

(n) to the extent constituting an Investment, any Permitted Equity Derivative, including the payment of premiums in connection therewith;

(o) Investments by: (i) any Credit Party in any other Credit Party; (ii) any Subsidiary of Borrower which is not a Credit Party in another Subsidiary of Borrower which is not a Credit Party; (iii) any Subsidiary of Borrower which is not a Credit Party in any Credit Party; (iv) any Credit Party in a Subsidiary of Borrower which is not a Credit Party, not to exceed $[***] in the aggregate outstanding at any time; and (v) Borrower and its Subsidiaries consisting of Equity Interests in their respective Subsidiaries existing on the Tranche B Closing Date;

(p) Repurchases of capital stock of Borrower or any of its Subsidiaries deemed to occur upon the exercise of options, warrants or other rights to acquire capital stock of Borrower or such Subsidiary solely to the extent that shares of such capital stock represent a portion of the exercise price of such options, warrants or such rights;

(q) Investments consisting of non-cash consideration received for any Permitted Transfer;

(r) Investments consisting of acquisitions from third parties of inventory, equipment, office supplies, software and other similar assets in the ordinary course of business;

(s) Investments consisting of in-licensing agreements, provided that no Indebtedness that is not Permitted Indebtedness is incurred or assumed in connection therewith;

(t) other Investments, not to exceed $[***] outstanding at any time; and

(u) (i) unsecured Hedging Agreements entered into for hedging and not speculative purposes, and (ii) Hedging Agreements with respect to interest rates that are secured by cash or Cash Equivalents and entered into for hedging and not speculative purposes,

provided, however, that, none of the foregoing Investments shall be a "Permitted Investment" if any Indebtedness or Liens assumed in connection with such Investment are not otherwise permitted under Section 6.4 or 6.5, respectively.

"**Permitted Licenses**" means, collectively: (a) any exclusive or non-exclusive license or covenant not to sue in any geography within the Territory other than the U.S., Japan, France, Germany, Italy, Spain and the United Kingdom of or with respect to any Intellectual Property; (b) licenses pursuant to any Manufacturing Agreement or otherwise with a contract manufacturer, in each case, solely with respect to the services provided under such agreement; (c) any non-exclusive licenses with respect to any research and development in the Territory; (d) any exclusive or non-exclusive grant in any geography within the Territory other than the U.S., Japan, France, Germany, Italy, Spain and the United Kingdom of or with respect to any development, manufacturing, production, commercialization, marketing, co-promotion, distribution, sale, lease or similar commercial rights; and (e) any intercompany license or other similar arrangement among Credit Parties. Notwithstanding the foregoing or any other provision of this Agreement, no Excluded License with respect to Product entered into after the Tranche B Closing Date shall be a "Permitted License" hereunder without the prior written consent of the Collateral Agent or the Required Lenders, other than any such license entered into pursuant to the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such license is described in Exhibit F hereto).

"**Permitted Liens**" means:

(a) Liens in favor and for the benefit of any Lender and the other Secured Parties securing the Obligations pursuant to any Loan Document;

(b) Liens existing on the Tranche B Closing Date and set forth on Schedule 12.4 of the Disclosure Letter;

(c) Liens for Taxes, assessments or governmental charges which (i) are not yet due and payable or (ii) if due and payable, are being contested in good faith and by appropriate proceedings; provided that, in each case, adequate reserves therefor have been set aside on the books of the applicable Person and maintained in conformity with GAAP;

(d) pledges or deposits made in the ordinary course of business (other than Liens imposed by ERISA) in connection with workers' compensation, payroll taxes, employment insurance, unemployment insurance, old-age pensions, or other similar social security legislation, (ii) pledges or deposits made in the ordinary course of business securing liability for reimbursement or indemnification obligations of (including obligations in respect of letters of credit or bank guarantees for the benefit of) insurance carriers providing property, casualty or liability insurance to Borrower or any of its Subsidiaries, (iii) subject to Section 6.2(b), statutory or common law Liens of landlords, (iv) Liens otherwise arising by operation of law in favor of the owner or sublessor of leased premises and confined to the property rented, (v) Liens that are restrictions on transfer of securities imposed by applicable securities laws, (vi) Liens resulting from a filing by a lessor as a precautionary filing for a true lease, and (vii) pledges or deposits to secure performance of tenders, bids, leases, statutory or regulatory obligations, surety and appeal bonds, government contracts, performance and return-of-money bonds and other obligations of like nature, in each case other than for borrowed money and entered into in the ordinary course of business;

(e) Liens arising from attachments or judgments, orders, or decrees in circumstances not constituting an Event of Default under either Section 7.4 or 7.7;

(f) Liens (including the right of set-off) in favor of banks or other financial institutions incurred on deposits made in accounts held at such institutions in the ordinary course of business; provided that such Liens (i) are not given in connection with the incurrence of any Indebtedness, (ii) relate solely to obligations for administrative and other banking fees and expenses incurred in the ordinary course of business in connection with the establishment or maintenance of such accounts and (iii) are within the general parameters customary in the banking industry;

(g) Liens that are contractual rights of set-off (i) relating to pooled deposit or sweep accounts of Borrower or any of its Subsidiaries to permit satisfaction of overdraft or similar obligations incurred in the ordinary course of business or (ii) relating to purchase orders and other agreements entered into with customers of Borrower or any of its Subsidiaries in the ordinary course of business, including vendors' liens to secure payment arising under Article 2 of the Code or similar provisions of Requirements of Law in the ordinary course of business, covering only the goods sold and securing only the unpaid purchase price for such goods and related expenses;

(h) Liens solely on any cash earnest money deposits made by Borrower or any of its Subsidiaries in connection with any Permitted Acquisition, Permitted Investment or other acquisition of assets or properties not otherwise prohibited under this Agreement;

(i) Liens existing on assets or properties at the time of its acquisition or existing on the assets or properties of any Person at the time such Person becomes a Subsidiary of Borrower, in each case after the Tranche B Closing Date; provided that (i) neither such Lien was created nor the Indebtedness secured thereby was incurred in contemplation of such acquisition or such Person becoming a Subsidiary of Borrower, (ii) such Lien does not extend to or cover any other assets or properties (other than the proceeds or products thereof and other than after-acquired assets or properties subject to a Lien securing Indebtedness and other obligations incurred prior to such time and which Indebtedness and other obligations are permitted hereunder that requires, pursuant to its terms and conditions in effect at such time, a pledge of after-acquired assets or properties, it being understood that such requirement shall not be permitted to apply to any assets or properties to which such requirement would not have applied but for such acquisition), (iii) the Indebtedness and other obligations secured thereby is permitted under Section 6.4 hereof and (iv) such Liens are of the type otherwise permitted under Section 6.5 hereof;

(j) Liens securing Indebtedness permitted under clause (d) of the definition of "Permitted Indebtedness" (including any extensions, refinancings, modifications, amendments or restatements of such Indebtedness permitted under clause (w) of the definition of "Permitted Indebtedness"); provided, that such Lien does not extend to or cover any assets or properties other than those that are (i) subject to such Capital Lease Obligations or (ii) acquired with or otherwise financed or refinanced by such Indebtedness;

(k) servitudes, easements, rights-of-way, restrictions and other similar encumbrances on real property imposed by Requirements of Law and encumbrances consisting of zoning or building restrictions, easements, licenses, restrictions on the use of property or minor defects or other irregularities in title which, in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any Credit Party or any Subsidiary of any Credit Party;

(l) to the extent constituting a Lien, escrow arrangements securing indemnification obligations associated with any Permitted Acquisition or Permitted Investment;

(m) (i) leases or subleases of real property granted in the ordinary course of business (including, if referring to a Person other than a Credit Party or a Subsidiary, in the ordinary course of such Person's business), (ii) licenses, sublicenses, leases or subleases of personal property (other than Intellectual Property) granted to third parties in the ordinary course of business, in each case which do not interfere in any material respect with the operations of the business of any Credit Party or any of its Subsidiaries and do not prohibit granting the Collateral Agent a security interest in any Credit Party's personal property held at such location for the benefit of the Lenders

and other Secured Parties, (iii) Permitted Licenses, and (iv) retained interests of lessors or licensors or similar parties under any in-licenses;

(n) Liens on cash or other current assets pledged to secure: (i) Indebtedness in respect of corporate credit cards, purchasing cards or bank card products, provided, that any such Indebtedness shall not exceed $[***] in the aggregate at any time outstanding; or (ii) Indebtedness in the form of letters of credit or bank guarantees entered into in the ordinary course of business, provided, that any such Indebtedness is secured solely by cash or Cash Equivalents;

(o) Liens on any properties or assets of Borrower or any of its Subsidiaries which do not constitute Collateral under the Loan Documents, other than (i) any Company IP that does not constitute Collateral under the Loan Documents but is related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory and (ii) Equity Interests of any Subsidiary;

(p) Liens on any properties or assets of Borrower or any of its Subsidiaries imposed by law or regulation which were incurred in the ordinary course of business, including landlords', carriers', warehousemen's, mechanics', materialmen's, contractors', suppliers of materials', architects' and repairmen's Liens, and other similar Liens arising in the ordinary course of business; provided that such Liens (i) do not materially detract from the value of such properties or assets subject thereto or materially impair the use of such properties or assets subject thereto in the operations of the business of Borrower or such Subsidiary or (ii) are being contested in good faith by appropriate proceedings which conclusively operate to stay the sale or forfeiture of any portion of such properties or assets subject thereto, and for which adequate reserves have been set aside on the books of the applicable Person and maintained in conformity with GAAP, if required;

(q) Liens in favor of customs and revenue authorities arising as a Requirement of Law which were incurred in the ordinary course of business, to secure payment of customs duties in connection with the importation of goods in the ordinary course of business;

(r) Liens on any goods sold to Borrower or any of its Subsidiaries in the ordinary course of business in favor of the seller thereof, but only to the extent securing the unpaid purchase price for such goods and any related expenses;

(s) Liens securing Permitted Indebtedness of a Credit Party in favor of any other Credit Party;

(t) Liens securing Indebtedness owed by a Subsidiary of Borrower that is not a Credit Party permitted under clause (i) of the definition of "Permitted Indebtedness," in favor of a Credit Party or another Subsidiary of Borrower that is not a Credit Party;

(u) other Liens to the extent that the obligations secured thereby (determined as of the date such Lien is incurred) do not exceed $[***];

(v) any security interest or right to set-off arising under articles 24 or 25 respectively of the general terms and conditions (*algemene voorwaarden*) of any member of the Dutch Bankers' Association (*Nederlandse Vereniging van Banken*) or similar terms applied by an account bank;

(w) Liens on cash and Cash Equivalents securing Hedging Agreements with respect to interest rates that are entered into for hedging and not speculative purposes; and

(w) subject to the provisos immediately below, the modification, replacement, extension or renewal of the Liens described in clauses (a) through (w) above; provided, however, that any such modification, replacement, extension or renewal must (i) be limited to the assets or properties encumbered by the existing Lien (and any additions, accessions, parts, improvements and attachments thereto and the proceeds thereof) and (ii) not increase the principal amount of any Indebtedness secured by the existing Lien (other than by any reasonable premium or

other reasonable amount paid and fees and expenses reasonably incurred in connection therewith); provided, further, that to the extent any of the Liens described in clauses (a) through (w) above secure Indebtedness of a Credit Party, such Liens, and any such modification, replacement, extension or renewal thereof, shall constitute Permitted Liens if and only to the extent that such Indebtedness is permitted under Section 6.4 hereof.

"**Permitted Negative Pledges**" means:

(a) prohibitions or limitations with regard to specific properties or assets encumbered by Permitted Liens, if and only to the extent each such prohibition or limitation applies only to such properties or assets;

(b) prohibitions or limitations set forth in any lease or other similar agreement entered into in the ordinary course of business, or in any license or other similar agreement not prohibited hereunder;

(c) prohibitions or limitations relating to Permitted Indebtedness, in the case of each relevant agreement, document or instrument if and only to the extent such prohibitions or limitations, taken as a whole, are not materially more restrictive than the prohibitions and limitations set forth in this Agreement and the other Loan Documents, taken as a whole (as reasonably determined by a Responsible Officer of Borrower in good faith);

(d) customary provisions restricting assignments, subletting, sublicensing or other transfer of properties or assets subject thereto set forth in leases, subleases, licenses (including Permitted Licenses) and other similar agreements that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such restriction applies only to the properties or assets subject to such leases, subleases, licenses or agreements, and customary provisions restricting assignment, pledges or transfer of any agreement entered into in the ordinary course of business;

(e) prohibitions or limitations imposed by Requirements of Law;

(f) prohibitions or limitations that exist as of the Tranche B Closing Date under Indebtedness existing on the Tranche B Closing Date;

(g) customary prohibitions or limitations arising in connection with any Permitted Transfer or contained in any agreement relating to any Permitted Transfer pending the consummation of such Permitted Transfer;

(h) customary provisions in shareholders' agreements, joint venture agreements, Operating Documents or similar binding agreements relating to, or any agreement evidencing Indebtedness of, any joint venture entity or non-Wholly-Owned Subsidiary and applicable solely to such joint venture entity or non-Wholly-Owned Subsidiary and the Equity Interests issued thereby;

(i) customary net worth provisions set forth in real property leases entered into by Subsidiaries of Borrower, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Borrower in good faith);

(j) customary net worth provisions set forth in customer agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Borrower in good faith);

(k) restrictions on cash or other deposits (including escrowed funds) imposed by agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document;

(l) prohibitions or limitations set forth in any agreement in effect at the time any Person becomes a Subsidiary (but not any amendment, modification, restatement, renewal, extension, supplement or replacement expanding the scope of any such restriction or condition); provided that such agreement was not entered into in contemplation of such Person becoming a Subsidiary and each such prohibition or limitation does not apply to Borrower or any other Subsidiary (other than such Person and any other Person that is a Subsidiary of such first Person at the time such first Person becomes a Subsidiary);

(m) prohibitions or limitations imposed by any Loan Document;

(n) customary provisions set forth in joint venture agreements or agreements governing minority investments that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to the joint venture entity or minority investment that is the subject of such agreement;

(o) limitations imposed with respect to any license acquired in a Permitted Acquisition;

(p) customary provisions restricting assignments or other transfer of properties or assets subject thereto set forth in any agreement entered into in the ordinary course of business, if and only to the extent each such restriction applies only to the properties or assets subject to such agreement;

(q) prohibitions or limitations imposed by any agreement evidencing any Permitted Indebtedness of the type described in clause (d) of the definition of "Permitted Indebtedness"; and

(r) prohibitions or limitations imposed by any amendments, modifications, restatements, renewals, extensions, supplements or replacements of any of the agreements referred to in clauses (a) through (q) above, except to the extent that any such amendment, modification, restatement, renewal, extension, supplement or replacement expands the scope of any such prohibition or limitation.

"**Permitted Subsidiary Distribution Restrictions**" means, in each case notwithstanding Section 6.8:

(a) prohibitions or limitations with regard to specific properties or assets encumbered by Permitted Liens, if and only to the extent each such prohibition or limitation applies only to such properties or assets;

(b) prohibitions or limitations set forth in any lease, license or other similar agreement entered into in the ordinary course of business;

(c) prohibitions or limitations relating to Permitted Indebtedness, in the case of each relevant agreement, document or instrument if and only to the extent such prohibitions or limitations, taken as a whole, are not materially more restrictive than the prohibitions and limitations set forth in this Agreement and the other Loan Documents, taken as a whole (as reasonably determined by a Responsible Officer of Borrower in good faith);

(d) customary provisions restricting assignments, subletting, sublicensing or other transfer of properties or assets subject thereto set forth in leases, subleases, licenses (including Permitted Licenses) and other similar agreements that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such restriction applies only to the properties or assets subject to such leases, subleases, licenses or agreements, and customary provisions restricting assignment, pledges or transfer of any agreement entered into in the ordinary course of business;

(e) prohibitions or limitations on the transfer or assignment of any properties, assets or Equity Interests set forth in any agreement entered into in the ordinary course of business that is not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to such properties, assets or Equity Interests;

(f) prohibitions or limitations imposed by Requirements of Law;

(g) prohibitions or limitations that exist as of the Tranche B Closing Date under Indebtedness existing on the Tranche B Closing Date;

(h) customary prohibitions or limitations arising in connection with any Permitted Transfer or contained in any agreement relating to any Permitted Transfer pending the consummation of such Permitted Transfer;

(i) customary provisions in shareholders' agreements, joint venture agreements, Operating Documents or similar binding agreements relating to, or any agreement evidencing Indebtedness of, any joint venture entity or non-Wholly-Owned Subsidiary and applicable solely to such joint venture entity or non-Wholly-Owned Subsidiary and the Equity Interests issued thereby;

(j) customary net worth provisions set forth in real property leases entered into by Subsidiaries of Borrower, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Borrower in good faith);

(k) customary net worth provisions set forth in customer agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Borrower in good faith);

(l) restrictions on cash or other deposits (including escrowed funds) imposed by agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document;

(m) prohibitions or limitations set forth in any agreement in effect at the time any Person becomes a Subsidiary (but not any amendment, modification, restatement, renewal, extension, supplement or replacement expanding the scope of any such restriction or condition); provided that such agreement was not entered into in contemplation of such Person becoming a Subsidiary and each such prohibition or limitation does not apply to Borrower or any other Subsidiary (other than such Person and any other Person that is a Subsidiary of such first Person at the time such first Person becomes a Subsidiary);

(n) prohibitions or limitations imposed by any Loan Document or the Royalty Revenue Documents;

(o) customary provisions set forth in joint venture agreements or agreements governing minority investments that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to the joint venture entity or minority investment that is the subject of such agreement;

(p) customary provisions restricting assignments or other transfer of properties or assets subject thereto set forth in any agreement entered into in the ordinary course of business, if and only to the extent each such restriction applies only to the properties or assets subject to such agreement;

(q) prohibitions or limitations imposed by any agreement evidencing any Permitted Indebtedness of the type described in clause (d) of the definition of "Permitted Indebtedness"; and

(r) prohibitions or limitations imposed by any amendments, modifications, restatements, renewals, extensions, supplements or replacements of any of the agreements referred to in clauses (a) through (q) above, except to the extent that any such amendment, modification, restatement, renewal, extension, supplement or replacement expands the scope of any such prohibition or limitation.

41 "**Permitted Transaction**" is defined in Section 2.2(c)(iii).

"**Permitted Transfers**" means:

(a) Transfers of any properties or assets which do not constitute Collateral under the Loan Documents, other than any Company IP that does not constitute Collateral under the Loan Documents but is related to any aspect of the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory (other than, for the avoidance of doubt, any such Company IP Transferred pursuant to any Permitted License);

(b) Transfers of Inventory in the ordinary course of business;

(c) Transfers of surplus, damaged, worn out or obsolete equipment that is, in the reasonable judgment of a Responsible Officer of Borrower exercised in good faith, no longer economically practicable to maintain or useful in the ordinary course of business, and Transfers of other properties or assets in lieu of any pending or threatened institution of any proceedings for the condemnation or seizure of such properties or assets or for the exercise of any right of eminent domain;

(d) Transfers made in connection with (i) the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such Transfers are described in Exhibit F hereto), (ii) Permitted Liens, (iii) Permitted Acquisitions or (iv) Permitted Investments;

(e) Transfers of cash and Cash Equivalents in the ordinary course of business for equivalent value and in a manner that is not prohibited under this Agreement or the other Loan Documents;

(f) Transfers (i) between or among Credit Parties, including pursuant to the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such Transfers are described in Exhibit F hereto), provided that, with respect to any properties or assets constituting Collateral under the Loan Documents, any and all steps as may be required to be taken in order to create and maintain a first priority security interest in and Lien upon such properties and assets in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties are taken contemporaneously with the completion of any such Transfer, (ii) by Credit Parties to non-Credit Parties, not to exceed $[***] in the aggregate per fiscal year, and (iii) between or among non-Credit Parties, including pursuant to the Intercompany Reorganization (but only to the extent described in clause (a) of the definition of Intercompany Reorganization, and then, only if and to the extent such Transfers are described in Exhibit F hereto).

(g) (i) the sale or issuance of Equity Interests of any Subsidiary of Borrower to any Credit Party or Subsidiary, provided, that any such sale or issuance by a Credit Party shall be to another Credit Party; and (ii) the sale, transfer, issuance or other disposition of a *de minimis* number of shares of the Equity Interests of any Subsidiary of Borrower in order to qualify members of the governing body of such Subsidiary if required by Requirements of Law;

(h) the discount without recourse or sale or other disposition of unpaid and overdue accounts receivable arising in the ordinary course of business in connection with the compromise, collection or settlement thereof and not part of a financing transaction;

(i) any abandonment, disclaimer, forfeiture, dedication to the public, cancellation, non-renewal or discontinuance of use or maintenance of Company IP that a Responsible Officer of Borrower reasonably determines in good faith (i) is no longer economically practicable to maintain or useful in the ordinary course of business and that (ii) could not reasonably be expected to be adverse to the rights, remedies and benefits available to, or conferred upon, the Collateral Agent or any Lender under any Loan Document in any material respect;

(j) Transfers by Borrower or any of its Subsidiaries pursuant to any Permitted License;

(k) intercompany licenses or grants of rights of distribution, co-promotion or similar commercial rights: (i) between or among Credit Parties; or (ii) between or among Credit Parties and Subsidiaries of Borrower that are not Credit Parties which in each case is not otherwise prohibited hereunder;

(l) any involuntary loss, damage or destruction of property or any involuntary condemnation, seizure or taking, by exercise of the power of eminent domain or otherwise, or confiscation or requisition of use of property;

(m) licenses, sublicenses, leases or subleases, in each case other than relating to any Company IP, granted to third parties in the ordinary course of business and not material to any aspect of the research, development, manufacture, production, use (by any Credit Party or its Subsidiaries), commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Product in the Territory;

(n) the abandonment disclaimer, forfeiture, dedication to the public, or other disposition of any Company IP that is (i) not material to any aspect of the research, development, manufacture, production, use (by any Credit Party or its Subsidiaries), commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale or lease, distribution or sale or lease of Product in the Territory or (ii) no longer used or useful in any material respect in any Product line of business of Borrower and its Subsidiaries;

(o) any involuntary disposition or any sale, lease, license or other disposition of property (other than, for the avoidance of doubt, any Company IP) in settlement of, or to make payment in satisfaction of, any property or casualty insurance;

(p) sales, leases, licenses, transfers or other dispositions of property to the extent that (i) such property is exchanged for credit against the purchase price of similar replacement property or (ii) the proceeds of such sale, lease, license, transfer or other disposition are promptly applied to the purchase price of similar replacement property;

(q) any early unwind, settlement or termination of any Permitted Equity Derivative;

(r) other Transfers made in the ordinary course of business on commercially reasonable arm's length terms; and

(s) other Transfers of assets or property, so long as the fair market value (as reasonably determined in good faith by a Responsible Officer of the Borrower) thereof does not exceed, individually or in the aggregate, $[***] per fiscal year.

"**Person**" means any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, exempted company, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Personal Data**" means information protected as "personal data," "personal information," "personally identifiable information," "protected health information," "medical information," "identifiable private information," or any similar terms under applicable Data Protection Laws.

"**Personal Data Breach**" is defined in Section 4.22(b).

42 "**PHSA**" is defined in Section 4.19(b).

"**Plan**" means any employee pension benefit plan (other than a Multiemployer Plan) subject to the provisions of Title IV of ERISA or Section 412 of the IRC or Section 302 of ERISA which is maintained or contributed to by Borrower or its Subsidiaries or their respective ERISA Affiliates or with respect to which Borrower or its Subsidiaries have any liability (including under Section 4069 of ERISA).

43 "**PMDL**" is defined in Section 4.19(b).

"**Prepayment Premium**" means the Tranche A Prepayment Premium or the Tranche B Prepayment Premium, individually or collectively, as applicable.

44 "**Prior Loan Agreement**" is defined in the preamble hereof.

45 "**Prior Loan Documents**" is defined in Section 11.19(b).

46 "**Product**" means, collectively: (a) the biopharmaceutical product known as ARIKAYCE ® (amikacin liposome inhalation suspension) and the Lamira® Nebulizer System and any other device approved for use with ARIKAYCE ® (and foreign-named equivalents) and any successors used for the treatment of *Mycobacterium avium* complex (MAC) lung disease, or any lung disease, condition or disorder, including the product approved by the FDA under NDA 207356 and any supplements thereto or any other approval of a product owned or controlled by Borrower or any of its Subsidiaries that contains amikacin in any form for inhalation or non-systemic delivery to patients, in any dosage form, dosing regimen, strength or route of administration (collectively, "**ARIKAYCE®**"); and (b) any proposed or approved pharmaceutical product owned or controlled by Borrower or any of its Subsidiaries that contains as an active ingredient the chemical compound known as brensocatib in any form, and any successors thereto, for any indication including treatment of cystic fibrosis and related conditions, non-cystic fibrosis bronchiectasis and related conditions or any other lung disease, disorder or condition, in any dosage form, dosing regimen, strength or route of administration (collectively, "**Brensocatib**").

"**Product Revenue Forecast**" means that certain five-year revenue forecast included in the Insmed 2022 Strategic Plan dated August 31, 2022, made available by or on behalf of Borrower to the Collateral Agent and Lenders on the Datasite virtual deal site for Project Icon and included in Schedule 5.17 of the Disclosure Letter.

47 "**Purchase Agreement**" means that certain Agreement for the Sale and Purchase of Adrestia Therapeutics Ltd, dated as of June 30, 2023, by among Borrower, the sellers party thereto and Shareholder Representative Services LLC, as sellers' representative.

48 "**Refinancing Convertible Debt**" is defined in Section 2.2(c)(iii).

"**Registered Organization**" means any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"**Regulatory Agency**" means a U.S. or foreign Governmental Authority with responsibility for the approval, authorization, clearance, or licensure of the marketing and sale of pharmaceuticals or other regulation of pharmaceuticals, or otherwise having authority to regulate Product, including the FDA, EMA, PMDA and MHLW.

49 "**Regulatory Approvals or Licensures**" means all U.S., EU, Japanese, and any other foreign approvals, exclusivities, authorizations, licensure or clearances (including approval under FDCA §§ 505 or 515 and clearance under FDCA § 510(k)); licensures (including Orphan Drug exclusive approval under 21 C.F.R. § 316.34 and any foreign equivalents); designations (including (i) Orphan Drug designation under 21 C.F.R. § 316.24 and any foreign equivalents; (ii) Fast Track designation, Breakthrough Therapy designation, and Priority Review designation under 21 U.S.C. § 356 and any corresponding regulations and as interpreted through guidance documents by FDA (and foreign equivalents); and (iii) Qualified Infectious Disease Product designation under 21 U.S.C. § 355f (including an award of "GAIN" exclusivity) and any corresponding regulations and as interpreted through guidance documents by FDA (and foreign equivalents)); and any product or establishment licenses, registrations, approvals,

or authorizations of any Regulatory Agency necessary for the manufacture, use, import, export, storage, transport, offer for sale, or distribution or sale of Product.

"**Regulatory Submission Material**" means all regulatory filings, submissions, approvals, licensures, and authorizations related to any research, development, manufacture, production, use, commercialization, post-approval (or post-licensure, post-authorization, or post-clearance, as applicable) monitoring and reporting (including post-marketing safety reports for combination products), marketing, importing, storage, transport, offer for sale or lease, distribution or sale or lease of Product in the Territory, including all data and information provided in, and used to develop, any of the foregoing.

"**Related Parties**" means, with respect to any Person, such Person's Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors and representatives of such Person and of such Person's Affiliates.

"**Release**" means any release, spill, emission, leaking, pumping, pouring, injection, escaping, deposit, disposal, discharge, dispersal, dumping, leaching or migration of any Hazardous Material into the indoor or outdoor environment (including the abandonment or disposal of any barrels, containers or other closed receptacles containing any Hazardous Material), including the movement of any Hazardous Material through the air, soil, surface water or groundwater.

"**Required Lenders**" means Lenders representing greater than fifty percent (50%) of the principal amount of the Term Loans outstanding as of such date.

"**Requirements of Law**" means, as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, order, policy, rule or regulation or determination of an arbitrator or a court or other Governmental Authority (including Environmental Laws, Health Care Laws, Data Protection Laws and FDA Laws, EU Laws, Japanese Laws and all other applicable statutes, rules, regulations, standards, guidelines, policies and orders administered or issued by any foreign Governmental Authority) in each case, applicable to and binding upon such Person or any of its assets or properties or to which such Person or any of its assets or properties are subject, including, with respect to Borrower, the rules or requirements of any applicable U.S. national securities exchange applicable to Borrower or any of its Equity Interests.

"**Responsible Officers**" means, with respect to any Credit Party, collectively, each of the Chief Executive Officer, Chief Financial Officer, General Counsel, Chief People Strategy Officer, Chief Medical Officer, Chief Operating Officer, and Chief Commercial Officer of such Credit Party or, in each case, if none, of Borrower.

"**Royalty Revenue Contract**" means that certain Revenue Interest Purchase Agreement, dated as of the Tranche A Closing Date, by and between Borrower and OrbiMed.

"**Royalty Revenue Documents**" means, collectively, the Royalty Revenue Contract and each other "Transaction Document" (as such term is defined in the Royalty Revenue Contract).

"**Sanctioned Country**" means, at any time, a country or territory which is itself the subject or target of comprehensive Sanctions (currently, those portions of the Donetsk People's Republic and the Luhansk People's Republic regions (and such other regions) of Ukraine over which any Sanctions authority imposes comprehensive Sanctions, Crimea, Cuba, Iran, Syria and North Korea).

"**Sanctioned Person**" means an individual or entity that is, or is owned or controlled by individuals or entities that are: (i) the target of **Sanctions**; or (ii) located, organized or resident in a Sanctioned Country.

"**Sanctions**" is defined in Section 4.18(c).

"**SEC**" means the Securities and Exchange Commission and any analogous Governmental Authority.

"**Secretary's Certificate**" means, with respect to any Person, a certificate of such Person executed by its Secretary, authorized signatory or director certifying as to the various matters set forth therein.

"**Section 5 of the FTC Act**" means the Section 5(a) of the U.S. Federal Trade Commission Act (15 U.S.C. § 45), which prohibits unfair and deceptive acts or practices in or affecting commerce and serves as the primary basis for U.S. Federal Trade Commission authority on privacy and security.

"**Secured Parties**" means each Lender, each other Indemnified Person and each other holder of any Obligation of a Credit Party.

"**Securities Account**" means any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"**Security Agreement**" means the Guaranty and Security Agreement, dated as of the Tranche A Closing Date, by and among the Credit Parties and the Collateral Agent, in form and substance substantially similar to Exhibit C attached hereto or in such form or substance as the Credit Parties and the Collateral Agent may otherwise agree.

"**Security Incidents**" is defined in Section 4.22(b).

"**Security Program**" is defined in Section 4.22(b).

"**Sensitive Information**" means, collectively, (a) any Personal Data that is subject to any Data Protection Law(s), (b) any information in which Borrower or any of its Subsidiaries have IP Ancillary Rights or any other Intellectual Property rights (including Company IP), (c) any information with respect to which Borrower or any of its Subsidiaries have contractual non-disclosure obligations, and (d) nonpublic Regulatory Submission Materials.

"**Software**" means "Software", as such term is defined in the Security Agreement.

"**Solvent**" means, with respect to any Person as of any date of determination, that, as of such date, (a) the value of the assets (including goodwill minus disposition costs) of such Person (both at fair value and present fair saleable value) is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of such Person, (b) such Person is able to generally pay all liabilities (including trade debt) of such Person as such liabilities become absolute and mature in the ordinary course of business and (c) such Person does not have unreasonably small capital after giving due consideration to the prevailing practice in the industry in which it is engaged or will be engaged. In computing the amount of contingent or unliquidated liabilities at any time, such liabilities shall be computed at the amount that, in light of all the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability.

"**SSA**" means the Social Security Act of 1935, codified at Title 42, Chapter 7, of the United States Code.

"**Stock Acquisition**" means the purchase or other acquisition by Borrower or any of its Subsidiaries of any of the Equity Interests (by merger, stock purchase or otherwise) in any other Person.

"**Subordinated Debt**" means any Indebtedness in the form of or otherwise constituting term debt incurred by any Credit Party or any Subsidiary thereof (including any Indebtedness incurred in connection with any Acquisition or other Investment) that: (a) is subordinated in right of payment to the Obligations at all times until all of the Obligations have been paid, performed or discharged in full and Borrower has no further right to obtain any Credit Extension hereunder, pursuant to a subordination, intercreditor or other similar agreement that is in form and substance reasonably satisfactory to the Collateral Agent (which agreement shall include turnover provisions that are reasonably satisfactory to the Collateral Agent); (b) except as permitted by clause (d) below, is not subject to scheduled amortization, redemption (mandatory), sinking fund or similar payment and does not have a final maturity, in each case, before a date that is at least 180 days following the Term Loan Maturity Date; (c) does not include covenants (including financial covenants) and agreements (excluding agreements with respect to maturity,

amortization, pricing and other economic terms) that, taken as a whole, are more restrictive or onerous on the Credit Parties in any material respect than the comparable covenants and agreements, taken as a whole, in the Loan Documents (as reasonably determined by a Responsible Officer of such Credit Party in good faith); (d) is not subject to repayment or prepayment, including pursuant to a put option exercisable by the holder of any such Indebtedness, prior to a date that is at least 180 days following the final maturity thereof except in the case of an event of default or change of control (or, in each case, the equivalent thereof, however described); and (e) does not provide or otherwise include provisions having the effect of providing that a default or event of default (or the equivalent thereof, however described) under or in respect of such Indebtedness shall exist, or such Indebtedness shall otherwise become due prior to its scheduled maturity or the holder or holders thereof or any trustee or agent on its or their behalf shall be permitted (with or without the giving of notice, the lapse of time or both) to cause any such Indebtedness to become due, or to require the prepayment, repurchase, redemption or defeasance thereof, prior to its scheduled maturity, in any such case upon the occurrence of a Default or Event of Default hereunder unless and until the Obligations have been declared, or have otherwise automatically become, immediately due and payable pursuant to Section 8.1(a). Notwithstanding the foregoing, Indebtedness under the 2028 Convertible Notes (and the indenture relating thereto), Permitted Convertible Indebtedness and Indebtedness under the Royalty Revenue Contract and other Royalty Revenue Documents shall not constitute Subordinated Debt.

"**Subsidiary**" means, with respect to any Person, a corporation, partnership, limited liability company or other entity of which more than fifty percent (50.0%) of whose shares of stock or other ownership interests having ordinary voting power (other than stock or such other ownership interests having such power only by reason of the happening of a contingency) to elect a majority of the Board of Directors (or similar body, if applicable) of such corporation, partnership or other entity are at the time owned, directly or indirectly through one or more intermediaries, or both, by such Person. Unless the context otherwise requires, each reference to a Subsidiary herein shall be a reference to a Subsidiary of a Credit Party.

50 "**Swiss Federal Tax Administration**" means the tax authorities referred to in article 34 of the Swiss Withholding Tax Act.

51 "**Swiss Guarantor**" means an obligor incorporated in Switzerland and/or having its registered office in Switzerland and/or qualifying as a Swiss resident pursuant to art 9 of the Swiss Withholding Tax Act.

52 "**Swiss Security Documents**" means:

53 (a) the Swiss law governed quota pledge agreement between (i) BioPharma Credit, PLC (acting for itself and as direct representative in the name and on behalf of the other pledgees), (ii) Insmed Incorporated as pledgor, and (iii) Insmed Switzerland GmbH as the company whose quotas are pledged; and

54 (b) the Swiss law governed bank accounts pledge agreement between (i) BioPharma Credit, PLC (acting for itself and as direct representative in the name and on behalf of the other pledgees), and (ii) Insmed Switzerland GmbH as pledgor; and

55 (c) the Swiss law governed intellectual property pledge agreement between (i) BioPharma Credit, PLC acting for itself and as direct representative in the name and on behalf of the other pledgees, and (ii) Insmed Switzerland GmbH as pledgor; and

56 (d) the Swiss law governed security assignment agreement between (i) BioPharma Credit, PLC (acting for itself and for the benefit of the other secured parties) and (ii) Insmed Switzerland GmbH as assignor; and

57 (e) any other Collateral Document governed by the laws of Switzerland.

58 "**Swiss Withholding Tax**" means taxes imposed under the Swiss Withholding Tax Act.

59 "**Swiss Withholding Tax Act**" means the Swiss Federal Act on the Withholding Tax of 13 October 1965 (*Bundesgesetz über die Verrechnungssteuer*), together with the related ordinances, regulations and guidelines, all as amended and applicable from time to time.

"**Systems**" is defined in Section 4.22(a).

"**Tax**" means any taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges of any nature or hereafter imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"**Term Loan**" means each of the Tranche A Term Loan and the Tranche B Term Loan, as applicable, and " **Term Loans**" means, collectively, the Tranche A Term Loans and, to the extent funded, the Tranche B Term Loans.

"**Term Loan Amount**" means each of the Tranche A Term Loan Amount and the Tranche B Term Loan Amount, as applicable.

"**Term Loan Maturity Date**" means September 30, 2029; provided, however, that if the aggregate principal amount outstanding under the 2028 Convertible Notes is more than $50,000,000.00 as of February 1, 2028, then the Term Loan Maturity Date is February 1, 2028.

"**Term Loan Note**" means a promissory note in substantially the form attached hereto as Exhibit B-1 and Exhibit B-2, as it may be amended, restated, supplemented or otherwise modified from time to time.

"**Term Loan Rate**" is defined in Section 2.3(a)(i).

"**Territory**" means anywhere in the world.

"**Third Party IP**" is defined in Section 4.6(l).

"**Trademarks**" means (a) all trademarks, trade names, corporate names, company names, business names, fictitious business names, service marks, elements of package or trade dress of goods or services, logos and other source or business identifiers, together with the goodwill associated therewith, including all registrations and recordings thereof, and all applications in connection therewith, in the United States Patent and Trademark Office or in any similar office or agency of the United States or any state thereof or in any similar office or agency anywhere in the world in which foreign counterparts are registered or issued, and (b) all renewals thereof.

60 "**Trading Day**" means a day on which exchanges in the United States are open for the buying and selling of securities.

61 "**Tranche A Additional Consideration**" is defined in Section 2.7(a).

62 "**Tranche A Closing Date**" means October 19, 2022.

63 "**Tranche A Exit Fee**" means, with respect to any prepayment of the Tranche A Term Loans by Borrower pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Tranche A Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date, or any repayment of the Tranche A Term Loans by Borrower pursuant to Section 2.2(b) or otherwise (including, for the

avoidance of doubt, on the Term Loan Maturity Date), in any such case, an amount equal to the product of (a) the amount of any principal so prepaid or repaid, multiplied by (b) 0.02.

64 "**Tranche A Makewhole Amount**" means, as of the date of any prepayment of the Tranche A Term Loan occurring prior to the 3rd-year anniversary of the Effective Date (including any prepayment as a result of the acceleration of the maturity of the Tranche A Term Loans as provided in the proviso in the definition of Term Loan Maturity Date), an amount equal to the sum of all interest that would have accrued and been payable (or would have accrued and been capitalized, as the case may be) from such date of prepayment through the 3rd-year anniversary of the Effective Date on the amount of principal prepaid.

65 "**Tranche A Prepayment Premium**" means, with respect to any prepayment of the Tranche A Term Loan by Borrower pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Tranche A Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date, an amount equal to the product of the amount of any principal so prepaid, multiplied by:

66 (a) if such prepayment occurs prior to the 3rd-year anniversary of the Effective Date, 0.03;

67 (b) if such prepayment occurs on or after the 3rd-year anniversary of the Effective Date but prior to the 4th-year anniversary of the Effective Date, 0.02; and

68 (c) if such prepayment occurs on or after the 4th-year anniversary of the Effective Date but prior to the Term Loan Maturity Date, 0.01.

69 For the avoidance of doubt, no Prepayment Premium shall be due and owing for any payment of principal of the Tranche A Term Loans made on the Term Loan Maturity Date.

"**Tranche A Term Loan**" and "**Tranche A Term Loans**" are defined in Section 2.2(a)(i).

"**Tranche A Term Loan Amount** " means an aggregate original principal amount equal to the sum of (a) $350,000,000.00, *plus* (b) $46,769,917.00 of aggregate paid-in-kind interest thereon accrued and capitalized prior to the date hereof pursuant to the terms of the Prior Loan Agreement.

"**Tranche A Term Loan Commitment** " means, with respect to any Lender, the commitment of such Lender to make the Credit Extensions relating to the Tranche A Term Loans on the Tranche A Closing Date in the original principal amount set forth opposite such Lender's name on Exhibit D attached hereto. For purposes of this Agreement, as of the Effective Date, each Lender's Tranche A Term Loan Commitment is zero.

"**Tranche A Term Loan Note** " means, with respect to each Lender, a promissory note in substantially the form attached hereto as Exhibit B-1, which amends and restates in its entirety that certain Term Loan Note issued to such Lender on October 19, 2022, as it may be further amended, restated, supplemented or otherwise modified from time to time.

70 "**Tranche B Additional Consideration**" is defined in Section 2.7(b).

71 "**Tranche B Closing Date**" means the date on which the Tranche B Term Loans are advanced by Lenders, which, subject to the satisfaction of the conditions precedent to the Tranche B Term Loans set forth in Sections 3.2, 3.5, 3.6 and 3.7, shall be the Effective Date.

72 "**Tranche B Exit Fee**" means, with respect to any prepayment of the Tranche B Term Loans by Borrower pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Tranche B Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date, or any repayment of the Tranche B Term Loans by Borrower pursuant to Section 2.2(b) or otherwise (including, for the avoidance of doubt, on the Term Loan Maturity Date), in any such case, an amount equal to the product of (a) the amount of any principal so prepaid or repaid, multiplied by (b) 0.02.

73 "**Tranche B Makewhole Amount**" means, as of the date of any prepayment of the Tranche B Term Loans occurring prior to the 3rd-year anniversary of the Tranche B Closing Date (including any prepayment as a result of the acceleration of the maturity of the Tranche B Term Loans as provided in the proviso in the definition of Term Loan Maturity Date), an amount equal to the sum of all interest that would have accrued and been payable (or would have accrued and been capitalized, as the case may be) from such date of prepayment through the 3rd-year anniversary of the Tranche B Closing Date on the amount of principal prepaid.

74 "**Tranche B Prepayment Premium**" means, with respect to any prepayment of the Tranche B Term Loans by Borrower pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Tranche B Term Loans pursuant to Section 8.1(a) or as provided in the proviso in the definition of Term Loan Maturity Date, in each case that occurs prior to the Term Loan Maturity Date, an amount equal to the product of the amount of any principal so prepaid, multiplied by:

75 (a) if such prepayment occurs prior to the 3rd-year anniversary of the Tranche B Closing Date, 0.03;

76 (b) if such prepayment occurs on or after the 3rd-year anniversary of the Tranche B Closing Date but prior to the 4th-year anniversary of the Tranche B Closing Date, 0.02; and

77 (c) if such prepayment occurs on or after the 4th-year anniversary of the Tranche B Closing Date but prior to the Term Loan Maturity Date, 0.01.

78 For the avoidance of doubt, no Prepayment Premium shall be due and owing for any payment of principal of the Tranche B Term Loans made on the Term Loan Maturity Date.

"**Tranche B Term Loan**" and "**Tranche B Term Loans**" are defined in Section 2.2(a)(ii).

"**Tranche B Term Loan Amount**" means an aggregate original principal amount equal to One Hundred and Fifty Million Dollars ($150,000,000.00).

"**Tranche B Term Loan Commitment**" means, with respect to any Lender, the commitment of such Lender to make the Credit Extensions relating to the Tranche B Term Loans on the Tranche B Closing Date in the aggregate principal amount set forth opposite such Lender's name on Exhibit D attached hereto.

"**Tranche B Term Loan Note**" means, with respect to each Lender, a promissory note in substantially the form attached hereto as Exhibit B-2, as it may be amended, restated, supplemented or otherwise modified from time to time.

"**Transfer**" is defined in Section 6.1.

"**Treasury Regulations**" mean those regulations promulgated pursuant to the IRC.

"**TRICARE**" means, collectively, a program of medical benefits covering former and active members of the uniformed services and certain of their dependents, financed and administered by the United States Departments of Defense, Health and Human Services and Transportation, and all laws applicable to such programs.

"**UKBA**" is defined in Section 4.18(a).

"**United States**" or "**U.S.**" means the United States of America, its fifty (50) states, the District of Columbia, Puerto Rico and any other jurisdiction within the United States of America.

"**Wholly-Owned Subsidiary**" means, with respect to any Person, a Subsidiary of such Person, all of the Equity Interests of which (other than directors' qualifying shares or nominee or other similar shares required pursuant to Requirements of Law) are owned by such Person or another Wholly-Owned Subsidiary of such Person. Unless the context otherwise requires, each reference to a Wholly-Owned Subsidiary herein shall be a reference to a Wholly-Owned Subsidiary of a Credit Party.

"**Withdrawal Event**" means (a) any voluntary withdrawal or removal of ARIKAYCE® in the United States or Japan by any Credit Party or any of its Subsidiaries, (b) the loss of marketing authorization for ARIKAYCE® in the United States or Japan, or (c) the receipt by any Credit Party or any of its Subsidiaries of any written notice from the FDA or any other Regulatory Agency of a final decision to withdraw marketing authorization for ARIKAYCE® in the United States or Japan.

"**Withdrawal Liability**" means liability to a Multiemployer Plan as a result of a complete or partial withdrawal from such Multiemployer Plan, as such terms are defined in Part I of Subtitle E of Title IV of ERISA.

"**Withholding Agent**" is defined in Section 2.6(b).

13.2 Irish terms. In this Agreement, any reference to an " **examiner**" shall mean an examiner (including an interim examiner) appointed under section 509 of the Irish Companies Act and "**examinership**" shall be construed accordingly.

[Signature pages follow]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

INSMED INCORPORATED,
as Borrower and a Credit Party

By /s/ Sara Bonstein

Name: Sara Bonstein

Title: Chief Financial Officer

INSMED GENE THERAPY LLC,
as an additional Credit Party

By /s/ Sara Bonstein

Name: Sara Bonstein

Title: Vice President

INSMED NETHERLANDS HOLDINGS B.V.,
as an additional Credit Party

By /s/ John Diependaal

Name: John Diependaal

Title: Director

INSMED NETHERLANDS B.V.,
as an additional Credit Party

By /s/ John Diependaal

Name: John Diependaal

Title: Director

INSMED SWITZERLAND GMBH,
as an additional Credit Party

By /s/ John Diependaal

Name: John Diependaal

Title: President of the Management

79

SIGNED AND DELIVERED as a **DEED**
for and on behalf of
INSMED IRELAND LIMITED
by its lawfully appointed attorney:

/s/ Sara Bonstein
(Signature of Attorney)

Sara Bonstein

in the presence of:

/s/ Michael A. Smith
(Witness' Signature)

Michael A. Smith
(Witness' Name)

[***]
(Witness' Address)

Lawyer
(Witness' Occupation)

80

SIGNED AND DELIVERED as a **DEED**
for and on behalf of
INSMED HOLDINGS LIMITED
by its lawfully appointed attorney:

/s/ Sara Bonstein
(Signature of Attorney)

Sara Bonstein

in the presence of:

/s/ Michael A. Smith
(Witness' Signature)

Michael A. Smith
(Witness' Name)

[***]
(Witness' Address)

Lawyer
(Witness' Occupation)

INSMED GODO KAISHA,
as an additional Credit Party

By /s/ Nobuhide Shimizu

Name: Nobuhide Shimizu

Title: Executor of Duties

81 **INSMED INNOVATION UK LTD**
as an additional Credit Party

82
By /s/ John Diependaal

Name: John Diependaal

Title: Director

83
84
85

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BPCR LIMITED PARTNERSHIP,
as a Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP,
as Lender

By: BioPharma Credit Investments V GP LLC,
its General Partner

By: Pharmakon Advisors, LP,
its Investment Manager

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

EXHIBIT A

LOAN ADVANCE REQUEST FORM

Reference is made to that certain Amended and Restated Loan Agreement, dated as of October 31, 2024, by and among INSMED INCORPORATED, a Virginia corporation ("**Borrower**"), the Guarantors signatory thereto or otherwise party thereto from time to time, as additional Credit Parties, BIOPHARMA CREDIT PLC (in its capacity as "**Collateral Agent**"), BPCR LIMITED PARTNERSHIP (a "**Lender**") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP (a "**Lender**"), acting by its general partner, BioPharma Credit Investments V GP LLC (the " **Loan Agreement**"); with any capitalized term not otherwise defined herein having the meaning ascribed to such term in the Loan Agreement. This Loan Advance Request is being delivered pursuant to Section 3.5 of the Loan Agreement.

The undersigned, being the duly elected and acting _____ of Borrower does hereby certify to each Lender and the Collateral Agent, solely in his/her capacity as an authorized officer of Borrower and not in his/her personal capacity, that, on the [_____, 20__] (the "**Tranche B Closing Date**"):

1. Borrower hereby requests a borrowing of the Tranche B Term Loans;

2. the representations and warranties made by the Credit Parties in Section 4 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects, unless any such representation or warranty is stated to relate to a specific earlier date, in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (it being understood that any representation or warranty that is qualified as to "materiality," "Material Adverse Change," or similar language shall be true and correct in all respects on the Tranche B Closing Date or as of such earlier date, as applicable);

2. no Default or Event of Default has occurred or is occurring as of the date hereof;

3. each of the Credit Parties is in compliance with the covenants and requirements contained in Sections 5 and 6 of the Loan Agreement;

4. all conditions referred to in Section 3 of the Loan Agreement to the making of the Tranche B Term Loans on the Tranche B Closing Date have been satisfied (or waived in writing by the Required Lenders);

5. no Material Adverse Change or Withdrawal Event has occurred;

6. the undersigned is a Responsible Officer of Borrower; and

7. the proceeds of the Tranche B Term Loans shall be disbursed as set forth on Attachment A hereto[1].

Dated: _____, 20__

[Signature page follows]

[1]To be prepared by Lenders' counsel.

INSMED INCORPORATED,
as Borrower

By_____

Name:_____

Title:_____

EXHIBIT B-1

THIS TRANCHE A TERM LOAN NOTE HAS BEEN ISSUED WITH "ORIGINAL ISSUE DISCOUNT" (WITHIN THE MEANING OF SECTION 1273 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED). HOLDERS OF THIS TRANCHE A TERM LOAN NOTE SHOULD CONTACT SARA BONSTEIN, CHIEF FINANCIAL OFFICER, INSMED INCORPORATED, 700 US HIGHWAY 202/206, BRIDGEWATER, NEW JERSEY 08807 IN WRITING TO OBTAIN (1) THE ISSUE PRICE AND ISSUE DATE OF THIS TRANCHE A TERM LOAN NOTE, (2) THE AMOUNT OF ORIGINAL ISSUE DISCOUNT ON THIS TRANCHE A TERM LOAN NOTE AND (3) THE YIELD TO MATURITY OF THIS TRANCHE A TERM LOAN NOTE.

AMENDED AND RESTATED SECURED TRANCHE A TERM LOAN PROMISSORY NOTE

$[•] Dated: October 31, 2024

FOR VALUE RECEIVED, the undersigned, INSMED INCORPORATED, a Virginia corporation (" **Borrower**"), HEREBY PROMISES TO PAY to [BPCR LIMITED PARTNERSHIP] [BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP] ("**Lender**"), or its registered assignees, the principal amount of [●], *plus* interest on the aggregate unpaid principal amount of this Amended and Restated Secured Tranche A Term Loan Promissory Note (this " **Tranche A Term Loan Note**") at a rate equal to nine and six tenths percent (9.60%) *per annum*, and in accordance with the terms of the Loan Agreement, dated as of October 31, 2024, by and among Borrower, the Guarantors from time to time party thereto, BioPharma Credit PLC, as Collateral Agent, and the Lenders from time to time party thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date. This Amended and Restated Secured Tranche A Term Loan Promissory Note amends and restates in its entirety that certain Secured Term Loan Promissory Note, dated October 19, 2022, in an aggregate original principal amount equal to the sum of (a) [one hundred and forty million dollars and no cents ($140,000,000.00)] [two hundred and ten million dollars and no cents ($210,000,000.00)] and reflects the accrual and capitalization of [$18,677,384.00] [$28,092,533.00] of paid-in-kind interest. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

86 Subject to any acceleration of the Term Loan Maturity Date pursuant to the definition of "Term Loan Maturity Date," Borrower shall make eight (8) equal quarterly payments of principal of the Tranche A Term Loan commencing on January 1, 2028 and continuing on each Payment Date through the Term Loan Maturity Date. All unpaid principal with respect to the Tranche A Term Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date. Interest shall accrue on this Tranche A Term Loan Note commencing on, and including, the date of this Tranche A Term Loan Note, and shall accrue on this Tranche A Term Loan Note, or any portion thereof, for the day on which this Tranche A Term Loan Note or such portion is paid. Interest on this Tranche A Term Loan Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche A Term Loan Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche A Term Loan Note.

The Loan Agreement, among other things, (a) provides for the making of secured Tranche A Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche A Term Loan Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche A Term Loan Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche A Term Loan Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche A Term Loan Note are hereby waived.

THIS TRANCHE A TERM LOAN NOTE SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche A Term Loan Note shall be registered on a record of ownership maintained by the Collateral Agent. Notwithstanding anything else in this Tranche A Term Loan Note to the contrary, the right to the principal of, and stated interest on, this Tranche A Term Loan Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche A Term Loan Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche A Term Loan Note on the part of any other Person.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Amended and Restated Tranche A Term Loan Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

INSMED INCORPORATED,
as Borrower

By: _____

Name: _____

Title: _____

EXHIBIT B-2

THIS TRANCHE B TERM LOAN NOTE HAS BEEN ISSUED WITH "ORIGINAL ISSUE DISCOUNT" (WITHIN THE MEANING OF SECTION 1273 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED). HOLDERS OF THIS TRANCHE B TERM LOAN NOTE SHOULD CONTACT SARA BONSTEIN, CHIEF FINANCIAL OFFICER, INSMED INCORPORATED, 700 US HIGHWAY 202/206, BRIDGEWATER, NEW JERSEY 08807 IN WRITING TO OBTAIN (1) THE ISSUE PRICE AND ISSUE DATE OF THIS TRANCHE B TERM LOAN NOTE, (2) THE AMOUNT OF ORIGINAL ISSUE DISCOUNT ON THIS TRANCHE B TERM LOAN NOTE AND (3) THE YIELD TO MATURITY OF THIS TRANCHE B TERM LOAN NOTE.

SECURED TRANCHE B TERM LOAN PROMISSORY NOTE

$[•] Dated: October 31, 2024

FOR VALUE RECEIVED, the undersigned, INSMED INCORPORATED, a Virginia corporation (" **Borrower**"), HEREBY PROMISES TO PAY to [BPCR LIMITED PARTNERSHIP] [BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP] ("**Lender**"), or its registered assignees, the principal amount of [[•] DOLLARS AND NO CENTS ($[•])] [[•] DOLLARS AND NO CENTS ($[•])], *plus* interest on the aggregate unpaid principal amount of this Amended and Restated Secured Tranche B Term Loan Promissory Note (this "**Tranche B Term Loan Note**") at a rate equal to nine and six tenths percent (9.60%) *per annum*, and in accordance with the terms of the Loan Agreement, dated as of October 31, 2024, by and among Borrower, the Guarantors from time to time party thereto, BioPharma Credit PLC, as Collateral Agent, and the Lenders from time to time party thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

87 Subject to any acceleration of the Term Loan Maturity Date pursuant to the definition of "Term Loan Maturity Date," Borrower shall make eight (8) equal quarterly payments of principal of the Tranche B Term Loan commencing on January 1, 2028 and continuing on Each Payment Date through the Term Loan Maturity Date. All unpaid principal with respect to the Tranche B Term Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date. Interest shall accrue on this Tranche B Term Loan Note commencing on, and including, the date of this Tranche B Term Loan Note, and shall accrue on this Tranche B Term Loan Note, or any portion thereof, for the day on which this Tranche B Term Loan Note or such portion is paid. Interest on this Tranche B Term Loan Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche B Term Loan Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche B Term Loan Note.

The Loan Agreement, among other things, (a) provides for the making of secured Tranche B Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche B Term Loan Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche B Term Loan Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche B Term Loan Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche B Term Loan Note are hereby waived.

THIS TRANCHE B TERM LOAN NOTE SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche B Term Loan Note shall be registered on a record of ownership maintained by the Collateral Agent. Notwithstanding anything else in this Tranche B Term Loan Note to the contrary, the right to the principal of, and stated interest on, this Tranche B Term Loan Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche B Term Loan Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche B Term Loan Note on the part of any other Person.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Tranche B Term Loan Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

INSMED INCORPORATED,
as Borrower

By: _____

Name: _____

Title: _____

EXHIBIT C

FORM OF SECURITY AGREEMENT

[***]

EXHIBIT D

COMMITMENTS; NOTICE ADDRESSES

88

Lender	Commitments	Notice Address
BPCR Limited Partnership	Tranche A Term Loan Commitment: $140,000,000.00 Tranche B Term Loan Commitment: $60,000,000	BPCR LIMITED PARTNERSHIP c/o Company Matters Ltd. Central Square 29 Wellington Street Leeds United Kingdom LS1 4DL Attn: Company Secretary Tel: +44 01 392 477 500 Email: [***] with copies (which shall not constitute notice) to: PHARMAKON ADVISORS, LP 110 East 59th Street, #2800 New York, NY 10022 Attn: Pedro Gonzalez de Cosio Phone: +1 (212) 883-2296 Email: [***] and AKIN GUMP STRAUSS HAUER & FELD LLP One Bryant Park New York, NY 10036-6745 Attn: Geoffrey E. Secol Phone: +1 (212) 872-8081 Email: [***]
BioPharma Credit Investments V (Master) LP	Tranche A Term Loan Commitment: $210,000,000.00 Tranche B Term Loan Commitment: $90,000,000	BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP c/o BioPharma Credit Investments V GP LLC c/o Walkers Corporate Limited 190 Elgin Avenue, George Town, Grand Cayman KY1-9008 Attn: Pedro Gonzalez de Cosio with copies (which shall not constitute notice) to: PHARMAKON ADVISORS, LP 110 East 59th Street, #2800 New York, NY 10022 Attn: Pedro Gonzalez de Cosio Phone: +1 (212) 883-2296 Email: [***] and AKIN GUMP STRAUSS HAUER & FELD LLP One Bryant Park New York, NY 10036-6745 Attn: Geoffrey E. Secol Phone: +1 (212) 872-8081 Email: [***]

EXHIBIT E

FORM OF COMPLIANCE CERTIFICATE

TO: BIOPHARMA CREDIT PLC

FROM: INSMED INCORPORATED

The undersigned authorized officer of INSMED INCORPORATED., a Virginia corporation, hereby certifies, solely in his/her capacity as a Responsible Officer of Insmed Incorporated and not in his/her personal capacity, that in accordance with the terms and conditions of the Amended and Restated Loan Agreement (the "**Loan Agreement**"; capitalized terms used, but not defined herein having the meanings given them in the Loan Agreement) dated as of [•] by and among INSMED INCORPORATED (as "**Borrower**"), the Guarantors from time to time party thereto, BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales with company number 10443190 (as the "**Collateral Agent**") and the Lenders:

(i) The Credit Parties are in complete compliance for the period ending _____, 202_ with all required covenants except as noted below;

(ii) No Default or Event of Default has occurred and is continuing, except as noted below;

(iii) Each Credit Party and each of its Subsidiaries has timely filed all required U.S. federal and material state, local and foreign income and other material Tax returns and reports or extensions therefor of each Credit Party and each of its Subsidiaries required to be filed by any of them and such returns and reports are correct in all material respects, and has timely paid all U.S. federal and material state, local and foreign Taxes, assessments, deposits and contributions imposed upon it or any of its properties or assets or in respect of any of its income, businesses or franchises, except as otherwise permitted pursuant to the terms of Section 5.3 of the Loan Agreement; and

Attached are the required documents, if any, supporting our certification(s). The undersigned Responsible Officer on behalf of Borrower further certifies that the attached financial statements (which shall not be attached if such financial statements are deemed delivered by filing with the SEC on Form 10-Q or 10-K as applicable) fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Borrower and its Subsidiaries as of applicable the dates and for the applicable periods in accordance with GAAP consistently applied.

Date: _____

[signature page follows]

INSMED INCORPORATED,
as Borrower

By_____

Name: _____

Title: _____

[Signature Page to Compliance Certificate]

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

89

	Reporting Covenant	Requirement	Complies		
1)	Annual Financial Statements	90 days after year end	Yes	No	N/A
2)	Quarterly Financial Statements	45 days after quarter end	Yes	No	N/A
3)	Other Information after an Event of Default	5 Business Days after request	Yes	No	N/A
4)	Legal Action Notice	Promptly	Yes	No	N/A
5)	Notice of Default, etc.	Promptly (within 5 Business Days) after knowledge	Yes	No	N/A

90

Deposit and Securities Accounts ***(Please list all accounts and indicate each Excluded Account with an asterisk (*); attach separate sheet if additional space needed)***

	Bank	Account Number	New Account?		Acct Control Agmt in place?	
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No
5)			Yes	No	Yes	No
6)			Yes	No	Yes	No

Other Matters

Have there been any changes in management since the last Compliance Certificate?	Yes	No
Have there been any prohibited Transfers?	Yes	No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state “No exceptions.” Attach separate sheet if additional space needed.)

LENDER USE ONLY	
Compliance Status	Yes

EXHIBIT F

INTERCOMPANY REORGANIZATION

[***]

Exhibit 10.27

Pursuant to Item 601(b)(10)(iv) of Regulation S-K, confidential information (indicated by [***]) has been omitted from Exhibit 10.27 because it (i) is not material and (ii) is the type of information the Company both customarily and actually treats as private or confidential.

COMMERCIAL MANUFACTURING AND SUPPLY AGREEMENT

THIS COMMERCIAL MANUFACTURING AND SUPPLY AGREEMENT (the " Agreement") is entered into as of the last date of signature below (the "Effective Date") by and between Insmed Incorporated, a corporation organized under the laws of Virginia, with registered office in 700 US Highway 202/206, Bridgewater, NJ 08807-1704 ("CUSTOMER") and **ESTEVE QUÍMICA, S.A.**, a corporation organized under the laws of Spain, with registered office in Torre ESTEVE, Passeig de la Zona Franca, 109, Planta 4ª, 08038 Barcelona, Spain ("EQ").

CUSTOMER and EQ may be referred to individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, EQ is a commercial manufacturer of active pharmaceutical ingredients, intermediates and materials for use by third parties in finished pharmaceutical products;

WHEREAS, EQ and CUSTOMER executed a Master Services Agreement effective January 23, 2018 ("Master Services Agreement"). This Agreement shall be separate and distinct from and shall not interfere with the Master Services Agreement, which shall continue apply to the provision of development product and this Agreement shall apply to the provision of commercial manufacturing and supply;

WHEREAS, CUSTOMER is in the business of development and research of certain pharmaceutical products and desires to purchase API INS1007 for commercial use from EQ and EQ desires to provide such products to CUSTOMER, according to the terms and conditions contained herein;

NOW THEREFORE, in consideration of the promises and mutual covenants set forth herein, the Parties hereby agree as follows:

1. Definitions. In addition to various terms defined throughout the Agreement, the following capitalized terms shall have the meanings set forth below:

Affiliate means with respect to either CUSTOMER or EQ, any corporation, company, partnership, joint venture and/or firm which controls, is controlled by or is under common control with CUSTOMER or EQ, as applicable. As used in this definition, "control" means (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction); and (ii) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect more than fifty percent (50%) of the members of the governing body of such non-corporate entity.

Agreement means this Commercial Manufacturing and Supply Agreement, together with all Appendixes, Quality Agreements, and Schedules attached hereto, as amended from time to time by the Parties, and all related Purchase Orders entered into by the Parties.

Applicable Law means any laws, rules, regulations, guidelines, or other requirements of any Authorities that may be in effect from time to time and that may be applicable to any of the activities performed by any of the Parties pursuant to this Agreement in the country where any such activity is performed, such activity shall include but not be limited to manufacturing, distribution, and marketing activity; including but not limited to, those relating to anti-bribery or anticorruption, as well as Good Manufacturing Practices**,** environmental laws and all others now known or that become effective in the future.

Authority means any supra-national, federal, national, regional, state, provincial, or local authority responsible for granting approvals for the Manufacturing of the Product under this Agreement or for issuing any Applicable Law or for exercising authority with respect to the Manufacture of any Product or Facility including without limitation the FDA and EMEA.

Batch means a specific quantity of Product that is intended to be of uniform character and quality, within specified limits, and is produced during the same cycle of Manufacture as defined by the applicable Batch Record.

Batch Documentation means, for each Batch, the Certificate of Compliance, the Certificate of Analysis, and the Batch Records (including analytical testing data, if any).

Batch Record means the set of detailed processing instructions which EQ follows or has followed to Manufacture each Batch of Product.

Certificate of Analysis means a document signed by an authorized representative of EQ, describing testing methods applied to Product, and the results of testing.

Certificate of Compliance means a document signed by an authorized representative of EQ, certifying that a particular Batch was Manufactured in accordance with cGMP, the Applicable Law to such Manufacturing, and the Specifications.

cGMP means current Good Manufacturing Practices and regulations applicable to the Manufacture of the Product that are promulgated by any Authority and which may be in effect from time to time in the territory where such Manufacture is performed.

CUSTOMER Equipment means any Equipment that, to the extent agreed by the Parties, is provided by CUSTOMER to EQ for the purposes of Manufacturing the Product.

CUSTOMER Materials means all documentation, information, and biological, chemical or other materials controlled by CUSTOMER and provided to EQ by or on behalf of CUSTOMER, or acquired by EQ on behalf of CUSTOMER, for the purposes of Manufacturing the Product.

CUSTOMER Technology means any Technology of CUSTOMER (i) existing prior to the Effective Date or (ii) developed or obtained by or on behalf of CUSTOMER independent of this Agreement and without reliance upon EQ Technology or the Confidential Information of EQ.

EQ Improvements means any discoveries, inventions, developments, modifications, innovations, updates, enhancements, improvements or rights (whether or not protectable under patent, trademark, copyright or similar laws) to EQ Technology that are conceived, discovered, invented, developed, created or made by or on behalf of EQ, in connection with the Manufacturing of the Product under this Agreement excluding any CUSTOMER Materials and CUSTOMER Technology.

EQ Technology means any Technology of EQ (a) existing prior to the Effective Date or (b) developed or obtained by or on behalf of EQ independent of this Agreement and without reliance upon CUSTOMER Technology or the Confidential Information of CUSTOMER.

Equipment means any equipment or machinery, including CUSTOMER Equipment, used by EQ in the Manufacturing of Product for CUSTOMER.

Facility means any of the premise or premises owned by EQ or its Affiliates.

Force Majeure means any event or circumstance outside a Party's reasonable control which has not been caused or materially contributed to by that Party, and which results in either Party's delay or failure to observe or perform on time an obligation under this Agreement.

Manufacture and **Manufacturing** means any steps, processes and activities necessary to produce Product including the manufacturing, processing, packaging, labeling, quality control testing, storage, supply and release by EQ of the Product for CUSTOMER and any related control up until the time that a Certificate of Compliance is signed.

Product means the active pharmaceutical ingredient, intermediate or material described in Schedule 1.

Purchase Order means a written purchase order referencing this Agreement issued by CUSTOMER for the Manufacturing of the Product by EQ under this Agreement.

Records means all records, including Batch Documentation, transactional financial records, reports, accounts, notes and data of all information and results obtained from the Manufacturing of the Product.

Specifications means the technical and quality assurance stipulations for the Manufacture of the Product to which the Product shall conform and which serve as a basis for the quality evaluation to approve and release the Product.

Technology means any methods, techniques, trade secrets, copyrights, know-how, data, documentation, regulatory submissions, specifications and other intellectual property of any kind (whether or not protectable under patent, trademark, copyright or similar laws).

Term means the period of time during which this Agreement is in force.

Territory means worldwide.

Third Party means any person or entity other than EQ, CUSTOMER and their respective Affiliates.

2. Manufacturing of Product.

2.1. General. CUSTOMER hereby appoints EQ to Manufacture the Product according to the terms and conditions set forth in this Agreement. EQ will Manufacture the Product described in each Purchase Order issued by CUSTOMER, and shall exercise commercially reasonable skill, care and diligence. The Purchase Order will be governed by this Agreement, which shall be deemed to be incorporated to the Purchase Order.

2.2. Minimum Manufacturing Obligation. CUSTOMER shall purchase from EQ in a calendar year [***]% of CUSTOMER's Global Demand.

Notwithstanding the above, CUSTOMER is not required to submit Purchase Orders every year in the event that the [***]% of CUSTOMER Global Demand is below [***] in a calendar year.

In the event that CUSTOMER's Global Demand is lower than [***] in a calendar year, EQ shall not be required to Manufacture. Notwithstanding, CUSTOMER agrees to request EQ as the principal source option for the Manufacture of the less than [***] demand and the decision to proceed with such Manufacture shall be mutually agreed with CUSTOMER.

2.3. Applicable Law. EQ will perform the Manufacturing of the Product in compliance with any Applicable Laws. In case that CUSTOMER requires EQ to comply with any requirements beyond what is set forth in such Applicable Law, EQ shall review such request; and the Parties shall discuss in good faith how to proceed. As a general rule, CUSTOMER shall bear any costs in relation to implementing or complying with such additional requirements outside the scope of Applicable Law.

2.4. Validation and approvals. EQ will be responsible for performing and documenting all validation of the Facility, Equipment, the Manufacturing process and any cleaning and maintenance processes employed in the Manufacturing Process in accordance with cGMP, EQ's Standard Operating Procedures, the applicable Quality Agreement and Applicable Law. EQ will be responsible for obtaining from any Authority, at its expense, the approvals related to the Facility as may be necessary for the Manufacturing of the Product by EQ.

2.5. Audits and visits. With a minimum of [***] prior written notice by CUSTOMER to EQ, EQ will allow CUSTOMER or its representatives (CUSTOMER representatives mean any Third Party appointed by CUSTOMER, who is reasonably acceptable to EQ), during normal business hours and, at CUSTOMER's sole cost and expense, to observe the Manufacturing of the Product by EQ at the Facility, review the Records pertaining to the Manufacturing of the Product and inspect that part of the Facilities used by EQ for the Manufacturing of the Product. Except for cause or with the prior consent of EQ, such audits shall not take place more than [***] per calendar year. If additional inspections or audits are requested by CUSTOMER, a cost proposal for such audit will be submitted to CUSTOMER. Further details regarding audits and auditing procedure shall be included in the Quality Agreement. Technical visits to observe the Manufacturing process at the Facility, requested by CUSTOMER and agreed with EQ, will not be considered an "audit" for the purposes of this provision and will not be limited to one visit per calendar year.

2.6. Inspections. Unless prohibited by Applicable Law, EQ will permit CUSTOMER to be present and participate in any inspection by any Authority to the extent such inspection relates to the Product or the Manufacturing process. EQ will give as much advance written notice as possible to CUSTOMER of any such inspection. Unless expressly prohibited by Applicable Law, EQ will provide CUSTOMER with a copy of any report or other written communication received from such Authority in connection with such inspection, and will consult CUSTOMER for CUSTOMER's review and comment on any draft responses and incorporate comments from CUSTOMER into the responses or documents to be provided to the Authority before responding to each such communication. Further details regarding inspections and expectations shall be included in the Quality Agreement.

2.7. Records Retention. EQ will maintain all materials Records, in a secure area. All Records will be retained by EQ for the longer of [***] following completion of the applicable Purchase Order, or the period required by Applicable Law. All Records will be the property and Confidential Information of CUSTOMER. EQ will not transfer, deliver or otherwise provide any Records to any party other than EQ Affiliates, CUSTOMER or its Affiliates, without the prior written approval of CUSTOMER. EQ will, at the direction and written request of CUSTOMER, and at CUSTOMER's cost and expense, promptly deliver Records to CUSTOMER or its designee, or dispose of the Records, unless the Records are required to be retained by EQ by Applicable Law or for insurance purposes. Once the retention period of the Records has expired, EQ shall provide CUSTOMER with written notification and request for confirmation whether CUSTOMER requires the return or destruction of the Records. Upon receipt of return address information from CUSTOMER, EQ shall timely return the Records to CUSTOMER, at CUSTOMER's cost and expense. If EQ does not receive a request from CUSTOMER for to return the Records with the return address information within [***] of written notification, EQ shall be entitled to destroy the Records, at CUSTOMER'S cost and expense. In case of any conflict or discrepancy between the retention period indicated in this provision and the relevant period defined in the Quality Agreement, the retention period set forth in the Quality Agreement shall prevail.

2.8. Sample Retention. EQ will take samples of Product Manufactured under this Agreement and shall retain them for such period and in such quantities as may be required by cGMP or any Applicable Law. Upon CUSTOMER's request and at CUSTOMER's cost and expense, EQ will promptly provide CUSTOMER with samples if EQ has them in excess of those that EQ is required to retain according to Applicable Law. Further details regarding sampling and sample retention shall be included in the Quality Agreement.

2.9. Testing. The Product Manufactured under this Agreement will be Manufactured in accordance with the Manufacturing Process approved by CUSTOMER, the terms of this Agreement and the Quality Agreement, and under cGMP (unless otherwise expressly stated in the applicable Purchase Order) and Applicable Law. Each Batch of Product will be sampled and tested by EQ against the Specifications in accordance with the Quality Agreement, and the quality assurance department of EQ will review the documentation relating to the Manufacture and testing of the Batch and will assess if the Manufacture and testing has taken place in compliance with cGMP and the Manufacturing Process.

2.10. Safety procedures. EQ shall be responsible for implementing and maintaining health and safety procedures for the Manufacturing and for the handling of any Materials or hazardous waste used in or generated by the Manufacturing in compliance with Applicable Laws.

3. Technology transfer and Changes to the Manufacturing Process or Specifications.

3.1. Technology Transfer. The Parties acknowledge that the CUSTOMER Technology required for the Manufacturing of the Product was transferred by CUSTOMER to EQ under the applicable process validation pursuant to the Master Services Agreement. During the Term of this Agreement, CUSTOMER shall transfer to EQ all CUSTOMER Technology newly developed or obtained by or on behalf of CUSTOMER and which may be required for the Manufacturing of the Product. Any CUSTOMER Technology transferred to EQ for the Manufacturing of the Product has been and shall be generated in compliance with any Applicable Law, and shall be true, complete and correct in all material respects.

3.2. Changes to the Manufacturing Process or Specifications. Any change to the Manufacturing Process or Specifications must be approved in accordance to the Quality Agreement, irrespective of whether the change is proposed by either Party or becomes mandatory under any Applicable Law.

Before approving and implementing any such change, the Parties will negotiate in good faith and agree on the allocation of any resulting cost savings or incremental additional costs to be incurred. As a general rule, the Party proposing such change shall bear any resulting incremental additional costs but account shall also be taken of the benefits or advantages that any such change may report to the other Party. However, in case of changes that become mandatory under any Applicable Law and applicable solely to CUSTOMER Product or Specifications, CUSTOMER shall bear all resulting additional costs. In the circumstance that such changes apply to all process and customers at the facility, CUSTOMER shall bear the resulting additional costs proportionally.

4. Forecast. Delays and Cancellation fees.

4.1. Forecasts. During the Term, on the [***] of each quarter of calendar year, CUSTOMER shall provide EQ with a rolling [***]forecast ("Rolling Forecast") for API INS1007 indicating its expected needs of Product for each quarter going forward. The [***] period nearest the date of the Rolling Forecast shall be binding on CUSTOMER ("Binding Forecast"). The remaining [***] will be projected in good faith but will remain non-binding for each Party ("Non-binding Forecast"). The first initial Rolling Forecast is attached hereto as Schedule 2, and the first update will be due on the [***] of the first calendar quarter following Effective Date of this Agreemen.

EQ shall respond to each Rolling Forecast in writing or electronically with [***] of receipt (a business day for such purpose being a day in which banks are generally open to the public in the city of Barcelona, Spain). Its response shall either confirm the quantity of Product and the date for delivery, or suggest amendments in the volume of Product to be supplied and/or the timing of delivery, in which case the relevant planning personnel from each Party will use reasonable efforts to agree and confirm any necessary changes, and following which CUSTOMER shall issue a revised Rolling Forecast reflecting the agreed changes to which EQ shall confirm within [***] (as such term is defined above in this paragraph).

4.2. Binding Forecast. EQ shall review the Rolling Forecast and assess if it is able to Manufacture or otherwise supply all CUSTOMER needs for Product in accordance with the Non-Binding and Binding Forecast periods. For the avoidance of doubt, the Binding Forecast is only binding on the CUSTOMER and it is not binding on EQ. CUSTOMER will issue a Purchase Order according to the Binding Forecast within [***] of EQ's written confirmation of the Binding Forecast to CUSTOMER. Upon receipt of such Purchase Order, the Binding Forecast and Purchase Order become binding on EQ. EQ shall use commercially reasonable efforts to satisfy any changes in quantity, delivery phasing or dates requested by CUSTOMER in respect of any Binding Forecast or any order for additional Product at no additional cost to CUSTOMER (save the cost of the additional Product and any reasonable costs incurred by EQ, reasonably evidenced to the CUSTOMER, directly related with the change requested by CUSTOMER). Any Purchase Order for additional Product confirmed by EQ pursuant to this Section 4.2 shall be deemed to be a Binding Forecast.

In the event that, upon receipt of a Rolling Forecast, EQ anticipates that it shall not be able to Manufacture all needs for Product if Customer were to place Purchase Orders for all of the Rolling Forecast amounts, EQ shall inform Customer in writing. Customer shall then be entitled to obtain from alternative suppliers the amount of Product which EQ has indicated that it would not be able to supply, and EQ shall provide reasonable technology transfer and other assistance to enable such alternative suppliers to Manufacture such Product (provided, however, that EQ shall not transfer any patented or otherwise registered technology licensed by Third Parties or belonging to EQ, nor any confidential know-how or information of EQ or of Third Parties, except for its use only to the extent necessary for the Manufacture of Product for CUSTOMER and in the amounts of Product that EQ is not able to Manufacture as indicted in this paragraph). In such case, following CUSTOMER written request, EQ will commence and use commercially reasonable efforts to timely (i) provide to a Third Party designated by CUSTOMER ("Third Party Manufacturer"), a copy of documentation, data, know-how and information used by EQ to Manufacture Product in accordance with the Specifications and Applicable Law, including Product IP, EQ Project IP, and Joint Project IP to the extent included in the Manufacturing process, and (ii) provide such Third Party Manufacturer reasonable technical assistance, test methods and cooperation by appropriate employees of EQ to assist such Third Party Manufacturer in Manufacturing a first batch of Product in accordance with the Specifications (collectively, the "Technology Transfer"). The process for such Technology Transfer will be set forth in a written plan mutually agreed to by the Parties.

4.3. Non-Binding Forecasts. Non-Binding Forecasts given by CUSTOMER shall be made in good faith, using the degree of diligence that CUSTOMER would apply in the event that CUSTOMER would Manufacture or otherwise supply the Product itself. In the event that CUSTOMER requires additional Product during the period covered the Binding Forecast but that was not included in the applicable Binding Forecast, EQ will use commercial reasonable efforts to fulfill the additional Product requirement of CUSTOMER, without having an obligation.

4.4. Delays. The Parties are responsible for fully meeting all obligations set forth in this Agreement and each particular Purchase Order, and for providing their activities in accordance with the timeline agreed in each Purchase Order.

The Parties shall closely monitor progress of each deliverable per each particular Purchase Order and shall notify the other Party in writing whenever there are possible delays and likely effect on the overall period of the Manufacturing of the Product.

4.4.1. Delays of EQ: If EQ is delayed in the performance of its activities, and such delay is caused by EQ, its Affiliates or subcontractors, EQ shall be entitled to a reasonable extension of time agreed between the Parties in writing. EQ shall also propose to CUSTOMER recovery actions to be taken by EQ to regain the original schedule. If the Manufacturing of the Product or the recovery actions are still not performed by EQ after the extension period, CUSTOMER shall be entitled to cancel the Purchase Order. In case of cancellation of the Purchase Order, the price for any raw materials purchased by EQ or committed, where such raw materials cannot be reused for future deliveries and other non-cancellable expenses incurred by EQ for the Manufacturing of the Product shall be paid by CUSTOMER.

Notwithstanding, EQ shall make commercially reasonable efforts to alleviate such a delay or failure to meet delivery timeline, including but not limited to priority placement of CUSTOMER's Manufacturing to regain original delivery timeline. Notwithstanding such efforts, CUSTOMER does not waive its available rights to recover direct damages in accordance with Section 14.

4.4.2. Delays or Cancellation by Customer: If the Manufacturing of the Product is delayed or cancelled due to Customer's decision or primarily attributable to Customer's fault or for a reason attributable to Customer, the following penalties shall apply to Customer.

Without prejudice to the conditions set forth below, in case of delays attributable to CUSTOMER, EQ shall be entitled to plan a new schedule for the Manufacturing of the Product based on its internal possibilities, capacities and plans, as EQ deems appropriate and as commercially reasonable.

(i) Penalties in case of delays attributable to CUSTOMER: In case of delays communicated by the CUSTOMER or occurring as a consequence of a reason attributable to CUSTOMER a delay fee will be charged to CUSTOMER at the time the initial delivery was scheduled as follows:

If communication from CUSTOMER to EQ occurs within a period of between [***] and [***]prior to the initially agreed start date, the delay fee shall be [***]% of the total value of the Conversion Costs corresponding to the relevant Purchase Order.

If communication from CUSTOMER to EQ occurs within [***] or less prior to the initially agreed start date, the delay fee shall be [***]% of the total value of the Conversion Costs corresponding to the relevant Purchase Order.

(ii) Cancellation fees: In case a cancellation of a Purchase Order is communicated by the CUSTOMER to EQ or occurs as a consequence of a reason attributable to CUSTOMER, a cancellation fee will be charged to CUSTOMER at the time the initial delivery was scheduled as follows:

a. If the cancellation is communicated by CUSTOMER between [***] and [***] prior to the initially scheduled start date, the cancellation fee shall be [***]% of the total value of the Conversion Costs corresponding to the relevant Purchase Order for the cancelled activities;

b. If the cancellation is communicated by CUSTOMER less than [***]prior to the initially scheduled start date, the cancellation fee shall be the total value of the Conversion Costs corresponding to the relevant Purchase Order for the cancelled activities.

In all cancellation cases, in addition to the applicable cancellation fee, the price for any raw materials purchased or committed, where raw material cannot be reused for current Purchase Order for future deliveries or anticipated Rolling Forecast, and other non-cancellable expenses incurred by EQ for the Manufacturing of the Product shall be paid by CUSTOMER.

5. Purchase Orders.

5.1. Throughout the Term, CUSTOMER shall place Purchase Orders covering all the quantities of Product contained in the Binding Forecast. CUSTOMER or its Affiliate shall issue Purchase Orders that include timelines for delivery and quantity of Product to be supplied by EQ, the destination and such other details as may be agreed to by the Parties in writing. In the event that the Purchase Order includes CUSTOMER's terms and conditions, the same shall not apply to the contractual relationship between EQ and CUSTOMER, which is governed exclusively by the conditions of this Agreement and its Schedules. In case of any conflict between the conditions of the Purchase Order and this Agreement, the conditions of this Agreement will prevail, unless otherwise expressly agreed in writing by the Parties.

5.2. Thereafter, CUSTOMER will issue a Purchase Order with each Rolling Forecast that covers the new calendar quarter added to the Binding Forecast. Each Purchase Order will be confirmatory of, and supplemental to, the Binding Forecast rather than creating a new legal obligation.

5.3. No Purchase Order placed by CUSTOMER shall be deemed accepted and binding on EQ until EQ's express acceptance of the Binding Forecast in accordance with Clause 4.2.

5.4. EQ shall deliver the Product within the term agreed by the Parties in the corresponding Purchase Order.

5.5. Purchase Orders that have been accepted by both Parties shall be firm and binding and may not be cancelled, neither totally nor partially, unless both Parties agree to such cancellation in writing. Any change on any Purchase Order shall require the prior written agreement of EQ and CUSTOMER and a Change Order. For the avoidance of doubt, even if CUSTOMER fails to deliver the Purchase Order as set out in this Agreement, the CUSTOMER is still obliged to comply with the Binding Forecast.

5.6. EQ shall not be liable for any delay in the Manufacturing the Product when such delay is due to circumstances controlled by CUSTOMER (e.g. not being provided with CUSTOMER Materials, CUSTOMER Equipment or CUSTOMER Technology, as required to Manufacture the Product) or due to circumstances not controlled by EQ (e.g. the fact that EQ may have rejected any other materials required for the Manufacturing of the Products from any of its suppliers due to quality defects; or that any Third Party taking any action against EQ which may impede EQ to Manufacture the Product). EQ shall promptly inform CUSTOMER in writing of any circumstance which may cause delays in the Manufacturing the Product and both Parties will make commercially reasonable efforts to mitigate the effects of any delay. Notwithstanding the foregoing, CUSTOMER shall be entitled to take actions set forth in Section 4.4.1 in the event of EQ delay in the Manufacturing the Product.

6. Supply of Materials.

6.1. EQ will supply all materials to be used by EQ under a Purchase Order except for CUSTOMER Materials, which shall be delivered by CUSTOMER at EQ Facility at no cost for EQ. Any and all costs assumed by EQ due to the import, transport or delivery for CUSTOMER Materials shall be invoiced to CUSTOMER with an estimate of such costs being provided to CUSTOMER in advance of CUSTOMER's issuance of Purchase Order followed by EQ delivery of the corresponding invoice with final costs included.

EQ will maintain at all times at least enough inventory of key raw materials to meet [***]% of the CUSTOMER requirements for the Binding Forecast, rounded up to the next full batch size of PRODUCT, provided that CUSTOMER will provide the corresponding Purchase Order for this additional quantity of inventory of key raw materials, not covered by Binding Forecast period requirements, prior to its purchase. EQ will invoice this to CUSTOMER, at least, once per year, in case the materials are not intended to be used in the following production as per Binding Forecast. This additional inventory will be purchased based on EQ internal purchase planning calendar illustrated in Schedule 3, where end to end activities to produce the Product are written.

For the avoidance of doubt, although EQ will store enough inventories of key raw materials to meet [***]% of the CUSTOMER requirements, manufacturing of additional quantities of Product will be governed by Clause 4.2. of this Agreement.

6.2. If agreed by the Parties, CUSTOMER or its designees will provide EQ with the CUSTOMER Materials. EQ agrees (a) not to provide CUSTOMER Materials to any Third Party without the express prior written consent of CUSTOMER; (b) not to use CUSTOMER Materials for any purpose other than the Manufacturing of the Product. EQ shall destroy or return to CUSTOMER at CUSTOMER's cost and expense, all unused quantities of CUSTOMER Materials according to CUSTOMER's indications which shall not be unreasonably rejected by EQ.

6.3. CUSTOMER will at all times retain title to and ownership of the CUSTOMER Materials, but EQ shall accept custody upon receipt of any CUSTOMER Materials and bear responsibility for their care, storage, and use. EQ will provide within the Facility an area where the CUSTOMER Materials and the Product are segregated and stored in accordance with the Specifications and cGMP, and in such a way as to be able to distinguish such CUSTOMER Materials and Product from other products and materials belonging to EQ, or held by it for a Third Party. EQ will immediately notify CUSTOMER if at any time it believes any CUSTOMER Materials, the Product, or any intermediates or components of CUSTOMER Materials or Product, have been damaged, lost or stolen.

6.4. CUSTOMER shall be responsible for delivery of the CUSTOMER Materials DDP (Incoterms 2020) at the Facility. If applicable, EQ shall provide CUSTOMER with reasonable assistance to obtain and maintain any necessary import approvals, licenses and customs clearance applications, forms and other correspondence in connection with the delivery of the CUSTOMER Materials.

6.5. CUSTOMER will ensure that CUSTOMER Materials, if any, are delivered according to the timelines set forth in the Purchase Order and that such CUSTOMER Materials meet with specifications. Prior to using any CUSTOMER Materials, EQ will review and test them against specifications, unless pre-approved or prequalified by CUSTOMER or EQ.

7. Delivery and Acceptance Process.

7.1. Delivery. If, based upon the review performed by EQ, a Batch of Product conforms to the Specifications and was Manufactured according to cGMP and the Manufacturing Process, then a Certificate of Compliance will be completed and EQ shall notify to CUSTOMER that the Product has been cleared for delivery, and EQ shall issue the corresponding invoice. Together with such notice, EQ will deliver the Batch Documentation to CUSTOMER. Upon receipt of Batch Documentation, CUSTOMER will have [***] to review and release the Product. In this respect, EQ will deliver Product to CUSTOMER in the name

and on behalf of the CUSTOMER and at the CUSTOMER's risk and cost, within the term set forth in the applicable Purchase Order, or such other date as that may be agreed to in writing by the Parties from time to time. During this period, CUSTOMER has the right to request reasonable additional clarifying information which EQ shall provide promptly if available to EQ. When clearing any Product for delivery, EQ shall do so in accordance with the instructions for shipping and packaging specified in the applicable Purchase Order accepted by the Parties or as otherwise agreed to by the Parties in the Quality Agreement.

7.2. Delivery terms. Deliveries of Product will be made Free Carrier Facility (FCA) (Incoterms 2020). As soon as reasonably practicable from the date in which EQ has communicated to CUSTOMER that the Product is cleared for delivery, but except as otherwise specifically agreed by the Parties, within [***]from the date of issuance of the corresponding undisputed invoice, EQ will deliver the Product to CUSTOMER by placing them at the disposal of CUSTOMER at the agreed point in the applicable Purchase Order.

7.3. Title. As an exception to articles A3 and B3 of FCA Incoterm 2020, title to Product shall pass to CUSTOMER upon [***]. EQ shall be responsible for risk of loss or damage of Product within [***] from the date of issuance of the corresponding undisputed invoice to CUSTOMER or until pick-up by CUSTOMER, whichever occurs first. If Product is not picked up by CUSTOMER within [***] from issuance of the corresponding undisputed invoice, the Parties will arrange for appropriate storage of Product.

7.4. Review of Product. CUSTOMER will review the Product upon receipt and test it against the Specifications and will notify EQ in writing of its acceptance or rejection of such Batch as promptly as possible after its receipt. If CUSTOMER intends to reject a Batch on the grounds of non-conformity to the Specifications or damaged or incorrect packaging, CUSTOMER shall notify such rejection to EQ in writing within [***] from receipt of the Batch by CUSTOMER (or from discovery in case of latent defects not reasonably discoverable by CUSTOMER when reviewing the Product upon receipt and testing it against the Specifications) and to be accompanied by a sample of the Product analyzed by CUSTOMER and with all relevant documentation regarding such analysis, including but not limited to the certificate of analysis and a report indicating the methods used by CUSTOMER. If CUSTOMER does not report the failure within such period of [***] from receipt of the Batch (or from discovery in case of latent defects not reasonably discoverable by CUSTOMER when reviewing the Product upon receipt and testing it against the Specifications), such Batch shall be deemed to have been accepted by CUSTOMER as conforming to the applicable Specifications and CUSTOMER will not be entitled to exercise the remedies indicated in Clause 7.6. in relation to such delivered Product.

7.5. Disputes. In case of any disagreement between the Parties regarding acceptance of delivery or as to whether any Batch or Product conforms to the Specifications, the quality assurance representatives of the Parties will attempt to resolve any such disagreement in good faith. If the disagreement is not resolved in a reasonable time (which will not exceed [***] from notice), a representative sample of the Product and/or relevant documentation will be submitted for tests and final determination to an independent testing laboratory of recognized standing in the industry and agreed upon by the Parties or, failing such agreement, to the testing laboratory of Instituto Químico de Sarrià (Barcelona, Spain).

Such laboratory will use the test methods contained in the applicable Specifications. The determination of conformance by such laboratory will be final and binding on the Parties with regard to conformation to the Specification. The fees and expenses of the laboratory will be paid by the Party against whom the determination is made.

7.6. Product Non-Compliance and Remedies. If a Batch of Product fails to conform to the Specifications, and provided that such failure is directly attributable to EQ meaning it existed when the Product was delivered by EQ and it was caused by EQ's failure to comply with its responsibilities under this Agreement; then (save in respect of any claims by Third Parties, which shall be subject to the limit set forth below in this Agreement) EQ's liability shall be limited to (i) reworking or reprocessing the Product, at EQ's cost and expense, so that the Batch can conform to Specifications and according to Applicable Law, (ii) refunding in full the price paid by CUSTOMER for such Batch; or (iii) at EQ's cost and expense, Manufacturing and supply to CUSTOMER a new Batch of Product (in the same quantity as the Batch that has been deemed to be non-conforming) as soon as commercially reasonably possible. In the event that the Batch cannot be released, but the failure is not determined attributable to EQ, meaning the failure did not exist when the Product was delivered by EQ and it was not caused by EQ's failure to comply with its responsibilities under this Agreement, CUSTOMER shall pay the price of such Batch. The Parties will negotiate, in good faith, which option is the more reasonable one in each particular case taking into account all relevant circumstances, and when so doing they shall attempt to mitigate the inconveniences resulting from the situation for both of them. The remedies in this Clause are exclusive and CUSTOMER may not seek any other rights or remedy.

7.7. Disposition of Non-Conforming Product. The ultimate disposition of non-conforming Product, which shall be carried out in accordance with Applicable Law, will be the responsibility of CUSTOMER's quality assurance department. The costs associated with the disposal of any non-conforming Product directly attributable to EQ shall be borne by EQ.

8. Subcontracting.

The Parties agree that EQ may subcontract the performance of specific obligations of EQ under a Purchase Order to a qualified Third Party, prior written communication to CUSTOMER and with CUSTOMER's prior consent; provided, that (a) such Third Party performs those activities in a manner consistent with the terms and conditions of this Agreement; and (b) EQ remains liable for the performance of such Third Party. Further details regarding subcontractors and expectations shall be included in the Quality Agreement.

9. Quality Agreement.

The Parties will agree upon a quality agreement as soon as practicable but in no event later than [***] following the Effective Date, describing the quality assurance responsibilities and obligations of the Parties for the Manufacture of Product ("Quality Agreement"). In case of discrepancy between the provisions of this Agreement and the ones contained in the Quality Agreement, this Agreement shall prevail except for what concerns quality and/or technical matters.

10. Price, Invoices and Payments.

10.1. Price and Currency. The price for the Manufacturing of the Product by EQ will be calculated as set forth in Schedule 4. Payments to be made under this Agreement will be made in currency declaration of the Purchase Order; using a currency stipulated in Schedule 4.

10.2. Invoice. EQ will deliver invoice to Customer via e-mail at [***] or as otherwise instructed by Customer from time to time, for the total amount of the price, on the date when EQ notifies that the Product has been released by EQ and available for delivery to CUSTOMER. EQ will invoice CUSTOMER referencing in each such invoice the (i) Purchase Order(s) to which the invoice relates, (ii) the quantity of Product, and (iii) any other amounts reimbursable pursuant to the Agreement. Unless otherwise agreed by both Parties, such invoice will not be provided earlier than date of delivery stated in the PO.

10.3. Payments. Payment on undisputed invoices will be due [***] after the receipt of the invoice and reasonable supporting documentation for such invoice. CUSTOMER will make all payments pursuant to this Agreement by ACH bank transfer to a bank account designated by EQ, without deduction of any transfer charges or banking commissions. Payments must be made in all cases under these conditions even if CUSTOMER does not take delivery of the Products after EQ has communicated that they have been cleared for delivery. For disputed invoices or the disputed portion of an invoice, CUSTOMER shall provide to EQ, in writing, within [***], a description of the disputed amounts. CUSTOMER and EQ shall negotiate in a timely, good faith manner to resolve billing queries.

10.4. Interest on Late Payments. Any undisputed amounts not paid on the date such payments are due under this Agreement shall be subject to interest from the foregoing date through and including the date upon which payment is received. Interest shall accrue on a daily basis and be calculated on the daily rate of [***] percent ([***]%) per annum above the base rate of the Bank of England from time to time until undisputed payment is received in full. Any accrued interest shall be paid together with the overdue amount. In case that, due to exceptional circumstances, CUSTOMER is not able to perform [***] on time, interest for the pending invoice will not apply for the first [***] after due date. Interest shall not apply to invoices that are disputed by CUSTOMER in accordance with Section 10.3.

10.5. Taxes. The prices specified in this Agreement are exclusive of any sales, VAT or similar taxes, and of any export and import duties which may be levied as a result of the shipment of the Product or delivery of CUSTOMER Materials. It shall be EQ's sole obligation to report all compensation received by EQ hereunder for the Manufacturing of the Product as may be required by Applicable Law. CUSTOMER shall pay all applicable sales and use taxes, including all applicable goods and services tax, value added tax, local taxes, applicable duties, electronic delivery taxes, sales, use and excise taxes, levies and import and export fees (collectively, "Taxes") that are required by law in connection with the Manufacturing of the Product and that are not recoverable by EQ. EQ shall reasonably cooperate and assist CUSTOMER in getting back any recoverable taxes that are due by CUSTOMER. Where any Taxes are paid directly to a tax authority or government by CUSTOMER, CUSTOMER shall not deduct this amount from any amount due to EQ.

11. Representations and Warranties.

11.1. EQ represents and warrants as follows:

11.1.1. Organization of EQ. EQ is and will remain a corporation or company duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

11.1.2. Enforceability of this Agreement. The execution and delivery of this Agreement by EQ has been authorized by all requisite corporate or company action. This Agreement is and will remain a valid and binding obligation of EQ, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.

11.1.3. Absence of Other Contractual Restrictions. EQ is under no contractual or other obligation or restriction that is inconsistent with EQ's execution or performance of this Agreement. EQ will not enter into any agreement, either written or oral, that would conflict with EQ's responsibilities under this Agreement.

11.1.4. Qualifications of EQ Personnel. EQ has engaged, will engage and will cause its Affiliates involved in the Manufacturing of the Product to engage, employees and permitted subcontractors including consultants (collectively, "EQ Personnel") with the proper skill, training and experience. Before Manufacturing of the Product, EQ Personnel must be subject to agreements with EQ as customary in the jurisdiction where such EQ Personnel is located under which they (a) have confidentiality obligations with regard to CUSTOMER's Confidential Information (as defined below) that are consistent with the terms of this Agreement; and (b) assign and effectively vest in EQ any and all rights that such personnel might have in the results of their work without any obligation to CUSTOMER to any royalties or other consideration to such EQ Personnel.

11.1.5. Rights of Third Parties. The use of EQ Technology by EQ for the Manufacture of the Products for CUSTOMER as contemplated in this Agreement, will not violate any patent, trade secret or other proprietary or intellectual property rights of any Third Party in the territory where the Products are Manufactured by EQ.

11.1.6. Compliance. EQ will perform the Manufacturing of the Product with requisite care, skill and diligence, in accordance with Applicable Law, cGMPs, the terms of the Quality Agreement and industry standards.

11.1.7. Absence of Debarment. To the best of EQ's knowledge, EQ, its Affiliates, EQ Personnel and each of their respective officers and directors involved in the Manufacture of Product or providing related services pursuant to this Agreement or a Purchase Order, as applicable; (a) are not debarred, as per FDA debarment list published in the Federal Register, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications, pursuant to section 306 of the United Sates Food and Drug Cosmetic Act, 21 U.S.C. §§ 335a and are not subject to a pending debarment, and will EQ will not

knowingly use in any capacity in connection with the Manufacture of Product any person who has been debarred or is subject to a pending debarment; (b) are not disqualified by FDA from performing specific services, and are not subject to pending disqualification proceedings; and (c) have not been convicted of a criminal offense related to the provision of healthcare items or services and are not subject to pending action. EQ will provide CUSTOMER with immediate notice if EQ receives any information demonstrating that the foregoing statement becomes untrue and will promptly remove any implicated entity or personnel from participation in the Manufacture of Product or providing related services. In the event of EQ's failure to satisfy one or more of the requirements set for in this section, CUSTOMER reserves the right to pursue remedy pursuant to Section 15.2.

11.2. CUSTOMER represents and warrants as follows:

11.2.1. Organization of CUSTOMER. CUSTOMER is and will remain a corporation or company duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

11.2.2. Enforceability of this Agreement. The execution and delivery of this Agreement by CUSTOMER has been authorized by all requisite corporate or company action. This Agreement is and will remain a valid and binding obligation of CUSTOMER, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.

11.2.3. Absence of Other Contractual Restrictions. CUSTOMER is under no contractual or other obligation or restriction that is inconsistent with CUSTOMER's execution or performance of this Agreement. CUSTOMER will not enter into any agreement that would conflict with CUSTOMER's responsibilities under this Agreement except for secondary suppliers.

11.2.4. CUSTOMER Technology transfer. Any CUSTOMER Technology transferred to EQ for the Development and/or Manufacturing of the Product has been and shall be generated in compliance with any Applicable Law and shall be true, complete and correct in all material respects.

11.2.5. Rights of Third Parties. CUSTOMER Materials and CUSTOMER Technology provided to EQ for the Manufacturing of the Product shall have been generated in compliance with Applicable Law and regulations and shall be true, complete and correct in all material respects. The use by EQ of CUSTOMER Materials and CUSTOMER Technology as provided to EQ for the Manufacturing of the Product will not violate any patent, trade secret or other proprietary or intellectual property rights of any Third Party.

11.2.6. Review and use of the Product. When reviewing the Product and testing it against the Specifications, CUSTOMER shall comply with any Applicable Law and shall do so with requisite care, skill and diligence. CUSTOMER shall only use the Product for the purposes of developing and commercializing a drug product containing the Product in final dosage form and not for any other purposes.

11.2.7. Compliance. Any activities carried out by CUSTOMER, its Affiliates, officers, directors, employees and agents in connection with the Product shall be compliant with any Applicable Law.

Disclaimer of Other Representations and Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF NONINFRINGEMENT, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE.

12. Proprietary Rights.

12.1. CUSTOMER Technology. All rights to and interests in CUSTOMER Technology will remain solely in CUSTOMER and, other than as set forth herein, no right or interest therein is transferred or granted to EQ under this Agreement. EQ acknowledges and agrees that it does not acquire a license or any other right to CUSTOMER Technology except for the limited purpose of Manufacturing the Product under this Agreement and that such license will expire automatically upon the expiration or termination of this Agreement.

12.2. EQ Technology. All rights to and interests in EQ Technology will remain solely in EQ and, except as otherwise set forth in this Agreement, no right or interest therein is transferred or granted to CUSTOMER under this Agreement. EQ hereby grants to CUSTOMER a worldwide, non-exclusive, perpetual, irrevocable, royalty-free, transferable and sub-licensable license to CUSTOMER solely to use Product supplied by EQ to CUSTOMER under this Agreement for (i) the development, manufacture, sale, offer for sale, importation and/or commercialization of Product or (ii) any other legally permitted use or exploitation of such Product.

12.3. EQ Improvements. EQ agrees to communicate in writing to CUSTOMER any EQ Improvements made by EQ in the Manufacturing of the Product prior to their implementation by EQ. Any and all rights and title to EQ Improvements made by EQ in the Manufacturing (patentable or not) will be the sole and exclusive property of EQ; and that EQ hereby grants to CUSTOMER a perpetual, irrevocable license to use such EQ Improvements included in the Product, but subject to the confidentiality obligations set forth in this Agreement, for the exploitation of such Product delivered by EQ to CUSTOMER as a result of the Manufacturing of the Product, including for the development, manufacture and/or commercialization of such Product.

13. Confidential Information.

13.1. "Confidential Information" means any and all non-public scientific, technical, financial or business information, or data or trade secrets in whatever form (written, oral or visual) that is furnished or otherwise made known directly or indirectly by one Party (the "Discloser") to the other (the "Recipient") pursuant to the terms of this Agreement or otherwise in connection with this Agreement, whether marked confidential or not, and irrespective of whether such information was furnished or otherwise made known prior to or after the Effective Date. Confidential Information of CUSTOMER includes, but is not limited to, (i) Materials and Records; (ii) development and marketing plans, regulatory and business strategies, financial information, and forecasts of CUSTOMER; and (iii) all information of third parties that CUSTOMER has an obligation to keep confidential.

13.2. Obligations. During the Term of this Agreement and for a period of [***] thereafter (and in the case of trade secrets, until such time as Discloser no longer treats such information as a trade secret), Recipient agrees to (a) hold in confidence all Discloser's Confidential Information, and not disclose Discloser's Confidential Information except as expressly provided in this Agreement, without the prior written consent of Discloser; (b) use Discloser's Confidential Information solely to carry out Recipient's rights or obligations under this Agreement; (c) treat Discloser's Confidential Information with the same degree of care Recipient uses to protect Recipient's own confidential information but in no event with less than a reasonable degree of care; and (d) reproduce Discloser's Confidential Information solely to the extent necessary to carry out Recipient's rights or obligations under this Agreement, with all such reproductions being considered Discloser's Confidential Information.

13.3. Permitted Disclosures. Recipient may provide Discloser's Confidential Information solely to its employees or contractors (but if Recipient is EQ, then solely to EQ Personnel who are in compliance with Section 11.1.4) on a need-to-know basis and solely as necessary to carry out Recipient's rights or obligations under this Agreement; provided that Recipient remains liable for the compliance of such employees or contractors (or if EQ is Recipient, the compliance of such EQ Personnel) with the terms of this Agreement. If Recipient is required by a governmental authority or by order of a court of competent jurisdiction to disclose any of Discloser's Confidential Information, when permitted or possible, Recipient will give Discloser prompt written notice of such requirement or order and Recipient will take all reasonable and lawful actions to avoid or minimize the degree of such disclosure. Recipient will cooperate reasonably with Discloser in any efforts to seek a protective order. Notwithstanding any other provision of this Agreement, CUSTOMER may disclose EQ Confidential Information to Third Parties with whom it is developing and commercializing a drug product containing the Product in final dosage form; provided that EQ's prior specific consent is previously obtained (which shall not be unreasonably withheld or denied) and that such Third Party is under confidentiality obligations at least as restrictive as set forth herein. CUSTOMER shall remain liable for the compliance of any such Third Party with its confidentiality obligations.

13.4. Exceptions. Recipient's obligations of non-disclosure and non-use under this Agreement will not apply to any portion of Discloser's Confidential Information that Recipient can demonstrate, by competent proof:

(a) is generally known to the public at the time of disclosure or becomes generally known through no wrongful act on the part of Recipient;

(b) is in Recipient's possession at the time of disclosure other than as a result of Recipient's breach of any legal obligation;

(c) becomes known to Recipient on a non-confidential basis through disclosure by sources other than Discloser having the legal right to disclose such Confidential Information; or

(d) is independently developed by Recipient without reference to or reliance upon Discloser's Confidential Information.

13.5. Public Announcements. Neither Party shall issue any public announcement, press release, or other public disclosure regarding this Agreement without the other Party's prior written consent, except for any such disclosure that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed. Both Parties agree that each of them may disclose that CUSTOMER has appointed EQ as manufacturer for the Product.

14. Indemnification and Insurance.

14.1. Indemnification by EQ. EQ will indemnify, defend and hold harmless CUSTOMER, its Affiliates, and its respective officers, directors, employees and agents (collectively, the "CUSTOMER Indemnitees") against any and all losses, damages, liabilities or expenses (including without limitation reasonable attorneys', accounts', and other expert fees, and other costs of defense) (collectively, "Losses") that any of them may suffer in connection with any and all suits, investigations, claims, or demands of Third Parties (collectively, "Third Party Claims") arising from, relating to or occurring as a result of (a) performance of EQ's obligations under this Agreement; (b) breach of any of the warranties granted by EQ under this Agreement; (c) any EQ Indemnitee's negligence or willful misconduct in performing obligations under this Agreement; or (d) EQ's breach of this Agreement; all of it except and to the extent that such Losses are within the scope of the indemnification obligation of CUSTOMER as set forth in this Agreement. For clarity, as regards product liability claims, EQ shall not be obliged to indemnify CUSTOMER if the relevant Product conformed to the Specifications at the time of delivery and accepted in accordance with Section 7.4 if not determined to be a latent defect in accordance with Section 7.4.

14.2. Indemnification by CUSTOMER. CUSTOMER will indemnify, defend and hold harmless EQ, its Affiliates, and its and their respective officers, directors, employees and agents (collectively, the "EQ Indemnitees") against that any of them may suffer in connection with any Third Party Claims arising from, relating to or occurring as a result of (a) any breach of any of the warranties granted by CUSTOMER under this Agreement; (b) the possession or use of the Product infringes any Third Party intellectual property rights; (c) the development, manufacture, commercialization or use of any product containing the Product in violation of any Third Party rights or (d) the use of the CUSTOMER Materials, CUSTOMER Technology or CUSTOMER Equipment provided to EQ in connection with the Manufacturing of the Product in violation of any patent, trade secret or other proprietary or intellectual property rights of any Third Party; or (e) any CUSTOMER Indemnitee's negligence or willful misconduct in performing obligations under this Agreement; or (f) CUSTOMER's breach of this Agreement; all of it except and to the extent that such Losses are within the scope of the indemnification obligation of EQ as set forth in this Agreement or to the extent such Losses result from EQ's gross negligence or willful misconduct.

14.3. Indemnification Procedures. Each Party must promptly notify the other Party after receipt of any Third Party Claims made for which the other Party might be liable under Clause 14.1 or 14.2, as applicable. The indemnifying party will have the primary right to defend, negotiate, and settle such claims. The

indemnified party will be entitled to participate in the defense of such matter and to employ counsel at its expense to assist in such defense; provided, however, that the indemnifying party will have final decision-making authority regarding all aspects of the defense of the claim. The indemnified party will provide the indemnifying party with such information and assistance as the indemnifying party may reasonably request, at the expense of the indemnifying party. Neither party will be responsible or bound by any settlement of any claim or suit made without its prior written consent; provided, however, that the indemnified party will not unreasonably withhold or delay such consent.

14.4. Exclusion of Indirect and Consequential Damages. NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL (INCLUDING LOST PROFITS, BUSINESS OR GOODWILL), PUNITIVE OR INDIRECT DAMAGES SUFFERED OR INCURRED BY THE OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, WHETHER OR NOT SUCH DAMAGES WERE REASONABLY FORESEEABLE OR THAT PARTY HAD BEEN ADVISED OF THE POSSIBILITY OF ANY SUCH PERSON SUFFERING SUCH DAMAGES.

14.5. Liability limitation. EQ's MAXIMUM AGGREGATE TOTAL LIABILITY UNDER THIS AGREEMENT FOR DIRECT, INDIRECT, SPECIAL, INCIDENTAL AND/OR CONSEQUENTIAL DAMAGES OR ANY KIND INCLUDING WITHOUT LIMITATION ALL COSTS, WILL NOT EXCEED [***]THE TOTAL AMOUNT PAID OR PAYABLE BY CUSTOMER TO EQ HEREUNDER FOR PRODUCT DURING THE [***] PERIOD IMMEDIATELY PRECEDING THE LIABILITY EVENT.

14.6. NOTHING IN THIS AGREEMENT SHALL LIMIT OR EXCLUDE THE LIABILITY OF EITHER PARTY FOR DEATH OR PERSONAL INJURY, GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT, FOR DAMAGES RESULTING FROM BREACHES OF ITS DUTY OF CONFIDENTIALITY OR ANY OTHER LIABILITY WHICH CANNOT BE LIMITED OR EXCLUDED BY LAW.

14.7. Insurance. The Parties will carry, with financially reputable insurers, insurance coverage (including worker's compensation at or above the applicable statutory limits, comprehensive liability coverage with contractual liability, and professional liability/errors and omissions coverage) with respect to the conduct of its business against loss from such risks and in such amounts in the amounts set forth below sufficient to support its obligations under this Agreement.

EQ will procure and maintain during the term of this Agreement and for [***] following the expiration date of the last Product manufactured by EQ pursuant to this Agreement, (i) Product/Completed Operations Liability insurance with limits not less than $[***] per claim and $[***] in the aggregate, (ii) Commercial General Liability insurance amount with limits not less than $[***] per claim and $[***] in the aggregate, which may cover any operation of EQ, (iii) Workers' Compensation insurance (or equivalent in the country) to cover all employees, such insurance shall be maintained with limits not less than $[***] Bodily Injury by disease and $[***] policy limit, and (v) Umbrella or Excess Liability, or regional equivalent, limits not less than $[***], and (vi) Property Insurance coverage for EQ property at the manufacturing facility required for EQ to perform its obligations pursuant to this Agreement. EQ shall ensure contractually that any contractors or other parties involved in the manufacturing of Product hold appropriate Workers Compensation, or equivalent in the country, to cover such contractors and other

parties at a level consistent with the coverage outlined above. If requested by CUSTOMER, EQ will provide CUSTOMER a certificate of insurance evidencing the above.

Waiver of Subrogation shall apply in favor of CUSTOMER.

CUSTOMER shall procure and maintain, during the term of this Agreement and for a period of [***] following the expiration date of the last Product manufactured by EQ pursuant to this Agreement, (i) Product/Completed Operations Liability insurance with limits not less than $[***] per claim and $[***] in the aggregate and (ii) Commercial General Liability insurance amount with limits not less than $[***] per claim and $[***] in the aggregate, which may cover any operation of CUSTOMER. CUSTOMER will provide a certificate of insurance evidencing the above insurance coverage upon written request from EQ.

If a Party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the Party will without delay notify the other Party in writing and the Parties will negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

15. Term and Termination.

15.1. Term. This Agreement enters into force on the Effective Date and will expire on the third anniversary from the Effective Date (the **"Initial Term"**). Thereafter, this Agreement will automatically renew for subsequent twelve-month periods (each twelve-month period, a "**Renewal Term**" and the Initial Term and any Renewal Term, the "**Term**"), unless one of the Parties notifies in writing the other its intention not to renew it at least twelve (12) months prior to the end of the Initial Term or any Renewal Term, or unless earlier terminated according to the following provisions.

15.2. Termination for breach. Either Party may terminate this Agreement or any Purchase Orders if the other Party fails to cure a material breach within [***] after receiving written notice from the non-breaching Party. Such termination shall be with immediate effect, at any time upon written notice to the other Party in the event of a material breach of this Agreement by such other Party which cannot be cured (*e.g.*, breach of confidentiality obligations). EQ may terminate this Agreement or Purchase Order in the event CUSTOMER substantially delays or fails to make payment of [***] ([***]) or more invoices in any given calendar year within [***]of providing CUSTOMER with written notice.

15.3. Termination by EQ. In addition to termination as indicated in Clause 15.2, EQ reserves the right to terminate this Agreement and/or any Purchase Order upon written notice to CUSTOMER as soon as information is available to EQ, but not less than [***]prior written notice to the Customer in the following event:

(a) as a consequence of a regulatory restrictions, provided, however that EQ explains to CUSTOMER the reasons why the Manufacturing of the Product are impacted by relevant regulatory restriction which prevents EQ to Manufacture the Product.

15.4. Termination by CUSTOMER. CUSTOMER may terminate this Agreement or any Purchase Order upon [***]prior written notice to EQ if CUSTOMER decides to discontinue the manufacture of the finished dosage form that contain the Product. CUSTOMER may terminate immediately upon written notice to EQ if the FDA delays or denies approval of CUSTOMER's new drug application for the finished dosage form that contains the PRODUCT.

15.5 Termination by Either Party. Either party may terminate this Agreement or any Purchase Order upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings of the other party, or upon an assignment of a substantial portion of the assets of the other party for the benefit of creditors of the other party, or in the event a receiver or custodian is appointed for such other party's business is subject to attachment or similar process; provided, however, that in the case of any involuntary bankruptcy proceeding such rights to terminate shall only become effective if the proceeding is not dismissed within [***] after the filing thereof.

15.6 Effects of Termination or Expiration. Upon termination or expiration of this Agreement, neither EQ nor CUSTOMER will have any further obligations under this Agreement provided that, such termination or expiration shall be without prejudice to any rights that have accrued to the benefit of a Party prior to such expiration or termination and, further provided, that:

(a) CUSTOMER will immediately pay to EQ: (i) the price of any existing inventories of Product or Product in-process held by EQ that are subject to the Binding Forecast or a Purchase Order in effect at the time of such expiration or termination; (ii) the cost of any unused Materials which EQ purchased or committed to purchase and related to any Purchase Order or the Binding Forecast in effect at the time of such expiration or termination; (iii) the cost of any unused Materials which EQ has purchased for Manufacture of the Product, acting diligently in the ordinary course of business in order to Manufacture the Product in accordance with the Binding Forecast, and have not yet begun such Manufacture at the time of such expiration or termination; (iv) the unamortized cost of any manufacturing equipment purchased by EQ after the Effective Date or of any other special investment made by EQ after the Effective Date, in both cases if these have been made in connection with the Binding Forecast or any Purchase Order and communicated to CUSTOMER prior to EQ accepting such Binding Forecast or Purchase Order; (v) the costs and expenses in relation to the termination of irrevocable commitments specifically made in connection with the Binding Forecast or any pending Purchase Order prior to termination; and (vi) the costs of terminating on-going work under the Binding Forecast or any applicable accepted Purchase Orders. At CUSTOMER's election in writing and at CUSTOMER'S expense, EQ will deliver or destroy such Product and Materials as directed by CUSTOMER. CUSTOMER and EQ will reconcile and offset all pending amounts (including advanced payments) immediately after termination or expiration of this Agreement.

(b) EQ shall return to CUSTOMER or destroy, as elected by CUSTOMER and in both cases at CUSTOMER's cost and expense, any CUSTOMER Materials in the possession of EQ, except to the extent such CUSTOMER Materials are required for EQ to fulfill any surviving obligations of this Agreement.

(c) Each Recipient will promptly return to the Discloser all of Discloser's Confidential Information (including all copies) provided to Recipient under this Agreement or under any Purchase Order which

has been terminated or has expired, except for one (1) copy which Recipient may retain solely to monitor Recipient's surviving obligations of confidentiality and non-use and, in the case of CUSTOMER, to exercise all surviving rights of CUSTOMER under this Agreement; and

(d) The terms and conditions under Articles 11, 12, 13, 14, 16 will survive any such termination or expiration.

16. Miscellaneous.

16.1. Independent Contractor. EQ is an independent contractor and not an agent or employee of CUSTOMER. EQ will not in any way represent itself to be an agent, employee or partner of or with CUSTOMER, and EQ has no authority to obligate or bind CUSTOMER by contract or otherwise for any sum or in any manner whatsoever. For all purposes, the legal relationship of the Parties under this Agreement will be of independent contractors. EQ has full power and authority to determine the means, manner and method of performance for the Manufacturing of the Product. EQ is responsible for, and will withhold and/or pay, any and all applicable federal, state or local taxes, payroll taxes, workers' compensation contributions, unemployment insurance contributions, or other payroll deductions from the compensation of EQ's employees and other EQ Personnel and no such employees or other EQ Personnel will be entitled to any benefits applicable to or available to employees of CUSTOMER.

16.2. Force Majeure.

16.2.1. "Force Majeure" means the occurrence of an event or circumstance that prevents or delays a Party from performing one or more of its contractual obligations under the Agreement, if and to the extent that that Party proves: [a] that such impediment is beyond its reasonable control; and [b] that it could not reasonably have been foreseen at the time of the conclusion of the Agreement; and [c] that the effects of the impediment could not reasonably have been avoided or overcome by the affected Party.

16.2.2. In the absence of proof to the contrary, the following events affecting a Party shall be presumed to fulfil conditions (a) and (b) under paragraph 1 of this Clause: (i) war (whether declared or not), hostilities, invasion, act of foreign enemies, extensive military mobilization; (ii) civil war, riot, rebellion and revolution, military or usurped power, insurrection, act of terrorism, sabotage or piracy; (iii) currency and trade restriction, embargo, sanction; (iv) act of authority whether lawful or unlawful, compliance with any mandatory public health law or governmental order following a pandemic situation, expropriation, seizure of works, requisition, nationalization; (v) epidemic, pandemic, including any enforceable or recommended authority decision intended to prevent the occurrence, spread or consequences of a pandemic or epidemic event; vi) natural disaster or extreme natural event; (vii) explosion, fire, destruction of equipment, prolonged break-down of transport, telecommunication, information system or energy; (viii) general labor disturbance such as boycott, strike and lock-out, go-slow, occupation of factories and premises.

16.2.3. A Party invoking this Clause is relieved from its duty to perform its obligations under this Agreement and from any liability in damages or from any other contractual remedy for breach of

contract, from the time at which the impediment causes inability to perform, provided that the notice thereof is given without delay, no later than [***] after the occurrence of the event.

If notice thereof is not given without delay, the relief is effective from the time at which notice thereof reaches the other Party. Where the effect of the impediment or event invoked is temporary, the above consequences shall apply only as long as the impediment invoked impedes performance by the affected Party. Where the duration of the impediment invoked has the effect of substantially depriving the contracting Parties of what they were reasonably entitled to expect under the contract, either Party has the right to terminate this Agreement by a [***] prior notice.

16.2.4. Unless otherwise agreed, the Parties expressly agree that the Agreement may be terminated by either Party if the duration of the impediment exceeds [***].

16.2.5. Force majeure can never prevent the compliance with a payment obligation.

16.3. Notices. All notices must be in writing and sent to the address for the recipient set forth below or at such other address as the recipient may specify in writing under this procedure. All notices must be given (a) by personal delivery, with receipt acknowledged; or (b) by prepaid certified or registered mail, return receipt requested; (c) by prepaid recognized express delivery service; or (d) machine confirmed email or facsimile transmission. This clause is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement. Notices will be effective upon receipt or at a later date stated in the notice.

To CUSTOMER:
Insmed Incorporated
700 US Highway 202/206
Bridgewater, NJ 08807-1704
Attention: Chief Legal Officer
Email: [***]
Cc:

To EQ:
ESTEVE QUÍMICA, S.A.
Torre ESTEVE – Pg. Zona Franca, 109, Planta 4ª
08038 Barcelona (Spain)
Tel: [***]
Attention: Andrea Oro
Email: [***]
Cc: Daniel Girona – Chief Legal Officer
Email: [***]

16.4. Entire Agreement. This Agreement, together with the attached Appendixes and Schedules and any Binding Forecasts and Purchase Orders accepted by the Parties as set forth in this Agreement, each of which shall be deemed as incorporated into this Agreement, constitute the entire agreement between

the parties with respect to the subject matter of this Agreement and all prior agreements, oral or written, with respect to such subject matter are superseded, excluding the Master Services Agreement which shall continue apply to the provision of development product. If there is any conflict, discrepancy or inconsistency between the terms of this Agreement and any Purchase Order, the terms of this Agreement will prevail.

16.5. No Modification. This Agreement (including Purchase Orders accepted by the Parties as set forth in this Agreement) may be changed only by a writing signed by authorized representatives of each Party.

16.6. Assignment. Neither Party shall have the right to assign any or all of its rights or obligations under this Agreement without the other Party's prior written consent, which consent shall not unreasonably be withheld, delayed or conditioned. Notwithstanding the foregoing, prior written consent shall not be required in connection with a merger, reorganization, consolidation, or a sale of all or substantially all of a Party's assets or relevant business to which this Agreement relates and, if such sale or merger is to a Third Party, then the assigning Party shall cause the Third Party to assume the assigning Party's rights and obligations hereunder, provided that this Section shall not apply to an assignment by CUSTOMER to an Affiliate of CUSTOMER. For clarity, CUSTOMER agrees that it shall not, directly or indirectly, assign or transfer its rights to commercialize Product without also assigning (to the same assignee or transferee for Product) this Agreement with EQ, provided that this Section shall not apply to an assignment by CUSTOMER to an Affiliate of CUSTOMER.

The Parties agree to notify the other as soon as commercially reasonable, should any such assignment to a Third Party occur. This Agreement is binding upon, and will inure to the benefit of, the Parties and their respective successors and permitted assigns.

16.7. No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors, Affiliates, licensees, collaborators, and permitted assigns, and they will not be construed as conferring any rights on any other persons.

16.8. Severability. Each provision in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable because any other provision is found by a proper authority to be invalid or unenforceable in whole or in part. If any provision of this Agreement is found by such an authority to be invalid or unenforceable in whole or in part, such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision and the intent of the Parties, within the limits of applicable law.

16.9. Governing Law. This Agreement and any disputes arising out of or in relation to this Agreement shall be construed, interpreted and governed by the laws of United Kingdom without regard to any choice of law principle that would require the application of the law of another jurisdiction. The Parties expressly reject as well any application of the United Nations Convention on Contracts for the International Sale of Goods to this Agreement.

16.10. Jurisdiction. If any dispute arises between the Parties with respect to the effects, interpretation or the Parties' obligations established in the Agreement, the Parties agree to negotiate in good faith to reach an agreement for a remedy within [***] of the Parties' becoming aware of such dispute. If the Parties are unable to reach an agreement within the aforementioned period, to settle any dispute in connection with the Agreement both Parties agree to submit to the Tribunals and Courts of the city of London, England, expressly waiving their right to any other jurisdiction they might otherwise be entitled. This does not prejudice the right of any of the Parties to submit the dispute to any other competent court or tribunal, in order to apply for the adoption of precautionary measures.

16.11. Waivers. Any delay in enforcing a Party's rights under this Agreement, or any waiver as to a particular default or other matter, will not constitute a waiver of such party's rights to the future enforcement of its rights under this Agreement.

16.12. Protection of Personal Data. Each party will comply with its own duties and obligations regarding data protection concerning the processing of personal data required for the performance and management of this Agreement in accordance with all applicable data protection laws.

EQ is the data controller of the following data: a) those of the legal representatives and and/or proxies of CUSTOMER, whose data are included in this Agreement and related documents; and b) those of the persons who, while providing the services for the CUSTOMER, come into contact with EQ (items (a) and (b) are collectively referred to as "Contact Data") in order to enable the maintenance, development and management of the contractual relationship between EQ and CUSTOMER. CUSTOMER shall convey the full content of this Clause to such persons. CUSTOMER takes note that EQ will process the Contact Data controlled by the EQ as follows:

In compliance with the provisions of the applicable regulations on personal data protection, the personal data indicated above will be processed by EQ for the maintenance, development and management of the contractual relationship. The data processed for this purpose will be stored for the duration of this relationship and, once it has ended, for the storage and liability periods provided for in law. The legal basis for data processing in relation to the contact persons, whether legal representatives and/or proxies or persons providing services for the CUSTOMER, is EQ's legitimate interest in contacting the CUSTOMER through these persons.

Personal data will not be transferred by EQ for use by third parties unless EQ has obtained the consent of the data subject or when legally required. Likewise, during the course of EQ's activities, it may be necessary for EQ to provide access to personal data to other companies in the Esteve group (see the group companies at www.esteve.com/es/aviso-legal), which support EQ in the services EQ offers to CUSTOMER. The data may be disclosed to the following categories of specialized providers that help EQ provide its services and are considered data processors: providers of electronic communications, office automation, hosting, housing, computer maintenance, administrative processing, accounting, auditing, consulting and legal representation, among others.

The data may also be transferred and processed outside the European Economic Area (EEA), to countries whose level of data protection may be lower than that of European countries. In such cases,

EQ will adopt adequate security guarantees for the international transfer of personal data, for example by entering into specific agreements with the importer of such data. Data subjects may exercise their rights to access, rectification, erasure, limitation on data processing, data portability and objection with EQ, under the terms established in the applicable laws and regulations. To exercise these rights, the data subject can send a written request to Esteve Química, S.A., Passeig de la Zona Franca, 109, 4ª Planta, 08038, Barcelona (Att.: Data Protection Officer) or an email to [***].

In any case, the data subject has the right to file a complaint with the Spanish Data Protection Agency, if he or she deems it appropriate.

16.13. Compliance and Anti-Bribery. Both Parties are committed to acting with integrity, responsibility and diligence, adopting behaviours that are aligned with the principles and standards of ethical and responsible behaviour foreseen in EQ's Code of Conduct (available on EQ's corporate website: www.esteve.com), in the version applicable at the Effective Date.

Both Parties agree to comply with all applicable laws, regulations and codes of conduct, including the regulations related to the defence of competition, sustainable development and corporate social responsibility and to conduct this Agreement in compliance with the applicable jurisdiction.

Both Parties agree not to be a participant in any type of corruption, extortion or bribery and to apply internal policies that avoid actions that could be considered acts of bribery and/or corruption. Further, both Parties are aware of, and agrees to abide by, all laws and regulations, including the United States Foreign Corrupt Practices Act and the UK Anti-Bribery Act, with respect to dealing with payments or gifts to governments or related persons for the purpose of obtaining or retaining business for or with, or directing business to, any person.

Both Parties conduct their activity following ethical business practices, with respect for labor rights and protection of human rights, have good health and safety practices throughout their supply chain and comply with applicable environmental regulations in force in the countries in which they operates. Besides, both Parties are committed to ensuring respect for the principles of the United Nations Global Compact and the Universal Declaration of Human Rights in the performance of their activities whether these are carried out by their employees or by their subcontractors or agents.

During the term of the Agreement, both Parties shall comply with all laws regarding economic or trade embargoes and sanctions laws that are applicable to their activity ("Sanctions Regulations").

Both Parties declare that they are not a listed person nor owned or controlled by a listed person under any of the Sanctions Regulations.

In the event of the breach of this Clause, the other party will have the right to temporarily suspend or immediately terminate this Agreement, notwithstanding the provisions stated in the termination clause, and claim compensation for losses and damages arising from the other party's violation of this Clause.

16.14. No Strict Construction; Headings; Interpretation. This Agreement has been prepared jointly and will not be strictly construed against either Party. The section headings are included solely for convenience of reference and will not control or affect the meaning or interpretation of any of the provisions of this Agreement. The words “include,” “includes” and “including” when used in this Agreement are deemed to be followed by the phrase “but not limited to”.

16.15. Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed to be an original and all of which together will constitute one and the same instrument. A facsimile or portable document format (“.pdf”) copy of this Agreement, including the signature pages, will be deemed an original. The Parties recognize the use of simple electronic signatures (through DocuSign or equivalent platforms) as legally valid and binding for entering into this Agreement, unless Applicable Law mandates any other form of execution.

16.16. Government Contracts Requirements. As applicable, the Government Contracts Requirements (as defined below and as set forth in Appendix A) are incorporated in this Agreement in Appendix A and apply to EQ as applicable, considering the commercial products and services provided by EQ and its contractual position under the applicable Purchase Order as a subcontractor to a federal prime contractor, to the extent the Government Contracts Requirements do not conflict with EQ's obligations under local laws and regulations in which the activities are being performed by EQ.

Unless otherwise specifically stated in the Government Contracts Requirements incorporated below and in Appendix A, the terms: (i) “Contractor” shall mean EQ (except in the term “prime contractor,” which shall mean Insmed, (ii) “subcontractor” shall mean EQ’s subcontractor (if any), (iii) “Contract” shall mean this Agreement (except in the term “prime contract,” which shall retain its original meaning), (iv) “Contracting Officer” shall mean Insmed’s authorized contract representative, and (v) “Government” shall mean Insmed or as otherwise indicated.

EQ may rely on compliance with its obligations under local laws and regulations for purposes of compliance with the applicable Government Contracts Requirements. EQ has a Compliance Program that includes a Code of Conduct, a Third Party Code, an antibribery and conflicts of interest policy and a whistleblowing channel aligned with the applicable Government Contracts Requirements.

Nothing in this Agreement shall be construed to prohibit or otherwise restrict either Party from lawfully reporting waste, fraud, or abuse related to the performance of a government contract to a designated investigate or law enforcement representative of a federal department or agency authorized to receive such information.

For purposes of this Agreement, Government Contracts Requirements shall mean:

- 48 C.F.R. 52.203-6, Restrictions on Contractor Sales to the Government
- 48 C.F.R. 52.203-13 Contractor Code of Business Ethics and Conduct
- 48 C.F.R. 52.203-17 Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights
- 48 C.F.R. 52.203-19 Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements

- 48 C.F.R. 52.204-21 Basic Safeguarding of Covered Contractor Information Systems
- 48 C.F.R. 52.222-50 Combating Trafficking in Persons
- 48 C.F.R. 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
- 48 C.F.R. 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

In addition, to the extent Contractor performs obligations under the Agreement outside of the United States by employees who were not recruited in the United States, the Government Contracts Requirements will not include the provisions listed below. To the extent Contractor performs obligations under the Agreement in the United States by employees that were recruited in the United States, the Government Contracts Requirements will include the provisions listed below:

- 48 C.F.R. 52.219-8 Utilization of Small Business Concerns
- 48 C.F.R. 52.222-21 Prohibition of Segregated Facilities
- 48 C.F.R. 52.222-26 Equal Opportunity
- 48 C.F.R. 52.222-35 Equal Opportunity for Veterans
- 48 C.F.R. 52.222-36 Affirmative Action for Workers with Disabilities
- 48 C.F.R. 52.222-37 Employment Reports on Veterans
- 48 C.F.R. 52.222-40 Notification of Employee Rights Under the National Labor Relations Act
- CUSTOMER and EQ shall abide by the requirements of 41 CFR 60-300.5(a), as applicable. This regulation prohibits discrimination against qualified protected veterans and requires affirmative action by covered prime contractors and Contractors to employ and advance in employment qualified protected veterans.

IN WITNESS WHEREOF, each party has caused this Agreement to be executed by its duly authorized representative as of the Effective Date.

Insmed Incorporated

By: /s/ Don Nociolo

Print Name: Don Nociolo

Title: VP Technical Operations
19-Aug-2024

ESTEVE QUÍMICA, S.A

By: /s/ Andrea Oro

Print Name: Andrea Oro

Title: Global Head of Business Development, APIs
04-Sep-2024

ESTEVE QUÍMICA, S.A

By: /s/ Pere Mane

Print Name: Pere Mane

Title: General Manager
05-Sep-2024

SCHEDULE 1
PRODUCT

AP INS1007

SCHEDULE 2

[***]

SCHEDULE 3
CALENDAR OF PURCHASING OF MATERIALS (in months)

[***]

SCHEDULE 4
PRICE PER ANNUM

[***]

Appendix A
Full text of applicable Regulations set forth in Section 16.17

[***]

Exhibit 19.1

Insmed Incorporated
Insider Trading Policy
Effective June 10, 2024

I. Introduction and Purpose

This Insider Trading Policy (this "Policy") prohibits any trading of securities while in possession of material nonpublic information gained in the course of performing services for Insmed Incorporated (the "Company") and any unauthorized disclosure of such information. The Company is subject to various federal and state laws and regulations governing trading in its securities. The Company's Board of Directors has adopted this Policy to promote compliance with securities laws that prohibit persons who are aware of material nonpublic information about a company from: (i) trading that company's securities or (ii) providing material nonpublic information to other persons who may trade on the basis of that information. The procedures set forth in this Policy are designed to help you comply with insider trading laws, handle confidential information properly and avoid potentially embarrassing public disclosures and the appearance of impropriety. If you have questions regarding the Policy or a particular situation, you should contact the Legal Department before engaging in any transaction.

II. Persons Subject to this Policy

This Policy applies to all officers and employees of the Company and its consolidated subsidiaries and to all members of the Company's Board of Directors. The Company also may determine that other persons should be subject to this Policy, including consultants or contractors who have or may have access to material nonpublic information. It is the personal obligation and responsibility of each person subject to this Policy to adhere to this Policy. In addition, it is the Company's policy not to transact in its own securities while in possession of material nonpublic information regarding the Company.

If you are subject to this Policy, this Policy also applies to any family members who live with you, including your spouse or domestic partner, children, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws, as well as anyone else who lives in your household and any family members who do not live in your household but whose securities transactions are directed by you or are subject to your influence and control, such as children away at college or parents or children who consult with you before they trade (collectively, "Family Members"). You are responsible for the transactions of your Family Members and should make them aware of the need to confer with you before they trade any securities of the Company and before they trade the securities of any other entity about which you have communicated nonpublic information that you obtained in the course of your role with the Company. You should treat all such transactions for the purposes of this Policy and applicable securities laws as if the transactions are made by you.

This Policy also applies to all entities that you influence or control, including any corporations, partnerships or trusts. Transactions by these entities will be regarded for the purposes of this Policy and the applicable securities laws as though they are made by you.

Following the termination of service to or employment with the Company, this Policy shall continue to apply until any material nonpublic information possessed by any such person has become public or is no longer material, whichever is earlier.

In addition, this Policy contains additional provisions set forth in Annex A that apply only to Section 16 Reporting Persons and other Designated Insiders (each as defined therein).

III. Transactions Subject to this Policy

This Policy applies to all transactions in Company securities, whether direct or indirect. Examples of indirect transactions include transactions in Company securities held in any Company 401(k) retirement savings plan, pension plan, retirement plan or other similar plan. This Policy also applies to the securities of other companies, including competitors, customers, suppliers or other business partners and companies that operate in similar markets or are involved in potential transactions or relationships with the Company. You may not use any nonpublic information that you learn during the course of your role with the Company to trade in the securities of any other company.

IV. Policy Against Insider Trading

A. Prohibition of Insider Trading and Tipping

Federal and state securities laws prohibit the purchase or sale of a company's securities by any insider who is aware of material information about that company that is not generally known or available to the public. These laws also prohibit any insider who is aware of material nonpublic information from disclosing that information to others who may trade. Companies and their controlling persons are subject to liability if they fail to take reasonable steps to prevent insider trading by company personnel.

Any person subject to this Policy who is aware of any material nonpublic information concerning the Company or another company may not:

- engage in transactions in the Company's securities, directly or indirectly, or in the securities of the other company to which such information relates, except as specifically noted herein;
- engage in any other action to take personal advantage of the material nonpublic information, including disclosing (*i.e.,* "tipping") that information to any other person who may use the information to benefit by trading in the Company's securities or the securities of the other company to which such information relates;
- recommend the purchase or sale of the Company's securities or the securities of the other company to which such information relates;
- disclose material nonpublic information internally within the Company to individuals whose roles do not require them to have that information or to individuals outside of the Company unless the disclosure is made in accordance with the Company's policies regarding the protection of confidential information and authorized external disclosures; or
- assist anyone engaged in any of the above activities.

These restrictions begin as soon as you obtain material nonpublic information and end *after* the second full Trading Day after the information is publicly disseminated or once the information is no longer material (regardless of whether you continue to serve the Company). A "Trading Day" means a day on which the Nasdaq stock exchange is open for trading.

Detection and punishment of insider trading is a top enforcement priority of law enforcement and the consequences of insider trading can be severe. Cases have been successfully prosecuted in connection with trading by family members and friends and for trading involving only a small amount of securities.

Criminal prosecutions for insider trading are commonplace and can result in substantial fines and/or imprisonment.

This Policy is designed to deter improper trading and compliance is mandatory. Violation of this Policy may lead to disciplinary action up to and including termination for cause or removal, whether or not failure to comply results in a violation of law. The Company may need to alert appropriate authorities if required or if it decides, in its sole discretion, that the situation so warrants.

B. Key Questions and Answers Regarding this Policy

The following questions and answers provide additional information regarding this Policy's prohibition of insider trading and tipping.

1. ***What is "insider trading"?*** Insider trading includes: (1) trading while in possession of material nonpublic information; (2) disclosing or "tipping" material nonpublic information to others or recommending the purchase or sale of securities on the basis of such information; or (3) assisting someone who is engaged in any of the foregoing activities.

2. ***Who is an "insider"?*** The term "insider" applies to anyone who, by virtue of their relationship with a company, possesses material nonpublic information about a company. All officers and employees of the Company and its consolidated subsidiaries as well as all members of the Company's Board of Directors and all Family Members and entities they control are "insiders." Persons not associated with the Company who have material nonpublic information disclosed to them privately by an insider ("tippees"), are, in many cases, also treated as insiders. If illegal trading by a tippee occurs, then the insider who provided the information could be found liable and, under certain circumstances, the actions of the insider may be imputed to the Company.

3. ***What is "material information"?*** Information is considered "material" if there is a substantial likelihood that a "reasonable investor" would consider the information important in making a decision to buy, hold or sell securities. Any information that could reasonably be expected to affect the price of the security is material. There are certain categories of information that are particularly sensitive and, are reasonably likely to be considered material, including, but not limited to, the following:

- quarterly or annual earnings information and guidance, including estimates or revisions;
    - earnings that are inconsistent with the consensus expectations of the investment community, reaffirming previously issued earnings guidance or a decision to suspend earnings guidance;
    - events that may result in the creation of a significant reserve or write-off or other significant adjustments to the financial statements;
- a pending or proposed merger, acquisition or tender offer or an acquisition, disposition or license of a significant amount of assets or intellectual property rights or technologies that are important to a company's business;
- establishment of, or developments in, strategic partnerships, joint ventures or similar collaborations or loss thereof;
- a significant company restructuring or bankruptcy or liquidity concerns or developments;
- a change in senior management;

- major events regarding a company's securities, including an offering, redemption or repurchase of securities, the declaration of a stock split or a significant change in dividend policy;
- actual or threatened litigation, investigations or administrative or regulatory actions or other material developments regarding such matters, including their resolution;
- significant product developments or innovations or results from clinical trials or information regarding the review of products or product candidates by regulatory agencies like the U.S. Food and Drug Administration;
- notice of issuance or denial or the loss of patents protecting products or product candidates;
- a disruption in operations or breach or unauthorized access of property or assets, including facilities and information technology infrastructure, that affects a company or third-party providers that support a company's business operations;
- any event or circumstance impacting product manufacturing or product quality, especially one that may impact product supplies; and
- any other facts that might cause a company's financial results to be substantially affected.

This is a non-exclusive list and positive, negative and neutral information can be material depending on the circumstances. The materiality of particular information is subject to reassessment on a regular basis. Because securities trades may receive scrutiny after the fact with the benefit of hindsight, questions concerning the materiality of particular information should be addressed conservatively.

4. ***What is "nonpublic information"?*** Information is "nonpublic" if it is not generally known or available to the public. Information is considered to be available to the public only when it has been released broadly to the marketplace (such as by a press release or in a filing with the Securities and Exchange Commission ("SEC")) and the investing public has had sufficient time to absorb the information fully. For purposes of this Policy, information is considered nonpublic until after the second full Trading Day following the public dissemination of the information.

5. ***What is "tipping"?*** Tipping is when a person subject to this Policy discloses material nonpublic information about the Company or another company to another person or recommends that another person trade in the securities of any company while in possession of material nonpublic information about that company and the other person either: (1) trades that company's securities while in possession of that material nonpublic information; or (2) provides the material nonpublic information to a third party who then trades in such company's securities. Tipping is illegal even if you do not personally make a trade or otherwise benefit from disclosing material nonpublic information.

6. ***What are the potential consequences of insider trading?*** There are no limits on the size of a transaction that will trigger insider trading liability and even relatively small trades can result in an investigation and potential liability. Individuals found liable for insider trading face penalties of up to three times the profit gained or loss avoided, a criminal fine of up to $5 million and up to 20 years in prison. In addition to potential civil and criminal liability, in certain circumstances the Company may be able to recover all profits made by an insider who traded illegally, plus collect other damages. Furthermore, the Company (and its executive officers and directors) could face penalties of the greater of $1 million or three times the profit gained or loss avoided as a result of an insider's violation and a criminal penalty of up to $25 million for failing to take adequate steps to prevent insider trading.

C. Additional Trading Restrictions for Certain Transactions

In addition to the prohibitions on insider trading and tipping described above, this Policy also contains restrictions on the following types of transactions under which an insider could potentially abuse, or be seen to abuse, their access to material nonpublic information.

I. Short Sales. No person subject to this Policy may engage in the short sale of the Company's securities. A short sale is a sale of securities not owned by the seller and may be based on an expectation on the part of the seller that the securities will decline in value. Short sales reduce the seller's incentive to improve the Company's performance and may signal the market that the seller lacks confidence in the Company's prospects. For these reasons, short sales are prohibited. In addition, Section 16(c) of the Securities Exchange Act of 1934 (the "Exchange Act") prohibits officers and directors from engaging in short sales.

II. Public Options and Other Derivative Securities. Persons subject to this Policy are restricted from trading in derivative securities that are tied to the value of Company securities. "Derivative securities" include options, warrants, stock appreciation rights or similar rights whose value is derived from or related to the value of the Company's securities. This prohibition includes, but is not limited to, trading in Company-based put or call option contracts, trading in straddles and similar transactions. These transactions are prohibited because they may cause an insider to focus on short-term performance at the expense of the Company's long-term objectives. Note that this Policy does not restrict holding and exercising stock options, restricted stock units or other derivative securities granted under the Company's equity compensation plans or in connection with a person's service to the Company.

III. Margin Accounts. Securities held in margin accounts as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call, which may occur suddenly and at a time when the account holder is aware of material nonpublic information or is otherwise restricted from trading. Due to these factors, persons subject to this Policy are prohibited from holding the Company's securities in margin accounts. This means such persons are prohibited from borrowing from a brokerage firm, bank or other entity in order to purchase or hold the Company's securities (other than in connection with "cashless" exercises of stock options as further described in Section IV.D.1, "Transactions Under Equity Compensation Plans").

IV. Restrictions on Hedging and Monetization Transactions. Hedging and monetization transactions of Company securities acquired through the Company's equity compensation plans or otherwise may result in a person having ownership of an economic interest in such securities but without the full risks and rewards of ownership, which may differ from the interests of the Company's other stockholders. In addition, hedging and monetization transactions can eliminate or mitigate the intended alignment of incentives under the Company's equity compensation programs. Accordingly, persons subject to this Policy may not purchase financial instruments such as prepaid variable forward contracts, equity swaps, collars, exchange funds, puts, calls, forwards and other derivative instruments, or otherwise engage in transactions that hedge or offset, or that are designed to hedge or offset, any decrease in the market value of Company securities that are (1) issued by the Company as part of such person's compensation package or (2) held, directly or indirectly, by such person.

V. Restrictions on Pledging Company Securities. Securities that are pledged or hypothecated as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan, which could occur at a time when the pledgor is aware of material nonpublic information or is otherwise restricted from trading. Accordingly, persons subject to this Policy may not pledge or hypothecate Company securities as collateral for a loan unless the pledge has been approved in advance by the Chief Legal Officer and Chief Financial Officer. Any request for approval of such a pledge must be submitted in writing at least two weeks prior to the proposed execution of documents evidencing the proposed pledge. Any request for approval of such a pledge by Section 16 Reporting Persons must be submitted to and approved by the Compensation Committee. Any

such pledge request submitted by a Section 16 Reporting Person will be considered by the Compensation Committee on a case-by-case basis.

VI. Standing and Limit Orders. Standing and limit orders are not prohibited under this Policy, but persons subject to this Policy must be aware that these orders create risks for insider trading violations because you have no control over the timing of purchase or sales that result from standing instructions to a broker. As a result, the broker could execute a transaction when you are in possession of material nonpublic information, even though the order may have been placed at a time when you were not aware of material nonpublic information. If you come into possession of material nonpublic information and fail to terminate a standing or limit order in these circumstances, there is a risk that the trade will be executed while you are in possession of inside information. Accordingly, persons subject to this Policy are encouraged to refrain from placing a standing or limit order unless it is limited to a short duration and otherwise complies with applicable restrictions and procedures outlined in Annex A. Any person who is considering a standing or limit order for a longer period should instead consider implementing a Rule 10b5-1 Plan as described in Section V, "Transactions Under Rule 10b5-1 Trading Plans."

D. Certain Permitted Transactions

This Policy does not restrict the transactions set forth in this Section IV.D, except as specifically noted. While these transactions are generally not subject to the restrictions set forth in this Policy, a Section 16 Reporting Person (as defined in Annex A) or their Family Members should still pre-clear the proposed transaction with the Company's Legal Department in accordance with Annex A.

1. **Transactions under Equity Compensation Plans**. This Policy does not apply to the exercise of stock options granted under the Company's equity compensation plans or in connection with a person's service to the Company *if the exercise is not followed by the open market sale of any of the shares at issue*. This means that the Policy does not apply to a cashless exercise where shares are surrendered to the Company (including, for the avoidance of doubt, any "net exercise" under a Company policy or award agreement) *but it does apply to any sale of the underlying shares of common stock by a broker as part of a broker-assisted cashless exercise transaction*.

This Policy also does not apply to the receipt of restricted stock units ("RSUs") or performance stock units ("PSUs") under the Company's equity compensation plans, nor does it apply to the exercise of a tax withholding right pursuant to which a person elects to have the Company withhold (or the Company automatically withholds) shares subject to an RSU or PSU in order to satisfy tax withholding requirements. *This Policy does apply, however, to any open market sale of the Company's common stock for the purpose of generating the cash needed to satisfy tax withholding requirements with respect to the vesting of an RSU or PSU.*

Any subsequent sale of shares acquired under the Company's equity compensation plans is subject to this Policy.

2. **Certain 401(k) Plan Transactions**. This Policy does not apply to purchases of Company securities in the Company's 401(k) plan resulting from periodic contributions pursuant to your payroll deduction election. This Policy does apply, however, to certain elections made under the plan, including: (1) an election to increase or decrease the percentage of periodic contributions that are allocated to the Company stock fund; (2) an election to make an intra-plan transfer of an existing account balance into or out of the Company stock fund; (3) an election to borrow money against your plan account if the loan will result in a liquidation of some or all of your Company stock fund balance; and (4) an

election to prepay a plan loan if the prepayment will result in allocation of loan proceeds to the Company stock fund.

3. **Employee Stock Purchase Plan**. This Policy does not apply to purchases of Company securities in an employee stock purchase plan resulting from the periodic contribution of money to the plan pursuant to an election you made at the time of your enrollment in the plan. This Policy does apply, however, to your election to participate or increase your level of participation in the plan. This Policy also applies to any sale of Company securities acquired through the plan.

4. ***Bona Fide* Gifts**. *Bona fide* gifts of Company securities are generally permitted. However, whether a gift is *bona fide* will depend on the circumstances surrounding a specific gift. For example, gifts where there is an expectation of a sale of the securities in close proximity to the gift may imply some economic benefit to the donor that could result in the gift not being considered *bona fide.* Accordingly, if you expect or intend for the recipient of a gift of Company securities to promptly sell the securities (as is typically the case for charitable gifts to tax-exempt entities) and you are in possession of material nonpublic information you should consult the Legal Department prior to making the gift. Gifts that are part of a plan to circumvent the insider trading rules are not permitted.

V. Transactions Under Rule 10b5-1 Trading Plans

Rule 10b5-1 under the Exchange Act provides an affirmative defense from insider trading liability. In order to be eligible to rely on this affirmative defense, a person subject to this Policy must enter into a Rule 10b5-1 plan for transactions in Company securities that meets the conditions specified in the following paragraph (a "Rule 10b5-1 Plan"). If the plan meets the requirements of Rule 10b5-1, Company securities may be purchased or sold under the Rule 10b5-1 Plan without regard to certain insider trading restrictions.

To comply with the Policy, a Rule 10b5-1 Plan must be approved by the Chief Legal Officer and the Chief Financial Officer, provided that neither shall be involved in the approval of their own Rule 10b5-1 Plan. A person subject to this Policy may only enter into a Rule 10b5-1 Plan when that person is not aware of material nonpublic information. To establish the affirmative defense provided by Rule 10b5-1(c)(1), a person who is not then aware of material nonpublic information must enter into a binding contract, provide an instruction to another person or adopt a written plan for trading securities that:

- specifies the amount of securities to be bought or sold, as well as the price and date for the transaction;
- includes a written formula, algorithm or computer program for determining the amount, price and date of the purchase or sale; or
- does not permit the person to exercise any subsequent influence over how, when or whether to effect purchases or sales, while at the same time ensuring that any person effecting trades under the Rule 10b5-1 Plan is not aware of any material nonpublic information while doing so.

Once a Rule 10b5-1 Plan is adopted, the person must not exercise any influence over the number of securities to be traded, the price at which they are traded or the date of the trade. The Rule 10b5-1 Plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party.

Any Rule 10b5-1 Plan must be submitted to the Chief Legal Officer and Chief Financial Officer for approval at least five days prior to the entry into the Rule 10b5-1 Plan. In order for a Rule 10b5-1 Plan to be approved, the following requirements must be observed:

- the person adopting the Rule 10b5-1 Plan must include a representation certifying that they are adopting the plan in good faith, at a time when they are not in possession of material nonpublic information and not as part of a plan to evade insider trading prohibitions;
- the Rule 10b5-1 Plan must include a cooling-off period between the adoption of the Rule 10b5-1 Plan and the first trade under the Rule 10b5-1 Plan that (i) for Section 16 Reporting Persons (as defined in Annex A) lasts until the later of (A) 90 days after the adoption of the Rule 10b5-1 Plan and (B) two business days following the disclosure of the Company's financial results on a Form 10-Q or Form 10-K for the completed fiscal quarter in which the Rule 10b5-1 Plan is adopted; provided, however, that in no event will the required cooling-off period exceed 120 days following the adoption of the Rule 10b5-1 Plan and (ii) for all other persons subject to this Policy is at least 30 days after the adoption of the Rule 10b5-1 Plan;
- a person subject to this Policy may not have more than one Rule 10b5-1 Plan in effect at the same time other than under the following limited exceptions: (i) a series of separate contracts with different broker-dealers or other agents to execute trades that are treated as part of a single plan, provided each individual contract satisfies Rule 10b5-1; (ii) one later-commencing Rule 10b5-1 Plan for purchases or sales of securities in the open market under which trading is not authorized to begin until after all trades under the earlier-commencing Rule 10b5-1 Plan have been completed or the earlier Rule 10b5-1 Plan has expired without execution; and (iii) a Rule 10b5-1 Plan that authorizes an agent to sell only securities that are necessary to satisfy tax withholding obligations arising exclusively from the vesting of compensatory awards and the person does not exercise control over the timing of sales;
- a person subject to this Policy may not have more than one Rule 10b5-1 Plan that is intended to effect the open-market purchase or sale of a total amount of securities as a single transaction in any 12-month period (other than transactions for tax withholding purposes as described in clause (iii) above); and
- for any Section 16 Reporting Person or Designated Insider, as well as their Family Members and entities any of them control, the Rule 10b5-1 Plan may only be adopted (or amended) during a Trading Window (as each such term is defined in Annex A).

Any modification to the amount, pricing or timing of purchases or sales of securities under a Rule 10b5-1 Plan will constitute the termination of the Rule 10b5-1 plan and the adoption of a new plan, which means that any such modification will trigger the need for the new trading plan to satisfy all of the elements of Rule 10b5-1 and the restrictions set forth above, including a new cooling-off period, before trading can begin under the new plan.

If a Rule 10b5-1 Plan is approved, no further pre-approval of transactions conducted pursuant to the Rule 10b5-1 Plan will be required. Any proposed amendment or cancellation of a Rule 10b5-1 Plan must be submitted to the Chief Legal Officer and Chief Financial Officer for approval at least five days before the proposed effective date of the amendment or cancellation.

VI. Reporting Violations

Any person who suspects or becomes aware of violations of this Policy must report them promptly to the Legal Department or via the Insmed Hotline. No one who in good faith reports any suspected problem or wrongdoing will suffer retaliation or adverse employment consequences for having made such a report. Failing to properly report suspected violations of this Policy is viewed with the utmost seriousness by the Company.

VII. Policy Administration and Questions

This Policy shall be administered by the Company's Legal Department under the authority of the Chief Legal Officer or their designee. Any person who has a question about this Policy or its application to any proposed transaction may obtain additional guidance from the Legal Department.

ANNEX A

Additional Requirements Applicable to Section 16 Reporting Persons and Designated Insiders

The following additional requirements apply to Section 16 Reporting Persons (as defined below) and certain other employees who are designated by the Company from time to time ("Designated Insiders"), as well as Family Members and entities that they control. A "Section 16 Reporting Person" is a member of the Company's Board of Directors or an officer or recently departed director or officer who is subject to the reporting and "short-swing profit" liability provisions of Section 16 of the Exchange Act. A "Designated Insider" includes any employee who, in the ordinary course of their duties to the Company, has regular access to material nonpublic information, as determined by the Chief Legal Officer, the Chief Financial Officer, or their designee. Designated Insiders will be notified by the Chief Legal Officer or their designee that they are subject to additional trading restrictions as set forth in this Annex A.

Under special circumstances, certain employees who are not Section 16 Reporting Persons or Designated Insiders may gain access to material nonpublic information and the Company, in its discretion, may determine that these employees are subject to the additional restrictions and procedures set forth in this Annex A (irrespective of whether such persons become Designated Insiders). These employees will be notified of this status and will be subject to the restrictions set forth herein for a period of time that the Company deems appropriate.

A. Additional Trading Restrictions for Section 16 Reporting Persons and Designated Insiders

The following additional restrictions apply to trading Company securities by Section 16 Reporting Persons and Designated Insiders:

1. No Trading Outside of Open Trading Window. Section 16 Reporting Persons, Designated Insiders, their Family Members and entities any of them control may trade in Company securities only during open trading windows that are announced by the Company (the "Trading Window"). Generally, the four trading windows consist of the periods that begin on two full Trading Days after the Company's issuance of a press release (or other method of broad public dissemination) announcing its quarterly or annual material financial results and end at the close of trading on the 15th day before the end of a fiscal quarter or fiscal year, as applicable. If, however, the trading window closes on a non-Trading Day, the trading window will close on the completion of the previous full Trading Day.

By way of example, if the Company issues its earnings release on August 3rd before the market opened, the trading window would open on August 5th (assuming August 4th is a Trading Day). If, however, the Company released earnings during or after the market close on August 3rd, then the trading window would not open until August 6th (two full Trading Days after the earnings release, assuming August 4th and August 5th are Trading Days). In either case, the window would close at the close of trading on September 15th (unless the 15th fell on a weekend, in which case, the window would close the Friday immediately preceding the 15th).

Despite the general timing of Trading Windows described above, if there is or may be material nonpublic information during an anticipated Trading Window, the Company may not open the Trading Window or may suspend trading during a Trading Window.

2. No Trading During Event-Specific Trading Restriction Periods. From time to time, the Company may determine that specific individuals should be restricted from trading in Company securities because they are aware of a specific event or information regarding a potential transaction that is material to the Company that has not been publicly disclosed. In these instances, the Chief Legal Officer or their designee will notify these individuals that they are prohibited from trading until further notice. In some circumstances, the Company may determine that material nonpublic information requires that certain other employees not be permitted to trade in Company securities and the Company may notify these employees of the trading restriction without disclosing the reason. The existence of an event-specific trading restriction period will not be announced to the Company as a whole and should not be communicated to any other person. Even if you have not been specifically notified not to trade Company securities, you are still prohibited from trading if you are or become aware of any material nonpublic information.

A. Trading by Section 16 Reporting Persons; Pre-Clearance Requirements

If a Section 16 Reporting Person, their Family Member or an entity they control is contemplating a transaction in the Company's securities (including a gift of securities), the proposed transaction must be pre-cleared with the Company's Chief Legal Officer and Chief Financial Officer, even if the proposed transaction is to take place during a Trading Window, and provided that neither shall be involved in the approval of their own transactions.

A request for pre-clearance should be submitted to the Chief Legal Officer at least two days in advance of the proposed transaction. The Chief Legal Officer and the Chief Financial Officer are under no obligation to approve a transaction submitted for pre-clearance and may determine not to permit the transaction. If a person who seeks pre-clearance and permission to engage in the transaction is denied, then they should refrain from initiating any transaction in Company securities and should not inform any other person of the restriction. If pre-clearance is granted for a particular transaction, the transaction should be completed promptly, and in any event within three Trading Days following receipt of pre-clearance unless an exception is granted (provided that if you become aware of material nonpublic information before executing the transaction, you must cancel the transaction). Approved transactions that are not effected within this period will be subject to receiving pre-clearance again.

The Section 16 Reporting Person is responsible for ensuring compliance with Section 16 reporting requirements for all transactions and, where applicable, Rule 144 under the Securities Act of 1933; the Chief Legal Officer will assist a Section 16 Reporting Person in their reporting if requested. All transactions by a Section 16 Reporting Person (including transactions pursuant to a Rule 10b5-1 Plan or Non-Rule 10b5-1 Trading Arrangement) are required to be reported to the Chief Legal Officer or their designee no later than the end of the day in which the transaction occurs.

If you request pre-clearance under this Policy, you should consider carefully whether you are aware of any material nonpublic information about the Company and should describe fully those circumstances to the Chief Legal Officer and Chief Financial Officer when making your request.

EXHIBIT 21.1

List of Subsidiaries January 2025

Name	Jurisdiction of Incorporation
Celtrix Pharmaceuticals, Inc.	Delaware
Insmed Gene Therapy LLC	Delaware
Insmed Limited	England and Wales
Insmed Holdings Limited	Ireland
Insmed Innovation UK Limited	England and Wales
Insmed Ireland Limited	Ireland
Insmed Netherlands Holdings B.V.	The Netherlands
Insmed Netherlands B.V.	The Netherlands
Insmed Germany GmbH	Germany
Insmed France SAS	France
Insmed Godo Kaisha	Japan
Insmed Switzerland GmbH	Switzerland
Insmed Italy S.R.L.	Italy

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement on Form S-3 No. 333-272088 of Insmed Incorporated, and

(2) Registration Statements on Form S-8 Nos. 333-39200, 333-87878, 333-129479, 333-175532, 333-188852, 333-204503, 333-218668, 333-225323, 333-233407, 333-238558, 333-256307, 333-265078, 333-272091 and 333-279400 of Insmed Incorporated;

of our reports dated February 20, 2025, with respect to the consolidated financial statements of Insmed Incorporated and the effectiveness of internal control over financial reporting of Insmed Incorporated included in this Annual Report (Form 10-K) of Insmed Incorporated for the year ended December 31, 2024.

/s/ Ernst & Young LLP

Iselin, New Jersey

February 20, 2025

EXHIBIT 31.1

Section 302 Certification

I, William H. Lewis, Chairman and Chief Executive Officer of Insmed Incorporated, certify that:

(1) I have reviewed this annual report on Form 10-K of Insmed Incorporated;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 20, 2025

/s/ William H. Lewis

William H. Lewis

Chair and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Section 302 Certification

I, Sara Bonstein, Chief Financial Officer of Insmed Incorporated, certify that:

(1) I have reviewed this annual report on Form 10-K of Insmed Incorporated;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 20, 2025

/s/ Sara Bonstein

Sara Bonstein

Chief Financial Officer

(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO

18 USC. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2003

In connection with this Annual Report on Form 10-K of Insmed Incorporated (the "Company") for the period ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William H. Lewis, Chairman and Chief Executive Officer of the Company, certify, pursuant to 18 USC. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2003, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ William H. Lewis

William H. Lewis

Chair and Chief Executive Officer
(Principal Executive Officer)

February 20, 2025

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Insmed Incorporated under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO

18 USC. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2003

In connection with this Annual Report on Form 10-K of Insmed Incorporated (the "Company") for the period ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sara Bonstein, Chief Financial Officer of the Company, certify, pursuant to 18 USC. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2003, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Sara Bonstein

Sara Bonstein

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: February 20, 2025

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Insmed Incorporated under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.