
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 000-30739

INSMED INCORPORATED

(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)

(Zip Code)

(908) 977-9900

(Registrant's telephone number including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

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 x 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 x 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No x

As of October 25, 2024, there were 178,902,721 shares of the registrant's common stock outstanding.

INSMED INCORPORATED
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2024

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Unless the context otherwise indicates, references in this Form 10-Q to "Insmed Incorporated" refers 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 Form 10-Q also contains trademarks of third parties. Each trademark of another company appearing in this Form 10-Q is the property of its owner.

PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

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

	As of	As of
	September 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 461,451	\$ 482,374
Marketable securities	1,006,457	298,073
Accounts receivable	42,317	41,189
Inventory	98,470	83,248
Prepaid expenses and other current assets	41,150	24,179
Total current assets	1,649,845	929,063
Fixed assets, net	75,265	65,384
Finance lease right-of-use assets	18,951	20,985
Operating lease right-of-use assets	16,030	18,017
Intangibles, net	59,915	63,704
Goodwill	136,110	136,110
Other assets	96,856	96,574
Total assets	<u>\$ 2,052,972</u>	<u>\$ 1,329,837</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 248,684	\$ 214,987
Finance lease liabilities	2,871	2,610
Operating lease liabilities	7,633	8,032
Total current liabilities	259,188	225,629
Debt, long-term	954,831	1,155,313
Royalty financing agreement	160,049	155,034
Contingent consideration	157,600	84,600
Finance lease liabilities, long-term	24,841	27,026
Operating lease liabilities, long-term	9,692	11,013
Other long-term liabilities	3,356	3,145
Total liabilities	<u>1,569,557</u>	<u>1,661,760</u>
Shareholders' equity:		
Common stock, \$0.01 par value; 500,000,000 authorized shares, 178,846,991 and 147,977,960 issued and outstanding shares at September 30, 2024 and December 31, 2023, respectively	1,788	1,480
Additional paid-in capital	4,605,449	3,113,487
Accumulated deficit	(4,124,369)	(3,446,145)
Accumulated other comprehensive income (loss)	547	(745)
Total shareholders' equity (deficit)	<u>483,415</u>	<u>(331,923)</u>
Total liabilities and shareholders' equity (deficit)	<u>\$ 2,052,972</u>	<u>\$ 1,329,837</u>

See accompanying notes to the unaudited consolidated financial statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Product revenues, net	\$ 93,425	\$ 79,072	\$ 259,265	\$ 221,515
Operating expenses:				
Cost of product revenues (excluding amortization of intangible assets)	21,170	16,706	59,591	47,130
Research and development	150,809	109,148	418,640	433,982
Selling, general and administrative	118,930	90,626	318,601	254,971
Amortization of intangible assets	1,263	1,263	3,789	3,789
Change in fair value of deferred and contingent consideration liabilities	14,682	8,997	106,482	12,997
Total operating expenses	306,854	226,740	907,103	752,869
Operating loss	(213,429)	(147,668)	(647,838)	(531,354)
Investment income				
Interest expense	(21,054)	(20,288)	(63,363)	(60,910)
Change in fair value of interest rate swap	(3,852)	(1,301)	(1,106)	(1,650)
Other income (expense), net	1,843	285	474	(314)
Loss before income taxes	(219,510)	(158,389)	(675,783)	(561,949)
Provision for income taxes	1,014	544	2,441	1,557
Net loss	\$ (220,524)	\$ (158,933)	\$ (678,224)	\$ (563,506)
Basic and diluted net loss per share	\$ (1.27)	\$ (1.11)	\$ (4.27)	\$ (4.06)
Weighted average basic and diluted common shares outstanding	173,721	142,899	159,013	138,960
Net loss	\$ (220,524)	\$ (158,933)	\$ (678,224)	\$ (563,506)
Other comprehensive income (loss):				
Foreign currency translation gains (losses)	2,872	(1,075)	823	(3,448)
Unrealized gain on marketable securities	505	248	469	614
Total comprehensive loss	\$ (217,147)	\$ (159,760)	\$ (676,932)	\$ (566,340)

See accompanying notes to the unaudited consolidated financial statements

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

	Common Stock		Additional Paid-in Capital		Accumulated Deficit		Accumulated Other Comprehensive Income (Loss)		Total
	Shares	Amount							
Balance at June 30, 2023	142,750	\$ 1,428	\$ 2,945,229		\$ (3,101,151)		\$ (1,251)		\$ (155,745)
Comprehensive loss:									
Net loss							(158,933)		(158,933)
Other comprehensive loss							(827)		(827)
Exercise of stock options and ESPP shares	121	—		2,258					2,258
Issuance of common stock for vesting of RSUs	1	—							—
Deferred payments for Business Acquisition	177	2		3,895					3,897
Stock-based compensation expense			19,993						19,993
Balance at September 30, 2023	143,049	\$ 1,430	\$ 2,971,375		\$ (3,260,084)		\$ (2,078)		\$ (289,357)
Balance at June 30, 2024	166,667	\$ 1,667	\$ 3,943,826		\$ (3,903,845)		\$ (2,830)		\$ 38,818
Comprehensive loss:									
Net loss							(220,524)		(220,524)
Other comprehensive loss							3,377		3,377
Exercise of stock options and ESPP shares	1,219	12		26,868					26,880
Net proceeds from issuance of common stock	5,022	50		370,928					370,978
Issuance of common stock for vesting of RSUs	1	—							—
Deferred payments for Business Acquisition and Vertuis Bio, Inc.	197	2		14,080					14,082
Issuance of common stock upon conversion of convertible notes	5,741	57		224,202					224,259
Stock-based compensation expense			25,545						25,545
Balance at September 30, 2024	178,847	\$ 1,788	\$ 4,605,449		\$ (4,124,369)		\$ 547		\$ 483,415

See accompanying notes to the unaudited consolidated financial statements

INSMED INCORPORATED

Consolidated Statements of Shareholders' Equity (Deficit) (unaudited)
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive Income (Loss)	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount					
Balance at December 31, 2022	135,654	\$ 1,357	\$ 2,782,416	\$ (2,696,578)	\$ 756	\$ 87,951	
Comprehensive loss:							
Net loss				(563,506)			(563,506)
Other comprehensive loss					(2,834)		(2,834)
Exercise of stock options and ESPP shares	716	7	10,674				10,681
Net proceeds from issuance of common stock	2,028	20	37,994				38,014
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			54,795				54,795
Balance at September 30, 2023	143,049	\$ 1,430	\$ 2,971,375	\$ (3,260,084)	\$ (2,078)	\$ (289,357)	
Balance at December 31, 2023	147,978	\$ 1,480	\$ 3,113,487	\$ (3,446,145)	\$ (745)	\$ (331,923)	
Comprehensive loss:							
Net loss				(678,224)			(678,224)
Other comprehensive loss					1,292		1,292
Exercise of stock options and ESPP shares							
issuance	4,498	45	99,458				99,503
Net proceeds from issuance of common stock	19,537	195	1,083,941				1,084,136
Issuance of common stock for vesting of RSUs	896	9					9
Deferred payments for Business Acquisition and Vertuus Bio, Inc.	197	2	14,080				14,082
Issuance of common stock upon conversion of convertible notes	5,741	57	224,202				224,259
Stock-based compensation expense			70,281				70,281
Balance at September 30, 2024	178,847	\$ 1,788	\$ 4,605,449	\$ (4,124,369)	\$ 547	\$ 483,415	

See accompanying notes to the unaudited consolidated financial statements

INSMED INCORPORATED
Consolidated Statements of Cash Flows (unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2024	2023
Operating activities		
Net loss	\$ (678,224)	\$ (563,506)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4,483	4,052
Amortization of intangible assets	3,789	3,789
Stock-based compensation expense	70,281	54,795
Amortization of debt issuance costs	5,136	5,568
Paid-in-kind interest capitalized	19,233	17,202
Royalty financing non-cash interest expense	14,979	14,016
Accretion of discount on marketable securities, net	(8,133)	(6,291)
Finance lease amortization expense	2,034	2,034
Non-cash operating lease expense	2,230	8,423
Change in fair value of deferred and contingent consideration liabilities	106,482	12,997
Change in fair value of interest rate swap	1,106	1,650
Vertuis acquisition	—	10,250
Adrestia acquisition	—	76,481
Changes in operating assets and liabilities:		
Accounts receivable	(1,115)	(7,428)
Inventory	(14,922)	(9,179)
Prepaid expenses and other current assets	(16,981)	(1,196)
Other assets	5,625	(16,905)
Accounts payable and accrued liabilities	3,462	(6,554)
Other liabilities	(7,368)	(5,626)
Net cash used in operating activities	<u>(487,903)</u>	<u>(405,428)</u>
Investing activities		
Purchase of fixed assets	(15,151)	(11,135)
Purchase of marketable securities	(999,782)	(292,689)
Cash acquired in asset acquisition	—	3,417
Maturities of marketable securities	<u>300,000</u>	<u>75,000</u>
Net cash used in investing activities	<u>(714,933)</u>	<u>(225,407)</u>
Financing activities		
Proceeds from exercise of stock options and ESPP	99,503	10,763
Proceeds from issuance of common stock, net	1,084,136	38,014
Payments of finance lease principal	(1,924)	(2,383)
Payment of debt issuance costs	—	(1,218)
Net cash provided by financing activities	<u>1,181,715</u>	<u>45,176</u>
Effect of exchange rates on cash and cash equivalents	<u>198</u>	<u>(1,264)</u>
Net decrease in cash and cash equivalents	<u>(20,923)</u>	<u>(586,923)</u>
Cash and cash equivalents at beginning of period	482,374	1,074,036
Cash and cash equivalents at end of period	<u>\$ 461,451</u>	<u>\$ 487,113</u>
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ 25,327	\$ 27,461
Cash paid for income taxes	<u>\$ 2,251</u>	<u>\$ 1,880</u>

See accompanying notes to the unaudited 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 United States (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 *Mycobacterium avium complex* (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 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 and treprostinil palmitil inhalation powder (TPIP), as well as early-stage research programs. Brensocatib is a small molecule, oral, reversible inhibitor of dipeptidyl peptidase 1 (DPP1), which the Company is 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). The Company's early-stage 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 United Kingdom (UK), and Japan.

The accompanying unaudited interim consolidated financial statements have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by accounting principles generally accepted in the US (GAAP) for complete consolidated financial statements are not included herein. The unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's [Annual Report on Form 10-K for the year ended December 31, 2023](#). Any references in these notes to applicable accounting guidance are meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

The results of operations of any interim period are not necessarily indicative of the results of operations for the full year. The unaudited interim consolidated financial information presented herein reflects all normal adjustments that are, in the opinion of management, necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. All intercompany transactions and balances have been eliminated in consolidation.

The Company had \$461.5 million in cash and cash equivalents and \$ 1.0 billion in marketable securities as of September 30, 2024 and reported a net loss of \$678.2 million for the nine months ended September 30, 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 research and development (R&D) activities for ARIKAYCE, brensocatib, TPIP 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 rare 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

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****1. The Company and Basis of Presentation (Continued)**

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.

2. Summary of Significant Accounting Policies

The Company's complete listing of significant accounting policies is set forth in Note 2 of the notes to the consolidated financial statements in the Company's [Annual Report on Form 10-K for the year ended December 31, 2023](#). Selected significant accounting policies are discussed in detail below.

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, and accounting for research and development costs. Actual results could differ from those estimates.

Concentration of Credit Risk—Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company places its cash equivalents 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 as of the nine months ended September 30, 2024 and their respective percentages for the nine months ended September 30, 2023.

	Nine Months Ended September 30,	
	2024	2023
Customer A	35%	35%
Customer B	31%	35%
Customer C	19%	18%

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.

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

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of Significant Accounting Policies (Continued)**

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.

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 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 as of September 30, 2024. Upon recognition of a 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 Earnings 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

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of Significant Accounting Policies (Continued)**

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.

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. As of September 30, 2024 and December 31, 2023, the Company continues to operate as one reporting unit. The Company performs an impairment test for goodwill annually as of October 1. See Note 6 - *Intangibles, Net and Goodwill* for further details.

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 the 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 income (loss).

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 has not elected hedge accounting treatment for the changes in the fair value of derivatives. Changes in the fair value of derivatives are recorded each period and are 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

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of Significant Accounting Policies (Continued)**

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.

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), performance stock units (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 common shares used to compute basic and diluted net loss per share for the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	\$ (220,524)	\$ (158,933)	\$ (678,224)	\$ (56)
Denominator:				
Weighted average common shares used in calculation of basic net loss per share:	173,721	142,899	159,013	13
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	173,721	142,899	159,013	13
Net loss per share:				
Basic and diluted	\$ (1.27)	\$ (1.11)	\$ (4.27)	\$

The following potentially dilutive securities have been excluded from the computations of diluted weighted average common shares outstanding as of September 30, 2024 and 2023, respectively, as their effect would have been anti-dilutive (in thousands):

	As of September 30,	
	2024	2023
Common stock options	22,371	22,496
Unvested RS and RSUs	3,375	2,787
PSUs	665	666
Convertible debt securities	17,692	23,438

Recent Accounting Pronouncements—Not Yet Adopted

In November 2023, the 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

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of Significant Accounting Policies (Continued)**

within fiscal years beginning after December 15, 2024, with early adoption permitted. These amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of adoption of ASU 2023-07 on its consolidated financial statements and footnotes.

In December 2023, the FASB issued ASU 2023-09, Income Taxes—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.

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.

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 September 30, 2024						
	Carrying Value	Fair Value				
		Level 1	Level 2	Level 3		
Assets						
Cash and cash equivalents	\$ 461.5	\$ 461.5	\$ —	\$ —		
Marketable securities	\$ 1,006.5	\$ 1,006.5	\$ —	\$ —		
Collateral for interest rate swap	\$ 6.0	\$ 6.0	\$ —	\$ —		
Liabilities						
Interest rate swap	\$ 2.3	\$ —	\$ 2.3	\$ —		
Contingent consideration	\$ 183.7	\$ —	\$ —	\$ 183.7		

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Fair Value Measurements (Continued)**

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 nine months ended September 30, 2024, \$ 1.0 billion of marketable securities were purchased and \$ 300.0 million of marketable securities matured, each consisting of US Treasury Notes.

The Company recognizes transfers between levels within the fair value hierarchy, if any, at the end of each quarter. The collateral for interest rate swap and the interest rate swap are recorded in other assets and accounts payable and accrued liabilities, respectively, in the consolidated balance sheet as of September 30, 2024 and December 31, 2023. The collateral for interest rate swap is cash, a Level 1 asset. The interest rate swap is a Level 2 liability as it uses observable inputs other than quoted market prices in an active market. There were no transfers in or out of Level 1, Level 2 or Level 3 during the nine months ended September 30, 2024. During the nine months ended September 30, 2024, new Level 1 assets were added in connection with the Company's purchase of available-for-sale securities.

As of September 30, 2024, the Company held \$ 1.0 billion available-for-sale securities. 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 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 nine months ended September 30, 2024.

Deferred Consideration

The deferred consideration arose from the acquisition of Motus Biosciences, Inc. (Motus) in August 2021. 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 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. 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 is a directly observable input at the measurement date and for the duration of the liabilities' anticipated lives. Deferred consideration expected to be settled within twelve months or less is classified as a current liability within accounts payable and accrued liabilities. As of September 30, 2024, there is no remaining deferred consideration.

Contingent Consideration

The contingent consideration liabilities arose from the acquisitions of Motus and AlgaeneX, Inc. (AlgaeneX) (together, the Business Acquisition) in August 2021 (see *Note 16 - Acquisitions*). The contingent consideration liabilities consist of developmental and regulatory milestones, a priority review voucher milestone and net sales milestones. Upon the achievement

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Fair Value Measurements (Continued)**

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 September 30, 2024, the weighted average probability of success 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, the Company is obligated to pay to the Motus equityholders a portion of the value of the priority review voucher, subject to certain reductions. The potential payout will 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 will be settled in cash.

The contingent consideration liabilities for net sales milestones were valued using an option pricing model with Monte Carlo simulation. As of September 30, 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 expected to be settled within twelve months or less is classified as a current liability within accounts payable and accrued liabilities. Contingent consideration expected to be settled in more than twelve months is classified as a non-current liability. As of September 30, 2024, the fair value of the current and non-current contingent consideration was \$26.1 million and \$157.6 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 development and regulatory milestones and the priority review voucher milestone as of September 30, 2024:

Fair Value as of September 30, 2024 (in millions)	Valuation Technique	Unobservable Inputs	Values
Development and regulatory milestones	\$176.3	Probability-adjusted	Probabilities of success 14% - 97%
Priority review voucher milestone	\$5.7	Probability-adjusted discounted cash flow	Probability of success Discount rate 16.4% 14.9%

The following table is a summary of the changes in the fair value of the Company's valuations for the deferred and contingent consideration liabilities for the nine months ended September 30, 2024 and 2023 (in thousands):

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Fair Value Measurements (Continued)**

	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	1,200	11,800
Payments	(3,900)	—
Balance as of September 30, 2023	<u>\$ 4,700</u>	<u>\$ 69,900</u>
Balance as of December 31, 2023	\$ 5,700	\$ 84,600
Additions	—	—
Change in fair value	7,400	99,100
Payments	(13,100)	—
Balance as of September 30, 2024	<u>\$ —</u>	<u>\$ 183,700</u>

Convertible Notes

The fair value of the Company's 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 Company's 0.75% convertible senior notes due 2028 (the 2028 Convertible Notes) (categorized as a Level 2 liability for fair value measurement purposes) as of September 30, 2024 was \$1.3 billion, determined using Current Market Factors and the ability of the Company to obtain debt on comparable terms to the 2028 Convertible Notes. See Note 10 - *Debt* for further details.

Synthetic Royalty Financing Agreement

In October 2022, the Company entered into a revenue interest purchase agreement (the Royalty Financing Agreement) with OrbiMed Royalty & Credit Opportunities IV, LP (OrbiMed). Under the Royalty Financing Agreement, OrbiMed paid the Company \$150 million in exchange for the right to receive, on a quarterly basis, royalties in an amount equal to 4% 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 of at least \$150 million on or prior to March 31, 2028, the Company must make a one-time payment to OrbiMed for the difference between the \$150 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 million. The total Revenue Interest Payments payable by the Company 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.

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 with 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. See Note 11 - *Royalty Financing Agreement* for further details.

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

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Product Revenues, Net (Continued)**

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 three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
US	\$ 66,868	\$ 59,203	\$ 187,010	\$ 165,935
Japan	20,983	16,033	56,985	44,782
Europe and rest of world	5,574	3,836	15,270	10,798
Total product revenues, net	\$ 93,425	\$ 79,072	\$ 259,265	\$ 221,515

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.

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

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Product Revenues, Net (Continued)**

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 Company also recognizes revenue related to various early access programs (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.

5. Inventory

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

	As of	
	September 30, 2024	December 31, 2023
Raw materials	\$ 22,668	\$ 24,562
Work-in-process	38,991	33,480
Finished goods	36,811	25,206
	\$ 98,470	\$ 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 contract manufacturing organizations (CMOs) to produce its inventory.

6. Intangibles, Net and Goodwill**Intangibles, Net***Finite-lived Intangible Assets*

As of September 30, 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 the Lamira® Nebulizer System (Lamira) for the delivery of ARIKAYCE to patients as a result of the US Food and Drug Administration (FDA) and EC approvals of ARIKAYCE in September 2018 and October 2020, respectively. The Company began amortizing its acquired ARIKAYCE R&D and PARI milestone-related 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 September 30, 2024, the Company's indefinite-lived intangible assets consisted of acquired IPR&D from the Business Acquisition (see *Note 16 - Acquisitions*). Indefinite-lived intangible assets are not amortized. A rollforward of the Company's intangible assets for the nine months ended September 30, 2024 and September 30, 2023 is as follows (in thousands):

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Intangibles, Net and Goodwill (Continued)

	Intangible Asset	December 31, 2023	Additions	Amortization	September 30, 2024
R&D	Acquired ARIKAYCE	\$ 32,738	\$ —	\$ (3,638)	\$ 29,100
	Acquired IPR&D	29,600	—	—	29,600
	PARI milestones	1,366	—	(151)	1,215
		\$ 63,704	\$ —	\$ (3,789)	\$ 59,915
	Intangible Asset	December 31, 2022	Additions	Amortization	September 30, 2023
R&D	Acquired ARIKAYCE	\$ 37,588	\$ —	\$ (3,638)	\$ 33,950
	Acquired IPR&D	29,600	—	—	29,600
	PARI milestones	1,568	—	(151)	1,417
		\$ 68,756	\$ —	\$ (3,789)	\$ 64,967

Goodwill

The Company's goodwill balance of \$136.1 million as of September 30, 2024 and December 31, 2023, resulted from the August 2021 Business Acquisition. See Note 16 - Acquisitions for further details.

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):

Asset Description	Estimated Useful Life (years)	As of	
		September 30, 2024	December 31, 2023
Lab equipment	7	\$ 25,070	\$ 22,660
Furniture and fixtures	7	6,428	6,428
Computer hardware and software	3-5	6,369	6,001
Office equipment	7	89	89
Manufacturing equipment	7	1,336	1,336
Leasehold improvements	2-10	38,058	38,049
Construction in progress	—	46,855	35,449
		124,205	110,012
Less: accumulated depreciation		(48,940)	(44,628)
		\$ 75,265	\$ 65,384

INSMED INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. Accounts Payable and Accrued Liabilities

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

	As of	
	September 30, 2024	December 31, 2023
Accounts payable and other accrued operating expenses	\$ 64,950	\$ 65,393
Accrued clinical trial expenses	19,456	23,711
Accrued professional fees	19,627	13,885
Accrued technical operation expenses	8,953	9,187
Accrued compensation and employee related costs	55,698	48,933
Accrued royalty and milestones payable	6,639	5,674
Accrued interest payable	1,437	2,175
Revenue Interest Payments payable	3,723	3,347
Accrued sales allowances and related costs	14,458	10,937
Accrued France ATU reimbursement payable	19,117	14,685
Deferred and contingent consideration	26,100	6,700
Other accrued liabilities	8,526	10,360
	<hr/> <u>\$ 248,684</u>	<hr/> <u>\$ 214,987</u>

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 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 also records variable consideration for variable lease payments in excess of fixed fees or minimum guarantees. Variable consideration related to the Company's leasing arrangements was \$12.3 million and \$3.9 million for the three months ended September 30, 2024 and 2023, respectively, and \$20.4 million and \$8.1 million for the nine months ended September 30, 2024 and 2023, respectively. 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 supplemental non-cash disclosures of the Company's leases included in its consolidated financial statements (in thousands):

INSMED INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Leases (Continued)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Finance right-of-use assets obtained in exchange for lease obligations	\$ —	\$ —	\$ —	\$ —
Operating right-of-use assets obtained in exchange for lease obligations	\$ —	\$ —	3,089	\$ 5,656

In addition to the Company's lease agreements that have previously commenced and are reflected in the consolidated financial statements, the Company has entered into additional lease agreements that have not yet commenced. The Company entered into certain agreements with Patheon UK Limited (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. Costs of \$56.9 million and \$49.1 million incurred by the Company under these additional agreements have been classified within other assets in the Company's consolidated balance sheet as of September 30, 2024 and December 31, 2023, respectively. 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 September 30, 2024 and December 31, 2023 (in thousands):

	As of	
	September 30, 2024	December 31, 2023
Convertible notes	\$ 566,663	\$ 788,909
Term Loan	388,168	366,404
Debt, long-term	\$ 954,831	\$ 1,155,313

Convertible Notes

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 amount 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.

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 of 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

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Debt (Continued)**

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 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 the 2028 Convertible Notes, as determined following a request by a holder of such 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.

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, 2022, prior to the adoption of ASU 2020-06. The 2028 Convertible Notes have a remaining term of approximately 3.67 years.

The \$566.7 million carrying value of the 2028 Convertible Notes as of September 30, 2024 is net of \$ 8.3 million of

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Debt (Continued)**

unamortized debt issuance costs. The remaining outstanding 2025 Convertible Notes were redeemed by the Company on August 9, 2024, such that none were outstanding as of September 30, 2024. The 2028 Convertible Notes are long-term liabilities as of September 30, 2024. The following table presents the carrying value of the Company's convertible notes balance (in thousands):

	As of	
	September 30, 2024	December 31, 2023
Face value of outstanding convertible notes	\$ 574,990	800,000
Debt issuance costs	(8,327)	(11,091)
Total long-term convertible notes	\$ 566,663	\$ 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, the 2028 Convertible Notes became convertible, through the end of the third quarter of 2024, 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 September 30, 2024, holders of ten thousand dollars of aggregate principal amount of 2028 Convertible Notes elected to convert their notes, resulting in an issuance of an aggregate of 306 shares of the Company's common stock. On October 1, 2024, the 2028 Convertible Notes became convertible, through the end of the fourth quarter of 2024, 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. 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 a \$ 350 million senior secured term loan agreement with Pharmakon Advisors LP (Pharmakon), manager of the BioPharma Credit funds (the Term Loan). The Term Loan matures on October 19, 2027 and bears 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. Up to 50% of the interest payable during the first 24 months from the closing of the Term Loan may be paid-in-kind at the Company's election. If elected, paid-in-kind interest will be capitalized and added to the principal amount of the Term Loan. The Term Loan, including the paid-in-kind interest, will be repaid in eight equal quarterly payments starting in the 13th quarter following the closing of the Term Loan (i.e., the quarter ending March 31, 2026), except that the repayment start date may be extended at the Company's option for an additional four quarters, so that repayments start in the 17th quarter following the closing of the Term Loan, subject to the achievement of specified ARIKAYCE data thresholds and certain other conditions. Net proceeds from the Term Loan, after deducting the lenders' fees and deal expenses of \$15.2 million, were \$334.8 million. During the nine months ended September 30, 2024, paid-in-kind interest capitalized was \$ 19.2 million.

The following table presents the carrying value of the Company's Term Loan balance as of September 30, 2024 (in

INSMED INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Debt (Continued)

thousands):

	As of	
	September 30, 2024	December 31, 2023
Original Term Loan balance	\$ 350,000	\$ 350,000
Paid-in-kind interest capitalized	46,770	27,537
Term Loan issuance costs, unamortized	(8,602)	(11,133)
Term Loan	<u>\$ 388,168</u>	<u>\$ 366,404</u>

As of September 30, 2024, future principal repayments of debt for each of the years through maturity were as follows (in thousands):

Year Ending December 31:
2024
2025
2026
2027
2028
2029 and thereafter
<u>\$ 971,760</u>

Interest Expense

Interest expense related to debt and finance leases for the three and nine months ended September 30, 2024 and 2023 is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Convertible debt contractual interest expense	\$ 1,194	\$ 2,063	\$ 5,319	\$
Term Loan contractual interest expense	13,325	12,002	38,466	3
Royalty Financing Agreement interest expense	5,264	4,447	14,979	1
Amortization of debt issuance costs	1,485	1,840	5,136	
Swap interest income	(765)	(666)	(2,229)	(
Total debt interest expense	20,503	19,686	61,671	5
Finance lease interest expense	551	602	1,692	
Total interest expense	<u>\$ 21,054</u>	<u>\$ 20,288</u>	<u>\$ 63,363</u>	<u>\$ 6</u>

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 million in exchange for the right to receive, on a quarterly basis, royalties in an amount equal to 4% 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 million on or prior to March 31, 2028, the Company must make a one-time payment to OrbiMed for the difference between the \$150 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 million. The total Revenue Interest Payments payable by the Company to OrbiMed are capped at 1.8x of the purchase price or up to a maximum.

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. Royalty Financing Agreement (Continued)**

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 \$3.8 million were, \$146.2 million.

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.

The following table shows the activity within the liability account for the nine-month period ended September 30, 2024 and year ended December 31, 2023 (in thousands):

	Nine Months Ended September 30, 2024	Twelve Months Ended December 31, 2023
Royalty financing agreement liability - beginning balance	\$ 158,162	\$ 151,538
Revenue Interest Payments paid and payable	(10,357)	(12,222)
Interest expense recognized	14,979	18,846
Royalty financing agreement liability - ending balance	<u>\$ 162,784</u>	<u>\$ 158,162</u>
Royalty financing issuance costs:		
Royalty issuance costs, unamortized - beginning balance	\$ (3,128)	\$ (3,523)
Amortization of issuance costs	393	521
Other	—	(126)
Deferred issuance costs, unamortized - ending balance	<u>\$ (2,735)</u>	<u>\$ (3,128)</u>
Royalty Financing Agreement	<u><u>\$ 160,049</u></u>	<u><u>\$ 155,034</u></u>

The Revenue Interest Payments payable in connection with the royalty financing agreement were \$ 3.7 million and \$3.3 million as of September 30, 2024 and December 31, 2023, respectively, which were recorded within accounts payable and accrued expenses on the consolidated balance sheet. Non-cash interest expense is recorded within interest expense in the consolidated statements of comprehensive loss.

12. Shareholders' Equity

Common Stock—As of September 30, 2024, the Company had 500,000,000 shares of common stock authorized with a par value of \$ 0.01 per share and 178,846,991 shares of common stock issued and outstanding. In addition, as of September 30, 2024, the Company had reserved 22,370,575 shares of common stock for issuance upon the exercise of outstanding stock options, 3,375,445 shares of common stock for issuance upon the vesting of RSUs and 664,724 shares for issuance upon the vesting of PSUs. The Company has also reserved 17,691,984 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 2,889,367 shares of the Company's common stock in connection with the Business Acquisition (see Note 16 - 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.

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****12. Shareholders' Equity (Continued)**

In the third quarter of 2024, in connection with the redemption and conversions of the 2025 Convertible Notes and conversions of the 2028 Convertible Notes, the Company issued 5,741,063 and 306 shares of the Company's common stock, respectively.

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 Therapeutics Ltd. (Adrestia), the Company issued 3,430,867 shares of the Company's common stock as consideration at closing. See *Note 16 - Acquisitions* for further details.

In connection with the Company's acquisition of Vertuis Bio, Inc. (Vertuis) in January 2023, the Company issued an aggregate of 500,000 shares of the Company's common stock to Vertuis' former stockholders and an individual entitled to receive a portion of the acquisition consideration (collectively, the Vertuis equityholders). In July 2024, the Company issued the Vertuis equityholders an additional 14,773 shares of common stock. See *Note 16 - Acquisitions* for further details.

In October 2022, the Company completed an underwritten offering of 13,750,000 shares of the Company's common stock at a public 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 expense of \$ 16.2 million, were \$258.8 million.

In the first quarter of 2021, the Company entered into a sales agreement with SVB Leerink LLC (now known as Leerink Partners LLC) (Leerink), 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 an "at the market" equity offering program (the ATM program), under which Leerink acted as sales agent. In 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 a new sales agreement with Leerink 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 a new "at the market" equity offering program (the new ATM program), under which Leerink acts 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. As of September 30, 2024, an aggregate of \$120.1 million of shares of common stock remain available to be issued and sold under the new ATM program.

Preferred Stock—As of September 30, 2024, the Company had 200,000,000 shares of preferred stock authorized with a par value of \$ 0.01 per share 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, 2024. The 2019 Incentive Plan replaced the Insmed Incorporated 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. At the May 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 September 30, 2024, 4,877,539 shares remain available for future issuance under the 2019 Incentive Plan. The 2019 Incentive Plan will terminate on April 3, 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 nine months ended September 30, 2024, the Company granted inducement stock options covering 1,207,710 shares of the Company's common stock to new employees.

On May 15, 2018, the 2018 Employee Stock Purchase Plan (ESPP) was approved by shareholders at the Company's 2018 Annual Meeting of Shareholders. The Company has reserved the following for issuance under the ESPP: (i) 1,000,000 shares of common stock, plus (ii) commencing on January 1, 2019 and ending on December 31, 2023, an additional number of shares to be added on the first day of each calendar year equal to the lesser of (A) 1,200,000 shares of common stock, (B) 2% of the number of outstanding shares of common stock on such date and (C) an amount determined by the administrator.

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****13. Stock-Based Compensation (Continued)**

Stock Options—As of September 30, 2024, there was \$163.8 million of unrecognized compensation expense related to unvested stock options. As of September 30, 2024, the Company had performance-conditioned options totaling 114,780 shares outstanding which had not yet met the recognition criteria.

Restricted Stock Units—As of September 30, 2024, there was \$64.8 million of unrecognized compensation expense related to unvested RSU awards.

Performance Stock Units—As of September 30, 2024, there were 265,887 unvested PSUs outstanding with an unrecognized compensation expense of \$10.4 million. The PSUs are subject to two performance conditions based on brensocatib milestones. As of June 30, 2024, the Company achieved the first performance condition by issuing a press release announcing certain topline results from the ASPEN trial by June 30, 2024. 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). 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, pending the achievement of the second performance condition, the acceptance of an NDA by the FDA for brensocatib, and satisfaction of the remaining service condition to such awards.

The following table summarizes the aggregate stock-based compensation expense recorded in the consolidated statements of comprehensive loss related to stock options, RSUs and the ESPP during the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 12,586	\$ 9,653	\$ 34,222	\$ 26,339
Selling, general and administrative	12,959	10,340	36,059	28,456
Total	\$ 25,545	\$ 19,993	\$ 70,281	\$ 54,795

There was no stock-based compensation expense recorded in the consolidated statements of comprehensive loss related to PSUs during the nine months ended September 30, 2024 or September 30, 2023, as the second performance condition associated with the PSU awards was not probable as of either date.

14. Income Taxes

The Company recorded a provision for income taxes of \$ 1.0 million and \$0.5 million for the three months ended September 30, 2024 and 2023, respectively, and \$2.4 million and \$1.6 million for the nine months ended September 30, 2024 and 2023, respectively. The provisions recorded for the three and nine months ended September 30, 2024 and 2023 are primarily a result of certain of the Company's international subsidiaries, which had taxable income during the periods. Additionally, the Company is impacted by certain state taxes which effectively impose income tax on modified gross revenues. In jurisdictions where the Company has 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 is subject to US federal, state and international income taxes and the statute of limitations for tax audit is open for the Company's federal tax returns for the years ended 2020 and later, generally open for certain states for the years 2019 and later, and generally open for international jurisdictions for the years 2018 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. As of September 30, 2024 and December 31, 2023, the Company had recorded reserves for unrecognized income tax benefits against certain deferred tax assets in the US. However, given the Company's valuation allowance position, these reserves do not have an impact on the balance sheet as of September 30, 2024 and December 31, 2023 or the consolidated statements of comprehensive loss for the three and nine months ended September 30, 2024 and 2023. The Company has not recorded any accrued interest or penalties related to uncertain tax positions. The Company does not anticipate any material changes in the amount of unrecognized tax positions over the next twelve months.

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

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****14. Income Taxes (Continued)**

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.

15. Commitments and Contingencies

Rent expense charged to operations was \$3.0 million and \$2.6 million for the three months ended September 30, 2024 and 2023, respectively, and \$ 8.9 million and \$6.9 million for the nine months ended September 30, 2024 and 2023, respectively.

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.

16. 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, 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 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. 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.

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 closing share price on June 28, 2024. 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 issued in July 2024	1.00
Total purchase price	\$ 10.25

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****16. Acquisitions (Continued)**

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.

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 and is obligated to issue to the 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. 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.

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 the AlgaeneX equityholders an aggregate of 368,867 shares of the Company's common stock upon the achievement of a development milestone event and pay to the AlgaeneX equityholders a 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. The results of Motus's and AlgaeneX's operations have been included in the Company's 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.

INSMED INCORPORATED**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****17. Subsequent Events****Amended and Restated Loan Agreement**

On October 31, 2024, the Company entered into an Amended and Restated 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 Amended and Restated Loan Agreement amends and restates the Term Loan, dated as of October 19, 2022. The Amended and Restated Loan Agreement, among other items, provides an additional \$150.0 million senior secured term loan tranche (the Tranche B Term Loan and, together with the Term Loan, the Term Loans). The Amended and Restated 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. 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.

In connection with the Amended and Restated Loan Agreement, the Company settled and terminated the interest rate swap contract in October 2024.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q 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, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (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 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 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, 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 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 or TPIP 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 or TPIP, or acceptable prices for ARIKAYCE or, if approved, brensocatib or TPIP;
- 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 secured senior loan with certain funds managed by Pharmakon and our royalty financing with 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 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;

- *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 recent 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 are not 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 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 Quarterly Report on Form 10-Q 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" in this Quarterly Report on Form 10-Q and included in our [Annual Report on Form 10-K for the fiscal year ended December 31, 2023](#). 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.

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The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the consolidated financial statements and related notes thereto in our [Annual Report on Form 10-K for the year ended December 31, 2023](#).

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 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 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 and TPIP, as well as early-stage 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. Our early-stage 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.

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

ARIKAYCE

- We announced positive topline results from the ARISE trial in the third quarter of 2023.
- 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. In September 2024, we closed screening of new patients in the ENCORE study which we expect will result in us exceeding our target enrollment of 400 patients in the study.
- We anticipate reporting topline data from ENCORE in the first quarter of 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.
- We remain on track to file an NDA with the FDA for brensocatib in patients with bronchiectasis in the fourth quarter of 2024. We are advancing commercial readiness activities in preparation for a launch of brensocatib for patients with bronchiectasis, if approved. If a priority review is granted and brensocatib is approved, Insmed anticipates a US launch in mid-2025. Launches in Europe and Japan are expected in the first half of 2026, pending approvals.
- We are conducting further studies to explore the potential of brensocatib in additional neutrophil-mediated diseases. The Phase 2b BiRCh trial of brensocatib in patients with CRSsNP is underway and we expect to initiate a Phase 2 study of brensocatib in patients with HS in the fourth quarter of 2024.

TPIP

- Enrollment in the Phase 2 study of TPIP in PAH remains ongoing. We anticipate topline results in the second half of 2025.
- In May 2024, we reported topline safety data and certain exploratory efficacy endpoints from the Phase 2 study of TPIP in patients with PH-ILD. Based on these Phase 2 results in PH-ILD, we are advancing toward discussions with global regulatory authorities on the design of a Phase 3 study in PH-ILD, which we anticipate initiating in the second half of 2025.

Early-Stage Research

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- We continue to progress our early-stage 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.

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 and rare 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 590 mg (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, and TPIP, our Phase 2 product candidate that may offer a differentiated product profile for patients with PH-ILD and PAH. We announced positive topline results from our Phase 3 ASPEN trial in brensocatib in May 2024 and plan to file an NDA with the FDA for brensocatib in patients with bronchiectasis in the fourth quarter of 2024, followed by filings with the European and Japanese regulatory authorities. We are also advancing our early-stage 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;
- Produce topline clinical data readouts in the near and long term;
- Advance commercial readiness activities to serve significantly more patients facing serious diseases; 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 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. 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.

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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. Based on these results, we have proposed to the FDA that the change of the respiratory score derived from the QOL-B respiratory domain PRO be the primary endpoint for the ENCORE study. 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 8 questions from the QOL-B respiratory domain PRO. In September 2024, we closed screening of new patients in the ENCORE study which we expect will result in us exceeding our target enrollment of 400 patients in the study. We anticipate reporting topline data in the first quarter of 2026.

Regulatory Pathway 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 patients across the European Union (EU) countries as well as in the 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 (GKV-SV) towards an agreement on the 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. We are working to ensure an uninterrupted supply of ARIKAYCE for patients in Germany and to provide physicians and pharmacists the information they need to obtain ARIKAYCE for their patients through the importation pathway. In January 2023, we agreed upon reimbursement terms with the French authorities. To date, we have been unable to reach an acceptable agreement of a nationally reimbursed price with the Italian Medicines Agency (AIFA); 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

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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 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.

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.

Based on the results of ARISE, we plan to explore accelerating the filing for approval of ARIKAYCE in newly infected patients with MAC lung disease with the FDA. Consistent with our expectations, the PMDA in Japan confirmed that it 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

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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 ARISE and 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 8 questions from the QOL-B respiratory domain PRO. In September 2024, we closed screening of new patients in the ENCORE study which we expect will result in us exceeding our target enrollment of 400 patients in the study. 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.

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 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 is 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. 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.

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. As a result, the ASPEN trial includes 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 2 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.

As part of the ASPEN study's conduct, more than 460 trial sites were engaged in nearly 40 countries. After excluding sites that did not enroll any patients and all sites in Ukraine, due to the ongoing conflict, the total number of active sites in ASPEN was 391 sites in 35 countries. Adult 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. We remain on track to file an NDA with the FDA for brensocatib in patients with bronchiectasis in the fourth quarter of 2024.

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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=0.0046*
Secondary Endpoints				
Prolongation of time to first PE	18.7%	p=0.0100*	17.5%	p=0.0182*
Increase in odds of remaining exacerbation free over 52 weeks	41.2%	p=0.0059*	40.0%	p=0.0074*
Change from baseline in post-bronchodilator forced expiratory volume in 1 second (FEV1) at week 52	11 mL	p=0.3841	38 mL	p=0.0054*
Reduction in annualized rate of severe PEs	25.8%	p=0.1277	26.0%	p=0.1025
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=0.0004^

* - 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 is 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.

In January 2023, we reported topline data from the Phase 2, multiple-dose, pharmacokinetic/pharmacodynamic study of brensocatib in patients with CF. This Phase 2 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 2 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 (corticosteroid 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 and we expect to initiate a Phase 2 study of brensocatib in patients with HS in the fourth quarter of 2024.

Treprostинil Palmitil Inhalation Powder

TPIP is an investigational inhaled formulation of a treprostинil 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.

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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 2 study of TPIP in patients with PH-ILD. Based on these Phase 2 results in PH-ILD, we are advancing toward discussions with global regulatory authorities on the design of a Phase 3 study in PH-ILD, which we anticipate initiating in the second half of 2025. We also have an ongoing Phase 2 study designed to investigate the effect of TPIP in patients with PAH. Enrollment in the Phase 2 study of TPIP in PAH remains ongoing and we anticipate topline results in the second half of 2025.

Early-Stage Research

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 and AlgaeneX, preclinical stage companies engaged in the research, development and manufacturing of gene therapies for rare genetic disorders. In January 2023, we acquired 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, 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 early-stage 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 and rare diseases that currently have significant unmet needs. We are focused broadly on serious and rare disease therapeutics and prioritizing those areas that best align with our core competencies.

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 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, including medical affairs and program management. R&D expenses also includes 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 and early-stage research activities. Our R&D expenses related to clinical trials are primarily related to activities at contract research organizations (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: our stock price; the probability of achieving milestones; 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.

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 balance sheet reflects debt, net of the debt issuance costs paid to the lender, and other third-party costs. Unamortized debt issuance costs associated with extinguished debt are expensed in the period of the extinguishment.

Change in Fair Value of Interest Rate Swap

We record derivative and hedge transactions in accordance with GAAP. In the fourth quarter of 2022, we entered into an interest rate swap contract (the Swap Contract) with a notional value of \$350 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 has not been designated as a hedging instrument for accounting purposes. Consequently, all changes in the fair value of the Swap Contract are reported as a component of net loss in the consolidated statements of comprehensive loss.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended September 30, 2024 and 2023

Overview - Operating Results

Our operating results for the three months ended September 30, 2024, included the following:

- Product revenues, net, increased \$14.4 million, or 18.2%, as compared to the same period in the prior year as a result of the growth in ARIKAYCE sales;
- Cost of product revenues (excluding amortization of intangible assets) increased \$4.5 million as compared to the same period in the prior year as a result of the increase in sales volumes of ARIKAYCE;
- R&D expenses increased \$41.7 million as compared to the same period in the prior year primarily as a result of increases in manufacturing and compensation and benefit-related expenses;
- SG&A expenses increased \$28.3 million as compared to the same period in the prior year primarily as a result of increases in compensation and benefit-related expenses and stock-based compensation costs;
- Amortization of intangible assets of \$1.3 million was consistent with the same period in the prior year;
- Change in fair value of deferred and contingent consideration liabilities increased \$5.7 million, primarily as a result of the change in our share price;
- Investment income increased \$6.4 million as compared to the same period in the prior year primarily due to an increase in our average cash and cash equivalents and marketable securities balances; and
- Interest expense increased \$0.8 million as compared to the same period in the prior year due to the Term Loan.

Product Revenues, Net

Product revenues, net, consists of net sales of ARIKAYCE. The following table summarizes revenue by geography for the three months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Increase (decrease)	
	2024	2023	\$	%
US	\$ 66,868	\$ 59,203	\$ 7,665	12.9%
Japan	20,983	16,033	4,950	30.9%
Europe and rest of world	5,574	3,836	1,738	45.3%
Total product revenues, net	\$ 93,425	\$ 79,072	\$ 14,353	18.2%

Product revenues, net, for the three months ended September 30, 2024 increased to \$93.4 million as compared to \$79.1 million in the same period in 2023, an increase of 18.2%, as a result of growth in ARIKAYCE sales in the US, Japan and Europe and the rest of the world.

Cost of Product Revenues (excluding amortization of intangible assets)

Cost of product revenues (excluding amortization of intangible assets) for the three months ended September 30, 2024 and 2023 were comprised of the following (in thousands):

	Three Months Ended September 30,		Increase (decrease)	
	2024	2023	\$	%
Cost of product revenues (excluding amortization of intangible assets)	\$ 21,170	\$ 16,706	\$ 4,464	26.7 %
Cost of product revenues, as % of revenues	22.7 %	21.1 %		

Cost of product revenues (excluding amortization of intangible assets) increased by \$4.5 million, or 26.7%, to \$21.2 million for the three months ended September 30, 2024 as compared to \$16.7 million in the same period in 2023. The increase in cost of product revenues (excluding amortization of intangibles) for the three months ended September 30, 2024 was primarily attributable to the increase in product revenues discussed above.

R&D Expenses

R&D expenses for the three months ended September 30, 2024 and 2023 were comprised of the following (in thousands):

	Three Months Ended September 30,		Increase (decrease)	
	2024	2023	\$	%
External Expenses				
Clinical development and research	\$ 39,117	\$ 39,395	\$ (278)	(0.7)
Manufacturing	31,562	11,296	20,266	179.4
Regulatory, quality assurance, and medical affairs	6,533	4,813	1,720	35.7
Subtotal—external expenses	\$ 77,212	\$ 55,504	\$ 21,708	39.1
Internal Expenses				
Compensation and benefit-related expenses	50,778	35,027	\$ 15,751	45.0
Stock-based compensation	12,586	9,653	2,933	30.4
Other internal operating expenses	10,233	8,964	1,269	14.2
Subtotal—internal expenses	\$ 73,597	\$ 53,644	\$ 19,953	37.2
Total R&D expenses	\$ 150,809	\$ 109,148	\$ 41,661	38.2

R&D expenses increased to \$150.8 million during the three months ended September 30, 2024 from \$109.1 million in the same period in 2023. The \$41.7 million increase in R&D expenses was due to a \$20.3 million increase in manufacturing expense and an \$18.7 million increase in compensation and benefit-related expenses and stock-based compensation costs due to an increase in headcount.

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External R&D expenses by product for the three months ended September 30, 2024 and 2023 were comprised of the following (in thousands):

	Three Months Ended September 30,		Increase (decrease)	
	2024	2023	\$	%
ARIKAYCE external R&D expenses	\$ 16,370	\$ 13,485	\$ 2,885	21.4
Brensocatib external R&D expenses	17,288	23,015	(5,727)	(24.9)
TPIP external R&D expenses	16,635	8,680	7,955	91.6
Other external R&D expenses	26,916	10,324	16,592	160.7
Total external R&D expenses	\$ 77,209	\$ 55,504	\$ 21,705	39.1

SG&A Expenses

SG&A expenses for the three months ended September 30, 2024 and 2023 were comprised of the following (in thousands):

	Three Months Ended September 30,		Increase (decrease)	
	2024	2023	\$	%
Compensation and benefit-related expenses	\$ 47,578	\$ 29,316	\$ 18,262	62.3 %
Stock-based compensation	12,959	10,340	2,619	25.3 %
Professional fees and other external expenses	42,204	38,341	3,863	10.1 %
Facility related and other internal expenses	16,189	12,629	3,560	28.2 %
Total SG&A expenses	\$ 118,930	\$ 90,626	\$ 28,304	31.2 %

SG&A expenses increased to \$118.9 million during the three months ended September 30, 2024 from \$90.6 million in the same period in 2023. The \$28.3 million increase resulted primarily from a \$20.9 million increase in compensation and benefit-related expenses and stock-based compensation costs due to an increase in headcount and a \$3.9 million increase in professional fees and other external expenses driven by commercial readiness activities for brensocatib.

Amortization of Intangible Assets

Amortization of intangible assets for both the three months ended September 30, 2024 and 2023 was \$1.3 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 EC approvals of ARIKAYCE.

Change in Fair Value of Deferred and Contingent Consideration Liabilities

The change in fair value of deferred and contingent consideration for the three months ended September 30, 2024 was \$14.7 million. The change is related to the fair value of the potential future consideration to be paid to former equityholders of the businesses we acquired. The change in fair value of deferred and contingent consideration for the three months ended September 30, 2024 was primarily due to the increase in our share price.

Investment Income

Investment income increased to \$17.0 million for the three months ended September 30, 2024 as compared to \$10.6 million in the same period in 2023 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 increased to \$21.1 million for the three months ended September 30, 2024 as compared to \$20.3 million in the same period in 2023 primarily due to interest related to the Term Loan. See Note 10 - *Debt* and Note 11 - *Royalty Financing Agreement* in this Quarterly Report on Form 10-Q for further details.

Change in Fair Value of Interest Rate Swap

The change in fair value of interest rate swap for the three months ended September 30, 2024 was \$3.9 million. Adjustments to the fair value are due to changes in interest rates as of September 30, 2024 relative to the fair value of interest rate swap as of December 31, 2023.

Comparison of the Nine Months Ended September 30, 2024 and 2023

Overview - Operating Results

Our operating results for the nine months ended September 30, 2024, included the following:

- Product revenues, net, increased \$37.8 million, or 17.0%, as compared to the same period in the prior year as a result of the growth in ARIKAYCE sales;
- Cost of product revenues (excluding amortization of intangible assets) increased \$12.5 million as compared to the same period in the prior year as a result of the increase in sales volumes of ARIKAYCE;
- R&D expenses decreased \$15.3 million as compared to the same period in the prior year primarily as a result of the non-cash costs of the Adrestia and Vertuis acquisitions in 2023;
- SG&A expenses increased \$63.6 million as compared to the same period in the prior year primarily as a result of increases in compensation and benefit-related expenses and stock-based compensation costs;
- Amortization of intangible assets of \$3.8 million was consistent with the same period in the prior year;
- Change in fair value of deferred and contingent consideration liabilities increased \$93.5 million, primarily as a result of the change in our share price;
- Investment income increased \$3.8 million as compared to the same period in the prior year due to an increase in our average cash and cash equivalents and marketable securities balances; and
- Interest expense increased \$2.5 million as compared to the same period in the prior year due to the Term Loan.

Product Revenues, Net

Product revenues, net, consists of net sales of ARIKAYCE. The following table summarizes revenue by geography for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,		Increase (decrease)	
	2024	2023	\$	%
US	\$ 187,010	\$ 165,935	\$ 21,075	12.7 %
Japan	56,985	44,782	12,203	27.2 %
Europe and rest of world	15,270	10,798	4,472	41.4 %
Total product revenues, net	\$ 259,265	\$ 221,515	\$ 37,750	17.0 %

Product revenues, net, for the nine months ended September 30, 2024 increased to \$259.3 million as compared to \$221.5 million in the same period in 2023, an increase of 17.0%, as a result of growth in ARIKAYCE sales in the US, Japan and Europe and the rest of the world.

Cost of Product Revenues (excluding amortization of intangible assets)

Cost of product revenues (excluding amortization of intangible assets) for the nine months ended September 30, 2024 and 2023 were comprised of the following (in thousands):

	Nine Months Ended September 30,		Increase (decrease)	
	2024	2023	\$	%
Cost of product revenues (excluding amortization of intangible assets)	\$ 59,591	\$ 47,130	\$ 12,461	26.4 %
Cost of product revenues, as % of revenues	23.0 %	21.3 %		

Cost of product revenues (excluding amortization of intangible assets) increased by \$12.5 million, or 26.4%, to \$59.6 million for the nine months ended September 30, 2024 as compared to \$47.1 million in the same period in 2023. The increase in cost of product revenues (excluding amortization of intangibles) for the nine months ended September 30, 2024 was primarily attributable to the increase in product revenues discussed above.

R&D Expenses

R&D expenses for the nine months ended September 30, 2024 and 2023 were comprised of the following (in thousands):

	Nine Months Ended September 30,		Increase (decrease)	
	2024	2023	\$	%
External Expenses				
Clinical development and research	\$ 126,766	\$ 127,808	\$ (1,042)	(0.8)
Milestone payment to AstraZeneca	12,500	—	12,500	↑
Manufacturing	62,025	43,069	18,956	44.0
Regulatory, quality assurance, and medical affairs	18,814	20,107	(1,293)	(6.4)
Non-cash asset acquisitions	—	86,747	(86,747)	(100.0)
Subtotal—external expenses	\$ 220,105	\$ 277,731	\$ (57,626)	(20.7)
Internal Expenses				
Compensation and benefit-related expenses	136,146	100,676	\$ 35,470	35.2
Stock-based compensation	34,222	26,339	7,883	29.9
Other internal operating expenses	28,167	29,236	(1,069)	(3.7)
Subtotal—internal expenses	\$ 198,535	\$ 156,251	\$ 42,284	27.1
Total R&D expenses	\$ 418,640	\$ 433,982	\$ (15,342)	(3.5)

R&D expenses decreased to \$418.6 million during the nine months ended September 30, 2024 from \$434.0 million in the same period in 2023. The \$15.3 million decrease in R&D expenses was primarily due to the \$86.7 million non-cash asset acquisition cost of Adrestia and Vertuis in the first half of 2023, partially offset by an increase of \$43.4 million in compensation and benefit-related expenses and stock-based compensation costs due to an increase in headcount, a \$19.0 million increase in manufacturing expenses, and a \$12.5 million milestone payment due to AstraZeneca upon our release of an official public statement that we intend to file an NDA for brensocatib.

External R&D expenses by product for the nine months ended September 30, 2024 and 2023 were comprised of the following (in thousands):

	Nine Months Ended September 30,		Increase (decrease)	
	2024	2023	\$	%
ARIKAYCE external R&D expenses	\$ 45,192	\$ 47,107	\$ (1,915)	(4.1)
Brensocatib external R&D expenses	74,612	76,289	(1,677)	(2.2)
TPIP external R&D expenses	45,190	36,948	8,242	22.3
Non-cash asset acquisitions	—	86,747	(86,747)	(100.0)
Other external R&D expenses	55,111	30,640	24,471	79.9
Total external R&D expenses	\$ 220,105	\$ 277,731	\$ (57,626)	(20.7)

SG&A Expenses

SG&A expenses for the nine months ended September 30, 2024 and 2023 were comprised of the following (in thousands):

	Nine Months Ended September 30,		Increase (decrease)	
	2024	2023	\$	%
Compensation and benefit-related expenses	\$ 115,250	\$ 85,480	\$ 29,770	34.8 %
Stock-based compensation	36,059	28,456	7,603	26.7 %
Professional fees and other external expenses	121,898	104,505	17,393	16.6 %
Facility related and other internal expenses	45,394	36,530	8,864	24.3 %
Total SG&A expenses	\$ 318,601	\$ 254,971	\$ 63,630	25.0 %

SG&A expenses increased to \$318.6 million during the nine months ended September 30, 2024 from \$255.0 million in the same period in 2023. The \$63.6 million increase resulted primarily from a \$37.4 million increase in compensation and benefit-related expenses and stock-based compensation costs due to an increase in headcount and a \$17.4 million increase in professional fees and other external expenses driven by commercial readiness activities for brensocatib.

Amortization of Intangible Assets

Amortization of intangible assets for both the nine months ended September 30, 2024 and 2023 was \$3.8 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 EC approvals of ARIKAYCE.

Change in Fair Value of Deferred and Contingent Consideration Liabilities

The change in fair value of deferred and contingent consideration for the nine months ended September 30, 2024 was \$106.5 million. The change is related to the fair value of the potential future consideration to be paid to former equityholders of the businesses we acquired. The change in fair value of deferred and contingent consideration for the nine months ended September 30, 2024 was primarily due to the increase in our share price.

Investment Income

Investment income increased to \$36.1 million for the nine months ended September 30, 2024 as compared to \$32.3 million in the same period in 2023 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 increased to \$63.4 million for the nine months ended September 30, 2024 as compared to \$60.9 million in the same period in 2023 primarily due to interest related to the Term Loan. See *Note 10 - Debt* and *Note 11 - Royalty Financing Agreement* in this Quarterly Report on Form 10-Q for further details.

Change in Fair Value of Interest Rate Swap

The change in fair value of interest rate swap for the nine months ended September 30, 2024 was \$1.1 million. Adjustments to the fair value are due to changes in interest rates as of September 30, 2024 relative to the fair value of interest rate swap as of December 31, 2023.

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 pre-commercialization 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 the first quarter of 2024, the Company entered into a new sales agreement with Leerink 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 acts as sales agent. During the nine months ended September 30, 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. As of September 30, 2024, an aggregate of \$120.1 million of shares of common stock remain available to be issued and sold under the new ATM program.

In October 2022, we entered into the \$350 million Term Loan with Pharmakon that matures on October 19, 2027. The Term Loan bears 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 Term Loan may be paid-in-kind at our election. If elected, paid-in-kind interest will be capitalized and added to the principal amount of the Term Loan. The Term Loan, including the paid-in-kind interest, will be repaid in eight equal quarterly payments starting in the 13th quarter following the closing of the Term Loan (i.e., the quarter ending March 31, 2026), except that the repayment start date may be extended at our option for an additional four quarters, so that repayments start in the 17th quarter following the closing of the Term Loan, subject to the achievement of specified ARIKAYCE data thresholds and certain other conditions. Net proceeds from the Term Loan, after deducting the lenders' fees and deal expenses of \$15.2 million, were \$334.8 million.

In October 2022, we entered into the Royalty Financing Agreement with OrbiMed, whereby OrbiMed paid us \$150 million in exchange for the right to receive, on a quarterly basis, royalties in an amount equal to 4% 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

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Payments equal to or greater than \$150 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 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 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 \$3.8 million, were \$146.2 million.

In October 2022, we also completed an underwritten offering of 13,750,000 shares of our common stock at a public offering price of \$20.00 per share. Our net proceeds from the sale of the shares, after deducting the underwriting discounts and offering expense of \$16.2 million, were \$258.8 million.

We may need to raise additional capital to fund our operations, the continued commercialization of ARIKAYCE, launch readiness activities for the potential launch of brensocatib for the treatment of patients with bronchiectasis, if approved, clinical trials for brensocatib, TPIP, and our future product candidates, and to develop, acquire, in-license or co-promote other products or product candidates, including those that address orphan or rare 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 the ASPEN trial, 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 our early-research programs.

Cash Flows

As of September 30, 2024, we had cash and cash equivalents of \$461.5 million, as compared with \$482.4 million as of December 31, 2023. In addition, as of September 30, 2024 we had marketable securities of \$1.0 billion, as compared with \$298.1 million as of December 31, 2023. The \$20.9 million increase in cash and cash equivalents and \$708.4 million increase in marketable securities was primarily due to our underwritten offering of common stock in May 2024, and proceeds from our ATM program, partially offset by our cash used in operating activities. Our working capital was \$1,390.7 million as of September 30, 2024, as compared with \$703.4 million as of December 31, 2023.

Net cash used in operating activities was \$487.9 million and \$405.4 million for the nine months ended September 30, 2024 and 2023, respectively. The net cash used in operating activities during the nine months ended September 30, 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 nine months ended September 30, 2024 compared to the corresponding period in 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 \$714.9 million and \$225.4 million for the nine months ended September 30, 2024 and 2023, respectively. The increase in the nine months ended September 30, 2024 is due to the purchase of marketable securities, partially offset by the maturities of marketable securities compared to the corresponding period in 2023.

Net cash provided by financing activities was \$1,181.7 million and \$45.2 million for the nine months ended September 30, 2024 and 2023, respectively. The increase in 2024 is due to net proceeds received from the issuance of common stock in our underwritten offering in May 2024, proceeds from our new ATM program, and proceeds from exercise of stock options and our ESPP in the nine months ended September 30, 2024.

Contractual Obligations

There were no material changes outside of the ordinary course of business in our contractual obligations during the nine months ended September 30, 2024 from those disclosed in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Contractual Obligations" in our [Annual Report on Form 10-K for the year ended December 31, 2023](#).

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

There have been no material changes to our critical accounting policies and estimates as disclosed in our [Annual Report on Form 10-K for the year ended December 31, 2023](#). For the required interim disclosure updates related to our

accounting policies and estimates, see *Note 2 - Summary of Significant Accounting Policies* in this Quarterly Report on Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of September 30, 2024, our cash and cash equivalents were in cash accounts and money market funds. Our investments in money market funds are not insured by the federal government. As of September 30, 2024, we had \$1.0 billion in marketable securities.

As of September 30, 2024, we had \$575.0 million of 2028 Convertible Notes outstanding. Our 2028 Convertible Notes bear interest at a coupon rate of 0.75%. In addition, as of September 30, 2024, we had a \$350 million Term Loan and a \$150.0 million Royalty Financing Agreement outstanding. The Term Loan accrues interest quarterly at the SOFR subject to a floor of 2.5%, plus a margin of 7.75% per annum. We entered into the Swap Contract as a hedge to the Term Loan variable interest rate. The Royalty Financing Agreement requires a Revenue Interest Payment of 4% 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 September 30, 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 and during the nine months ended September 30, 2024 and 2023, our results of operations were not materially affected by fluctuations in foreign currency exchange rates.

ITEM 4. 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 September 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended (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 as of September 30, 2024, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are party to various lawsuits, claims and other legal proceedings that arise in the ordinary course of our 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 1A. RISK FACTORS

Our business is subject to substantial risks and uncertainties. You should carefully consider the information contained in this Quarterly Report on Form 10-Q and the risk factors and other information contained in our other public filings in evaluating our business, including our [Annual Report on Form 10-K for the year ended December 31, 2023](#), which was filed with the SEC on February 22, 2024. Any of the risks and uncertainties described herein and in our other filings with the SEC, 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 Form 10-Q (please read "Cautionary Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q).

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, preclinical 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 Biotechnologies Inc. to provide our clinical and commercial supply of ARIKAYCE, and intend to also rely on Patheon in the future. We currently primarily rely on Esteve Pharmaceuticals, S.A. 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 Development, L.P., our CRO for the ARISE, ENCORE, ASPEN, BiRCh, and TPIP trials, and clinical laboratories. In addition, we rely on third parties to manufacture clinical materials for our early-stage 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 purchase services or products from, or otherwise collaborate with, any "biotechnology company of concern," which includes certain Chinese biotechnology companies, without losing the ability to contract with, or otherwise receive funding from, the US government. 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On August 4, 2021, the Company acquired all of the equity interests of Motus, a privately held, preclinical stage company. Among other consideration, in connection with the acquisition of Motus, 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 and is obligated to issue to the Motus equityholders up to 5,348,572 shares in the aggregate upon the achievement of certain development and regulatory milestone events, in each case, subject to certain reductions. On August 2, 2024, the third anniversary of the closing date, the Company fulfilled the payment due on such date by issuing 182,182 shares of the Company's common stock to the Motus equityholders. These shares of common stock were issued pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the Securities Act), and the number of such shares was

calculated based on a per-share value of \$27.11. The Company did not receive any proceeds from the issuance of common stock to the Motus equityholders.

On January 6, 2023, the Company acquired Vertuis, a privately held, preclinical stage company. Among other consideration, in connection with the acquisition of Vertuis, the Company was obligated to issue to Vertuis equityholders, on July 1, 2024, shares of the Company's common stock having an aggregate value of \$1.0 million, based on the share price on June 28, 2024. On July 1, 2024, the Company fulfilled the payment due by issuing 14,773 shares of common stock to the Vertuis equityholders. These shares of common stock were issued pursuant to Section 4(a)(2) of the Securities Act. The Company did not receive any proceeds from the issuance of common stock to the Vertuis equityholders.

On June 27, 2024, the Company issued a redemption notice for its 2025 Convertible Notes, with a Redemption Date of August 9, 2024. 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 during the third quarter of 2024. The shares of the Company's common stock issued to the holders of the 2025 Convertible Notes in connection with such conversions were issued pursuant to Section 3(a)(9) of the Securities Act. The Company did not receive any proceeds from the issuance of common stock to the holders of the 2025 Convertible Notes.

From July 2024 through September 2024, holders of ten thousand dollars of aggregate principal amount of 2028 Convertible Notes elected to convert their notes, resulting in an issuance of an aggregate of 306 shares of the Company's common stock. The shares of the Company's common stock issued to the holders of the 2028 Convertible Notes were issued pursuant to Section 3(a)(9) of the Securities Act. The Company did not receive any proceeds from the issuance of common stock to the holders of the 2028 Convertible Notes.

ITEM 5. OTHER INFORMATION

Rule 10b5-1 Trading Plans

Our policy governing transactions in our securities by our directors, officers and employees permits our directors, officers and employees to enter into trading plans complying with Rule 10b5-1 under the Exchange Act. The following table describes the written plans for the sale of our securities adopted, modified or terminated by our executive officers and directors during the third quarter of 2024, each of which was entered into during an open trading window and is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) (each, a Trading Plan).

Name and Title	Date of Adoption of Trading Plan	Scheduled Start Date of Trading Plan	Scheduled Expiration Date of Trading Plan (1)	Maximum Shares Subject to Trading Plan	Date Terminated
S. Nicole Schaeffer Chief People Strategy Officer	8/15/2024	1/13/2025 ⁽²⁾	08/01/2025	129,440	N
Sara Bonstein Chief Financial Officer	8/23/2024	1/21/2025	06/30/2025	65,033	N
Roger Adsett Chief Operating Officer	9/6/2024 ⁽³⁾	1/08/2025	02/28/2025	97,769	N
William Lewis ⁽⁴⁾ Chief Executive Officer	9/12/2024	12/12/2024	06/17/2025	477,146	N

(1) A Trading Plan may expire on an earlier date if all contemplated transactions are completed before such Trading Plan's expiration date, upon termination by broker or the holder of the Trading Plan, or as otherwise provided in the Trading Plan.

(2) Scheduled start date is contingent on the completion or expiration of Ms. Schaeffer's previously adopted Trading Plan.

(3) Modifying a Trading Plan adopted by Mr. Adsett on March 13, 2023.

(4) In Mr. Lewis' individual capacity and his capacity as co-trustee of the Katie Proctor Dynasty Trust.

ITEM 6. EXHIBITS

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 (effective as of May 11, 2023) (incorporated by reference from Exhibit 3.1 to Insmed Incorporated's Current Report on Form 8-K filed on May 11, 2023).
- [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 2002.
- [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 2002.
- [32.1](#) Certification of William H. Lewis, Chair and Chief Executive Officer (Principal Executive Officer) of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
- [32.2](#) Certification of Sara Bonstein, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
- 101 The following materials from Insmed Incorporated's quarterly report on Form 10-Q for the quarter ended September 30, 2024 formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of September 30, 2024 and December 31, 2023, (ii) Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2024 and 2023, (iii) Consolidated Statements of Shareholders' Deficit for the three and nine months ended September 30, 2024 and 2023, (iv) Consolidated Statements of Cash Flows for the nine months ended September 30, 2024 and 2023, (v) Notes to the Unaudited Consolidated Financial Statements, and (vi) Cover Page.
- 104 The cover page from the Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, formatted in iXBRL and contained in Exhibit 101.

SIGNATURE

Pursuant to the requirements 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.

INSMED INCORPORATED

Date: October 31, 2024

By /s/ Sara Bonstein
Sara Bonstein
Chief Financial Officer
(Principal Financial and Accounting Officer)

Section 302 Certification

I, William H. Lewis, Chief Executive Officer of Insmed Incorporated, certify that:

- (1) I have reviewed this quarterly report on Form 10-Q 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: October 31, 2024

/s/ William H. Lewis

William H. Lewis
Chair and Chief Executive Officer
(Principal Executive Officer)

Section 302 Certification

I, Sara Bonstein, Chief Financial Officer of Insmed Incorporated, certify that:

- (1) I have reviewed this quarterly report on Form 10-Q 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: October 31, 2024

Sara Bonstein

Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2003**

In connection with this Quarterly Report on Form 10-Q of Insmed Incorporated (the "Company") for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William H. Lewis, 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)

October 31, 2024

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2003**

In connection with this Quarterly Report on Form 10-Q of Insmed Incorporated (the "Company") for the period ended September 30, 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)

October 31, 2024

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.