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DELTA REPORT

10-K

2SEVENTY BIO, INC.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	4341
CHANGES	289
DELETIONS	2024
ADDITIONS	2028

REFINITIV

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022 December 31, 2023

OR

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

For transition period from to

Commission File Number 001-40791

2seventy bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**86-3658454**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

60 Binney Street
Cambridge, Massachusetts 02142
(339) 499-9300 (617) 675-7270

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**TSVT**	**The Nasdaq Stock Market LLC**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

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

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

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

The aggregate market value of common stock held by non-affiliates of the registrant based on the closing price of the registrant's common stock as reported on the Nasdaq Global Select Market on June 30, 2022 June 30, 2023, the last business day of the registrant's most recently completed second quarter was $496,765,830. $508,404,846.

The number of shares of registrant's common stock outstanding as of March 8, 2023 February 29, 2024 was 50,189,753. 51,311,132.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A relating to the 2023 2024 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2022 December 31, 2023. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "intends", "plans", "anticipates", "believes", "estimates", "predicts", "potential", "continue" or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our post-separation relationships with bluebird bio, Inc., or bluebird bio, third parties, collaborators and our employees;
- our and Bristol Myers Squibb's, (BMS) or BMS, plans for the continued commercialization of *Abecma* and the development and commercialization of earlier lines of therapy;
- our ability to operate as a stand-alone company and execute our strategic priorities;
- our ability to finance our operations and business initiatives and obtain funding for such activities;

- the anticipated benefits of the sale of our oncology and autoimmune research and development programs, clinical manufacturing capabilities, and related platform technologies to Regeneron Pharmaceuticals, Inc., or Regeneron, which we refer to in this Annual Report as the Asset Sale;
- the timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching, and commercializing our product candidates;*Abecma*;
- the perceived therapeutic benefits of *Abecma* and the potential indications and market opportunities therefor;
- our plans with respect to the development, manufacture or sale of our*Abecma* or future product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies;
- the operational capabilities and timelines with respect to our in-house manufacturing facility;
- sourcing supplies for the materials used to manufacture our product candidates;*Abecma*;
- the safety profile and related adverse events of our product candidates;
- *the perceived therapeutic benefits of our product candidates and the potential indications and market opportunities therefor;* *Abecma*;
- U.S. and foreign regulatory requirements for our product candidates,*Abecma*, including any post-approval development and regulatory requirements, and the ability of our product candidates*Abecma* to meet such requirements;
- our ability to attract and retain key employees needed to execute our business plans and strategies and our expectations regarding our ability to manage the impact of any loss of key employees;
- our ability to obtain and maintain intellectual property protection for our product candidates and the strength thereof;
- our future financial performance, including estimates of our future revenues, expenses, cash flows, profitability, tax obligations, capital requirements and our needs for additional financing, liquidity sources, real estate need and concentration of voting control, as well as the timing and drivers thereof, and internal control over financial reporting;
- our ability to compete with other companies that are or may be developing or selling products that are competitive with *Abecma*;
- our product candidates; post-separation relationships with bluebird bio, Inc., or bluebird bio, third parties, collaborators and our employees;
- the status of government regulation in the life sciences industry, particularly with respect to healthcare reform;
- the potential benefits of strategic collaboration agreements;

- potential indemnification liabilities we may owe to bluebird bio after the separation;
- our business and operations following the separation and any benefits or costs of the separation, including the tax treatment of the separation, the tax treatment of the distribution, and limitations imposed on us under the tax matters agreement that we entered with bluebird bio in connection with the separation and distribution; separation;

- the impact of rising inflation rates on our business, financial condition and results of operation;
- the fluctuation of the market price of our shares;
- trends and challenges in our current and potential markets; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

Any forward-looking statements in this Annual Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part I, Item 1A, “Risk Factors” and elsewhere in this Annual Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

All of our forward-looking statements are as of the date of this Annual Report only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Annual Report or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report that modify or impact any of the forward-looking statements contained in this Annual Report will be deemed to modify or supersede such statements in this Annual Report.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Annual Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

Summary of the Material and Other Risks Associated with Our Business

- We are a cell and gene therapy company with a limited operating history as an independent company. To date, we have not recognized any revenues from the sale of products by us. Our revenues have been derived

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from out-licensing arrangements and collaboration arrangements, including the collaboration revenue derived from sales of *Abecma* by BMS. We may never become profitable.

- We have Our business has incurred significant operating losses in recent periods and we anticipate that we will incur continued losses for the foreseeable near future.
- We will require may need to raise additional capital funding to advance *Abecma* and finance our operations, which may not be available to us on acceptable terms, or at all. If we are unable Failure to raise obtain capital when needed or on attractive terms, we would be forced may force us to delay, scale back limit or discontinue some terminate development or commercialization efforts or other operations. Raising additional capital may dilute our existing stockholders, restrict our operations or cause us to relinquish valuable rights.
- Our strategic realignment to focus the Company on the development and commercialization of *Abecma* may not be as successful as anticipated, fail to achieve the anticipated cost savings, and cause disruptions in our product candidate development programs or pre-commercialization efforts. business that could make it difficult to achieve our strategic objectives.
- We depend heavily on have recently undertaken internal restructuring activities, and may do so again in the success of our lead product candidates, SC-DARIC33 and bbT369. future. The assumptions underlying these activities may prove to be inaccurate, or we may fail to achieve the expected benefits.
- We cannot be certain that we will may not be able to obtain regulatory approval for, successfully or successfully commercialize, any timely complete the Asset Sale, which could materially impact the market price of our current or common stock, as well as our future product candidates. business prospects and our financial condition, results of

operations and cash flows.

- If we experience encounter delays or difficulties in the enrollment of patients recruiting or enrolling subjects in our clinical trials, our receipt of necessary regulatory approvals studies, we could be delayed or prevented.

- prevented from proceeding with clinical trials of *Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any. Abecma*.

- If the market opportunities for *Abecma* or any future approved products are smaller than we believe they are, and if we are not able to obtain, successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.

- Patients receiving T cell-based immunotherapies such as *Abecma* may experience serious adverse events, including neurotoxicity and cytokine release syndrome. Serious adverse events or if there are delays in obtaining, required regulatory approvals both for undesirable side effects associated with *Abecma* or our current or future product candidates we will not be able to commercialize, may result in delays, clinical holds, or will be delayed in commercializing, terminations of our current or future product candidates, and clinical trials, impact our ability to generate revenue obtain or maintain marketing approval, and impact market acceptance and commercial sales, which will be materially impaired.

- Even if we receive regulatory approval for any of significantly harm our current or future product candidates, we will be subject to ongoing obligations business, financial condition and continued regulatory review, which may result in significant additional expense. Additionally, our current or future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drugs.

- Manufacturing our current or future product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our current or future product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped. prospects.

- We rely, are dependent on BMS for the successful development, commercialization and expect manufacture of *Abecma*. If BMS does not devote sufficient resources to continue the commercialization, manufacture and further development of *Abecma*, is unsuccessful in its efforts, or chooses to terminate its agreements with us, our business will be materially harmed.

- We rely on third parties to conduct, supervise and monitor our ongoing clinical studies, and planned clinical trials for our current and future product candidates. If if these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we perform in an unsatisfactory manner, it may not be able to obtain marketing approval for or commercialize harm our current and potential future product candidates and our business could be substantially harmed. business.

- We may experience business interruptions rely on third parties to conduct some or negative market conditions arising out of global crises, including international conflicts, the ongoing COVID-19 global pandemic, or similar public health crises. Such events could cause a disruption of the development all aspects of our lentiviral vector production, drug product candidates manufacturing, and adversely impact our business. Such events testing, and these third parties may contribute to global market conditions that negatively impact our ability to raise needed capital on favorable terms and timelines. not perform satisfactorily.

- If we are unable to obtain and maintain patent and other or protect intellectual property protection for rights related to our technology and approved product or product candidates, or if the scope of the intellectual property protection obtained is we may not sufficiently broad, be able to compete effectively in our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired. markets.

PART I

Item 1. Business

Overview

We are a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. We are led by an accomplished team with significant expertise and experience in this field, from discovery through clinical development to regulatory approval of *Abecma* (idecabtagene vicleucel, or ide-cel), the first chimeric antigen receptor, or CAR, T cell therapy approved by the U.S. Food and Drug Administration, or FDA, for multiple myeloma. Our approach combines our expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. We are advancing multiple clinical programs, including SC-DARIC33, for the treatment of pediatric patients with relapsed and refractory acute myeloid leukemia, or AML, and bbT369, for the treatment of patients with B-cell non-Hodgkins lymphoma, or B-NHL, as well as multiple preclinical programs, including bbT4015, an engineered CAR T cell therapy targeting MUC16. Additionally, together Together with our partner, Bristol Myers Squibb, or BMS, we are delivering *Abecma* to multiple myeloma patients in the United States following approval by the FDA of *Abecma* in March 2021 for the treatment of adults with multiple myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 (cyclic ADP ribose hydrolase) monoclonal antibody.

In recent years, growing understanding of cancer cell metabolism and genomics, as well as of the body's immune response to tumor cells, has led to the development of new classes of therapies against cancer targets and pathways that have dramatically reshaped the treatment landscape. The advent of immunotherapy, particularly engineered cell therapies, has offered the potential to move past the treatment paradigm of maintenance of cancer as a "chronic" disease. Few curative therapies, however, exist and, in some settings, such as solid tumors, current approaches do not offer significant depth or durability of outcome for most cancer types and patients. Monotherapies have historically been of limited efficacy in cancer, and drugs are typically combined to deliver an outsized effect relative to the action of any of the individual components, with one potential advantage of combination therapies being the ability to address the heterogeneity of single target expression and/or mechanisms for relapse and resistance specific to a particular mechanism or target.

While medicines such as On January 29, 2024, we began undertaking a strategic realignment to focus on the development and commercialization of *Abecma* *Abecma.* have highlighted In connection with the power strategic realignment, we entered into an asset purchase agreement with Regeneron Pharmaceuticals, Inc., or Regeneron, to sell to Regeneron substantially all of first-generation CAR T the assets related to our solid tumor and other oncology and autoimmune cell therapy by achieving previously unobtainable levels programs, including our bbT369 program in b-NHL, SC-DARIC33 in AML, MUC16 in ovarian cancer, MAGE-A4, autoimmune, and several unnamed targets. Upon closing of efficacy the transaction, which is subject to customary closing conditions, Regeneron will assume all of the ongoing program, infrastructure and personnel costs related to these programs. The transaction is expected to close in the late line setting, we believe that to be broadly successful in the treatment first half of cancer, a combination therapy approach is necessary, and that our multiplex approach to next-generation autologous cellular therapy, which allows multiple encoded mechanisms of action to be delivered within a single drug product, may be a potential solution. Based on our experience in the research and development of 2024.*Abecma*, we believe we can develop next-generation, engineered cell therapies to bring new options to patients suffering from a broad range of different tumor types.

In designing our next-generation product candidates, we aim to address the limitations of first-generation T cell therapies by augmenting them with additional technologies. These limitations include: (1) targeting a single tumor-associated antigen that may be lost or down regulated; (2) heterogeneous target expression resulting in the sparing of tumor cells devoid of antigen; (3) expression of immunosuppressive molecules such as transforming growth factor-β, or TGFβ, or programmed death ligand 1, or PD-L1, in the tumor microenvironment; and/or (4) poor T cell engraftment and persistence.

Our Approach

Our approach is to create product candidates that are multiplex engineered cell therapies by combining: (1) CAR and T cell receptor technology, which programs T cells to recognize and kill cancer cells based on the cell surface expression or presentation of intracellular protein targets, respectively; (2) dual-targeting CAR architecture for multi-target tumor cell recognition; (3) our core lentiviral gene transfer technology which delivers these genetic cargos (and more) to program a patient's own T cells to the kill the cancer cells; (4) our megaTAL-based gene-editing technology which allows us to perform site specific gene addition or deletion from the genome to improve

the properties of the T cell; and (5) genetically encoded technologies for engineering T cells to enhance the cytotoxic activity and reprogram the tumor microenvironment for more effective anti-tumor responses. This approach is differentiated by: (1) careful analysis of clinical and correlative data with the goal of precisely defining the key attributes of a cellular therapy necessary for anti-tumor effect; (2) the ability to design and then engineer a cell with these key attributes; combined with (3) a technology suite capable of delivering multiple innovations within a single drug product.

We believe this approach will allow us to address began developing the challenges of achieving deep and durable clinical benefit to patients with cancers. We believe the ability of tumors to evade the immune system and to escape the action of a single drug intervention can be addressed by cellular therapies pre-armed with multi-layered strategies for tumor eradication and control. These multiplex cell therapies may have the potential to achieve a depth and durability of response, independent of the tumor type, that is not measured in weeks, but in months or years. We believe that our approach will allow us to improve how cell and gene therapies are discovered, developed, and manufactured, with the potential to transform the care of patients with cancer. For example, bbT369, our product candidate for B-NHL, uses multiple technologies in order to address the two main modes of failure observed with CD19-targeted T cell approaches: loss or diminution of antigen expression and reduction in T cell activation through loss or diminution of co-receptor signaling.

We believe that our past experience in the clinical setting also provides us with a unique advantage, given the relative nascency of the CAR T cell field and the consequent paucity of large data sets of autologous cellular therapies in cancer. We, including through our collaborators at BMS, have treated hundreds of patients with multiple myeloma in the clinical setting, and the clinical and correlative data sets from our collaboration with BMS provide us with a deep understanding of the biology of the tumor itself, its interplay with immune cells, and which cell therapy attributes may be key to patient response. We believe that understanding is critical to identifying the key barriers in the treatment of the cancer. Specifically, we believe that understanding the heterogeneity of target expression combined with any tumor-specific mechanisms of immune evasion at play can help define the

components of a cellular therapy with the potential for maximal anti-tumor activity. This understanding will be key to our product candidate design and selection, manufacturing process design and execution, and clinical trial design and development strategy.

In designing our next-generation product candidates, we start with the concept of a tumor-redirected T cell (via CAR or engineered T cell receptor, or TCR, technology) and then add one or more additional features or components from the suite of proprietary technologies we have developed with the purpose of overcoming specific limitations of first-generation T cell therapies. For example, these additional technologies may address:

- Tumor targets with off-tumor expression, through the application of our regulatable CAR T technology, dimerizing agent–regulated immunoreceptor complex, or DARIC;
- Immunosuppressive molecules in the tumor microenvironment, through the application of our chimeric TGFβ flip receptor, or CTBR, technology which turns a suppressive signal into a T cell supportive interleukin receptor signal;
- Antigen loss or down-regulation resulting in escape, through application of our dual-targeting CAR T cell technology; or
- Incomplete T cell activation or proliferation resulting in a loss of T cell potency, through the implementation of synergistic co-stimulatory pathways and the application of our gene-editing technology to knock-out intracellular checkpoints.

Our clinical programs in B-NHL and AML are illustrations of our multiplex approach, applied to address the specific challenges of treating those cancers:

We are developing our bbT369 product candidate as a potential treatment for patients with B-NHL. The advent of the first generation of anti-CD19 Anti-CD19 CAR T products represents a significant advancement in are considered the field of B-NHL and has established a new standard for the treatment of patients with relapsed and refractory B-NHL. However, more than half of patients treated with an anti-CD19 CAR T do not achieve durable remission. Prognosis remains poor for these patients, with median overall survival after axicabtagene ciloleucel, or axi-cel, of approximately six months for patients initially responding and less than two months for patients without initial response. The main B-NHL, but they have limitations, of the first-generation CAR T therapies are including the lack of complete response in some patients and the potential for late relapse, indicating a need for deeper and more durable treatment responses. We take took a differentiated approach from the approved anti-CD19 CAR T therapies: we have designed a dual-targeting CAR to target CD20 and CD79a to limit antigen escape (as has been seen with CD19-targeted therapies). We provide provided split co-stimulation to drive maximal activation of the T cell in response to antigens. We include included a gene edit designed to drive increased expansion, resist anergy, and maintain potency in sub-optimal conditions for T cell activation. Clinical study CRC-403, an open-label, multi-site Phase 1/2 dose-escalation study of bbT369, will serve served as a potential proof-of-concept assessment of our proprietary gene editing platform, dual-targeting strategies and split co-stimulation signaling technology. Dosing in the first cohort of CRC-403 was completed in 2022, and the trial is currently enrolling patients at the second dose level. patients.

We are began developing our SC-DARIC33 product candidate as a potential treatment for pediatric and young adult patients with relapsed or refractory AML. Although CAR T therapy has shown transformative potential and durable efficacy in other hematologic tumors, the use of CAR T therapy in the treatment of AML has been complicated by the expression of key targets such as CD33 across healthy myeloid cells in addition to leukemic blasts and stem cells. In other words, a highly potent CAR T cell directed towards one of these targets carries the significant risk of “on-target, off-tumor” toxicity because of broad myeloid aplasia. In developing SC-DARIC33 as a potential treatment for patients with AML, we seek to address the challenge of balancing potency and safety risk by combining advanced CAR T receptor technology with our DARIC technology, a pharmacologically controlled “on-off” switch to reversibly regulate the activity of the CAR T cell. We have designed the CAR to target both full-length and alternatively spliced CD33 variants to address heterogeneity in the disease, and to reduce the risk of antigen escape and disease relapse. We believe that the DARIC switch will give treating physicians the ability to turn off highly potent CAR T cell activity to allow for myeloid recovery, while being able to re-activate CAR T cell activity on demand. PLAT-08, the investigator-initiated proof-of-concept Phase 1 clinical trial of our SC-DARIC33 product candidate in pediatric and young adult relapsed or refractory AML patients, is led by our partner Seattle Children’s Therapeutics, a non-profit enterprise associated with Seattle Children’s Research Institute, or SCRI. The PLAT-08 trial is nearing completion of has completed the mandatory adult dosing phase, and the totality of initial data to-date suggests SC-DARIC33 activation by rapamycin. The PLAT-08 trial will allow us was designed to further assess our DARIC platform in light of the rapamycin-induced activation of SC-DARIC33 and potential for marrow recovery following rapamycin withdrawal. In August 2023, the FDA placed the study on clinical hold due to a fatal (Grade 5) serious adverse event, or SAE, in a patient enrolled in the Phase 1 trial of the PLAT-08 study. The clinical hold was lifted by the FDA in December 2023.

Our Strengths

We believe that the capabilities and experience that our team has accrued provide us with an opportunity to capitalize on recent progress in the understanding of genetics, gene-editing, gene expression, tumor biology, immunology, process analytics, computational biology and data analytics to discover, develop and bring to the market next-generation commercialize cell and gene therapies for cancer:

- ***Extensive suite of gene modification technologies allows us to create multiplex product concepts:*** We have access to a broad range of technologies that we can leverage to design product candidates that aim to address the challenges of specific cancers. With internal capabilities to knock-in, knock-out, modify, and control expression of genes across multiple modalities with gene addition, gene-editing, cell engineering, and synthetic biology approaches, we have the ability to apply a combination of technologies to design potential multiplex next-generation cell and gene therapies for cancer.

- ***Deep clinical experience and expertise with data science-driven iteration:*** From having treated hundreds thousands of patients with multiple myeloma in CAR T programs through our collaboration with BMS, we have gained a deep understanding of cell therapy itself as well as an appreciation for the value of iterating on clinical data to inform our product candidate design, selection, manufacturing, clinical trial design and development strategy. Additionally, we employ data analytics in manufacturing to understand the critical product attributes of successful cellular products.

- ***Manufacturing experience and capability:*** Our team has accumulated significant experience in the manufacturing, analytical testing, and quality aspects from of both lentiviral vectors and autologous lentiviral vector-transduced cellular drug products, from shepherding *Abecma* through clinical development, regulatory approval, and to commercialization in the United States, as well as from bluebird bio's betibeglogene autotemcel in Europe. Moreover, we in partnership with National Resilience Inc., or Resilience, have successfully scaled-up our suspension-based manufacturing process for lentiviral vector, or sLVV, which is being utilized in ongoing clinical trials for ide-cel. We recently added a Phase 1 cell therapy manufacturing facility in our Cambridge headquarters which we believe will enable us to improve the profile and accelerate timelines for the delivery of product candidates to patients. We anticipate the facility will be operational by mid-2023. We believe our experience spanning first-in-human to commercial manufacturing, quality control and quality assurance represents know-how critical to the efficient translation and development of our multiplex product candidates.

- ***Collaboration and connectivity:*** We have a strategic network of collaborations across industry, academic scientists, and medical experts to access technologies and expertise that supplement our proprietary technologies. We believe these collaborations and partnerships provide us with a rich suite of technologies permitting the design of impactful multiplex product candidates.

Who We Are

Our people form the most vital core of our company. We have assembled a diverse group of experienced scientists and researchers, manufacturing subject matter experts and engineers to execute our strategic plan. We have a passionate and energized team with a bold culture of innovation, focused on unleashing the discovery full potential of *Abecma* and development of therapies that we believe may have the potential to be first-in-class or best-in-class. We are committed to the research and development of other future therapeutic approaches that we believe may have the potential to transform the lives of patients with cancer.

Our chief executive officer, Nick Leschly, launched bluebird bio in 2010 and led the growth leadership team has a wide range of the pioneering gene and cell therapy company prior to the separation, leveraging his deep business strategy and entrepreneurial skills built over the last two decades. William "Chip" Baird, our chief financial officer and the chief financial officer of bluebird bio from 2019 until the separation, has more than 20 years of financial and strategic planning experience in the biopharmaceutical sector. Philip Gregory, D. Phil, our chief scientific officer, served as chief scientific officer at bluebird bio from 2015 until the separation. Dr. Gregory has led the scientific development of products for a range of diseases with our three gene therapy technology platforms: gene addition with lentiviral gene delivery, cell therapy and megaTAL-enabled gene-editing.

In addition to our executive leadership team, our company includes 97 individuals with medical or Ph.D. degrees, which include key scientists and researchers who have made important discoveries and progress across our technologies, as well as those industry with deep experience and expertise in building high growth and disruptive companies.

Our Strategy

Our *Abecma* offers significant clinical benefits and long-term potential in the treatment of patients with multiple myeloma and our strategy is to apply our broad range of technologies to design multiplex product candidates that address the key treatment challenges in cancer. Unlike other oncology-focused companies in our space, we believe our breadth of technology enables us to develop tailored products focused exclusively focus on the specific areas development and commercialization of cancer biology we have identified. We selectively combine the relevant features and components from our range of tools and technologies to address the defined attributes of a cellular therapy that we believe are necessary for anti-tumor effect.

To execute on our strategy, we plan to:

- Co-commercialize *Abecma*, including clinical expansion to earlier lines of therapy, through our collaboration with BMS, and leverage our clinical and operational experience under this collaboration and this product revenue stream to further invest in our next-generation proprietary programs. BMS.

- We expect a final PDUFA action following the planned Oncologic Drugs Advisory Committee, or ODAC, meeting on March 15, 2024 regarding the supplemental Biologics License Application, or sBLA, for *Leverage our leadership position in autologous CAR T therapies to advance through Abecma* based on the clinic our next-generation programs in B-NHL, AML, and multiple myeloma. KarMMA-3 clinical study. If approved, the sBLA would expand the *Abecma* label into the larger third line

- setting. We, along with BMS, plan to expand the *Apply our multiplex approach Abecma* site footprint to enable more patients to access the discovery treatment. This includes educating physicians on treatment sequencing and design the emerging data supporting the use of transformative cell BCMA-directed CAR Ts before other BCMA-targeted

therapies, and gene therapy products for competitively differentiating *Abecma*'s real-world safety, efficacy and product reliability and predictability profile. We will continue to support the treatment quality control of solid tumors.

- Seek to extend our approach to other cell types beyond T cells and to include off-the-shelf approaches, as we gain additional experience in our autologous T cell programs.
- Build upon our existing internal the lentiviral vector, or LVV, manufacturing know-how for *Abecma* and experience through both selective investments in manufacturing collaborations support the transition to suspension LVV which will deliver additional efficiencies and through our internal capabilities, including the build-out of our drug product manufacturing capabilities at our Cambridge, Massachusetts headquarters. The facility, which we anticipate will be operational by mid-2023, is designed to enable rapid translational research in our clinical trials, as well as allow us to manufacture drug product for preclinical and Phase 1 clinical development activities, over time, with the objectives of enabling rapid iteration on clinical learnings into research and development, increasing the efficiency of manufacturing processes, and improving the overall patient and healthcare professional experience. cost savings.

Background

Cancer is a leading cause of death worldwide. It is characterized by the uncontrolled growth of cells that have the ability to evade recognition by the immune system's surveillance. Cancer cells are abnormal cells that have developed mutations in essential cellular functions, driving increased cell division and growth as well as acquiring the ability to escape immune surveillance. In recent years, increased knowledge about cancer cell metabolism and genomics, as well as about the body's immune response, has led to new classes of therapies against cancer targets and pathways that have dramatically reshaped the treatment landscape. Despite these advances, there remains a high unmet medical need for additional products and treatments, especially for patients with recurrent tumors or cancer types that are resistant to current therapeutic options.

The advent of immunotherapy, and specifically engineered cell therapies, has offered the potential to move past the treatment paradigm of treatment of cancer as a "chronic" disease. By using engineered T cells, the first generation of engineered cell therapies directed the body's natural immune response against cancer cells. Compelling efficacy data in cancers with historically bleak outcomes, with patients experiencing deep responses lasting for extended periods of time across multiple indications, showed the potential for engineered cell therapy to achieve a functional cure for some patients. However, there remain major tumor types that do not respond to current cell and gene therapy approaches, and, even within tumor types where cell and gene therapy has been broadly successful, many patients fail to receive an optimal outcome.

Challenges that remain in the discovery and development of engineered cell therapies for cancer reflect the difficulties in striking balance between efficacy and safety in these therapies. These challenges include:

- **Selecting an appropriate target tumor antigen.** If a potential cancer target antigen is also expressed or presented on normal tissues, the risk of on-target, off-tumor toxicity is increased. If an engineered T cell is designed to target a singular antigen, the risk of tumor escape mechanisms increases. Similarly, if the expression of the antigen is reduced or lost due to selective pressure or due to cellular internalization, the risk of tumor escape increases. If any of these occur, the safety and/or efficacy of the engineered cell therapy would be compromised.
- **Engineering an optimal receptor.** The properties of the receptor and receptor construct are critical for the overall success of the therapy. These properties include the affinity and flexibility of the antigen-binding domains (which are important for tumor-specific recognition), and the co-stimulatory domains for CAR T cell activation (which are important for the metabolism, function and persistence of T cells).
- **Complex manufacturing.** The manufacture of individualized cell and gene therapies may be lengthy and complex. Patients typically wait approximately three weeks to two months to be treated with autologous engineered cells, and, in the meantime, such patients may experience complications or progressions from underlying disease without bridging therapies, which may introduce additional risk and toxicities for the patients, rendering them ineligible for treatment. In addition, the "process is the product" in the case of engineered cell therapies because of the complex nature of their manufacture, as compared to other common biologically derived modalities such as recombinant proteins and antibodies. Such therapies are inherently more complex to characterize and control, in part due to the variability of collected cells from the individual patients. Further, the process and analytical sciences to enable scale-up for commercial manufacturing are still significantly less advanced than that of proteins and antibodies, which limits access to patients.

Recent significant progress in the understanding of genetics, gene-editing, gene expression, tumor biology, immunology, process analytics and computational biology have converged to create an opportunity to markedly increase the breadth and depth of the potential impact of cell and gene therapies, and we believe that our capabilities provide us with an opportunity to capitalize on this opportunity to discover, develop and bring to the market next-generation cell and gene therapies for cancer.

Our Technologies

Our oncology programs use a lentiviral vector to deliver the genetic cargo with the potential to program a patient's own T cells to recognize specific proteins or protein fragments on the surface of cancer cells to kill the cancer cells. Our current programs are based on CAR technology designed to program T cells to recognize cancer cells based on

expression of specific cell surface antigens, and T cell receptor technology designed to program T cells to recognize cancer cells based on protein fragments derived from either intracellular or extracellular proteins displayed on the tumor cell surface. The genetically engineered T cells are designed to supplement a patient's immune system and we believe they have the potential to be further engineered to overcome immune evasion mechanisms employed by cancer cells. Our approach is to create multiplex engineered cell therapies by combining our foundational lentiviral vector and CAR/TCR technology with next-generation tools to address the challenges in existing cancer treatments. Certain of our technologies, described below, that relate to our solid tumor and other oncology and autoimmune cell therapy programs, will be sold to Regeneron upon the closing of the Asset Sale. See "Business - Overview".

- **Abecma.** *Abecma* uses a lentiviral vector, or LVV, to deliver a chimeric antigen receptor, or CAR, with the potential to program a patient's own T cells to recognize the plasma cell specific B cell maturation antigen, or BCMA, protein on the cell surface. BCMA is an ideal target in multiple myeloma, or MM, since it is near universally and abundantly expressed on both normal and malignant plasma cells, independent of disease stage, and its expression is absent from other normal tissues resulting in a robust therapeutic window. We have developed, patented or licensed critical technologies to the generation of *Abecma*. To recognize BCMA as a target, we performed multiple extensive screening campaigns to identify the ideal binder and CAR construct to ensure both low tonic signaling in the absence of antigen and robust efficacy in in vitro and in vivo models of MM. We have secured an exclusive license to the selected binder used in *Abecma* as well as several back up constructs. The *Abecma* CAR construct exploits both CD3z and 4-1BB signaling domains believed to result in a more progressive proliferation response that may give the CAR T cells improved persistence over CD28 based co-stimulation. The persistence of functional CAR T cells is likely a critical determinant of both the depth and the duration of response and as such *Abecma* is designed to achieve these key characteristics. We have developed improved methods for the generation and purification of LVVs, including suspension-based LVVs, which enable the generation of the vector used in drug product manufacture at significantly greater scale and lower cost. The suspension-based LVV manufacturing method has been established at Resilience, and we have generated the data required to support analytical comparability to adherent vector. Following a successful prior approval supplement (PAS) with the FDA, suspension-based LVV will be implemented into the *Abecma* commercial manufacturing processes. Our drug product manufacturing process was designed for simplicity and reproducibility. Our peripheral blood mononuclear cells (PBMC)-based drug product manufacturing process was designed for simplicity and reproducibility and employs a centralized manufacturing site model.

- **Dual-Targeting.** Polyclonal responses are a hallmark of adaptive immunity, but most T cell therapies have been devised with antigen receptors specific to a single target antigen. There are many documented cases of cancer deploying its intrinsic genetic plasticity to escape mono-targeted T cell therapies (both with cellular and more classical modalities, such as small molecules and antibodies). In such cases, our solution is to utilize a dual-targeting antigen receptor, including a multi-chain, dual-targeting architecture, to respond when either target antigen is present on a cancer cell, as well as an architecture that leverages the unique properties of humanized single-domain camelid-derived antibodies.

- **DARIC.** We have developed a dimerizing agent–regulated immunoreceptor complex, which we refer to as DARIC, that comprises separate antigen targeting and signal transduction componentry. DARIC receptors become poised for anti-tumor function only when the two components are brought together as heterodimers, a process that is strictly dependent on the bridging function of the drug rapamycin. This technology can enable pharmacological, "on-demand" control of engineered T cell responses. Controlling the "on" and "off" states of engineered T cells also creates opportunities to pursue cancers and cancer targets with disease characteristics and expression profiles that are incompatible with constitutively responsive antigen receptors.

- **Reversal of immunosuppression.** Patients who present in the clinic with advanced metastatic disease host tumors that have evolved to evade endogenous immunity via a variety of mechanisms. Tumor infiltrating T cells lose potency over time due to repetitive antigen stimulation and exhaustion in a tumor microenvironment that suppresses T cell function. Checkpoint engagement, hypoxia, poor nutrient conditions, and exposure to immunosuppressive cell types and cytokines all significantly blunt T cell potency and thwart attempts to regress tumors in clinically meaningful ways. We have developed a suite of synthetic biology innovations that antagonize and rewire immunosuppressive signaling and response pathways. We have focused significant attention on TGFβ, a profoundly immunosuppressive cytokine found at high levels in many solid tumors. Our chimeric TGFβ flip receptor, or CTBR, technology converts this suppressive signal into a supportive interleukin receptor signal that enhances T cell function. Suppressive to enhancing signal conversion operates in a localized, engineered T cell intrinsic manner, enhancing potency within the microenvironment of the tumor where the highest concentrations of activated TGFβ ligand are present. We have also developed several approaches to modulate T cell metabolism to allow for enhanced function and potency in the metabolically challenging tumor microenvironment.

- **Co-stimulation.** Parallel track costimulatory domains, also known as chimeric costimulatory receptors, offer a unique set of functional attributes that culminate in enhanced anti-tumor activity. This technology pairs enhanced targeting breadth with a qualitatively distinct and more potent functional response, simultaneously countering two potential mechanisms of resistance.

- **Gene-editing.** megaTALs are highly specific, compact nucleases that efficiently catalyze the formation and mutagenic resolution of double-stranded breaks at pre-specified genetic target sequences. Using our megaTAL gene-editing platform, we have demonstrated that disrupting genes that intersect with T cell signaling and response pathways can promote more potent immune responses. In addition, we have developed a full suite of on-target editing assays, functional bioassays, and off-target discovery and verification analytics to deeply characterize gene-editing events and their functional consequences in target cells, which may enable the potential application of this technology in the clinical setting.

- **mRNA capabilities.** We have also developed messenger RNA, or mRNA capabilities that enable transient gene expression, both in cells cultured ex vivo and for organ-specific in vivo delivery. We manufacture mRNA starting from a proprietary plasmid template outfitted with an encoded poly-A tract, an approach that results in highly homogenous mRNA species following in vitro transcription. Our purification process includes double-stranded RNA, or dsRNA depletion steps to minimize immunogenicity and optimize cell viability. A robust suite of analytical assays is in place to ensure that consistently pure and potent material is generated. We have developed clinical-scale electroporation processes for ex vivo mRNA delivery and are actively using these processes to improve T cell potency via our megaTAL gene-editing platform. This technology can potentially be further leveraged to transiently express other factors that may be advantageous to ex vivo manufactured T cells.

In addition, we continue to invest in our core foundational technologies and build upon our leadership position in autologous engineered cell therapy products based on CAR and TCR approaches:

- **Next-generation lentiviral vector design.** With a management team that collectively possesses decades of experience in this technology, we have extensively refined the componentry and methodology behind lentiviral vector design and manufacturing. Our transfer plasmid design elements include several innovations that have created advanced gene expression tuning capabilities and the delivery of large and complex genetic payloads via transgene stacking. We have developed proprietary codon optimization algorithms, promoter variants, and regulatory elements that we believe together enable constitutive and/or responsive expression profiles across a range of transgene expression levels. These mature capabilities enable highly efficient transfer of sophisticated genetic modules, such as the multiplex product concepts represented by our next-generation programs.

- **Target selection and validation.** Cancer targets with profiles that make them appropriate for cell therapy development have diverse structural features, biochemical properties, and sub-cellular distribution characteristics. To support novel target identification, we have developed significant in-house expertise and external collaborations in the areas of data mining, functional genomics, and primary tissue analysis. We have also built a full suite of target validation assays to perform confirmatory studies assessing tumor and normal tissue expression properties. In addition, we have developed significant internal expertise specifically aimed at de-risking potential off-target liabilities of TCR engineered T cells. We have focused the bulk of our efforts on select hematological and solid tumor indications. We believe this approach allows us to deeply interrogate the target landscape in cancers where T cell therapies may have the highest potential for technical success.

- **Receptor engineering.** We have access to state-of-the-art binder capabilities through our collaboration arrangements that cover the full range of potential cancer targets. For intracellular targets of interest, our partners develop TCRs and fully humanized “peptide-in-groove”, or PiG, single-chain variable fragment, or scFv, reagents. For surface proteins, we have multiple providers of immunization-sourced, fully humanized scFv and single-domain reagents.

- **Manufacturing process innovations.** Our analytical and process development, clinical bioassays, correlative research, and data sciences teams have exceptional access to clinical trial data using CAR T therapies. We are regularly interrogating these data sets to isolate key manufacturing variables and correlates of clinical signals that enable hypothesis testing. These activities derive insights that inform process research directions for optimizing T cell manufacturing through reagents, processes, and culture timing, and for the discovery of underlying biological relationships between clinical and correlative data.

Our Programs

B-Cell Non-Hodgkin’s Lymphoma

We are developing our bbT369 product candidate as a treatment for patients with B-NHL, a heterogeneous group of neoplasms that can result in enlarged nodes across the body, neck, and abdomen, often coinciding with “B-symptoms” that are significant to the prognosis and staging of the disease, such as fever, drenching night sweats, and rapid and extreme weight loss. B-cell NHLs represent more than 85% of all NHL cases worldwide, and we plan to develop bbT369 to treat several subtypes of B-cell NHLs, specifically diffuse large B-cell lymphoma, or DLBCL, high-grade B-cell lymphoma, or HGBCL, primary mediastinal large B-cell lymphoma, or PMBCL, follicular lymphoma, or FL, or transformed follicular lymphoma, or TFL. DLBCL is the most common form of NHL, accounting for a third of all NHL cases, with annual incidence in the United States estimated at approximately 25,000. DLBCL is a particularly aggressive form of NHL that requires immediate therapy upon diagnosis (with a median overall survival of less than one year in untreated patients).

CAR T cells targeting CD19 represent a significant advancement in the field of treatment for B-NHL and established a new standard of treatment for relapsed and refractory patients, with the potential for curative therapy. Specifically, anti-CD19 CAR T products axi-cel, tisagenlecleucel, and lisocabtagene maraleucel have been approved for the treatment of adult patients with relapsed and refractory large B-cell lymphoma (including DLBCL, HGBCL and TFL) after two or more lines of systemic therapy. However, survival for

certain high-risk subtypes (e.g., non-germinal center B-cell-like subtype of lymphoma and double-hit lymphoma) and relapsed and refractory patients is poor. More than half of patients treated with CD19 CAR T do not achieve durable remission. Prognosis remains poor for these patients with median overall survival after axi-cel of approximately six months for patients initially responding and less than two months for patients without initial response. The main limitations of the currently available CAR T treatments are the lack of complete response in some patients, and the potential for late relapse, indicating a need for deeper and more durable treatment options.

Our multiplex approach is intended to enhance the depth and duration of response in patients currently underserved by existing options. bbT369 is a non-CD19-containing CAR T that addresses the limitations of the currently available therapies by using unique layered technologies, designed with the following key features:

- A novel combination of CD20 and CD79a targets that are co-expressed in many B-NHL tumors to both allow treatment of CD19 negative / CD19 low tumors and to limit the potential for antigen escape;
- Split co-stimulation to drive optimal and complete immune signaling; and
- A gene edit to drive increased expansion, resist anergy, and maintain potency in sub-optimal tumor conditions.

In preclinical models, bbT369 clears a variety of B-NHL tumors, including both dual and single target positive tumors, and outperforms CD19 in cells with varying levels of antigen expression. Additionally, the gene edit demonstrates increased cytokine production and expansion in vitro, and when compared to the same dual-targeted, but unedited, construct, bbT369 results in a lower rate of late tumor relapses.

Dosing in the first cohort of clinical study CRC-403, an open-label, multi-site Phase 1/2 dose-escalation study of bbT369 in relapsed and/or refractory B-NHL after autologous SCT or two or more prior lines of therapy, was

completed in 2022. There have been no dose-limiting toxicities observed to-date. The manufacturing success rate and turnaround time are in line with other autologous CAR Ts despite the additional complexity of the product candidate. CRC-403 will serve as a potential proof-of-concept assessment of our proprietary gene editing platform, dual-targeting strategies and split co-stimulation signaling technology. Multiple clinical trial sites are currently recruiting patients who are either naïve to CD19 CAR T or who have relapsed after CD19 CAR T for the second dose level of the trial. The Phase 1 portion will be a dose-escalation study, with the Phase 2 stage allowing continued investigation of these two different patient populations at the recommended dose. The trial will be conducted at four study sites.

Acute Myeloid Leukemia

We are developing our SC-DARIC33 product candidate for the treatment of patients with acute myeloid leukemia (AML). Systemic therapy (including chemotherapy, hypomethylating agents, and targeted biologics) alongside hematopoietic stem cell transplant (HSCT) are the mainstays of AML treatment today. Of note, many adult patients are unfit for such intensive therapy, which in turn leads to less favorable clinical outcomes. Though HSCT provides meaningful clinical benefit to those who are eligible, the unmet need in this heterogenous and aggressive disease remains high. Prognosis is typically poor for adult patients, with a 5-year survival rate of 10-35% depending on disease subtype. In children and adolescents, the 5-year survival rate is 50 to 70%, with variation by subtype and other risk factors as seen in adults. Of note, median overall survival in adults with relapsed and refractory AML is less than 12 months, indicating a particularly high unmet need for these patients.

Although CAR T therapy has shown transformative potential and durable efficacy in other hematologic tumors, their use in the treatment of AML is complicated by the expression of key AML targets, such as CD33, across healthy myeloid cells in addition to leukemic blasts and stem cells. Thus, a highly potent CAR T cell directed towards one of these targets carries the potential risk of significant “on-target, off-tumor” toxicity because of broad myeloid aplasia. Achieving durable remission with a CAR T while balancing the safety risks is a critical challenge for the treatment of AML with CAR T therapy.

We seek to address this challenge with our SC-DARIC33 product candidate, which combines CAR T technology with DARIC, our dimerizing agent-regulated immunoreceptor complex technology. In our SC-DARIC33 product candidate, the traditional components of an anti-CD33 CAR are separated into two subunits which only enable T cell activation in the presence of sub-immunosuppressive doses of rapamycin, an orally-administered small molecule, which functions as an “on-off” toggle switch. In vitro and in vivo studies have shown that this regulated activation is reversible upon withdrawal of rapamycin and can be subsequently re-activated upon re-administration of rapamycin. Our SC-DARIC33 product candidate is designed to utilize this on-off toggle switch in the context of an autologous CD33-directed DARIC-T cell to drive deep responses in AML while “on” and allow myeloid compartment recovery while “off”.

In collaboration with Seattle Children’s Therapeutics, we are enrolling patients in PLAT-08, an investigator-initiated single-center proof-of-concept Phase 1 clinical trial of SC-DARIC33 in pediatric and young adult relapsed or refractory AML patients. This dose-finding trial is aimed at establishing safety, manufacturability, and early efficacy signals for SC-DARIC33 and we expect to conduct correlative analyses to confirm rapamycin-driven regulation in humans. We are nearing completion of the mandatory adult dosing phase, and the totality of the initial data suggests SC-DARIC33 activation by rapamycin. In parallel, we are also advancing next-generation, preclinical product concepts for pediatric and adult AML in partnership with SCRI. These concepts include multiplex targeting and additional enhancement technologies to address the heterogeneity of disease and prevent relapse. Specifically, a next-generation AML product candidate has been selected and will enter non-clinical development in 2023. This new candidate is built off of our new RESET receptor architecture and incorporates dual targeting along with a potency enhancement while retaining the DARIC-like drug regulation. The terms of our arrangements with Seattle Children’s Therapeutics and SCRI are described more fully below under “Strategic Collaborations—Seattle Children’s.”

Multiple Myeloma

Multiple myeloma is a blood cancer caused by malignant plasma cells and typically originates in the bone marrow. In the United States, more than 34,000 35,000 new cases of multiple myeloma are estimated to have been diagnosed in 2021. 2023. Despite advances in treatment, multiple myeloma remains an aggressive and incurable disease characterized by periods of remission and relapse. Most patients experience relapse following initial therapies, and depth and duration of response as well as survival outcomes decrease with each successive treatment. No standard of care has been established for patients who have disease progression despite receiving the three main classes of myeloma therapy (immunomodulatory drugs, proteasome inhibitors, and anti-CD38 antibodies), and outcomes are poor, with very low response rates (20% to 30%), a median progression-free survival of three to four months, and a median overall survival of eight to nine months. Through our collaboration with BMS, *Abecma* (ide-cel) is our lead program in multiple myeloma. The terms of our arrangements with BMS are described more fully below under "Strategic Collaborations—BMS. Collaborations." We are also conducting next-generation discovery programs in multiple myeloma on our own.

Abecma and our collaboration with BMS. In March 2021, *Abecma* (idecabtagene vicleucel; ide-cel) was approved by the FDA in the United States for the treatment of adults with multiple myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. *Abecma* is a first-in-class B cell maturation antigen, or BCMA, CAR T therapy for the treatment of multiple myeloma, and represents our first oncology product candidate that has progressed from bluebird bio's internal research programs, through clinical development to approval and commercialization, together with our collaboration partner, BMS. Gross revenue Revenue from sales of *Abecma* in the United States in 2022 2023 equaled $297 million $358 million, which is shared equally between us and BMS along with the related cost of sales and other commercialization costs. Together with BMS, we are in the process of increasing U.S. testing and manufacturing capacity, and therefore overall U.S. supply chain capacity, for expanding *Abecma*, site footprint to enable more patients to access the treatment, educating physicians on treatment sequencing and the emerging data supporting the use of BCMA-directed CAR Ts before other BCMA-targeted therapies, and competitively differentiating *Abecma*'s real-world safety, efficacy and product reliability and predictability profile.

BCMA is a cell surface protein that is nearly universally expressed on cancer cells in multiple myeloma, and on normal plasma cells and mature B cells, but not other cells. As the first CAR T cell therapy approved for multiple myeloma, *Abecma* is a potentially transformative, single-infusion, individualized treatment that offers patients who have limited effective treatment options the potential for long-term disease control. The approval of *Abecma* in the United States was based on positive results from the pivotal KarMMa study. In the KarMMa study, the overall response rate was 73%, and 33% of patients achieved a complete response. Onset of response was rapid with a median time to first response of one month. Median duration of response was 10.7 months and 19 months for those who achieved a complete response. *Abecma* has a well-established safety profile with mostly low-grade cytokine release syndrome (Grade ≥3: 5%; grade ≤2 events: 84%) and neurologic toxicities (Grade ≥3: 3%; grade ≤2 events: 18%) with early onset and resolution. Results from the KarMMa study were published in the February 24, 2021 issue of the New England Journal of Medicine. The FDA and EMA have granted Orphan Drug status to ide-cel for the treatment of patients with relapsed and refractory multiple myeloma. The EMA has granted PRIME eligibility to ide-cel for relapsed and refractory multiple myeloma. BMS is conducting studies to support the use of *Abecma* in earlier lines of therapy. Our and BMS' broad clinical development program for *Abecma* includes ongoing clinical trials in earlier lines of treatment for patients with multiple myeloma, including newly diagnosed multiple myeloma.

Additionally, under the collaboration arrangement with BMS, we have had an option to co-develop and co-promote bb21217, an investigational BCMA-targeted CAR T cell therapy, within the United States. However, following our review of data from the CRB-402 clinical trial, and based in part on the strength of *Abecma* clinical data and commercial sales to date, we, together with BMS, do not intend to pursue further development of bb21217.

*Next-generation approaches.**B-Cell Non-Hodgkin's Lymphoma*

We began developing our bbT369 product candidate as a treatment for patients with B-NHL, a heterogeneous group of neoplasms that can result in enlarged nodes across the body, neck, and abdomen, often coinciding with "B-symptoms" that are significant to the prognosis and staging of the disease, such as fever, drenching night sweats, and rapid and extreme weight loss. B-cell NHLs represent more than 85% of all NHL cases worldwide, and we plan to develop bbT369 to treat several subtypes of B-cell NHLs, specifically diffuse large B-cell lymphoma, or DLBCL, high-grade B-cell lymphoma, or HGBCL, primary mediastinal large B-cell lymphoma, or PMBCL, follicular lymphoma, or FL, or transformed follicular lymphoma, or TFL. DLBCL is the most common form of NHL, accounting for a third of all NHL cases, with annual incidence in the United States estimated at approximately 25,000. DLBCL is a particularly aggressive form of NHL that requires immediate therapy upon diagnosis (with a median overall survival of less than one year in untreated patients).

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Our multiplex approach is intended to patients, there are still significant challenges such as enhance the need to improve depth and duration of response and reduce manufacturing turnaround time. Our next-generation multiple myeloma program strategy in patients currently underserved by existing options. bbT369 is focused on leveraging our clinical experience from *Abecma* and bb21217, translational and correlative data, and technology platforms to solve definable and meaningful problems in the field. Leveraging our leadership in autologous a non-CD19-containing CAR T therapy, our next-generation autologous multiple myeloma program utilizes multiple that addresses the limitations of the currently available therapies by using unique layered technologies, including process improvements and dual targeting, designed with the goal following key features:

- A novel combination of achieving best-in- CD20 and CD79a targets that are co-expressed in many B-NHL tumors to both allow treatment of CD19 negative / CD19 low tumors and to limit the potential for antigen escape;
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Solid Tumors

Solid tumors represent the next frontier for cell and gene therapies. Survival expectations in patients with solid tumor who have relapsed after existing therapies are often less than one year. While cell and gene therapies have demonstrated durable remission in hematologic malignancies, none have yet been approved for treating solid tumors. Key challenges to the discovery and development of cell and gene therapies in solid tumors includes the lack of strongly and selectively expressed targets as well as a hostile tumor microenvironment that serves as a barrier for T cells accessing the tumor and suppresses immune-mediated responses. We believe that our set of technologies, partnerships and cell and gene therapy experience enables the engineering of multiplex products to uniquely address the key challenges of solid tumors. Our research-stage programs in solid tumors include tumors expressing the MUC16 antigen and tumors expressing the MAGE-A4 antigen, among others.

MUC16. Together with our partner, Regeneron, Pharmaceuticals, Inc., or Regeneron, we are began advancing our bbT4015 product candidate, an engineered T cell therapy targeting MUC16, through preclinical studies. We anticipate submitting submitted an Investigational New Drug Application, or IND, for a clinical trial of bbT4015 in patients with

ovarian cancer in late December 2023. This first in-human study will prospectively include combination agents, including those in Regeneron's pipeline, and will be the first program to utilize our new in-house drug product manufacturing facility.

MUC16 is a large extracellular protein expressed on over 80% of ovarian tumors, including all ovarian subtypes. Its overexpression in tumors and relatively lower expression on normal tissues makes MUC16 an attractive ovarian cancer target for cellular therapies and a logical fit for the deployment of orthogonal enhancement strategies. Our MUC16 program incorporates a highly potent CAR T that targets a region close to the transmembrane ("nub" region) of MUC16 and is not inhibited by the presence of high concentrations of CA-125. Encouraging preclinical data suggests that T cells expressing the "nub"-directed MUC16 CAR T are able to clear tumors in a highly stringent ovarian cancer tumor rechallenge xenograft mouse model. We intend to combine this potent CAR T with a titratable pharmacologic agent with the goal of enhancing tumor control.

MAGE-A4. Over ten types of solid tumors express the MAGE-A4 antigen, making it a promising target for cell therapy, including lung, head and neck, gynecologic and gastric cancers. Together with our partner Regeneron we are began advancing an engineered TCR therapy targeting MAGE-A4 through preclinical studies. We believe our MAGE-A4 program has the potential to address the challenges of solid tumors in a three-pronged way: (1) we have identified a potent T cell receptor targeting a prevalent intracellular peptide antigen from MAGE-A4, (2) engineered this receptor for a strong anti-tumor response, and (3) incorporated an innovative switch receptor (CTBR12) that converts the highly suppressive TGFβ signal in the hostile tumor microenvironment into a potent T cell intrinsic activation signal. The TGFβ signaling pathway has been broadly implicated as a key suppressive factor in the TME of multiple MAGEA4+ indications, including non-small cell lung, bladder, ovarian, and head and neck carcinomas. In 2022, we entered into an agreement with JW (Cayman) Therapeutics Co. Ltd., or JW Therapeutics, to clinically evaluate this potency enhanced MAGE-A4 TCR program. JW Therapeutics plans an investigator-initiated trial in China in 2023, initially focused on esophageal carcinoma. 2024.

Hemophilia A

Together with our partners partner, Novo Nordisk A/S, (" or Novo Nordisk") and Genevant Sciences Corporation ("Genevant"), Nordisk, we are also conducting preclinical studies of our product candidate in hemophilia A. Hemophilia A is a serious and rare inherited disease characterized by insufficient blood clotting that results from the lack of functional factor VIII, or FVIII. Hemophilia A is caused by mutations in the gene that encodes the coagulation FVIII protein. Our approach employs our gene editing technology (megaTALs) to insert a corrective copy of the FVIII gene directly into the genome of liver cells. We believe that this targeted integration approach may result in permanently corrected cells that have the potential to provide durable expression of therapeutic levels of FVIII protein.

Manufacturing

BMS is responsible for all *Abecma* commercial vector manufacturing within and outside of the United States. In June 2023, we assigned the Commercial Supply Agreement with National Resilience, Inc., or Resilience, to BMS and BMS assumed responsibilities for manufacturing ide-cel suspension lentiviral vector. We have also entered into agreements with external manufacturing partners in the United States and Europe to support our various preclinical and clinical programs in oncology, and to support *Abecma* commercial vector supply.

oncology. In addition, we have recently added a Phase 1 drug product cell therapy manufacturing facility in our Cambridge, Massachusetts headquarters, which became operational in 2023. Upon closing of the Asset Sale, we anticipate will be operational by mid-2023. We believe this assign to Regeneron certain agreements with external manufacturers for the programs sold to Regeneron and Regeneron will also lease the aforementioned Phase 1 drug product cell therapy manufacturing facility will enable us to rapidly iterate on clinical learnings in the development of our pipeline programs. We also have a strategic manufacturing collaboration with Resilience to increase the efficiency of vector manufacturing processes for cell and gene therapies to reduce the cost of supply and enable patient access. Cambridge, Massachusetts.

Strategic Collaborations

Given our multiplex approach to the discovery and development of next-generation cell and gene therapies for cancer, we have partnered strategically to access complementary technologies and disease-area expertise. We also have historically formed collaborations to access the substantial funding and other resources required to develop and commercialize cell and gene therapies for cancer. Currently, our strategic collaborations in oncology include:

Bristol Myers Squibb. bluebird bio began a collaboration with BMS in 2013 under a broad-ranging Master Collaboration Agreement with Celgene Corporation (now BMS following its acquisition of Celgene in November 2019) (the "BMS, or the BMS Collaboration Agreement"). Agreement. bluebird bio continued that collaboration with a series of agreements described below. In connection with the separation, bluebird bio assigned to us all of the agreements relating to its collaboration with BMS.

BMS Collaboration Agreement

In March 2013, bluebird bio entered into the BMS Collaboration Agreement to discover, develop and commercialize potentially disease-altering gene therapies in oncology. bluebird bio concurrently entered into a Platform Technology Sublicense Agreement, (the "Sublicense Agreement") or the Sublicense Agreement with BMS pursuant to which bluebird bio obtained a sublicense to certain intellectual property from BMS, originating under BMS's license from Baylor College of Medicine, for use in the collaboration.

In June 2015, both parties amended and restated the BMS Collaboration Agreement, (the "Amended or the Amended BMS Collaboration Agreement") Agreement to narrow the focus of the collaboration to exclusively work on anti-B-cell maturation antigen, ("BCMA") or BCMA product candidates for a new three-year term.

On a product candidate-by-product candidate basis, up through a specified period following enrollment of the first patient in an initial Phase 1 clinical trial for such product candidate, BMS had an option to obtain an exclusive worldwide license to develop and commercialize such product. Following BMS's license of each product candidate, we are entitled to elect to co-develop and co-promote each product candidate in the United States.

BMS Ide-cel related agreements

In February 2016, BMS exercised its option to obtain an exclusive worldwide license to develop and commercialize ide-cel, the first product candidate under the Amended BMS Collaboration Agreement, pursuant to an executed license agreement, (" or the Ide-cel License Agreement") Agreement, and paid the associated $10.0 million option fee. Pursuant to the Ide-cel License Agreement, BMS was responsible for development and related funding of ide-cel after the substantial completion of the Phase 1 clinical trial. bluebird bio was responsible for the manufacture of vector and associated payload throughout development and, upon BMS's request, throughout commercialization, the costs of which were reimbursable by BMS in accordance with the terms of the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement, as further described below. BMS was responsible for the manufacture of drug product throughout development and commercialization. Under the Ide-cel License Agreement, bluebird bio was eligible to receive (i) U.S. milestones of up to $85.0 million for the first indication to be addressed by ide-cel and royalties for U.S. sales of ide-cel and (ii) ex-U.S. milestones of up to $55.0 million and royalties for ex-U.S. sales of ide-cel.

In March 2018, bluebird bio elected to co-develop and co-promote ide-cel within the United States pursuant to the execution of the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement, (" or the Ide-cel CCPS"), CCPS, which replaced the Ide-cel License Agreement. As a result, we will share equally in all profits and losses related to developing, commercializing and manufacturing ide-cel within the United States and have the right to participate in the development and promotion of ide-cel in the United States. BMS is responsible for the costs

incurred to manufacture vector and associated payload for use outside of the United States, plus a markup. As a result of electing to co-develop and co-promote ide-cel within the United States, the milestones and royalties payable under the Ide-cel License Agreement were adjusted. Under the Ide-cel CCPS, bluebird bio was eligible to receive a $10.0 million milestone related to the development of ide-cel in the United States and, for the first indication to be addressed by ide-cel, ex-U.S. regulatory and commercial milestones of up to $60.0 million. Under the Ide-cel CCPS, the $10.0 million milestone related to the development of ide-cel in the United States was achieved in the second quarter of 2019 and subsequently paid by BMS.

BMS bb21217 License Agreement

In September 2017, BMS exercised its option to obtain an exclusive worldwide license to develop and commercialize bb21217, an investigational BCMA-targeted CAR T cell therapy, the second product candidate under the Amended BMS Collaboration Agreement, pursuant to an executed license agreement, (" or the bb21217 License Agreement") Agreement, and paid bluebird bio an option fee of $15.0 million. Pursuant to the bb21217 License Agreement, BMS is responsible for development and related funding of bb21217 after the substantial completion of the ongoing Phase 1 clinical trial. In 2019, the parties amended the protocol for the ongoing Phase 1 clinical trial to enroll additional patients for which we were reimbursed an agreed-upon amount per patient. Under the bb21217 License Agreement, we are eligible to receive U.S. milestones of up to $85.0 million for the first indication to be addressed by bb21217 and royalties for U.S. sales of bb21217. Additionally, the Company was we were eligible to receive ex-U.S. milestones of up to $55.0 million and royalties for ex-U.S. sales of bb21217.

May 2020 Amendments to Ide-cel and bb21217 agreements

In May 2020, the First Amendment to the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement, (as as amended, or the "Amended Amended Ide-cel CCPS") CCPS, and the Second Amended and Restated License Agreement, (" or the Amended bb21217 License Agreement" Agreement and, collectively with the Amended Ide-cel CCPS, the "May May 2020 Amendments"), Amendments, which replaced the bb21217 License Agreement, were executed. Under the Amended Ide-cel CCPS, the parties will continue to share equally in all profits and losses related to developing, commercializing and manufacturing ide-cel within the United States. However, the Amended Ide-cel CCPS changed our responsibilities with respect to manufacturing activities. Under the Amended Ide-cel CCPS, BMS assumed the contract manufacturing agreements related to ide-cel adherent lentiviral vector. Over time, BMS is also assuming responsibility for manufacturing ide-cel suspension lentiviral vector outside of the United States, while we remain responsible for manufacturing ide-cel suspension lentiviral vector in the United States.

Under In June 2023, we executed the Second Amendment to the Amended bb21217 License Ide-cel CCPS, pursuant to which we assigned the Commercial Supply Agreement with Resilience to BMS is assuming responsibility and BMS assumed responsibilities for global manufacturing ide-cel suspension lentiviral vector outside of the United States over time, while we remain responsible for manufacturing suspension lentiviral vector in the United States. Under the Amended bb21217 License Agreement, expenses that we incur associated with these activities are fully reimbursable by BMS at cost plus a mark-up. Throughout both development and commercialization, BMS is responsible for the manufacture of drug product. vector.

The May 2020 Amendments relieved BMS of its obligations to pay us for future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217 in exchange for an up-front, non-refundable, non-creditable payment of $200.0 million, which represents the aggregate of the probability-weighted, net present value of the future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217. In addition, the parties are released from future exclusivity related to BCMA-directed T cell therapies. There are no remaining milestones or royalties under the Amended Ide-cel CCPS. The Amended Ide-cel CCPS will continue on a country-by-country basis until there are no more payments owed by either party on ide-cel in such country, unless earlier terminated (a) by mutual consent of the parties, (b) by us following a material breach by BMS that remains uncured after a specified period, (c) by us at our discretion, following a specified notice period, (d) by BMS following a

material breach by us that remains uncured after a specified period, (e) by BMS at its discretion, following a specified notice period, or (f) pursuant to certain other negotiated termination provisions.

In March 2021, the FDA approved the marketing of Ide-cel as *Abecma* in the United States for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Under the Amended Ide-cel CCPS, BMS is primarily responsible for the commercialization of *Abecma*. As previously described, under the collaboration arrangement with BMS, we have an option to co-develop and co-promote bb21217 within the United States. However, following completion of the CRB-402 clinical trial, in January 2022 we, along with BMS,

evaluated our plans with respect to bb21217. Based in part on the strength of *Abecma* clinical data and commercial sales to date, we and BMS elected to discontinue development of bb21217 and, as such, we did not exercise our option to co-develop and co-promote bb21217 within the United States. We are still eligible to receive U.S. milestones and royalties for U.S. sales of bb21217, if further developed by BMS. Additionally, pursuant to the terms of the collaboration agreement, because we did not exercise our option to co-develop and co-promote bb21217, we received an additional fee in the amount of $10.0 million from BMS during the second quarter of 2022.

***Novo Nordisk*.** We have a collaboration with Novo Nordisk focused on the in vivo application of our megaTAL gene-editing technology to treat hemophilia A.

Seattle Children's. Through our collaboration with Seattle Children's Therapeutics, a non-profit enterprise associated with Seattle Children's, ("SCRI"), or SCRI, we and SCRI are working to advance the clinical development of SC-DARIC33 as a treatment for patients with AML. Upon or after the closing of the Asset Sale, the collaboration with SCRI will be assigned to Regeneron.

Regeneron. We have a broad collaboration with Regeneron covering the discovery, development, and commercialization of novel cell and gene therapies for cancer. Through this collaboration, we have access to Regeneron's platform technologies for the discovery and characterization of fully human antibodies as well as T cell receptors against tumor-specific proteins and peptides that we may leverage in our collaboration programs. Upon the closing of the Asset Sale, the collaboration agreement with Regeneron will terminate with certain provisions surviving such termination.

JW Therapeutics. Through our agreement agreements with JW Therapeutics, we are collaborating to establish a translational and clinical cell therapy development platform designed to more rapidly explore T cell-based immunotherapy products in the Chinese mainland, Hong Kong (China), and Macao (China). Upon or after the closing of the Asset Sale, the collaboration agreements with JW Therapeutics will be assigned to Regeneron.

Medigene. Through our collaboration, we have access to Medigene's proprietary platform for the generation and design of T cell receptors that we may leverage in our product candidates. Upon or after the closing of the Asset Sale, the collaboration agreement with Medigene will be assigned to Regeneron.

Inhibrx. Through our collaboration, we have access to Inhibrx's proprietary single-domain antibody platform to multiple cancer targets that we may leverage in our product candidates. Upon or after the closing of the Asset Sale, the collaboration agreement with Inhibrx will be assigned to Regeneron.

Gritstone Oncology. Through our collaboration with Gritstone, we intend to seek to validate cancer targets and discover T cell receptors that we may leverage in our product candidates.

***Novo Nordisk*.** We have a Upon or after the closing of the Asset Sale, the collaboration agreement with Novo Nordisk focused on the in vivo application of our megaTAL gene-editing technology Gritstone will be assigned to treat hemophilia A.

Genevant. Through our collaboration, we have access to Genevant's lipid nanoparticle, or LNP, technology platform for use in our collaboration with Novo Nordisk for the treatment of patients with hemophilia A. We intend to use Genevant's LNP platform in the delivery of megaTAL mRNA to hepatocyte cells within the liver. Regeneron.

We are also party to additional significant academic collaborations for the discovery, preclinical development, and initial clinical proof-of-concept of our product concepts, such as our collaboration with the University of North Carolina. concepts.

License Agreements

Biogen. In August 2014, bluebird bio entered into a license agreement with Biogen, pursuant to which bluebird bio co-exclusively licensed certain patents and patent applications directed towards aspects of T cell-based products that target BCMA. In connection with the separation, bluebird bio assigned this license agreement to us. Biogen retains the right to practice and use the licensed patents in the licensed field and territory. We have the right to grant sublicenses to third parties, subject to certain conditions. We are obligated to pay Biogen a percentage (in the low single digits) of net sales of products covered by the in-licensed intellectual property, including *Abecma*, as a

royalty. Additionally, we are subject to certain development and regulatory milestone obligations and must report on our progress in achieving those milestones on a periodic basis. We may be obligated to pay up to $23.0 million in the aggregate for each licensed product upon the achievement of remaining milestones. We may unilaterally terminate the license agreement at any time with prior written notice to Biogen. Either party may terminate the license in the event of the other party's material breach upon notice and following an opportunity for the breaching party to cure. Either party may also terminate the agreement in the event bankruptcy proceedings are opened against

the other party and are not dismissed within a specified period of time. Absent early termination, the agreement will automatically terminate upon the expiration of all patent rights covered by the agreement or ten years from the date of first commercial sale of a licensed product, whichever is later. The longest lived patent rights licensed to us are in a U.S. patent, currently expected to expire in 2032.

NIH. In August 2015, bluebird bio entered into a license agreement with the NIH, pursuant to which bluebird bio exclusively licensed certain patents and patent applications directed towards aspects of T cell-based products that target BCMA. In connection with the separation, bluebird bio assigned this license agreement to us. Any patents within this portfolio that have issued or may yet issue would have an expected statutory expiration date in 2033 to 2034. The NIH retains the right to practice the intellectual property licensed under the agreement on behalf of the government of the United States. We have the right to grant sublicenses to third parties, subject to certain conditions. For each such sublicense we grant we must pay the NIH a fee. Upon commercialization of our products covered by the in-licensed intellectual property, which includes *Abecma*, we will be obligated to pay the NIH a percentage of annual net sales as a royalty in the low single digits. We are subject to a domestic production requirement that licensed products, such as *Abecma*, sold or used in the U.S. or produced through use of the licensed processes must be manufactured substantially in the U.S., unless a waiver is obtained in advance from the NIH. Additionally, we are subject to certain development and regulatory milestone obligations and must report on our progress in achieving those milestones on a periodic basis. We may be obligated to pay up to $9.7 million in the aggregate for a licensed product upon the achievement of these milestones. We may unilaterally terminate the license agreement at any time with prior written notice to the NIH. The NIH may terminate the license in the event of our material breach upon notice and following an opportunity for us to cure the material breach. The NIH may also terminate the agreement in the event bankruptcy proceedings are opened against us and are not dismissed within a specified period of time. Absent early termination, the agreement will automatically terminate upon the expiration of the patent rights covered by the agreement. The longest lived patent rights licensed to us under the Agreement are currently expected to expire in 2034.

Institut Pasteur. Under a 2011 license agreement, Institut Pasteur granted a license to bluebird bio for certain patents relating to the use of DNA sequences, LVV and recombinant cells in the field of ex vivo gene therapy and CAR T cell-based therapy in a range of indications, excluding vaccinations, (the "Licensed or the Licensed Pasteur IP"). IP. In February 2023, we entered into a partial assumption and assignment agreement with bluebird bio and Institut Pasteur, by which bluebird bio assigned us its rights, obligations and interests under the 2011 license agreement, to any and all uses of the Licensed Pasteur IP in connection with the prevention, diagnosis or treatment of oncological diseases or disorders and hemophilia. We will pay Institut Pasteur an annual maintenance payment, a percentage of income received in the event of sublicensing arrangements and, upon commercialization of products covered by the Licensed Pasteur IP, a percentage of net sales as a royalty, which varies depending on the indication of the product. Prior to entering into the partial assignment and assumption agreement, the Licensed Pasteur IP was sublicensed by bluebird bio to us under the Intellectual Property License Agreement, dated as of November 3, 2021, entered into in connection with the Separation. The Agreement may be terminated for a substantial breach by either Party that is not cured within 60 days of notification Due to the expiration of the substantial breach. 2seventy may terminate last valid patent, we terminated the agreement, by providing to Institut Pasteur 90 days prior written notice. effective as of December 31, 2023.

bluebird bio. We entered into an intellectual property license agreement in connection with the separation with bluebird bio pursuant to which each party granted a license to certain intellectual property and technology. bluebird bio granted us a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license to certain intellectual property to allow us to use such intellectual property in connection with our ongoing and future research and development activities and product candidates. We granted to bluebird bio a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to certain intellectual property for use in

bluebird bio's existing products and product candidates. Such licenses between the parties generally allow current or future uses of the intellectual property in connection with each party's respective fields.

Competition

The biotechnology and pharmaceutical industries are characterized by intense and rapidly changing competition to develop new technologies and proprietary products. Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical, and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for treatments. Our competitors' treatments may be more effective, or more effectively marketed and sold, than any treatment for which we receive marketing approval and may render our approved

treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our treatments.

These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of different products driven by cost, discounts, or rebates. If our therapeutic product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products. Depending on how successful these competitive efforts are, it is possible they may increase the barriers to adoption and success of our approved product and product candidates.

We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, customer experience, reliability, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payers.

These efforts include the following:

Multiple Myeloma. The current standard of care for relapsed and refractory multiple myeloma includes IMiDs (e.g., thalidomide, lenalidomide, pomalidomide), proteasome inhibitors (e.g., bortezomib, carfilzomib, ixazomib), monoclonal antibodies (e.g., daratumamab, isatuximab, elotuzumab), cytotoxic agents, and HSCT. There are several companies developing autologous T cell therapies for relapsed and refractory multiple myeloma that use a similar autologous ex vivo approach, but a different target antigen, BCMA single-chain variable fragment or, we believe, cell processing techniques. These programs include: ciltacabtagene autoleucel, an anti-BCMA CAR T cell therapy marketed as Carvykti that was approved by the FDA in February 2022 (Janssen in collaboration with Legend Biotech); a CAR T-ddBCMA cell therapy in clinical development (pivotal Phase 2 iMMagine-1) jointly developed by Arcellx in partnership with Kite; an anti-BCMA CAR T cell therapy in clinical development (Phase 1) sponsored by BMS following the completion of its acquisition of Juno Therapeutics, Inc. and several other anti-BCMA CAR T cell therapies in Phase 1 study, including and not limited to Novartis and Gracell Biotechnologies Inc. In addition to these autologous T cell-based approaches, Allogene Therapeutics, Inc., Poseida, and CRISPR Therapeutics AG have disclosed preclinical and clinical programs for allogeneic BCMA targeted CAR T cell therapies. There are also other therapies using similar or novel modalities being developed by several groups, including multiple bispecific T cell engagers and specific antibody therapies, such as antibody-drug conjugates, (ADCs). or ADCs. In October 2022, the FDA approved Tecvayli (teclistamab, first-in-class BCMAxCD3 bispecific antibody) for patients with at least four prior therapies in relapsed and refractory multiple myeloma becoming the first treatment option with this modality to gain approval in the US. Two other BCMA-directed bispecific antibodies are Pfizer's elranatamab, which was approved in 2023, and Regeneron's linvoseltamab, are which is expected to be approved in 2023 and 2024, respectively. 2024. In addition to Tecvayli, potential approval of another bispecific antibody developed by Janssen, talquetemab (first-in-class GPRC5DxCD3), is expected was approved in the second half of 2023. After GSK noted the failure of the Phase 3 confirmatory DREAMM-3 study in

3L+ relapsed and refractory multiple myeloma, following the request of the FDA, GSK announced plans for full market withdrawal of Blenrep (BCMA targeting ADC). GSK continues to develop Blenrep, and the data from the Phase 3 DREAMM-7 and DREAMM-8 studies received a positive read-out in 2L relapsed and refractory multiple myeloma expected in the first half of 2023 will inform their future regulatory pathways.

B Cell Non-Hodgkin's Lymphoma. The current standard of care for majority of non-Hodgkin's lymphoma, or NHL, is focused around CD20 immunotherapy, mainly rituximab, combined with chemotherapy agents such as bendamustine or the four-drug cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) regimen as the first-line option; patients with certain mutations may receive a different chemotherapy cocktail called EPOCH. As patients fail these therapies and reach the relapsed/refractory setting, patients who are eligible for stem cell transplant have typically received CD20 antibodies and high-dose chemotherapy followed by autologous stem cell transplantation, or HDCT-ASCT. CD19 CAR T cell therapies axicabtagene ciloleucel (marked as Yescarta) and lisocabtagene maraleucel (marketed as Breyanzi) were both approved in 2022 for patients refractory to or relapsing within 12 months of initial therapy, replacing HDCT-ASCT as the standard of care for many patients; lisocabtagene maraleucel was also approved in the US for patients who are deemed ineligible for HDCT-ASCT. Axicabtagene ciloleucel and lisocabtagene maraleucel were also previously approved and launched as therapies for NHL patients who had failed at least two prior therapies, as was a third CD19 CAR T, tisagenlecleucel (marketed as Kymriah). More than 60 development programs for NHL therapies are in Phase 1 through Phase 3 trials in the US, including over 20 CAR T cell therapies, most of which target CD19. Among these programs are three dual targeting assets: Miltenyi's zamtocabtagene autoleucel, a CD19/20 targeting CAR T currently in two potentially registrational Phase 2 trials, Cellular Biomedicine Group's C-CAR039, a CD19/20 targeting CAR T which opened a Phase 1 trial in the US in 2022, and Autolus Therapeutics' AUTO3, a CD19/22 dual targeting CAR T for relapsed/refractory NHL with promising Phase 1/2 data which Autolus Therapeutics is aiming to partner or out-license. Most cell therapies, marketed or in the clinic, are exploring patient populations across the treatment paradigm with expectations of replacing current standard of care and procuring expanded labels. In addition to autologous therapies, efforts are ongoing for allogeneic platforms that offer "off-the-shelf" advantage with the option of potentially treating greater number of patients over currently marketed CARs. ALLO-501A, PBCAR0191, CTX110, and ADI-001 have shown promising preliminary data in R/R NHL including patients failed on or refractory to prior CARs, and potentially registrational trials have been initiated for ALLO-501A and CTX110. Beyond cell therapies, Roche's CD79b-targeting anti-body drug conjugate, polatuzumab vedotin (marketed as Polivy), received approval in relapsed/refractory NHL in the US in 2019 and a broader EMA approval in patients not eligible for stem cell transplant; polatuzumab also showed promising Phase 3 data in newly diagnosed NHL but has not yet been approved in that setting. Another anti-body drug conjugate, ADC Therapeutics' CD19-targeting loncastuximab tesirine (marketed as Zynlonta), was approved in relapsed/refractory

NHL patients after at least two prior therapies in the US in 2021. Morphosys' tafasitamab (marketed as Monjuvi), a CD-19 targeted antibody, was approved and launched in 2020 in the US in combination with lenalidomide for patients with relapsed or refractory disease ineligible for HDCT-ASCT. Bispecific antibody therapies include Roche's glofitamab, Genmab and AbbVie's epcoritamab, and Regeneron's odronextamab (all CD20 X CD3). Roche and AbbVie have filed BLAs for their respective agents, and Regeneron is expected to submit a BLA for odronextamab in late 2023.

Acute Myeloid Leukemia. The current standard of care for AML has changed in the last few years following a host of new small molecule and monoclonal antibody approvals since 2017: midostaurin (commercialized by Novartis), liposomal daunorubicin and cytarabine (commercialized by Jazz Pharmaceuticals plc), enasidenib (commercialized by BMS and Servier), gemtuzumab ozogamicin (commercialized by Pfizer), ivosidenib (commercialized by Servier), gilteritinib (commercialized by Astellas Pharma), venetoclax (commercialized by AbbVie and Genentech), and glasdegib (commercialized by Pfizer). Many of these drugs are first in class and some are biomarker driven, resulting in more segmentation in the AML treatment paradigm. There are several competitors exploring autologous CAR T therapies in Phase 1 trials for relapsed and refractory AML, some against targets that have approved monoclonal antibody competitors on the market already, while others have novel targets. Dual targeting CAR T cell-based approaches are also starting to enter the clinic, including the CD33/CLL-1 targeting CAR Ts being developed by iCell Gene Therapeutics and Legend Biotech. Other groups are exploring TCR-based autologous therapies against novel targets. In addition to autologous cell therapies, there are allogeneic CAR T cell therapies in early trials for AML, including MB-102 in a Phase 1 trial being developed by Mustang Bio, Inc, and UCART123 in a Phase 1 trial being developed by Cellectis as well as NK cell-based therapies. Other modalities,

such as bispecific antibodies, ADCs, and other immunotherapy-based approaches are also in development across a wide range of targets. For example, Janssen is developing JNJ-67571244, a bispecific antibody targeting CD33 and CD3, for the treatment of relapsed or refractory AML, and Immunogen is developing pivekimab sunirine (IMGN632), a CD123 ADC, as monotherapy or in combination with azacytidine +/- venetoclax in relapsed or refractory or newly diagnosed AML. In addition, Gilead is investigating magrolimab, a CD47 targeting antibody, through two ongoing pivotal Phase 3 studies: ENHANCE-3 investigating magrolimab combined with venetoclax and azacytidine in newly diagnosed intensive chemotherapy unfit AML patients and ENHANCE-2 magrolimab in combination with azacytidine vs. physicians' choice of venetoclax and azacytidine or intensive chemotherapy in newly diagnosed TP53 mutant AML patients. Data is expected for both studies in 2024.

Other Cell and Gene-Based Immunotherapies in Oncology. Hundreds of academic laboratories, biotechnology, and pharmaceutical companies are researching and developing cell-based immunotherapies in oncology, in addition to the programs described above. These include and are not limited to Novartis AG, Adaptimmune Inc., Bristol Myers Squibb Inc., Gilead Sciences, Inc., Pfizer Inc., Amgen, Inc., Sanofi, and Takeda among others. Many of the cell-based immunotherapy programs being developed by these companies are in Phase 1/2 clinical trials for multiple indications in hematologic and solid tumors. Given the complexities of treating heterogeneous solid tumors, early data from cell therapies is very limited and needs extensive exploration and validation. Cancer therapies in other modalities, such as bispecific antibodies, antibody-drug conjugates, and

dendritic cell vaccines, as well as combinatorial approaches are also in development across a wide range of targets and pose a competitive threat.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to the development of our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets relating to our proprietary technology platform and on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field fields of oncology and gene therapy that may be important for the development of our business. Additionally, we rely on regulatory protection afforded through orphan drug designations, data exclusivity, market exclusivity, and patent term extensions and supplementary protection certificates where available.

Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products may depend on the extent to which we have valid and enforceable patent rights or trade secrets that cover these activities. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

We have developed or in-licensed numerous patents and patent applications and possess substantial know-how and trade secrets relating to the development and commercialization of oncology and gene therapy products. Our proprietary intellectual property, including patent and non-patent intellectual property, is generally directed to, for example, certain cell therapies, chimeric antigen receptors, TCRs, genes, transgenes, methods of transferring genetic material into cells, genetically modified cells, processes to manufacture our lentivirus-based approved product and product candidates and other proprietary technologies and processes related to our approved product and product candidates.

As of February 8, 2023 January 3, 2024, our solely owned or co-owned patent portfolio includes the following:

- 66 consists of approximately 27 issued or allowed U.S. patents or patent applications that we own or have exclusively or co-exclusively in-licensed from third parties related to lentiviral vectors and vector manufacturing or production;

- 163 patents or approximately 45 pending U.S. patent applications that we own or have exclusively or co-exclusively in-licensed from third parties related to therapeutic cellular product candidates;
- 6 covering certain aspects of our cell therapy and gene editing technologies, inventions, and improvements, and covering key aspects of our clinical development candidates and commercial products, as well as approximately 394 granted patents or in jurisdictions outside of the United States, approximately 320 patent applications pending in jurisdictions outside of the United States that, we have non-exclusively in-licensed or optioned from third parties related in many cases, are counterparts to oncology the foregoing U.S. patents and therapeutic T cells;
- 660 patents or patent applications, that we own, have exclusively or co-exclusively in-licensed, or optioned from third parties related to oncology product candidates, including CAR T cell vector systems and manufacturing, T cell manufacturing, and therapeutic T cells;
- 179 patents or patent applications that we own or have exclusively or co-exclusively in-licensed from third parties related to gene-editing compositions and methods; and
- 2 patent applications that we have non-exclusively in-licensed from third parties related to gene-editing compositions and methods.approximately 9 international applications.

Our objective is to continue to expand protect our portfolio of patents and patent applications in order to protect our gene therapy product candidates and manufacturing processes. Examples of the products and technology areas covered by our intellectual property portfolio are described below. See also "—Strategic Collaborations." From time to time, we also evaluate opportunities to sublicense our portfolio of patents and patent applications that we own or exclusively license, and we may enter into such licenses from time to time.

While we maintain patents and patent applications in important foreign markets, such as in Europe, China, and Japan, we do not consider our patent portfolio outside of the United States to be material to 2seventy bio at this time. With respect to the patent portfolios for our commercial-stage product idecabtagene vicleucel, or ide-cel, development and commercialization rights have been exclusively licensed to BMS in exchange for an up-front payment. As a consequence, 2seventy bio will not receive royalties on sales of ide-cel outside of the United States.

In addition, our other oncology programs are in preclinical or early clinical stages and we have not initiated the clinical trials for these programs either in the United States or elsewhere. As as a result, we do not view the patent portfolios for these programs to be material to 2seventy bio at this time.

Ide-cel Program and Independent Multiple Myeloma Program Other BCMA-related IP

The multiple myeloma programs include the patent portfolios described below. These rights were assigned or sublicensed to us pursuant to the intellectual property license agreement and other agreements that we entered into with bluebird bio in connection with the separation. See "Certain Relationships and Related Person Transactions–Relationship with bluebird bio."

- **Pasteur Institute.** The in-licensed Pasteur patent portfolio contains patents and patent applications directed to FLAP/cPPT elements and lentiviral vectors used to produce ide-cel for multiple myeloma. As of February 8, 2023, we had a non-exclusive license in the field of oncology (from bluebird bio) to two issued U.S. patents. We expect the issued composition of matter patents to expire in 2022 and 2023 in the United States (excluding possible patent term extensions).
- **RDF.** The in-licensed RDF patent portfolio contains the patents and patent applications directed towards aspects of our lentiviral vectors used to produce ide-cel for multiple myeloma. As of February 8, 2023, we had a non-exclusive license in the field of oncology (bluebird bio) to 11 issued U.S. patents and one pending U.S. patent applications related to our lentiviral vector platform. Corresponding foreign patents related to our lentiviral vector platform include issued patents in Canada, Europe, and Israel. We expect the issued composition of matter patents to expire from 2021-2027 in the United States, and in 2022 in the rest of the world (excluding possible patent term extensions).
- **Biogen.** The in-licensed Biogen Inc. (formerly Biogen Idec MA Inc.; referred to herein as Biogen) patent portfolio, contains patents and patent applications directed toward aspects of T cell-based products that target BCMA. As of February 8, 2023, we had a co-exclusive license to five issued U.S. patents, one pending U.S. patent application, and 49 issued corresponding foreign patents related to T cell-based

products that target BCMA. We expect the issued composition of matter patents to expire from approximately 2024-2032 (excluding possible patent term extensions). Further, we expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from approximately 2024-2030 (worldwide, excluding possible patent term extensions).

- **NIH.** The in-licensed patent portfolio from National Institutes of Health, or NIH, contains patents and patent applications directed towards aspects of chimeric antigen receptor-based immunotherapies that target BCMA. As of February 8, 2023, we had an exclusive license to 16 issued U.S. patents, three pending U.S. patent applications, 27 issued corresponding foreign patents and 18 corresponding foreign patent applications related to chimeric antigen receptor-based immunotherapies that target BCMA and methods of use. We expect the issued composition of matter and methods patents to expire from approximately 2033-2034 (excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in approximately 2033 (worldwide, excluding possible patent term extensions).

- **2seventy bio IP.** The owned patent portfolio contains patents and patent applications directed to certain specific compositions of matter and methods for generating CAR T cells.

    - As of February 8, 2023 January 3, 2024, we owned 12 issued U.S. patents, 9 pending eight patent families of U.S. non-provisional patent applications, 310 corresponding foreign patents, applications, and 91 corresponding foreign patent applications associated issued patents related to CAR composition, methods of manufacture, and methods of treatment. We expect the issued composition of matter and methods patents to expire in approximately 2035 (worldwide, excluding possible patent term extensions). We expect any other patents, if issued from the pending patent applications or a corresponding national stage application, if applicable, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from approximately 2035-2040 (worldwide, excluding possible patent term extensions).

    - As of February 8, 2023 January 3, 2024, we owned one pending PCT application patent family of U.S. non-provisional applications and corresponding foreign applications related to alternative anti-BCMA binders, CARs, and corresponding methods. We expect any patents, if issued from a corresponding national stage application, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in approximately 2041 (worldwide, excluding possible patent term extensions).

Lentiviral Platform (e.g., Vectors, Manufacturing, and Cell Therapy Products)

The lentiviral platform, which is potentially applicable across our programs in severe genetic disease and oncology, includes the following patent portfolios described below. These rights were assigned or sublicensed to us pursuant to the intellectual property license agreement and other agreements that we entered into with bluebird bio in connection with the separation.

- **Pasteur Institute.** The Pasteur patent portfolio contains the patents and patent applications described above.

- **RDF**. The in-licensed RDF patent portfolio contains the patents and patent applications described above.

- **2seventy bio IP.** Another component of the owned patent portfolio includes the vector manufacturing platform and is potentially applicable to our oncology programs. This portion of the portfolio contains patent applications directed to improved methods for transfection and transduction of therapeutic cells. As of February 8, 2023 January 3, 2024, we owned one provisional application, one pending two families of U.S. patent application, 7 non-provisional applications and corresponding foreign patent applications, and one PCT application two international applications, related to vector manufacturing, purification, and formulation. We expect any composition of matter or methods patents, if issued from a corresponding national stage application, if applicable, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from approximately 2040-2043 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate

maintenance, renewal, annuity, or other governmental fees are paid, to expire from approximately 2040-2043 (worldwide, excluding possible patent term extensions).

- **SIRION.** The in-licensed patent portfolio from SIRION contains patents and patent applications directed to methods of manufacturing ex vivo gene therapy products with a lentiviral vector. We expect the issued method patents to expire in approximately 2033 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2040-2043 in approximately 2033 (worldwide, excluding possible patent term extensions).

Oncology Platform (e.g., T Cell-Based Products)

Our T cell-based oncology platform and oncology research program, which is applicable to our multiple myeloma programs and other potential programs in cancer, includes the following patent portfolios described below. These rights were assigned or sublicensed to us pursuant to the intellectual property license agreement and other agreements we

entered into with bluebird bio in connection with the separation.

- **2seventy bio IP**. One aspect of the owned or co-owned patent portfolio contains patent applications directed to certain specific compositions of matter for generating CAR T cells directed against various cancers and improved CAR T cell compositions.
    - As of February 8, 2023 January 3, 2024, we owned 27 19 patent families that include 4 issued of U.S. patents, 19 pending U.S. patent non-provisional applications, 17 corresponding foreign applications, and associated issued patents related to CAR/TCR compositions, switch receptors, cell therapies, and 93 corresponding foreign patent applications; one pending U.S. provisional application; and 6 pending PCT applications. methods of treatment. We expect the issued composition of matter patent to expire in 2034 (worldwide, excluding possible patent term extensions). We expect any other patents, if issued from a corresponding non-provisional patent application, the pending patent applications or a corresponding national stage application, if applicable, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from approximately 2034-2043 (worldwide, excluding possible patent term extensions).
    - Also as of January 3, 2024, we co-owned (with Seattle Children's Research Institute) one international application related to compositions and methods for treating patients with regulatable therapeutic T cells, and two provisional applications related to cytokine expressing immune cells. We expect any other composition of matter or methods patents, in this portfolio, if issued from a corresponding national stage application, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2042 (worldwide, excluding possible patent term extensions).
    - Also as of January 3, 2024, we co-owned (with Regeneron) one international application related to compositions and methods for treating patients with that express a particular antigen. We expect any composition of matter or methods patents, if issued from 2034-2043 a corresponding national stage application, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in approximately 2042 (worldwide, excluding possible patent term extensions).
- **T Cell Manufacturing Methods License.** We have in-licensed a nonexclusive license to certain patents and patent applications that are directed to specific methods for generating CAR T cells. As of February 8, 2023, we have a nonexclusive license to two issued U.S. patents, one pending U.S. patent application, and 30 corresponding issued foreign patents. We expect the issued method patents to expire in 2026 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in approximately 2026 (excluding possible patent term extensions).
- **T Cell Immunotherapy Product Candidate Licenses.** We have in-licensed certain patents and patent applications that are directed to specific compositions of matter for generating CAR T cells directed against various cancers and related methods of treatment.
    - As of February 8, 2023 January 3, 2024, we had an exclusive license to three families of U.S. non-provisional applications and corresponding foreign applications directed to compositions and methods for treating cancers that express particular target antigens. We expect any composition of matter or methods patents, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in approximately 2040 (worldwide, excluding possible patent term extensions).
    - In addition, as of February 8, 2023 January 3, 2024, we co-owned (with Medigene AG) two patent families of U.S. non-provisional applications and corresponding foreign applications directed to compositions and methods for treating cancers that express a particular antigen. We expect any composition of matter or methods patents, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in approximately 2040 (worldwide, excluding possible patent term extensions).
    - Also as of February 8, 2023 January 3, 2024, we co-owned (with Inhibrx, Inc.) four families of U.S. non-provisional applications and corresponding foreign applications directed to compositions and methods for treating cancers that express a particular antigen. We expect any composition of matter or methods patents, if issued from a corresponding national stage application, if applicable, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2040 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire from in approximately 2040 (worldwide, excluding possible patent term extensions).
    - Also as of February 8, 2023 January 3, 2024, we had a non-exclusive license to one family of U.S. non-provisional applications and corresponding foreign applications directed to compositions and methods for expressing transgenes. We expect any composition of matter or methods patents, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire from in approximately 2038 (worldwide, excluding possible patent term extensions).

- Also as of February 8, 2023, we co-owned (with Seattle Children's Research Institute) one international application directed to compositions and methods for treating patients with regulatable therapeutic T cells. We expect any composition of matter or methods patents, if issued from a corresponding national stage application, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2042 (worldwide, excluding possible patent term extensions).

- Also as of February 8, 2023, we co-owned (with Regeneron) one international application directed to compositions and methods for treating patients with that express a particular antigen. We expect any composition of matter or methods patents, if issued from a corresponding national stage application, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2042 (worldwide, excluding possible patent term extensions).

Gene-editing Platform (e.g., homing endonucleases, chimeric endonucleases, megaTALs, genetically modified cells, and related methods)

The gene-editing platform includes the following patent portfolios described below. These rights were assigned or sublicensed to us pursuant to the intellectual property license agreement and other agreements that we entered into with bluebird bio in connection with the separation.

- **Gene-editing License.** We have in-licensed certain patent portfolios that contain patents and patent applications directed to aspects of our gene-editing platform to produce genome modifying enzymes and genetically modified cells that are potentially applicable to oncology programs.

  - As of February 8, 2023 January 3, 2024, we had an exclusive/co-exclusive license to seven issued one family of U.S. patents, one pending U.S. patent application, 28 non-provisional applications, corresponding foreign patents, applications, and one corresponding foreign patent applications associated issued patents related to our gene-editing platform. platform and megaTAL binding domains. We expect the issued composition of matter patents to expire in 2030 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued from the pending patent applications and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in approximately 2030 (worldwide, excluding possible patent term extensions).

  - In addition, as of February 8, 2023 January 3, 2024, we had an exclusive license to two issued one family of U.S. patents and six non-provisional applications, corresponding foreign applications, and associated issued patents related to our gene-editing platform. platform and related vectors. We expect the issued composition of matter patent to expire from approximately 2027-2031 in the United States (excluding possible patent term extensions) and in 2027 in the rest of the world.

- **Academic Gene-editing Licenses.** We have in-licensed patent portfolios from multiple academic medical centers, each portfolio containing patents and patent applications directed to aspects of our gene-editing platform to produce genome modifying enzymes and genetically modified cells that are potentially applicable to our oncology programs.

  - As of February 8, 2023 January 3, 2024, we had an exclusive license to 7 issued one family of U.S. patents, 2 pending U.S. patent non-provisional applications, 25 corresponding foreign patents, applications, and one corresponding foreign patent application associated issued patents related to our gene-editing platform. We expect the issued patent patents to expire in 2027-2032 2027 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2027-2032 in approximately 2027 (worldwide, excluding possible patent term extensions).

  - As of February 8, 2023 January 3, 2024, we had an exclusive license to one family of U.S. non-provisional applications, corresponding foreign applications, and associated issued patents related to our gene-editing platform. We expect the issued patents to expire in approximately 2032 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in approximately 2032 (worldwide, excluding possible patent term extensions).

  - As of January 3, 2024, we also had a non-exclusive license to one family of U.S. non-provisional applications, corresponding foreign applications, and associated issued U.S. patent and one pending U.S. patent application patents related to our gene-editing platform. We expect the issued composition of matter patent to expire in 2035 (excluding possible patent term extensions). We expect any other patents in this portfolio, if issued and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in approximately 2035 (worldwide, excluding possible patent term extensions).

- **2seventy bio IP.** One aspect of the owned patent portfolio contains patent applications that are potentially applicable to certain aspects of our gene-editing platform to produce genome modifying enzymes and genetically modified cells that are potentially applicable to our oncology and other programs.

  - As of February 8, 2023 January 3, 2024, we owned 9 ten patent families that include 4 issued of U.S. patents, 10 pending U.S. patent provisional and non-provisional applications, 6 corresponding foreign patents, applications, and 56 corresponding foreign patent applications any associated issued patents related to our gene-

editing platform. We expect the issued composition of matter patent to expire in 2038 (excluding possible patent term extensions). platform, including specific gene editing compositions and methods. We expect any composition of matter or methods patents, if issued from the pending patent applications, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2037-2039 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire from 2037-2039 approximately 2037-2045 (worldwide, excluding possible patent term extensions).

- As of February 8, 2023, we also owned two international applications related to our gene-editing platform. We expect any composition of matter or methods patents, if issued from a corresponding national stage patent application, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2041 (worldwide, excluding possible patent term extensions).
- As of February 8, 2023 January 3, 2024, we co-owned (with Cellectis SA) two issued patent families of U.S. patents, 17 provisional and non-provisional applications, corresponding foreign patents, applications, and two corresponding foreign patent applications any associated issued patents related to our gene-editing platform. We expect the issued composition of matter patent to expire in 2034 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued from the pending patent applications and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in approximately 2034 (worldwide, excluding possible patent term extensions).

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent. Our patents expire at various times over the next 20 years, with patent protection for some expiring from 2023 2024 through 2027. 2034. We do not expect such expirations to materially affect our business as the patents set to expire during this time cover intellectual property that is used in combination with other proprietary technologies, which technologies are therefore are covered by patents and patent applications with expiration dates beyond 2027. 2032. For these reasons, among others, we believe that no single patent expiration would have a material adverse effect on our business as a whole.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration of a U.S. patent as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a BLA, we expect to apply for patent term extensions for patents covering our approved products or methods of using the same.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and third parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

The Separation and Distribution

In January 2021, bluebird bio announced its plans to separate its oncology portfolio and programs from its severe genetic disease portfolio and programs and spin off its oncology portfolio and programs into a separate publicly traded company, 2seventy bio. In furtherance of this plan, 2seventy bio was incorporated as a Delaware corporation in April 2021, and in September 2021, bluebird bio's board of directors approved the distribution of all of the issued and outstanding shares of 2seventy bio common stock on the basis of one share of 2seventy bio common stock for every three shares of bluebird bio common stock issued and outstanding on October 19, 2021, the record date for the distribution.

On November 3, 2021 we entered into a separation agreement with bluebird bio, which is referred to in this Annual Report on Form 10-K, or this Annual Report, as the separation agreement, as well as various other agreements with bluebird bio, including a tax matters agreement, an employee matters agreement, an intellectual property license agreement, a transition services agreement under which we temporarily receive certain services from bluebird bio, and a second transition services agreement under which we temporarily provide certain services to bluebird bio. These agreements also govern certain of our relationships with bluebird bio after the separation. For additional information regarding the separation agreement and the other related agreements, see "Risk Factors—Risks Related to the Separation" and "Certain Relationships and Related Person Transactions—Agreements with bluebird bio." As a result of the distribution, we became an independent, publicly traded company on November 4, 2021.

Government Regulation

In the United States, biological products, including cell and gene therapy products, are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, research, development, manufacturing, quality control, safety, efficacy, labeling, packaging, storage, record keeping, distribution, approval, reporting, import, export, post-approval monitoring and reporting, and advertising and other promotional practices involving biological products. FDA authorization must be obtained before clinical testing of biological products, and each clinical study protocol for a gene therapy product is reviewed by the FDA. FDA approval also must be obtained before marketing of biological products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals.

Within the FDA, the Center for Biologics Evaluation and Research, or CBER, regulates cell and gene therapy products. CBER works closely with the NIH. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols. The FDA also has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing

subjects involved in gene therapy studies for delayed adverse events, potency testing, and chemistry, manufacturing and control information in gene therapy Investigational New Drug Applications, or INDs.

Ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from successfully commercializing our product or any future products. New government requirements may be established that could delay or prevent regulatory approval of our product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

United States Biological Products Development Process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical studies may begin and must be updated annually and when certain changes are made;
- approval by an Institutional Review Board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical studies according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical studies, and payment of a user fee, unless waived;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with good manufacturing practices, or GMPs, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns

before the clinical study can begin. A clinical hold may either be a full clinical hold or a partial clinical hold that would limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical studies due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not commence or recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such studies.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain clinical studies of cells containing recombinant or synthetic nucleic acid molecules, including human gene transfer studies, are subject to oversight of institutional biosafety committees, or IBCs, as set forth in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA; however, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Such trials remain subject to FDA and other clinical trial regulations, and only after FDA, IBC, and other relevant approvals are in place can these protocols proceed.

Clinical studies involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical studies are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and effectiveness, including stopping rules that assure a clinical study will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical studies must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical study must be reviewed and approved by an IRB at or servicing each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients who have the disease or condition the product candidate is intended to treat. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2. The biological product is evaluated in a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical studies are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product

approval and labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

Post-approval clinical studies, sometimes referred to as Phase 4 clinical studies, may be conducted after initial marketing approval. These clinical studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. In some cases, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA. The FDA generally recommends that sponsors observe subjects for potential gene therapy-related

delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire, of study subjects.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Annual progress reports detailing the results of the clinical studies must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH, as applicable, and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Human gene therapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the study period, the number of patients the FDA will require to be enrolled in the studies in order to establish the safety, efficacy, purity and potency of human gene therapy products, or that the data generated in these studies will be acceptable to the FDA to support marketing approval.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life and to identify appropriate storage conditions for the product candidate.

United States Review and Approval Processes

After the completion of clinical studies of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, as amended, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration

for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted. The testing and approval

processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. Each BLA must be accompanied by a user fee, and the sponsor of an approved BLA is also subject to an annual program fee. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. For a cell or gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register

and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical studies were conducted in compliance with IND study requirements and GCP requirements. To assure GMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application, or request a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA

may require Phase 4 clinical studies, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

One of the performance goals agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, is to review 90% of standard BLAs in within 10 months of the 60-day filing date and 90% of priority BLAs in within six months of the 60-day filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides certain additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date. submission.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act of 1983 or the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting a new drug application, or NDA, or BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan designation may also be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of the patient with the rare disease or condition. Orphan product designation in the EU has similar, but not identical, benefits.

Expedited Development and Review Programs

The FDA has established several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include fast track designation, breakthrough therapy designation, priority review and accelerated approval.

New drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product at any time during the clinical development of the product. The FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. A product may be eligible for other types of FDA programs intended to expedite development and review, such as priority review, accelerated approval, and breakthrough therapy designation.

Under the breakthrough therapy program, products intended to treat a serious or life-threatening disease or condition may be eligible for the benefits of the fast track program when preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies. Breakthrough Therapy designation includes all of the benefits of Fast Track designation in addition to intensive

guidance on a development program beginning as early as Phase 1. Additionally, FDA will seek to ensure the sponsor of a breakthrough therapy product receives timely advice and interactive communications to help the sponsor design and conduct a development program as efficiently as possible. A product may also be eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the sponsor fails to conduct such studies in a timely manner and send the necessary updates to the FDA, or if a confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for accelerated approval, the FDA currently requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period, which could adversely impact the timing of the commercial launch of the product. Fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Regenerative Medicine Advanced Therapies Designation

As part of the 21st Century Cures Act, Congress amended the FD&C Act to facilitate an efficient development program for, and expedite review of regenerative medicine advanced therapies, which include cell and gene therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Regenerative medicine advanced therapies do not include those human cells, tissues, and cellular and tissue based products regulated solely under section 361 of the PHS Act and 21 CFR Part 1271. This program is intended to facilitate efficient development and expedite review of regenerative medicine therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and qualify for RMAT designation. A drug sponsor may request that FDA designate a drug as an RMAT concurrently with or at any time after submission of an IND. FDA has 60 calendar days to determine whether the drug meets the criteria, including whether there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

Post-Approval Requirements

Maintaining compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP. We will rely, and expect to continue to rely, on

third parties for the production of clinical and commercial quantities of any future products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. For certain commercial prescription drug and biologic products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. Other post-approval requirements applicable to biological products include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain GMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval. In addition, companies that manufacture or distribute drug or biological products or that hold approved BLAs must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a REMS or the conduct of post-marketing studies to assess a newly-discovered safety issue.

We also must comply with the FDA's and other jurisdictions' advertising and promotion requirements, such as those related to direct-to-consumer advertising and advertising to healthcare professionals, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. Consequences could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with healthcare professionals, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. Although physicians may prescribe

approved products for off-label use, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties, including liabilities under the False Claims Act where products carry

reimbursement under federal health care programs. Promotional materials for approved biologics must be submitted to the FDA in conjunction with their first use or first publication.

United States Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved biological product, a method for using it, or a method for manufacturing it may be extended. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant BLA.

A biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and patent terms. indications of the active moiety. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

The Patient Protection and Affordable Care Act, or Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. The BPCIA attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, a reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period. The FDA may approve multiple "first" interchangeable products so long as they are all approved on the same first day of marketing, and the exclusivity period may be shared among multiple first interchangeable products.

Healthcare and Privacy Laws

In addition to restrictions on marketing of pharmaceutical products, several other types of state/federal laws and trade association membership codes of conduct have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include Anti-Kickback and false claims statutes. The United States federal healthcare program Anti-Kickback statute prohibits, among other things, knowingly and willfully

offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging healthcare professionals or patients as speakers or consultants, may be subject to scrutiny if they do not fit squarely within the exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient assistance programs.

The United States federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payers if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the federal False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing the product for unapproved, and thus non-reimbursable, uses. Federal enforcement agencies also have showed increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, the Affordable Care Act amended federal law to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Criminal prosecution is possible for making or presenting a false or fictitious or fraudulent claim to the federal government.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The United States Federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics and medical supplies to engage in extensive tracking of payments and other transfers of value to physicians, certain other licensed health care practitioners and

teaching hospitals, including physician ownership and investment interests, and public reporting of such data. Pharmaceutical and biological manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program are required to track such payments, and must submit a report on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year. Additionally, federal government price reporting laws, which require us to calculate and report complex

pricing metrics in an accurate and timely manner to government programs and consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers, may apply to us. A number of other countries, states and municipalities have also implemented additional payment tracking and reporting requirements, which if not done correctly may result in additional penalties.

In addition, the United States Foreign Corrupt Practices Act, or the FCPA, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity. In many other countries, healthcare professionals who prescribe pharmaceuticals are employed by government entities, and the purchasers of pharmaceuticals are government entities. Our dealings with these prescribers and purchasers may be subject to the FCPA.

Other countries, including a number of EU member states, have laws of similar application, including anti-bribery or anti-corruption laws such as the UK Bribery Act. The UK Bribery Act prohibits giving, offering, or promising bribes to any person, as well as requesting, agreeing to receive, or accepting bribes from any person. Under the UK Bribery Act, a company that carries on a business or part of a business in the United Kingdom may be held liable for bribes given, offered or promised to any person in any country by employees or other persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability under the UK Bribery Act is strict, but a defense of having in place adequate procedures designed to prevent bribery is available.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In California the California Consumer Protection Act, ("CCPA"), or the CCPA, as amended by the California Privacy Rights Act, ("CPRA"), or the CPRA, which went into effect on January 1, 2023, establishes a privacy framework for covered businesses by creating an expansive definition of personal information, establishing data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. security incidents. The CPRA also created a new state agency that is vested with authority to implement and enforce the CCPA and the CPRA. While clinical trial data and information governed by HIPAA are currently exempt from the current version of the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope.

Certain other state laws impose similar privacy obligations, and we also anticipate that more states will increasingly enact legislation similar to the CCPA. The CCPA has prompted a number of proposals for new federal and state-level privacy legislation and in some states efforts to pass comprehensive privacy laws have been successful. For example, on January 1, 2023, the Virginia Consumer Data Protection Act, or CDPA, became effective. Further, many additional US state privacy laws will go into effect throughout 2023: Colorado Privacy Act, or CPA (July 1, 2023); Connecticut Data Privacy Act, or CTDPA (July 1, 2023); Utah Consumer Privacy Act, or UCPA (December 31, 2023). The CDPA, CPA, CTDPA, and UCPA are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including a general exemption for clinical trial data

and information governed by HIPAA. However, each of these laws also contain additional requirements that may impose additional compliance obligations upon us. Additionally, any of these laws may broaden their scope in the future, and similar laws have been proposed on both a federal level and in more than half of the states in the U.S. The existence of comprehensive privacy laws in different states in the country, if enacted, will add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources

in compliance programs, impact strategies and the availability of previously useful data, and has resulted in and will result in increased compliance costs and/or changes in business practices and policies.

Many US states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. In addition, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers, marketing expenditures, and drug pricing information. Certain state and local laws require the registration of pharmaceutical sales representatives. State laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. In addition, globally, many countries have enacted stringent privacy and data protection laws. In the event that we begin to conduct trials outside of the United States or otherwise process personal information in countries outside of the United States, we will have to implement a comprehensive compliance program to address these requirements.

In the United States, to help patients afford our products, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the Affordable Care Act's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities.

In September 2014, the OIG of the U.S. Department of Health and Human Services, or HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly

alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws.

On December 2, 2020, the HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers (PBMs), unless the price reduction is required by law. The rule also creates a new safe harbor for price

reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between PBMs and manufacturers. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and PBM service fees are currently under review by the current U.S. presidential administration and may be amended or repealed. Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug ("Accumulator Rule"). On May 17, 2022, the U.S. District Court for the District of Columbia granted the Pharmaceutical Research and Manufacturers of America's (PhRMA) motion for summary judgement invalidating the Accumulator Rule. We cannot predict how the implementation of and any further changes to this rule will affect our business. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U.S. presidential administration may reverse or otherwise change these measures, both the current U.S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

Because of the breadth of these various healthcare and privacy laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare and privacy laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, as well as the potential curtailment or restructuring of our operations. Even if we are not

determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert the attention of our management from operating our business.

Government Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical studies. In the EU, for example, a CTA must be submitted for each clinical trial to each country's national competent authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, the corresponding clinical study may proceed. In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which entered into application to replace Clinical Trials Directive 2001/20/EC on January 31, 2022. The new Regulation, which will be directly applicable in all EU member states (meaning that no national implementing legislation in each EU member state is required), aims at simplifying and streamlining the approval of clinical trials in the EU. The main characteristics of the Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

The requirements and process governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of a medicinal product in the EU, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, region-specific document requirements. Medicinal product candidates may only be commercialized after obtaining the marketing authorization application. A centralized marketing authorization is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for

Medicinal Products for Human Use, or CHMP, of the EMA, and is valid throughout the EU, and in the additional member states of the European Economic Area, or EEA (Norway, Iceland and Liechtenstein). The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines), and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

Under the centralized procedure the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a marketing authorization application under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

The EU also provides opportunities for market exclusivity. For example, in the EU, upon receiving marketing authorization, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the innovative medicinal product when applying for a generic or biosimilar marketing authorization in the EU during such eight-year period starting from the date of grant of the innovative medicinal product's marketing authorization. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity (and the grant of the relevant generic or biosimilar marketing authorization). The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an

innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on a marketing authorization application with a complete, independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Products receiving orphan designation in the EU and being granted a marketing authorization for an orphan medicinal product can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. A “similar medicinal product” is defined as a medicinal product

containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan product can also obtain an additional two years of market exclusivity in the EU where the application for a marketing authorization includes the results of all studies conducted in accordance with an agreed pediatric investigation plan for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an “orphan medicinal product” in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five (5) in ten thousand (10,000) persons in the EU when the

application is made, or (b) it is unlikely that the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation itself does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, a marketing authorization may be granted to a similar medicinal product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the marketing authorization holder of the authorized product consents to a second orphan medicinal product application; or
- the marketing authorization holder of the authorized product cannot supply enough orphan medicinal product.

In the EU, the advertising and promotion of our products will also be subject to EU member states’ laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, as well as other EU member state legislation that may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product’s approved Summary of Product Characteristics, or SmPC. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. The off-label promotion of medicinal products is prohibited in the EU. The applicable laws at the EU level and in the individual EU member states also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict communications concerning the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with healthcare professionals.

Failure to comply with the EU member state laws implementing the EU laws on medicinal products, and EU rules governing the promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, with the EU member state laws that apply to the promotion of medicinal products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements can result in enforcement action by the EU member state authorities (or in addition, in some member states, enforcement action from industry bodies or legal action from competitors), which may include any of the

following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

The national laws of certain EU member states require payments made to physicians to be publicly disclosed. Moreover, the European Federation of Pharmaceutical Industries and Associations, or EFPIA, Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organizations imposes a general obligation on members of the EFPIA or related national industry bodies to disclose transfers of value to healthcare professionals. In addition, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU member states.

The aforementioned EU rules are generally applicable in the EEA, which consists of the EU member states, plus Norway, Liechtenstein and Iceland.

For other countries outside of the EU, such as countries in Eastern Europe, Central and South America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. This act could have implications for our interactions with physicians in and outside the UK. In all cases, again, the clinical trials are conducted in accordance with GCP, applicable regulatory requirements, and ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, warning letters or untitled letters, injunctions, civil, administrative, or criminal penalties, monetary fines or imprisonment, suspension or withdrawal of regulatory approvals, suspension of ongoing clinical studies, refusal to approve pending applications or supplements to applications filed by us, suspension or the imposition of restrictions on operations, product recalls, the refusal to permit the import or export of our products or the seizure or detention of products.

Pricing, Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payers to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the United States Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payers tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the drug product. Third-party payers may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payers may provide coverage, but place stringent limitations on such coverage, such as requiring alternative treatments to be tried first. These third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services,

in addition to their safety, efficacy, and overall value. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to incurring the costs required to obtain FDA approvals. Our product candidates may not be considered medically reasonable or necessary or cost-effective. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of drug products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate systems under which products may be marketed only after a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of studies or analyses of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to set their own prices for medicines, but exert cost controls in other ways, including but not limited to, placing revenue caps on product sales, providing reimbursement for only a subset of eligible patients, mandating price negotiations after a set period of time, or mandating that prices not exceed an average basket of prices in other countries. The downward pressure on health care costs in general, particularly treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, European governments may periodically review and decrease prices based on factors, including but not limited to, years-on-market, price in other countries, competitive entry, new clinical data, lack of supporting clinical data, or other factors.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, the emphasis on managed care in the United States has increased and we expect will continue to exert downward pressure on pharmaceutical pricing. Coverage policies, third-party reimbursement rates and pharmaceutical pricing regulations may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

Payers, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under

Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- The U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. Subsequent legislation extended the 2% payment reduction which remains in effect through 2030. 2031.
- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which further reduced Medicare payments to several types of providers. providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In

February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Federal, state and local governments in the United States and foreign governments continue to consider other legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Specifically, there have been several recent United States Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FYs 2019 and 2018 reimbursement formula on specified covered outpatient drugs ("SCODs"). The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020 November 3, 2023, the U.S. District Court of Appeals for South Carolina issued an opinion in Genesis Healthcare Inc. v. Becerra et al. that may lead to an expansion of the District scope of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. Plaintiffs-appellees filed a petition for a writ patients eligible to access prescriptions at 340B pricing. The outcome of certiorari at the Supreme Court on February 10, 2021. On June 15, 2022, the Supreme Court unanimously reversed the Court of Appeals' decision, holding that HHS's 2018 and 2019 reimbursement rates for 340B hospitals were contrary to the statute and unlawful. this judicial proceeding is uncertain. We continue to review developments impacting the 340B program.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Human Capital Resources

As of February 1, 2023 February 1, 2024, we employ approximately 425 274 full-time employees, 97 62 of whom hold M.D. or Ph.D. degrees. To allow us flexibility in meeting varying workflow demands, we also engage consultants and temporary workers when needed. None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union. We consider our employee relations to be good.

In September 2023, we announced a reduction in workforce of approximately 40% in connection with a strategic restructuring and in January 2024, we announced a reduction in workforce of approximately 14% in connection with a strategic realignment to focus on the development and commercialization of *Abecma*.

Compensation and benefits programs

Our compensation programs are designed to align our employees' interests with the drivers of growth and stockholder returns by supporting our achievement of its primary business goals. Our goal is to attract and retain employees whose talents, expertise, leadership, and contributions are expected to sustain growth and drive long-term stockholder value. We are committed to providing comprehensive benefit options and it is our intention to offer benefits that will allow our employees and their families to live healthier and more secure lives, with a focus on both physical and mental well-being. All full-time employees are eligible for medical, dental, and vision insurance, paid time off, paid and unpaid leaves, an employee stock purchase plan, a 401(k) plan, and group life and disability coverage.

Employee development and training

The development, recruitment and retention of our employees is a critical success factor for our company. To ensure we provide a meaningful experience for our employees, we intend to offer training and development programs to increase our organizational learning and support the promotion and career development of our current employees.

Diversity

At 2seventy bio, we believe that it's about time that Diversity, Equity, Inclusion and Belonging become more than words. It is the core practice we are driven by in all we create. From our focus on patients, to how we are building our business and our culture, we believe diversity and belonging empower us to change the way we think, teach, and learn — from each other and about each other. Our mission is rooted in the belief that our cumulative and unique differences enable us to become better — better at our development of revolutionary scientific advancements and how we advance health equity by addressing cancer disparities with a goal of creating transformative treatments for those who need them. We strive to build an environment where we will deliver our best — that means having the

hard conversations and doing the hard work — so we can all be unencumbered and inspired to celebrate who we are fully as human beings.

Corporate Information

We were incorporated under the laws of the state of Delaware in April 2021. Our mailing address and executive offices are located at 60 Binney Street, Cambridge Massachusetts 02142 and our telephone number at that address is (339) 499 -9300. (617) 675-7270.

Available Information

The company intends

We intend to use its our website www.2seventybio.com as a means of disclosing material non-public information and for complying with its disclosure obligations under the Securities and Exchange Commission, ("SEC") or the SEC, Regulation FD. The information on our website is not incorporated by reference in this Annual Report on Form 10-K or in any other filings we make with the SEC.

We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Securities Exchange Act of 1934, as amended. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, exhibits and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC.

A copy of our Corporate Governance Guidelines, Code of Business Conduct and Ethics and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are posted on our website at https://ir.2seventybio.com/corporate-governance/governance-overview, under "Investors & Media – Corporate Governance."

The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding us and other issuers that file electronically with the SEC. The SEC's Internet website address is http://www.sec.gov.

Item 1A. Risk Factors

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Annual Report on Form 10-K, or this Annual Report, including our financial statements and related notes hereto, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Capital Needs

Our business has incurred significant losses and we anticipate that we will incur continued losses for the foreseeable near future. We have never recognized revenue from product sales and may never be profitable.

Our business has incurred operating losses due to costs incurred in connection with our research and development activities and general and administrative expenses associated with our operations. Our net loss for the year ended December 31, 2022 December 31, 2023 was $254.2 million $217.6 million, and our net losses for the years ended December 31, 2021 December 31, 2022 and 2020 2021 were $292.2 million $254.2 million and $120.1 million $292.2 million, respectively. We expect to incur operating losses for several years, as we continue our research activities and conduct development of, and seek regulatory approvals for, our product candidates, including *Abecma* for additional indications.

The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to recognize revenues. We have devoted significant financial resources to research and development, including our clinical and preclinical development activities for *Abecma*, which we expect to continue for the foreseeable future. Our current and future revenues will depend upon the size of any markets in which *Abecma* and any future products have has received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for *Abecma* and any future products in those markets.

We expect to continue to incur significant expenses and continued operating losses for in the foreseeable near future. We anticipate that our expenses will increase if and as we:

- continue our research and preclinical and clinical development of our product candidates, including any additional clinical trials of *Abecma*, which we are co-developing with Bristol Myers Squibb, or BMS;
- conduct commercialization activities for *Abecma*;
- obtain, build and expand manufacturing capacity, including capacity at third-party manufacturers;
- hire additional manufacturing personnel for our drug product facility;
- initiate additional research, preclinical, clinical or other programs as we seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- experience any delays or encounter issues with any of the above.

Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or the EMA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Even though *Abecma* has been approved by the FDA and even if one or more of the product candidates that we develop is approved for commercial sale, we may never recognize revenue in amounts sufficient to achieve and maintain profitability. The net losses we incur

may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We will need to raise additional funding to advance our product candidates, Abecma, which may not be available on acceptable terms, or at all. Failure to obtain capital when needed may force us to delay, limit or terminate our product development or commercialization efforts or other operations. Raising additional capital may dilute our existing stockholders, restrict our operations or cause us to relinquish valuable rights.

As of December 31, 2022 December 31, 2023, we held cash, cash equivalents and marketable securities of $267.7 million $221.8 million. We will require significant additional funding to advance our product candidates, alone or with strategic partners, through clinical studies and to seek marketing approval, as well as to continue advancing our research and development efforts with our preclinical product candidates. We may also need to raise additional funds sooner than currently anticipated if we choose to pursue additional indications or geographies for

Abecma or any future products for which we obtain regulatory approval, identify additional product candidates to advance through clinical development or otherwise expand more rapidly than we presently anticipate. In addition, if we obtain marketing approval for any other product candidates, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution. We also may elect to raise additional funds sooner because we believe market conditions are attractive or as a risk mitigation measure.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our approved product and product candidates.*Abecma*. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on

our business, operating results and prospects. Regardless of the terms of any debt or equity financing, our agreements and obligations under the tax matters agreement with bluebird bio, Inc., or bluebird bio, may limit our ability to issue stock. See "—Risks Related to the Separation."

If we are unable to obtain funding on a timely basis, or if revenues from collaboration arrangements or product sales are less than we have projected, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs for our product candidates or the commercialization of *Abecma* or any future products or be unable to expand our operations or otherwise capitalize on our business opportunities as desired, which could materially affect our business, financial condition and results of operations. In addition, if we are unable to obtain necessary funding on a timely basis, we may have to liquidate some or all of our assets and may receive less than the value at which those assets are carried on our audited financial statements, which could cause investors to lose all or a part of their investment.

Because we have a limited operating history, valuing our business and predicting our prospects is challenging.

We were incorporated in April 2021 and separated from bluebird bio in November 2021. Although our business was conducted as part of bluebird bio prior to our separation, we did not operate as an independent company prior to the completion of the separation. We are developing an oncology pipeline of cell and gene therapies for cancer, the first of which, *Abecma* (ide-cel), was approved by the FDA in March 2021. The FDA granted approval of *Abecma* to BMS, our partner with whom we are jointly commercializing *Abecma* in the U.S. through our co-development and co-promotion arrangement. Our revenues to date have been derived from out-licensing arrangements and

collaboration, including the collaboration revenue derived from commercial sales of *Abecma* by BMS. To date, we have not recognized any revenues from the sale of products by us. Our operating activities to date have been limited primarily to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates and clinical trial activities.

We have limited experience in commercial scale manufacturing of the lentiviral vector for *Abecma* and in the sales and marketing activities necessary for the commercialization of *Abecma*. In addition, we have not obtained marketing approval of any of our other product candidates. Our short operating history offers limited insight into our prospects for success or even viability and we expect our operating results to be subject to frequent fluctuations. We will encounter challenges frequently experienced by biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully navigate such challenges. If we do not address the challenges we face successfully, our business, prospects, financial condition and results of operations will be materially harmed.

Risks Related to Strategic Realignment

Our strategic realignment to focus on the development and commercialization of Abecma may not be as successful as anticipated, fail to achieve the anticipated cost savings, and cause disruptions in our business that could make it difficult to achieve our strategic objectives.

In January 2024, we announced a strategic realignment to focus on the development and commercialization of *Abecma.* In connection with the strategic realignment, we entered into an asset purchase agreement with Regeneron to sell substantially all of the assets related to our solid tumor and other oncology and autoimmune cell therapy

programs, or the Asset Sale. The Asset Sale is expected to close in the first half of 2024 and is subject to customary closing conditions. We have limited experience implementing similar strategic initiatives and, as a result, we may fail to achieve the associated benefits, or fail to anticipate the associated costs or manage any expected difficulties. If we are unable to successfully manage these realignment activities, our financial performance, results of operations, and prospects could be negatively affected. In addition, the impact of these initiatives could result in variations in our financial results from period to period, which could make comparisons of our financial performance more difficult.

We have recently undertaken internal restructuring activities, and may do so again in the future. The assumptions underlying these activities may prove to be inaccurate, or we may fail to achieve the expected benefits.

In September 2023, we announced a reduction in workforce of approximately 40% in connection with a strategic restructuring and in January 2024, we announced a reduction in workforce of approximately 14% in connection with a strategic realignment to focus on the development and commercialization of *Abecma*. These workforce reductions, and any other future reductions, and the attrition that may occur following them, may result in the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. These reductions and other additional measures we might take to reduce costs could yield unanticipated consequences, such as straining our workforce, diverting management attention, yielding attrition beyond our intended workforce reduction, or reducing employee morale. These unintended effects could cause us to delay, limit, reduce or eliminate certain development plans, or otherwise interfere with our ability to operate and grow our business effectively, which could have an adverse impact on our business, operating results and financial condition. We may not complete current or any future restructuring activities on the anticipated timetable, and even if successfully completed, we may not realize, in full or in part, the anticipated benefits and cost savings from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected cost savings from the restructuring, our operating results and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future.

We may not be able to successfully or timely complete the Asset Sale, which could materially impact the market price of our common stock, as well as our future business prospects and our financial condition, results of operations and cash flows.

The Asset Sale may not be completed, or may not be completed in the timeframe, on the terms or in the manner currently anticipated. The completion of the Asset Sale is subject to the satisfaction or waiver of customary closing conditions. There can be no assurance that these conditions will be satisfied or waived, or that other events will not intervene to delay or result in the failure to close the Asset Sale. If the Asset Sale is not consummated in a timely manner or at all, our ongoing business may be materially adversely affected, including without limitation, as follows:

- we may experience negative reactions from financial markets and our stock price could decline;
- we may experience negative reactions from employees, partners, suppliers or other third parties;
- our management's focus would have been diverted from pursuing other valuable opportunities; and
- our costs of completing the Asset Sale may be higher than anticipated and, in any event, would be borne entirely by us.

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

Research and development of biopharmaceutical products is inherently risky. We may encounter substantial delays in our clinical studies, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Our business depends heavily on successful clinical development, regulatory approvals and commercialization of *Abecma*. Our current Any future product candidates are in various stages of clinical and preclinical development. Our current product candidates, as well as any we may discover in the future, will require substantial additional development and testing, as well as regulatory approvals, prior to commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical and clinical studies that our product candidates are both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate benefit-risk profile for its intended use in its intended patient population. Failure can occur at any time during the preclinical study and clinical trial processes, and because many of our product candidates are in an early stage of development, there is a high risk of failure. processes. In some instances, significant variability in safety or efficacy appear in different clinical studies of the same product candidate due to numerous factors, including changes in study protocols, differences in the number and characteristics of the enrolled subjects, variations in the dosing regimen and other clinical study parameters or the dropout rate among study participants. Product candidates in later stages of clinical studies often fail to demonstrate adequate safety and efficacy despite encouraging preclinical study and earlier clinical trial results. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical studies. Most product candidates that begin clinical studies are never approved for commercialization by regulatory authorities. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our any product candidates, candidate, we may be prevented or delayed in obtaining marketing approval for such product candidates. candidates

If we encounter difficulties in recruiting or enrolling subjects in our clinical studies, we could be delayed or prevented from proceeding with clinical trials of our product candidates. Abecma.

Identifying and qualifying patients to participate in clinical studies of our product candidates*Abecma* is critical to our success. The timing of our clinical studies depends in part on the speed at which we our partner, BMS, can recruit patients to participate, in testing our product candidates, and we may experience delays in our clinical studies if we encounter difficulties in enrollment. The estimated incidence of our target indications, including newly diagnosed multiple myeloma, non-Hodgkin's lymphoma and acute myeloid leukemia, the target indications for our product candidates, vary varies considerably. Determining the incidence of these conditions, this condition, including in specific geographies or demographic groups, is challenging. The lower the actual incidence of these conditions, this condition, the more challenges we will encounter enrolling subjects in our clinical studies, which could delay development of our*Abecma* or future product candidates. Clinical trial recruitment and enrollment may also encounter difficulties for a variety of other reasons. The number of patients eligible for a clinical trial may be substantially limited by stringent eligibility criteria in a study protocol, such as the inclusion of biomarker-driven identification or other highly specific criteria related to stage of disease progression or to specific patient reported outcome measures. The number of patients required to power the statistical analysis of the study's endpoints may be very large leading to an extended enrollment period. Issues such as the proximity of subjects to a study site, the complexity of the study design, our ability to recruit investigators with appropriate skill and experience, competing clinical studies for similar therapies or targeting similar subjects, perceptions of the benefit-risk profile of the product candidate relative to other available therapies or product candidates, risk that patients enrolled in clinical trials drop out before clinical trial completion, and ability to obtain and maintain institutional review board, or IRB, approvals and patient consents all could have a substantial impact on the timing of clinical trial enrollment. In addition, our ability to recruit and enroll patients may be significantly delayed by the effects of public health crises, including the ongoing COVID-19 pandemic or the outbreak of a similar epidemic, and actual or anticipated government responses to such health events. If we are unable to enroll sufficient subjects in clinical studies in a timely way, obtaining study results will be delayed, which may harm our business, prospects, financial condition, and results of operations.

If the market opportunities for Abecma or any future approved products are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.

We focus our research, development, and commercialization efforts on treatments for cancer. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with *Abecma* or any future approved products, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower or more difficult to identify than expected. Additionally, the potentially addressable patient population for *Abecma* and any future approved products may be limited or may not be amenable to treatment with our products.

Even if we obtain significant market share for a product within an approved indication, because the potential target populations for our product and for the product candidates in our pipeline are small, we may never achieve profitability without obtaining marketing approval for additional indications. In the field of cancer, the FDA often approves new therapies initially only for use in patients with relapsed or refractory advanced disease. We expect to initially seek approval of our engineered cell therapy product candidates in cancer in this context. Subsequently, for those products that prove to be sufficiently beneficial, we would expect to seek approval in earlier lines of treatment and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. For example, BMS received marketing approval from the FDA for *Abecma* as a treatment for adult patients with relapsed and refractory multiple myeloma who have not responded to, or whose disease has returned after, at least four prior lines of therapy. BMS is conducting additional studies with the intention to generate data to support marketing approvals for earlier lines of therapy in multiple myeloma, but there is no assurance that such studies will be successful or be sufficient to support label expansion. For example, based on interim results from KarMMa-3, we plan to seek are seeking FDA approval for *Abecma* as a third line therapy in relapsed and refractory multiple myeloma patients; however, we may not be successful in our efforts to obtain regulatory approval for or successfully commercialize *Abecma* in this indication.

Any of these factors may negatively affect our ability to recognize revenues from sales of *Abecma* and any future products and our ability to achieve and maintain profitability and, as a consequence, our business may suffer.

We cannot predict when or if we will obtain marketing approval to commercialize our product candidates, and If the marketing approval of Abecma and any future approved products may is ultimately be for more narrow indications than we expect. If our product candidates are not approved in a timely manner or at all for any reason, expect, our business prospects, results of operations, and financial condition would be adversely affected.

Before obtaining marketing approval from regulatory authorities for the commercialization of each of our product candidates,*Abecma* in additional indications, we must complete preclinical studies and then conduct extensive clinical studies to demonstrate the safety, purity and potency, and efficacy, of the product candidate in humans. Preclinical and clinical testing humans in such indications, which is expensive, time-consuming and uncertain as to outcome. There is outcome and subject to a high failure rate for drugs and biologics proceeding through clinical studies. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical studies even after achieving encouraging results in preclinical studies or earlier stage clinical studies. rate. We cannot guarantee that any clinical studies will would be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- data collected from clinical trials may not be sufficient to support the submission or to obtain regulatory approval approval;
- delays in reaching, or failure to reach, a consensus with regulatory agencies on study design;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical study operations or study sites or due to unforeseen safety issues;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites;
- failure to obtain sufficient cells from patients to manufacture enough drug product or achieve target cell doses;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- delays or difficulties in initiating clinical study sites or patients dropping out of a study;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Furthermore, the timing of our clinical studies depends on the speed at which we can recruit eligible patients to participate, in testing our product candidates, and we may experience delays if we encounter difficulties in recruitment or enrollment. The conditions for which we plan to evaluate our current product candidates in severe genetic diseases are rare disorders with limited patient pools from which to draw for clinical studies. The eligibility criteria of our clinical studies will further limit the pool of available study participants, and the process of finding and diagnosing patients may prove costly. Patients may be unwilling to participate in our studies because of negative publicity from adverse events in the biotechnology or gene therapy industries or for other reasons, including competitive clinical studies for similar patient populations, the proximity and availability of clinical study sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval for our product candidates may be delayed. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical studies in a timely manner or as required by the FDA or comparable foreign regulatory authorities. We have experienced delays in some of our clinical studies in the past, and we may experience similar delays in the future.

Even if our product candidates demonstrate*Abecma* demonstrates safety and efficacy in additional indications in clinical studies, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. We may experience delays or rejections based upon additional government regulation from future legislation or administrative action, changes in regulatory agency policy, or additional regulatory feedback or guidance during the period of product development, clinical studies and the review process. The field of engineered cell therapy is evolving, and as more products are reviewed by regulatory authorities, regulatory authorities may

impose additional requirements that were not previously anticipated. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested, impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS, or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Furthermore, approvals by the EMA and the European Commission may not be indicative of what the FDA may require for approval. In general, the FDA requires the successful completion of two pivotal trials to support approval of a biologics license application, or BLA, but in certain circumstances, will approve a BLA based on only one pivotal trial. Additionally, certain factors beyond our and our collaborators' control may impact the timeliness of the regulatory reviews of our submissions or any applications for approval.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, are ultimately not approved the commercial prospects of our product candidates will be harmed, and our ability to recognize product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and recognize revenues for any reason, these product candidates.

Any of these occurrences may harm our business, prospects, financial condition, results of operations and financial condition would be adversely affected. prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of *Abecma* in additional indications.

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

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as

patient enrollment and treatment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Results from previous or ongoing studies are not necessarily predictive of our future clinical study results, and initial or interim results may not continue or be confirmed upon completion of the study. There is limited data concerning long-term safety and efficacy following treatment with our engineered cell therapy product candidates. These data, or other positive data, may not continue or occur for these patients or for any future patients in our ongoing or future clinical studies, and may not be repeated or observed in ongoing or future studies involving our product candidates. Furthermore, our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical studies. There can be no assurance that any of these studies will ultimately be successful or support further clinical advancement or

marketing approval of our product candidates. For instance, patients with relapsed and refractory multiple myeloma who have been treated with *Abecma* in clinical trials have experienced disease progression. We have experienced unexpected results in the past, and we may experience unexpected results in the future.

Delays in the commencement and completion of clinical trials could increase costs and delay or prevent regulatory approval and commercialization of our product candidates.

We cannot guarantee that clinical trials of our product candidates will be initiated or conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of the clinical trial process, and other events may cause us to temporarily or permanently stop a clinical trial. Events that may prevent successful or timely commencement and completion of clinical development include:

- negative preclinical data;
- delays in receiving the required regulatory clearance from the appropriate regulatory authorities to commence clinical trials or amend clinical trial protocols, including any objections to our Investigational New Drug Applications, or INDs, or protocol amendments from the FDA;
- delays in reaching, or a failure to reach, a consensus with regulatory authorities on study design;
- delays in reaching, or failure to reach, agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulties in adding a sufficient number of clinical trial sites and obtaining IRB or independent ethics committee approval at each site;
- challenges in recruiting suitable patients to participate in a trial;
- slower enrollment in clinical trials than anticipated or a larger number of patients required for a clinical trial than anticipated;
- the inability to enroll a sufficient number of patients in clinical trials to ensure adequate statistical power to detect statistically significant treatment effects;
- difficulties in having patients complete a trial or return for post-treatment follow-up;
- our CROs or clinical trial sites or other third parties failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a clinical trial;
- unforeseen safety issues, including occurrence of treatment emergent adverse events associated with the product candidate that are viewed to outweigh the product candidate's potential benefits;
- the need to suspend or terminate clinical trials for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- difficulties in adding new clinical trial sites;
- our preclinical studies or clinical trials failing to show safety or efficacy or otherwise producing ambiguous or negative interim results, leading us to decide, or regulators requiring us to conduct additional preclinical studies or clinical trials or abandon our research efforts for our other product candidates;
- lack of adequate funding to continue the clinical trial;
- greater costs than anticipated;

- difficulties in manufacturing sufficient quantities of acceptable product candidate for use in preclinical studies or clinical trials in a timely manner, or at all; or
- global health crises, including the ongoing COVID-19 pandemic or the outbreak of a similar epidemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to recognize product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and recognize revenues for these product candidates. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Our clinical trial results may not be successful, or even if successful, may not lead to regulatory approval.

Where appropriate, we may seek approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw the accelerated approval.

Where possible, we may pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for our one or more of our product candidates from the FDA, EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a therapeutic candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit, and the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified period after the date of approval. Sponsors must also update FDA on the status of these studies, and under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA has increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit.

Prior to seeking accelerated approval, we will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our

application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace. Moreover, even if we are able to obtain accelerated approval for any of our product candidates, there is no guarantee that post-approval studies will be able to confirm the clinical benefit, which could cause FDA to withdraw our approval.

We may seek fast track designation, breakthrough therapy designation and/or orphan drug designation from the FDA or similar designations from other regulatory authorities for one or more of our product candidates. Even if one or more of our product candidates receive any of these designations, we may be unable to obtain or maintain the benefits associated with such designation.

The FDA has established various designations to facilitate more rapid and efficient development and approval of certain types of drugs and biologics. Such designations include fast track designation, breakthrough therapy designation, and orphan drug designation. Fast track designation is designed to facilitate the development and expedite the review of therapies for serious conditions that fill an unmet medical need. Programs with fast track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. If any of our product candidates receive fast track designation but do not continue to meet the criteria for fast track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply or due to other issues, we will not receive the benefits associated with the fast track program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Designation as a breakthrough therapy is within the discretion of the FDA, and drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval. Even if one or more of our product candidates qualify as breakthrough therapies pursuant to FDA standards, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek breakthrough therapy designation for one or more of our current or future product candidates, there can be no assurance that we will receive breakthrough therapy designation.

Regulatory authorities in some jurisdictions, including the U.S. and the EU, may also designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, or the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the EU, the EMA's Committee for Orphan Medicinal Products (COMP) evaluates orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers, and it may entitle the therapeutic to exclusivity in the U.S. and the EU. Regulatory authorities may not grant our requests for orphan designation, or may require submission of additional data before making such determination. Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate.

If any of our programs or product candidates receive fast track, breakthrough therapy or orphan drug designation by the FDA or similar designations by other regulatory authorities, there is no assurance that we will receive any benefits from such programs or that we will continue to meet the criteria to maintain such designation. Even if we obtain such designations, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A fast track, breakthrough therapy, or orphan drug designation does not ensure that a product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw any such designation if it believes that the designation is no longer supported by data from our clinical development program.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, or if BMS is ultimately unable to obtain regulatory approvals for Abecma in additional or expanded indications, we will be unable to recognize product revenue and our business will be substantially harmed.

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors, including the type, complexity, and novelty of the product candidates involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept an application for review, or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies.

In September 2020, the FDA accepted for priority review the BLA submitted by BMS for *Abecma* (ide-cel) as a treatment for relapsed and refractory multiple myeloma and the FDA approved this BLA in March 2021. However, obtaining one regulatory approval does not guarantee that the FDA will conclude that the information BMS has submitted for earlier line indications and may submit for additional or expanded indications for *Abecma* will be sufficient to support approval for those indications and BMS may fail to obtain additional regulatory approvals in

the United States for *Abecma*. For example, there is no guarantee that the FDA will conclude that the information BMS has submitted to support the supplemental Biologics License Application, or sBLA, for *Abecma* for triple-class exposed relapsed or refractory multiple myeloma is sufficient to support approval. In February 2024, we and BMS announced that FDA will convene an advisory committee meeting in March 2024 to review data supporting the sBLA for *Abecma* for triple-class exposed relapsed or refractory multiple myeloma. An advisory committee may recommend against approval of the sBLA or may recommend that the FDA require, as a condition of approval, additional preclinical studies, clinical trials or investigations, limitations on approved labeling or distribution and use restrictions. Even if an advisory committee makes a favorable recommendation, the FDA may still not approve the sBLA. Additionally, certain factors beyond our and BMS' control may impact the timeliness of the regulatory reviews of our submissions or any applications for approval.

We may never be able to obtain regulatory approval for any other product candidates. If our product candidates, including *Abecma* for additional indications, are ultimately not approved for any reason, our business, prospects, results of operations and financial condition would be adversely affected.

Our ongoing clinical studies may not be completed on schedule, and our planned clinical studies may not begin on schedule, if at all. The completion or commencement of clinical studies can be delayed or prevented for a number of reasons, including, among others:

- the FDA or comparable foreign regulatory authorities may not authorize us or our investigators to commence planned clinical studies, or require that we suspend ongoing clinical studies through imposition of clinical holds;
- negative results from our ongoing studies or other industry studies involving engineered cell therapy product candidates;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to considerable negotiation and may vary significantly among different CROs and study sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical studies, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining ethics committee or IRB, approval to conduct a clinical study at a prospective site or sites;
- challenges in recruiting and enrolling subjects to participate in clinical studies, the proximity of subjects to study sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical study programs for similar indications;
- severe or unexpected drug-related side effects experienced by subjects in a clinical study, such as severe neurotoxicity and cytokine release syndrome;
- we may decide, or regulatory authorities may require us, to conduct additional clinical studies or abandon product development programs;
- the FDA or comparable foreign regulatory authorities may disagree with our clinical study design, implementation of clinical trials or our interpretation of data from clinical studies, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical studies;
- reports from preclinical or clinical testing of other competing candidates that raise safety or efficacy concerns; and
- difficulties retaining subjects who have enrolled in a clinical study but may be prone to withdraw due to rigors of the clinical studies, lack of efficacy, side effects, personal issues, or loss of interest.

Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical study may be suspended or terminated by us, the FDA or other comparable authorities, the IRBs or ethic committees at the sites where the IRBs or ethic committees are overseeing a clinical study, a data and safety monitoring board overseeing the clinical study at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including in response to the imposition of a clinical hold;
- unforeseen safety issues, including any that could be identified in our ongoing studies, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue clinical studies.

In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the use of any approved product, which will limit its prospects for commercialization, which could have a material and adverse effect on our business, prospects, financial condition and results of operations.

Patients receiving T cell-based immunotherapies such as Abecma may experience serious adverse events, including neurotoxicity and cytokine release syndrome. Serious adverse events or undesirable side effects associated with Abecma or our product candidates may result in delays, clinical holds, or terminations of our clinical trials, impact our ability to obtain or maintain marketing approval, and impact market acceptance and commercial sales, which will significantly harm our business, financial condition and prospects.

Abecma is a chimeric antigen receptor, or CAR, T cell-based immunotherapy. In previous and ongoing clinical studies involving CAR T cell products, including those involving ide-cel, patients experienced side effects such as neurotoxicity and cytokine release syndrome. There have been life-threatening events related to severe neurotoxicity and cytokine release syndrome, requiring intense medical intervention such as intubation or vasopressor support, and in several cases, resulted in death. Severe neurotoxicity is a condition that is currently defined clinically by cerebral edema, confusion, drowsiness, speech impairment, tremors, seizures, or other central nervous system side effects, when such side effects are serious enough to lead to intensive care. In some cases, severe neurotoxicity was thought to be associated with the use of certain lymphodepletion regimens used prior to the administration of the CAR T cell products. Cytokine release syndrome is a condition that is currently defined clinically by certain symptoms related to the release of cytokines, which can include fever, chills, low blood pressure, when such side effects are serious enough to lead to intensive care with mechanical ventilation or significant vasopressor support. The exact cause or causes of cytokine release syndrome and severe neurotoxicity in connection with treatment of CAR T cell products is not fully understood at this time. In addition, patients have experienced other adverse events in these studies, such as a reduction in the number of blood cells (in the form of neutropenia, thrombocytopenia, anemia or other cytopenias), febrile neutropenia, chemical laboratory abnormalities (including elevated liver enzymes), and renal failure.

Undesirable side effects caused by *Abecma*, other CAR T product candidates targeting B cell maturation antigen, or BCMA, or our other engineered cell therapy product candidates, could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in restrictions on the labeling, distribution, or marketing of our approved products or a requirement to conduct potentially costly post-approval studies or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authorities. For example, the prescribing information for *Abecma* includes a boxed warning for cytokine release syndrome, neurologic toxicities, and

hemophagocytic lymphohistiocytosis/macrophage activation syndrome, and *Abecma* is only available in the U.S. through a REMS program. Additionally, FDA has imposed a post-marketing requirement for *Abecma* that requires completion of an observational study to assess the long-term safety of *Abecma* and the risk of secondary malignancies occurring after treatment by following patients for a 15-year period. Further, in November 2023, the FDA announced that it would be conducting an investigation into reports of T cell malignancies following BCMA-directed or CD19-directed autologous CAR T cell immunotherapies following reports of T cell lymphoma in patients receiving these therapies. In January 2024, the FDA determined that new safety information related to T cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD-19-directed genetically modified autologous T cell immunotherapies, including *Abecma*. FDA further required within 30 calendar days the submission of a supplement proposing changes to the approved labeling or a notification to the FDA containing a rebuttal statement detailing the reasons why it is believed that no labeling change is warranted. Side effects and toxicities associated with *Abecma*, as well as the warnings, precautions, and requirements listed in the prescribing information, could affect the willingness of physicians to prescribe, and patients to use, *Abecma* and negatively affect market acceptance and commercial sales. In some cases, side effects such as neurotoxicity or cytokine release syndrome have resulted in clinical holds of ongoing clinical trials and/or discontinuation of the development of the product candidate. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In addition, in June 2023, the Phase 1 trial of the PLAT-08 study of SC-DARIC33 in AML was placed on hold by Seattle Children's Research Institute following a fatal (Grade 5) serious adverse event in a patient enrolled in the study and in August 2023 the FDA placed a clinical hold on the study. The clinical hold was lifted by the FDA in December 2023. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the studies or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from engineered cell therapies are not normally encountered in the general patient population and by medical personnel. Medical personnel may need additional training regarding engineered cell therapies to understand their side effects. Inadequate training in recognizing or failure to effectively manage the potential side effects of engineered cell therapies could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

If we or others identify undesirable side effects caused by *Abecma* or our product candidates, , a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of *Abecma* or our product candidates; ;
- regulatory authorities may require the addition of labeling statements, including a "boxed" warning or contraindications, such as the "boxed" warning included in the product label for *Abecma*;

- we and/or BMS may be required to change the way *Abecma* or such product candidates are is distributed or administered, conduct additional clinical trials or change the labeling for *Abecma* or such product candidates; ;
- regulatory authorities may require a REMS plan to mitigate risks, such as the REMS program for *Abecma*;
- we may be subject to regulatory investigations and government enforcement actions;
- we or BMS may decide to remove *Abecma* or such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking *Abecma* or our product candidates; ; and
- our reputation may suffer.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of Abecma our product candidates, and any future products or adversely affect our ability to conduct our business or obtain and maintain marketing approvals for Abecma and our product candidates.

Public perception may be influenced by claims that gene therapy, including gene editing technologies, is unsafe or unethical, and research activities and adverse events in the field, even if not ultimately attributable to us or *Abecma* or our future product candidates, could result in increased governmental regulation, unfavorable public perception, challenges in recruiting patients to participate in our clinical studies, potential regulatory delays in the testing or approval of our product candidates, labeling restrictions for *Abecma* or any future approved products, and a decrease in demand for any such product. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our future product candidates or demand for any approved products.

Changes in regulatory requirements, FDA guidance or unanticipated events during our preclinical studies and clinical studies of our product candidates may occur, which may result in changes to preclinical or clinical study protocols or additional preclinical or clinical study requirements, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements, FDA guidance or unanticipated events during our preclinical studies and clinical studies may force us to amend preclinical studies and clinical study protocols. The FDA or comparable foreign regulatory authorities may also impose additional preclinical studies and clinical study requirements. Amendments or changes to our clinical study protocols would require resubmission to the FDA or comparable foreign regulatory authorities and IRBs for review and approval, which may increase the cost or delay the timing or successful completion of clinical studies. Similarly, amendments to our preclinical studies may increase the cost or delay the timing or successful completion of those preclinical studies. If we experience delays completing, or if we terminate, any of our preclinical or clinical studies, or if we are required to conduct additional preclinical or clinical studies, the commercial prospects for our product candidates may be harmed and our ability to recognize product revenue will be delayed.

Obtaining and maintaining regulatory approval of our product candidates Abecma in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

In order to market any product outside of the United States, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA or other comparable foreign regulatory authority grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical or clinical studies, as studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the United States, as well as other risks. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our product candidates is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market our product candidates in such countries. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, prospects, financial condition and results of operations.

We may not be successful in our efforts to identify or discover additional product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our engineered cell therapy technologies. Our research programs in oncology may fail to identify other potential product candidates for clinical development for a number of reasons. We may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If any of these events occur, we may be forced to abandon our research, development or commercialization efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Risks Related to Our Reliance on Third Parties

We are dependent on BMS for the successful development, commercialization and manufacture of Abecma. If BMS does not devote sufficient resources to the commercialization, manufacture and further development of Abecma, is unsuccessful in its efforts, or chooses to terminate its agreements with us, our business will be materially harmed.

We are co-developing and co-promoting ide-cel, being marketed as *Abecma* in the United States, with BMS under our amended and restated co-development and co-promotion agreement with BMS, or the Ide-cel CCPS.

Under the Ide-cel CCPS, we and BMS share the obligation to develop and commercialize ide-cel in the United States.

In our partnership with BMS, BMS is obligated to use commercially reasonable efforts to develop and commercialize ide-cel. BMS may determine however, that it is commercially reasonable to de-prioritize or discontinue the development of ide-cel. These decisions may occur for many reasons, including internal business reasons (including due to the existence of other BMS programs that are potentially competitive with ide-cel), results from clinical trials or because of unfavorable regulatory feedback. Further, on review of the safety and efficacy data, the FDA may impose additional requirements on the program that renders it commercially nonviable. In addition, under our agreements with BMS, BMS has certain decision-making rights in determining the development and commercialization plans and activities. We may disagree with BMS about the development strategy it employs, but we will have limited rights to impose our development strategy on BMS. Similarly, BMS may decide to seek marketing approval for, and limit commercialization of, ide-cel to narrower indications than we would pursue. More broadly, if BMS elects to discontinue further development and commercialization of ide-cel, we may be unable to advance these efforts ourselves. In addition, we rely on BMS to deliver complete, accurate and timely information about its financial results related to ide-cel.

This partnership may not be scientifically or commercially successful for us due to a number of important factors, including the following:

- BMS has wide discretion in determining the efforts and resources that it will apply to its partnership with us. The timing and amount of any downstream commercial profits, milestones and royalties that we may receive under such partnership will depend on, among other things, BMS's efforts, allocation of resources and successful development and commercialization of ide-cel.
- BMS may develop and commercialize, either alone or with others, products that are similar to or competitive with ide-cel. For example, BMS is currently commercializing a number of its existing products, including lenalidomide and pomalidomide, for certain patients with relapsed and refractory multiple myeloma, as well as our CAR-T product candidate targeting BCMA.
- BMS may terminate its partnership with us without cause and for circumstances outside of our control, which could make it difficult for us to attract new strategic partners or adversely affect how we are perceived in scientific and financial communities.
- BMS may develop or commercialize *Abecma* in such a way as to elicit litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability.
- BMS may not comply with all applicable regulatory and compliance requirements, including failing to report safety data in accordance with all applicable regulatory requirements.
- If BMS were to breach its arrangements with us, we may need to enforce our right to terminate the agreement in legal proceedings, which could be costly and cause delay in our ability to receive *Abecma* rights back. If we were to terminate an agreement with BMS due to BMS's breach or if BMS were to terminate an agreement without cause, the development and commercialization of *Abecma* could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of these product candidates on our own if we choose not to, or are unable to, enter into a new collaboration for these product candidates.
- BMS may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or other change in control, which could divert the attention of its management and adversely affect BMS's ability to retain and motivate key personnel who are important to the

continued development of *Abecma*. In addition, the third-party to any such transaction could determine to re-prioritize BMS's development programs such that BMS ceases to diligently pursue the development of *Abecma* and/or cause the respective collaboration with us to terminate.

We rely on third parties to conduct, supervise and monitor our clinical studies, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical study sites to ensure our studies are conducted properly and on time. While we have agreements governing their activities, we will have limited influence over their actual performance. We control only certain aspects of our CROs' activities, and as a result, we have less direct control over the conduct, timing, and completion of our clinical studies and the management of data developed through studies than would be the case if we relied on our own staff. Nevertheless, we are responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's and other regulatory authorities' good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical studies to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical study participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical studies may be deemed unreliable and the FDA and other regulatory authorities may require us to perform additional clinical studies before approving any marketing applications.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our

clinical protocols or regulatory requirements, or for any other reasons, our clinical studies may be extended, delayed or terminated, and we may not be able to obtain marketing approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to recognize revenues could be delayed.

We rely on third parties to conduct some or all aspects of our lentiviral vector production, drug product manufacturing, and testing, and these third parties may not perform satisfactorily.

We do not independently conduct all aspects of our lentiviral vector production, drug product manufacturing, and testing. We currently rely, and expect to continue to rely, on third parties with respect to these items, including manufacturing and testing in the preclinical, clinical and commercial context.

Our reliance on these third parties for manufacturing, testing, research and development activities reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for products that we develop and commercialize on our own, we will remain responsible for ensuring that each of our IND-enabling studies and clinical studies are conducted in accordance with the study plan and protocols, and that our lentiviral vectors and drug products are manufactured in accordance with good manufacturing practices, or GMP, as applied in the relevant jurisdictions. Our third-party manufacturers are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, or manufacture our lentiviral vectors and drug products in accordance with GMP, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise, we will not be able to complete, or may be delayed in completing, the preclinical and clinical studies and manufacturing process validation activities required to support future IND, marketing authorisation authorization application, or MAA, and BLA submissions and approval of our product candidates, or to support commercialization of *Abecma* or any future products. Many of our agreements with these third parties contain termination provisions that allow these third parties to terminate their relationships with us at any time. If we need to enter into alternative arrangements, our product development and commercialization activities could be delayed.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the products ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities;
- the risk that these activities are not conducted in accordance with our study plans and protocols;

- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

We may be forced to manufacture lentiviral vector and drug product ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer, which we may not be able to do on reasonable terms or without delays, if at all. In some cases, the technical skills required to manufacture our lentiviral vector or drug product candidates may be unique or proprietary to the original manufacturer, and we may have difficulty or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Any of these events could lead to clinical study delays or failure to obtain marketing approval, or impact our ability to successfully commercialize *Abecma* or any future products. Some of these events could be the basis for FDA or comparable foreign regulatory action, including injunction, recall, seizure or total or partial suspension of production. In addition, if we are required to change third-party third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations.

We also may alter various aspects of *Abecma or* our product candidates, , such as the manufacturing, formulation, method of administration or other alterations designed to optimize the candidate or processes for scale necessary for later stage clinical trials and potential approval and commercialization. For example, we intend to switch to a suspension vector for *Abecma*and certain of our product candidates. . These changes may not produce the intended optimization, including production of drug substance and drug product of a quality and in a quantity sufficient for further clinical development or commercialization, which may cause delays in the initiation or completion of clinical trials or impact commercialization and result in greater costs. We will need to verify, such as through a manufacturing comparability study, that any new manufacturing process, by us or by a new manufacturer, will produce *Abecma* or our product candidate according to the specifications previously submitted to the FDA or another comparable foreign regulatory authority.

The delays associated with the verification of a new third-party manufacturer or new manufacturing process could negatively affect our ability to develop product candidates or commercialize any approved products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing Abecma and product candidates. Abecma. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for *Abecma* and our product candidates, , are subject to extensive regulation. *Abecma* and our product candidates in clinical studies must be manufactured in accordance with GMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of *Abecma* or our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA or MAA on a timely basis and where required, must adhere to good laboratory practices, or GLP, and GMP regulations enforced by the FDA or other regulators through facilities inspection programs. Some of our contract manufacturers have not produced a commercially-approved product and therefore have not obtained the requisite FDA or other marketing approvals to do so. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval for our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA or other marketing approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other regulators can impose regulatory sanctions including, among other things, refusal to approve a pending application

for a biologic product, or revocation of or restrictions to an approved BLA. As a result, our business, financial condition and results of operations may be materially harmed.

The manufacturing processes for our lentiviral vectors and our drug products are complex. We explore improvements to our manufacturing processes on a regular basis, as we evaluate clinical and manufacturing data and based on discussions with regulatory authorities. In some circumstances, changes in the manufacturing process, such as our planned switch to a suspension vector for *Abecma*, may require us to perform additional comparability studies, develop additional assays, modify release specifications, collect additional data from patients, submit additional regulatory filings, or comply with additional requirements, which may lead to delays in our clinical development and commercialization plans. Additionally, the FDA may not agree with our changes to the manufacturing process which could require us to perform additional development work and lead to further delays.

If supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. The number of manufacturers with the necessary manufacturing capabilities is limited. In addition, an alternative manufacturer would need to be qualified through a BLA supplement or similar regulatory submission which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of *Abecma* and any future products, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed, our commercial activities may be impacted, or we could lose potential revenues.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our vectors and our drug products, and because we collaborate with various organizations and academic institutions on the advancement of our engineered cell therapy technologies, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Any collaboration or license arrangements that we may enter into in the future may not be successful, which could impede our ability to develop and commercialize our product candidates.

We may seek collaboration or license arrangements for the commercialization, or potentially for the development, of certain of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration or license arrangements. We will face, to the extent that we decide to enter into such arrangements, significant competition in seeking appropriate partners. Moreover, collaboration and license arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement such arrangements should we so chose to enter into them. The terms of any collaborations, licenses or other arrangements that we may establish may not be favorable to us.

Any future collaboration or license arrangements that we enter into may not be successful. The success of such arrangements will depend heavily on the efforts and activities of our partners. Collaboration and license arrangements are subject to numerous risks, which may include risks that:

- partners have significant discretion in determining the efforts and resources that they will apply to collaborations;

- a partner with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaboration and license arrangements may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- partners may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaboration or license arrangements; and
- a partner's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Related to Our Intellectual Property Rights

If we are unable to obtain or protect intellectual property rights related to our approved product or product candidates, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our approved product or product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our approved product or product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our approved product or product candidates, third parties have and may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our approved product or product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patent applications we hold or have in-licensed with respect to our programs or approved product or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our approved product or product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future products. Several patent applications covering our product candidates have been filed recently. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of our approved product or any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate or our approved product. Furthermore, if third parties have filed such patent applications, an interference or derivation proceeding in the United States can be initiated by a third-party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available however the life of a patent, and the protection it affords, is limited. Even if patents covering our approved product or product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our approved product or product candidate discovery and development processes that involve proprietary know-how, and information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its transparency initiative, may consider whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation proceedings, oppositions, ex parte reexaminations, post-grant review, and inter partes review proceedings before the federal courts or the U.S. Patent and Trademark Office, or U.S. PTO, and corresponding foreign courts and patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we have an approved product or are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our approved product or product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our approved product or product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our approved product or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our approved product or product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize our approved product or the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to

pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to gene therapy product components and processes for our approved product or development pipeline through acquisitions and in-licenses.

Presently we have rights to the intellectual property, through licenses from third parties or sublicenses from bluebird bio and under patents that we own, to develop our product candidates and commercialize our approved product. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license, either through direct license or sublicenses, any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us

with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

Where we are a sublicensee of certain intellectual property rights from a third party, our sublicensed rights may be terminated due to defaults of our licensor, or for any other reasons, under the original license agreement between our licensor and the third party. In such a scenario, we may be unable to negotiate a license directly with the third party under terms that are acceptable to us, and as a result, our ability to develop and commercialize our products or product candidates may be impaired.

We may need to obtain licenses from third parties to advance the development of our product candidates or allow commercialization of our approved product, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates or approved product, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates, approved product, or future products, resulting in either an

injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected approved product or product candidates.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In patent litigation in the

United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligible subject matter, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. Third parties have and may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity challenges, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our approved product and/or product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Interference or derivation proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from

the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend

against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We have had in the past, and we may also have in the future, ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our approved product or product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and/or applications will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The U.S. PTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to the Commercialization of Our Product Candidates

We have limited experience as a commercial company and the marketing and sale of Abecma or any future approved products may be unsuccessful or less successful than anticipated.

Although BMS has responsibility for, and is undertaking, the key commercialization activities for *Abecma*, to the extent we are required to participate in commercialization activities we have limited experience in doing so, and we may not be able to successfully overcome many of the risks and uncertainties encountered by companies commercializing products in the biopharmaceutical industry. To execute our business plan, in addition to successfully marketing and selling any future products for which we gain regulatory approval, we will need to successfully:

- establish and maintain our relationships with healthcare providers who will be treating the patients who may receive *Abecma* and any future approved products; ;
- obtain adequate pricing and reimbursement for any future products, if approved;
- gain regulatory acceptance for the development and commercialization of the product candidates in our pipeline;
- develop and maintain successful strategic alliances; and
- manage our spending as costs and expenses increase due to clinical trials, marketing approvals, and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop product candidates, and commercialize Abecma or any future products, if approved, raise capital expand our business or continue our operations.

We may not be successful in supporting the commercialization of Abecma.

BMS is primarily responsible for the commercialization of *Abecma*, and there can be no guarantee that BMS will be able to commercialize *Abecma* successfully. Although we have recognized collaborative arrangement revenue related to commercial sales of *Abecma*, we cannot be certain that we will continue to generate such revenue. The extent to which we will recognize revenue from *Abecma* depends on a number of factors, including, but not limited to, BMS' ability to:

- set an acceptable price for *Abecma*;

- obtain commercial quantities of *Abecma*, at acceptable cost levels;

- establish and maintain a commercial sales force team for *Abecma*;
- obtain and maintain third-party coverage or adequate reimbursement for *Abecma*;
- achieve market acceptance of *Abecma*, in the medical community and with third-party payors; and
- have *Abecma* included in accepted clinical guidelines for the conditions for which *Abecma* is intended to target.

Additionally, our and BMS' ability to achieve the top end of our projected 2023 topline *Abecma* U.S. revenue of $470 million to $570 million depends upon successfully increasing vector and drug product manufacturing capacity, including an additional adherent vector manufacturing suite.

Furthermore, we expect to incur additional sales and marketing costs as we and our partner BMS commercialize *Abecma* pursuant to our co-development and co-promotion agreement. Even if we expend these costs, *Abecma* may not be commercially successful.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any future approved products, we may not be successful in commercializing those products if and when they are approved.

We do not currently have an infrastructure for the sale, marketing, market access, patient service and distribution of pharmaceutical products. In order to market any future products that receive regulatory approval from the FDA or any other regulatory authority outside the United States, we must build our sales, marketing, managerial and other non-technical capabilities, or arrange with third parties to perform these services. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time-consuming and could delay any product candidate launch. If commercialization is delayed or does not occur, we would have prematurely or unnecessarily incurred such expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any future products we may develop ourselves. In addition, we may fail to enter into arrangements with third parties to commercialize our Abecma or any future product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our any future products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, or if we are unable to do so on commercially reasonable terms, we will not be successful in commercializing our any future product candidates if approved and our business, prospects, financial condition and results of operations will be materially harmed.

Abecma or any future approved products may not achieve broad market acceptance by patients, physicians, healthcare payors or others in the medical community, which would limit the revenue that we recognize from their sales.

The commercial success of *Abecma* and any future products that may be approved by the FDA or other applicable regulatory authorities outside the United States, will depend upon the awareness and acceptance of these products among the medical community, including patients, physicians, and healthcare payors. If *Abecma* or any future products do not achieve an adequate level of acceptance by patients, physicians, healthcare payors and others in the medical community, we may not recognize sufficient revenue to become, or remain, profitable. Market acceptance of *Abecma* and any future products, will depend on a number of factors, including, among others:

- the efficacy and safety of our products as demonstrated in clinical trials;
- the clinical indications for which our products are approved, including our ability to obtain regulatory approval for *Abecma* in additional indications;

- product labeling or product insert requirements of the FDA or other regulatory authorities, including the expansion of the label for *Abecma*;
- limitations or warnings contained in the labeling approved by the FDA or other applicable regulatory authorities;
- our ability to educate physicians on treatment sequencing and the emerging data supporting the use of BCMA-directed CAR Ts before other BCMA-targeted therapies;
- any restrictions on the use of our*Abecma* or any future products together with other medications or restrictions on the use of our products in certain types of patients;

- the prevalence and severity of any adverse effects associated with our *Abecma* or any future products;
- the size of the target patient population, and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the safety, efficacy, cost, and other potential advantages of our products compared to other available therapies;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive products;
- our ability to generate cost effectiveness data that supports a profitable price;
- our ability to obtain sufficient reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of sufficient payor coverage;
- the timing of market introduction of our products as well as competitive products;
- our ability to competitively differentiate Abecma's real-world safety, efficacy and product reliability and predictability profile;
- the effectiveness of our sales and marketing strategies; or
- publicity concerning our products or competing products and treatments.

If *Abecma* or any future products do not achieve an adequate level of acceptance by patients, physicians and payors, we may not recognize sufficient revenue from our product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our future products, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the

medical community and third-party payors about the benefits of *Abecma* or any future products may require significant resources and may never be successful.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably. Price controls may be imposed in foreign markets, which may harm our future profitability.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Market acceptance and sales of *Abecma* and any approved product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors and government authorities and may be affected by existing and future health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. For more information, see the section of our this Annual Report on Form 10-K for the year ended December 31, 2021 titled *"Business – Government Regulations – Pricing, Coverage and Reimbursement."*

In the United States, Medicare and Medicaid are significant third party payors. Medicare is administered by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human

Services, or HHS and Medicaid is administered jointly by CMS and the individual states. Obtaining adequate coverage and reimbursement under Medicare and Medicaid is important for new drug products. Additionally, private payors may adopt coverage policies or reimbursement methodologies similar to Medicare. Reimbursement by a third-party payer may depend upon a number of factors, including the third-party payor's determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational. Novel and expensive cell therapies like CAR-T cell therapies have experienced and continue to experience coverage and reimbursement challenges. For example, Medicare only covers CAR-T cell therapies that meet specific criteria set forth in a national coverage decision. Other third party payors may impose coverage criteria more extensive than compliance with FDA labeling. We may have to negotiate coverage and reimbursement on a case-by case basis. Reimbursement, particularly if the cost of the therapy is reimbursed as part of a standard procedure, may not be adequate.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We or our partners may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our future product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our any future products. In addition, in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our partners may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Even though BMS has obtained marketing approval for Abecma, it, and any future approved product, will remain subject to regulatory scrutiny.

Abecma and any future product candidates for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements governing, among other things, the research, development, testing, manufacturing, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting of our products. These requirements include submissions of safety and other postmarketing information and reports, facility registration and drug listing requirements, as well as continued compliance with GMP. Even if we, BMS or any other of our collaborators obtain marketing approval in a jurisdiction, regulatory authorities may still impose significant restrictions on the indicated uses or marketing of any approved products, or impose ongoing requirements for potentially costly post-approval studies, post-market surveillance or patient or drug restrictions. Additionally, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP and adherence to commitments made in the BLA. If we, our collaborators, or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Additionally, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products.

If we fail to comply with applicable regulatory requirements following marketing approval for a product, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of our products, withdraw the product from the market, or impose a voluntary or mandatory product recall;
- impose limitations on approved uses or additional warnings, contraindications, or other safety information, or a REMS;
- require us and/or BMS to conduct additional post-market clinical trials to assess the product safety;
- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical studies;

- refuse to approve a pending marketing application, such as a BLA or supplements to a BLA submitted by us;
- seize product;
- refuse to permit the import or export of product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved product and recognize revenues.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting our products for unapproved or "off-label" uses, or in a manner inconsistent with the approved labeling, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for *Abecma* and any future product for which we or our collaborators obtain marketing approval. Post-approval marketing and promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA or comparable foreign regulatory authorities, Department of Justice, Department of Health and Human Services, or HHS, Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue a regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we or our collaborators are not able to obtain FDA or comparable foreign regulatory authority approval for desired uses or indications for our products or any future products, we and our collaborators may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, and must abide by the FDA or a comparable foreign regulatory authority's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we and any third parties engaged on our behalf are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA or comparable foreign regulatory authorities. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

If we are found to have impermissibly promoted our current product or any future product, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Furthermore, the use of our products for indications other than those approved by the FDA or comparable foreign regulatory authorities may not effectively treat such conditions. Any such off-label use of our products could

harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.

We are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties, reputational harm, and diminished profits and future earnings.

In the United States, the research, manufacturing, distribution, sale, and promotion of drugs and biologic products are subject to regulation by various federal, state, and local authorities in addition to FDA, including CMS, other divisions of the HHS, (e.g., the Office of Inspector General), the United States Department of Justice offices of the United States Attorney, the Federal Trade Commission and state and local governments. For more information, see the section of our this Annual Report on Form 10-K for the year ended December 31, 2021 titled "*Business – Government Regulation – Healthcare and Privacy Laws.*"

We are subject to state and foreign equivalents of these healthcare laws and regulations, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the May 2003 Office of Inspector General Compliance

Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make disclosures related to financial interactions with healthcare providers, marketing expenditures or prices to the state and/or require the registration of pharmaceutical sales representatives. State laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by Health Insurance Portability and Accountability Act of 1996, or HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

These laws apply to, among other things, our sales, marketing and educational programs. State and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the United States Congress continues to strengthen the arsenal of enforcement tools. For example, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have recently increased regulatory scrutiny and enforcement activity with respect to programs supported or sponsored by pharmaceutical companies, including reimbursement and co-pay support, funding of independent charitable foundations and other programs and activities that offer benefits for patients as well as interactions with patients and patient organizations. Several investigations into such activities have resulted in significant civil and criminal settlements.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. We are in the process of developing a compliance program to prevent and detect non-compliance. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be

subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs

associated with pursuing federal civil actions In addition to HIPAA, as amended by HITECH, and their respective implementing regulations, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General was able to commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Further, a new California privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. The CPRA created additional obligations with respect to processing and storing personal information that took effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Additionally, some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business. Already, in the United States, we have witnessed significant developments at the state level. For example, on March 2, 2021, Virginia enacted the Consumer Data Protection Act, (the "CDPA") or the CDPA, and, on July 8, 2021, Colorado's governor signed the Colorado Privacy Act, ("CPA"), or the CPA, into law. The CDPA and the CPA both became effective January 1, 2023. While the CDPA and CPA incorporate many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of regulated businesses. The new laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests.

A number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different

states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

In the European Union, interactions between pharmaceutical companies, healthcare professionals, and patients are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU member states. The provision of benefits or advantages to healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. Also, direct-to-consumer advertising of prescription-only medicinal products is prohibited at the European Union level and in the individual member states. In addition, the UK Bribery Act applies to any company incorporated in or "carrying on business" in the UK, irrespective of where in the world the alleged bribery activity occurs, which could have implications for our interactions with physicians both in and outside of the UK. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and

our ability to successfully commercialize Abecma and any future products. If our competitors obtain orphan drug exclusivity for products that regulatory authorities determine constitute the same drug and treat the same indications as Abecma or any future products, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

We are engaged in the development of gene therapies for cancer and this field is competitive and rapidly changing. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, one such competitive product, Janssen and Legend Biotech's ciltacabtagene autoleucel, an anti-BCMA CAR T cell therapy marketed as Carvykti, was approved by the FDA in February 2022. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, manufacturing capabilities, experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective, safer, or less costly than any products that we may develop, or achieve patent protection, marketing approval, product commercialization and market penetration earlier than us. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

Even if we are successful in achieving marketing approval to commercialize a product candidate faster than our competitors, we may face competition from biosimilars due to the changing regulatory environment. In the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or biosimilar, to or "interchangeable" with an FDA-approved biological product. This pathway could allow competitors to reference data from biological products already approved after 12 years from the time of approval. In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data from biological products already approved, but will not be able to get on the market until 10 years after the time of approval. This 10-year period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive

pressure and consequences. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired.

In addition, although *Abecma* has been granted orphan drug status by the FDA and EMA, there are limitations to the exclusivity. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In the United States, the exclusivity period for orphan drugs is seven years (with limited exceptions), and pediatric exclusivity adds six months to any existing patents or exclusivity periods. In Europe, orphan drugs may be able to obtain 10 years of marketing exclusivity and up to an additional two years on the basis of qualifying pediatric studies. However, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria. Additionally, a marketing authorization holder may lose its orphan exclusivity for a number of reasons, including if it consents to a second orphan drug application, its request for designation is found to be materially defective, or if the marketing authorization holder cannot supply enough drug. Orphan drug exclusivity also can be lost when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug, in that it is shown to be safer, more effective, or makes a major contribution to patient care compared with the product that has orphan exclusivity. Generally, if a product with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the European Commission from approving another marketing application for a product that constitutes the same

drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for our product for the exclusivity period for the applicable indication.

Finally, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors’ products. The availability of our competitors’ products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of Abecma or any of our product candidates and, if approved, our products harms patients, or is perceived to harm patients even when such harm is unrelated to such product candidate or product, our marketing approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of *Abecma* and our future product candidates in clinical studies and the sale of *Abecma* or any future products exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients participating in clinical trials, consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product or product candidates. There is a risk that *Abecma*, our product candidates or any future product for which we obtain marketing approval may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to develop our product candidates or commercialize any approved product; and
- decreased demand for any approved product.

We carry product liability insurance and we believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at commercially reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded

in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by *Abecma* and our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to *Abecma* or our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain marketing approval for any approved product, or require us to suspend or abandon our commercialization efforts for any approved product. Even in a circumstance in which we do not believe that an adverse event is related to our products the investigation into the circumstance may be time-consuming or inconclusive. These investigations may impact and limit the type of marketing approval our product candidates may receive or any approved product maintains. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For more information, see the section of our this Annual Report on Form 10-K for the year ended December 31, 2021 titled "*Business – Government Regulation – Healthcare Reform.*"

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products, if licensed;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Our future growth may depend, in part, on our ability to commercialize our product candidates outside the United States, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates outside the United States for which we may rely on partnerships with third parties. If we commercialize our product candidates outside the United States, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates outside the United States;
- our ability to gain reimbursement in foreign markets at a price that is profitable;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be harmed by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Risks Related to Our Business Operations

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. We may experience business interruptions or negative market conditions arising out of global crises, including international conflicts, the ongoing COVID-19 global pandemic, or similar epidemics or future public health events. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on our product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of third-party suppliers and manufacturers to manufacture *Abecma* as well as clinical trial materials for product candidates.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past led and may in the future lead to market-wide liquidity problems. On For example, in March 10 and March 12, 2023, 2023, the Federal Deposit Insurance Corporation ("FDIC") took control and was appointed receiver of Silicon Valley Bank ("SVB") and Signature Bank respectively, after each bank was unable to continue its operations. We are unable Although we assess our banking relationships as we believe necessary or appropriate, our access to predict the extent funding sources in amounts adequate to finance or nature of

the impacts of the failures of SVB capitalize our current and Signature Bank and related circumstances at this time. Similarly, we cannot predict the impact that the high market volatility and instability of the banking sector more broadly projected future business operations could have on economic activity and our business in particular. The failure of other banks and financial institutions and measures taken, or not taken, be significantly impaired by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations.

If the financial institutions with which we do business enter receivership have arrangements directly, or become insolvent the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the future, there is no guarantee that financial services industry or financial markets, or concerns or negative expectations about the Department of prospects for companies in the Treasury, the Federal Reserve and the FDIC will intercede to provide us and other depositors with access to balances in excess of the $250,000 FDIC insurance limit, that we would be able to access our existing cash, cash equivalents and investments, that we would be able to maintain any required letters of credit or other credit support arrangements, or that we would be able to adequately fund our business for a prolonged period of time or at all, any of which could have a

material adverse effect on our current and/or projected business operations and results of operations and financial condition. In addition, if any parties with which we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to continue to fund their business and perform their obligations to us could be adversely affected, which, in turn, could have a material adverse effect on our business, financial condition and results of operations. services industry.

Our prospects for success depend on our ability to retain our management team and to attract, retain and motivate qualified personnel.

We are highly dependent on our management and scientific and medical personnel, including our chief executive officer, chief financial officer, and chief scientific officer. personnel. Despite our efforts to retain valuable employees, members of our management and scientific and development teams may terminate their employment with us on short notice. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors and an inability to find suitable replacements could result in delays in product development and

harm our business. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We may not be able to attract, recruit or retain qualified management and scientific and medical personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we may be able to offer. We also experience competition for the hiring of scientific personnel from universities and research institutions. The failure to succeed in preclinical or clinical studies may make it more challenging to recruit and retain qualified personnel. In addition, in order to induce employees to continue their employment with us, we have provided equity awards that vest over time and the value to our employees of such equity awards may be significantly affected by movements in our stock price that are beyond our control and may be at any time insufficient to counteract more lucrative offers from other companies. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

Our operating results may fluctuate significantly, which would have the result of making our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our operating results will likely fluctuate from quarter to quarter and year to year and be difficult to predict. This uncertainty is heightened by the unpredictable scope of the impact of the COVID-19 pandemic, which has adversely affected the operations of third parties upon which we rely in our commercialization efforts, patient access to hospitals, physicians' offices, clinics and other administration sites, and global economic conditions, as well as caused a re-prioritization of healthcare services.

In addition, our licensing and collaboration agreements with other companies include research and development funding and milestone payments to us, and we expect that amounts earned from our collaboration agreements will be an important source of our revenues. Accordingly, our revenues will also depend on research and development funding and the achievement of development and clinical milestones under our existing collaboration and license agreements, including, in particular, our collaborations collaboration with BMS and Regeneron Pharmaceuticals, Inc., as well as entering into potential new collaboration and license agreements. BMS. These payments may vary significantly from quarter to quarter and any such variance could cause a significant fluctuation in our operating results from one quarter to the next.

Further, changes in our operations, such as increased development, manufacturing and clinical trial expenses, in connection with our expanding pipeline programs, or our undertaking of additional programs, or business activities, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses may also cause significant fluctuations in our expenses.

The cumulative effects of these factors, further exacerbated by the impacts of the ongoing COVID-19 pandemic on healthcare systems and economic conditions, will likely result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of February 1, 2023, we employed 425 full-time employees. As we mature, we expect to expand our full-time employee base and to hire more consultants and contractors. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to recognize and/or grow revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We expect to invest significant resources to establish and maintain our own manufacturing facility. We may fail to successfully operate this facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.

We are in the process of establishing our own manufacturing facility, which we intend to use for the manufacture of some of our product candidates. Our manufacturing facility will be subject to review and oversight by the FDA, and the FDA could object to use of our manufacturing facility for our product candidates. In addition, we will be required to manufacture our product candidates in accordance with GMP, which will require us to expend significant resources to ensure continued compliance with these requirements. We have limited experience manufacturing drug and biological products, and if we are unable to successfully manufacture material that conforms to the product specifications and the requirements of FDA, we will not be able to secure and maintain regulatory approval for the use of our manufacturing facility.

If we submit an application for marketing authorization of a product candidate manufactured at this facility, we would likely be subject to a pre-approval inspection by FDA, and any unresolved issues cited by FDA could result in a delay in obtaining, or an inability to obtain, such marketing authorization. If we manufacture approved products at this facility, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with GMP and other government regulations. Our ability to manufacture approved products and product candidates will be subject to continued regulatory review.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of The Nasdaq Global Market. Our financial results historically were included within the consolidated results of bluebird bio, and until the distribution occurred, we were not directly subject to reporting and other requirements of the Exchange Act and Section 404 of the Sarbanes-Oxley Act. We qualify as an "emerging growth company." For so long as we remain an emerging growth company, we will be exempt from Section 404(b) of the Sarbanes-Oxley Act, which requires auditor attestation to the effectiveness of internal control over financial reporting. We will cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total gross annual revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the distribution; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We cannot predict if investors will find our common stock less attractive because we may rely on the exemptions available to us as an emerging growth company. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We are subject to Section 404(a) of the Sarbanes-Oxley Act and, as of the expiration of our emerging growth company status, we will be broadly subject to enhanced reporting and other requirements under the Exchange Act and Sarbanes-Oxley Act. We are required to furnish, among other things, annual management assessments of the effectiveness of our internal control over financial reporting. These and other obligations place significant demands on our management, administrative and operational resources, including accounting and information technology resources. To comply with these requirements, we have implemented financial and management controls, reporting systems and procedures and maintain accounting, finance and information technology staff. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations carry legal and financial compliance costs and make some activities more time-consuming and costlier. If we are unable to maintain these controls, systems, and procedures, or if we are unable to retain the appropriate personnel, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired and our business, prospects, financial condition and results of operations could be harmed.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

Our computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, cybersecurity incidents, which could result in a material disruption of our product candidates' development programs and have a material adverse effect on our reputation, business, financial condition or results of operations.

Our computer systems and those of our current or future third-party collaborators, service providers, contractors and consultants may fail and are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Like other companies in our industry, we have experienced non-material threats and cybersecurity incidents relating to our, and our third-party vendors', data and information systems from time to time. The size and complexity of our information technology systems, and those of our collaborators, service providers, contractors and consultants, and the large amounts of information stored on those systems make those systems vulnerable to service interruptions, security breaches, cybersecurity incidents, or other failures, resulting from inadvertent or intentional actions by our employees or those of third-party business partners, or from cyber-attacks by malicious third parties. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized groups and individuals with a wide range of motives and expertise. In addition to extracting sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The prevalent use of mobile devices also increases the risk of data security incidents. If we experience a material system failure, accident or security breach cybersecurity incident that causes interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in significant reputational, financial, legal, regulatory, business or operational harm. For

example, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach cybersecurity incident results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. In addition, it is possible that unauthorized access to our data may be obtained through inadequate use of security controls by suppliers or other vendors. We rely on such third parties to implement effective security measures and identify and correct for any failures, deficiencies or breaches. cybersecurity incidents. Specifically, we rely on third-party service providers for management of the manufacture and delivery of drug product to patients in the commercial context, including for chain of identity and chain of custody. We also rely on third-party service providers for aspects of our internal control over financial reporting and such service providers may experience a material system failure or fail to carry out their obligations in other respects, which may impact our ability to produce accurate and timely financial statements, thus harming our operating results, our ability to operate our business, and our investors' view of us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to material failures, security breaches, cybersecurity incidents, cyberattacks and other related breaches. events.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations to third parties, or any data security incidents or other security breaches cybersecurity incidents that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us. These events could cause third parties to lose trust in us or could result in claims by third parties asserting that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. Moreover, data security incidents and other security breaches events can be difficult to detect, and any delay in identifying them may lead to increased harm. Because the techniques used by computer programmers who may attempt to penetrate and sabotage our network security or our website change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques. While we have implemented data security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents. Moreover, as we outsource more of our information systems to vendors and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems.

Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable foreign regulators, provide accurate information to the FDA and applicable foreign regulators, comply with healthcare fraud and abuse laws and

regulations in the United States and abroad, report financial information or data accurately and/or disclose unauthorized activities to us. In particular, research and development, sales, marketing and business arrangements in the healthcare industry are subject to considerable laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict, regulate or prohibit a wide range of activities pertaining to clinical trials including the informed consent process, data integrity, and conducting the study in accordance with the investigational plan, and for approved products, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Prior to effecting the distribution of any approved products, we will adopt We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of

significant fines or other sanctions, possible exclusions from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages and reputational harm.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act, or the FCPA, and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations. In some countries in which we operate, the pharmaceutical and life sciences industries are exposed to a high risk of corruption associated with the conduct of clinical trials and other interactions with healthcare professionals and institutions. While we intend to conduct any foreign operations in compliance with the FCPA, any such activities could expose us to potential liability under the FCPA, which may result in us incurring significant criminal and civil penalties and to potential liability under the anti-corruption laws and regulations of other jurisdictions in which we operate. In addition, the costs we may incur in defending against an FCPA investigation could be significant.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may fluctuate widely and you could lose part or all of your investment in our common stock as a result.

Our common stock has a limited trading history and the market price has fluctuated widely, and may in the future fluctuate widely, depending upon many factors, some of which are beyond our control, including the following:

- results and timing of preclinical studies and clinical studies of *Abecma* or our product candidates;
- the commercial performance of *Abecma* or any of our products that may be approved, as well as the costs associated with such activities;
- BMS' disclosure of revenue from *Abecma* in its earning releases or otherwise;
- results and timing of preclinical studies and clinical studies of *Abecma* or our product candidates;
- potential approval of *Abecma* in earlier lines of therapy;
- results of clinical studies of our competitors' products;
- failure to timely close the Asset Sale;
- failure to adequately protect our trade secrets;
- our inability to raise additional capital, if needed, and the terms on which we raise it;
- commencement or termination of any strategic partnership or licensing arrangement;
- regulatory developments with respect to our products or our competitors' products, including any developments, litigation or public concern about the safety of such products;
- announcements concerning product development results, including clinical trial results, the introduction of new products or intellectual property rights of us or others;
- actual or anticipated fluctuations in our financial condition and our quarterly and annual operating results;

- deviations in our operating results from any guidance we may provide or the estimates of securities analysts;
- additions and departures of key personnel;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- announcement or expectation of additional financing efforts;
- publication of research reports by securities analysts about us or our competitors or our industry and speculation regarding our company or our stock price in the financial or scientific press or in online investor communities;
- changes in market conditions in the pharmaceutical and biotechnology sector; and
- changes in general credit and financial markets and economic conditions.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, results of operations, financial condition and prospects. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

In addition, a decline or volatility in the market price of our common stock may affect our willingness and ability to raise equity capital through the sale of our common stock in public and/or private offerings, which may adversely affect our ability to fund our business operations.

If securities or industry analysts fail to initiate or maintain coverage of our stock, publish a negative report or change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us, our business, our market or our competitors. If securities or industry analysts fail to initiate coverage of our stock, the lack of exposure to the market could cause our stock price or trading volume to decline. If any of the analysts who cover us or may cover us in the future publish a negative report or change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who covers us or may cover us in the future were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Actual or potential sales of our common stock by our employees, including our executive officers, pursuant to pre-arranged stock trading plans could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by other investors.

In accordance with the guidelines specified under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, and the policies that we intend to adopt prior to the distribution regarding stock transactions, a number of our employees, including executive officers and members of our board of directors, may adopt stock trading plans pursuant to which they arrange to sell shares of our common stock from time to time in the future. Generally, sales under such plans by our executive officers and directors will require public filings. Actual or potential sales of our common stock by such persons could cause the price of our common stock to fall or prevent it from increasing for numerous reasons.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

In the future, your percentage ownership in the Company may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we plan to grant to our directors, officers and employees pursuant to our equity incentive plans. Such awards will have a dilutive effect on our earnings per share, which could adversely affect the market price of our common stock.

In addition, we are authorized under our amended and restated certificate of incorporation to issue, without the approval of our stockholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our common stock with respect to dividends and distributions, as our board of directors may determine. The terms of one or more classes or series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, we could grant the holders of preferred stock the right to elect some number of directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of the common stock.

The administrator of the 2021 Stock Option and Incentive Plan, or 2021 Plan, is authorized to exercise its discretion to effect the repricing of stock options and stock appreciation rights and there may be adverse consequences to our business if the administrator of the 2021 Plan exercises such discretion.

Pursuant to our 2021 Plan, we are authorized to grant equity awards, including stock options and stock appreciation rights, to our employees, directors and consultants. The administrator of the 2021 Plan (which is our compensation committee) is authorized to exercise its discretion to reduce the exercise price of stock options or stock appreciation rights or effect the repricing of such awards. Although we do not anticipate needing to exercise this discretion in the near term, or at all, if the administrator of the 2021 Plan were to exercise such discretion without seeking prior stockholder approval, certain proxy advisory firms or institutional investors may be unsupportive of such actions and publicly criticize our compensation practices, and proxy advisory firms may recommend an "against" or "withhold" vote for members of our compensation committee. In addition, if we are required to hold an advisory vote on named executive officer compensation (known as the "say-on-pay" vote) at the time of, or subsequent to, any such repricing, it is likely that proxy advisory firms would issue an "against" recommendation on our say on pay vote and institutional investors may not be supportive of our say-on-pay vote. If

proxy advisory firms or institutional investors are successful in aligning their views with our broader stockholder base and we are required to make changes to the composition of our board and its committees, or if we need to make material changes to our compensation and corporate governance practices, our business might be disrupted and our stock price might be negatively impacted. Even if we are able to successfully rationalize the exercise of such discretionary power, defending against any "against" or "withhold" recommendation for members of our compensation committee, any "against" recommendation on our say on pay vote or public criticism could be distracting to management, and responding to such positions from such firms or investors, even if remedied, can be costly and time-consuming.

In addition, if the administrator of the 2021 Plan does determine to reprice stock options or stock appreciation rights, even absent negative reactions from proxy advisory firms and institutional investors, management attention may be diverted and we could incur significant costs, including accounting and administrative costs and attorneys' fees. We may also be required to recognize incremental compensation expense as a result of such repricing. These

actions could cause our stock price to decrease and experience periods of increased volatility, which could result in material adverse consequences to our business.

We do not expect to pay any cash dividends for the foreseeable future.

We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. operations related to *Abecma*. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

Provisions in our amended and restated certificate of incorporation and by-laws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain, and Delaware law contains, provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and by-laws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, our chief executive officer or our president;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated by-laws; and

- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our amended and restated certificate of incorporation or amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws designate certain specified courts as the sole and exclusive forums for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware, or the Chancery Court, will be the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws, or (v) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision does not apply to any causes of action arising under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision. Our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing the claims identified above, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the Delaware Forum Provision and the Federal Forum Provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable in an action, we may incur additional costs associated with resolving such an action. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Chancery Court or the federal district courts of the United States of America may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Risks Related to Our Separation From bluebird bio

We have a limited history of operating as an independent company and we expect to incur increased administrative and other costs following the separation by virtue of our status as an independent public company. Our historical financial information is not necessarily representative of the results that we would have achieved as a separate, publicly traded company and should not be relied upon as an indicator of our future results.

For periods prior to our separation from bluebird bio, our historical information provided in this report refers to our business as operated by and integrated with bluebird bio. Our historical financial information included in this report for periods prior to our separation from bluebird bio has been derived from the consolidated financial statements and accounting records of bluebird bio. Accordingly, the historical financial information included in this report may not reflect the operating results, financial condition or cash flows that we would have achieved as a separate, publicly traded company during the periods presented, or the financial results we will achieve in the future. In particular, our future financial results may vary from the historical financial information included in this report as a result of the following factors, among others:

- for periods prior to the separation, our historical financial data reflects expense allocations for certain support functions that are provided on a centralized basis within bluebird bio, such as expenses for corporate administrative services, including information technology, research and development, finance, legal, insurance, compliance and human resources activities, that may be lower than the comparable expenses we would have actually incurred, or will incur in the future, as a stand-alone company;

- our cost of debt and our capital structure will be different from that reflected in our historical combined financial statements for periods prior to the separation;
- significant increases may occur in our cost structure as a result of becoming a stand-alone public company, including costs related to public company reporting, investor relations and compliance with the Sarbanes-Oxley Act; and
- the separation may have a material effect on our relationships with our suppliers, collaborators and other business relationships.

Our financial condition and future results of operations, after giving effect to the separation, will be materially different from amounts reflected in our historical financial statements included elsewhere in this report. As a result of the separation, it may be difficult for investors to compare our future results to historical results or to evaluate our relative performance or trends in our business.

If the distribution, together with certain related transactions, does not qualify as a transaction that is generally tax-free for U.S. federal income tax purposes, bluebird bio and its stockholders could be subject to significant tax liabilities, and we could be required to indemnify bluebird bio for material taxes pursuant to indemnification obligations under the tax matters agreement.

In connection with the separation and distribution, bluebird bio received a favorable private letter ruling from Internal Revenue Service, or the IRS, relating to the U.S. federal income tax treatment of the distribution. Consistent with the IRS's ruling guidelines, the IRS private letter ruling does not cover all of the issues that are relevant to determining whether the distribution is generally tax free for U.S. federal income tax purposes, including whether the distribution (i) satisfies the business purpose requirement in Section 1.355-2(b) of the Treasury Regulations, (ii) is used principally as a device for the distribution of our earnings and profits or the earnings and profits of bluebird bio or both or (iii) is part of a plan (or series of related transactions) pursuant to which one or more persons will acquire directly or indirectly stock representing a 50% or greater interest in bluebird bio or us. Accordingly, as a condition to the distribution, bluebird bio received an opinion of Goodwin Procter LLP, satisfactory to bluebird bio's board of directors, confirming that the distribution, together with certain related transactions, generally was tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of Internal Revenue Code, or the Code. The opinion of Goodwin Procter LLP delivered to bluebird bio and the IRS private letter ruling were based, among other things, on various facts and assumptions, as well as certain representations, statements and undertakings from us and bluebird bio (including those relating to the past and future conduct of us and bluebird bio). If any of these facts, assumptions, representations, statements or undertakings is, or becomes, inaccurate or incomplete, or if we or bluebird bio breach any of our respective covenants relating to the separation, the IRS private letter ruling and/or the opinion of Goodwin Procter LLP may be invalid. Accordingly, notwithstanding receipt of the favorable IRS private letter ruling and the opinion of Goodwin Procter LLP delivered to bluebird bio, the IRS could determine that the distribution and certain related transactions should be treated as taxable transactions for U.S. federal income tax purposes if it determines that any of the facts, assumptions, representations, statements or undertakings that were included in the request for the IRS private letter ruling or on which the opinion of Goodwin Procter LLP was based is inaccurate or incomplete or has been violated. In addition, the opinion of Goodwin Procter LLP delivered to bluebird bio represents the judgment of Goodwin Procter LLP, which is not binding on the IRS or any court. Accordingly, notwithstanding receipt by bluebird bio of the tax opinion and the favorable IRS private letter ruling referred to above, the IRS could assert that the distribution and/or certain related transactions did not qualify for tax-free treatment for U.S. federal income tax purposes.

If the distribution, together with certain related transactions, were to fail to qualify as a transaction that is generally tax-free under Sections 355 and 368(a)(1)(D) of the Code, in general, for U.S. federal income tax purposes, bluebird bio would recognize taxable gain as if it has sold our distributed common stock in a taxable sale for its fair market value and bluebird bio stockholders who received shares of our common stock in the distribution would be subject to tax as if they had received a taxable distribution equal to the fair market value of such shares.

In connection with the distribution, we and bluebird bio entered into a tax matters agreement pursuant to which we are responsible for certain liabilities and obligations following the distribution. In general, under the terms of the tax matters agreement, if the distribution, together with certain related transactions, were to fail to qualify as a transaction that is generally tax-free, for U.S. federal income tax purposes, under Sections 355 and 368(a)(1)(D) of the Code, and if and to the extent that such failure results from a prohibited change of control in bluebird bio under Section 355(e) of the Code or an acquisition of bluebird bio stock or assets or certain actions, omissions or failures to act, by bluebird bio, then bluebird bio will bear any resulting taxes, interest, penalties and other costs. If and to the extent that such failure results from a prohibited change of control in 2seventy bio under Section 355(e) of the Code or an acquisition of our stock or assets or certain actions by us, then we will indemnify bluebird bio for any resulting taxes, interest, penalties and other costs, including any reductions in bluebird bio's net operating loss carryforwards or other tax assets. If such failure does not result from a prohibited change of control in bluebird bio or 2seventy bio under Section 355(e) of the Code and both we and bluebird bio are responsible for such failure, liability will be shared according to relative fault. If neither we nor bluebird bio is responsible for such failure, bluebird bio will bear any resulting taxes, interest, penalties and other costs. For a discussion of the tax matters agreement, see the section of our Annual Report on Form 10-K for the year ended December 31, 2022 titled "Certain Relationships and Related Person Transactions—Agreements with bluebird bio — Tax Matters Agreement." Our indemnification obligations to bluebird bio under the tax matters agreement are not expected to be limited in amount or subject to any cap. If we are required to pay any taxes or indemnify bluebird bio and its subsidiaries and their respective officers and directors under the circumstances set forth in the tax matters agreement, we may be subject to substantial liabilities.

We may not be able to engage in attractive strategic or capital-raising transactions.

To preserve the tax-free treatment of the separation and the distribution for U.S. federal income tax purposes, for the four-year period beginning two years before and ending two years after the distribution, we are prohibited under the tax matters agreement, except in specific circumstances, from: (i) entering into or approving any transaction involving the acquisition of outstanding or newly issued 2seventy bio equity that, when combined with other non-excepted changes in ownership of our capital stock, results in a change in ownership of 30% or more; (ii) liquidating or partially liquidating, or merging or consolidating (unless we are the survivor); (iii) making or changing any entity classification election; (iv) ceasing to be engaged in an active trade or business, or selling, transferring or disposing of 25% or more of the assets of any active trade or business; (v) amending any of our organizational documents or taking any action affecting the voting rights of our capital stock; (vi) redeeming or otherwise repurchasing any of our outstanding stock or options; or (vii) taking or failing to take any other action that would prevent the distribution and certain related transactions from qualifying as a transaction that is generally tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1) (D) of the Code. These restrictions may limit for a period of time our ability to pursue certain strategic transactions, equity issuances or repurchases or other transactions that we may believe to be in the best interests of our stockholders or that might increase the value of our business. For more information, see the section of our Annual Report on Form 10-K for the year ended December 31, 2021 titled "*Certain Relationships and Related Person Transactions—Agreements with bluebird bio—Tax Matters Agreement*."

In connection with the separation, we assumed and agreed to indemnify bluebird bio for certain liabilities. If we are required to make payments pursuant to these indemnities to bluebird bio, we may need to divert cash to meet those obligations and our financial results could be harmed.

Pursuant to the separation agreement and certain other agreements we entered into with bluebird bio, we assumed and agreed to indemnify bluebird bio for certain liabilities for uncapped amounts, which may include, among other items, associated defense costs, settlement amounts and judgments, as discussed further in "Certain Relationships and Related Person Transactions—Agreements with bluebird bio" and "Index to Financial Statements—Audited Consolidated and Combined Financial Statements—Notes to Consolidated and Combined Financial Statements." Payments pursuant to these indemnities may be significant and could harm our business, particularly indemnities relating to our actions that could impact the tax-free nature of the distribution and certain related transactions. Third parties could also seek to hold us responsible for any of the liabilities of the bluebird bio business. bluebird bio has agreed to indemnify us for liabilities of the bluebird bio business, but such indemnity from bluebird bio may not be sufficient to protect us against the full amount of such liabilities, and bluebird bio may not fully satisfy its indemnification obligations. Moreover, even if we ultimately succeed in recovering from bluebird bio any amounts for which we are held liable, we may be temporarily required to bear these losses ourselves. Each of these risks could harm our business, prospects, financial condition and results of operations.

Our agreements with bluebird bio may not reflect terms that would have resulted from negotiations with unaffiliated third parties.
The agreements related to the separation, including, among others, the separation agreement, the employment matters agreement, the tax matters agreement, the intellectual property license agreement and the transition services agreements, were entered into while we were still controlled by bluebird bio. As a result, the terms may not reflect those that would have resulted from negotiations between unaffiliated third parties. For a more detailed description, see "Certain Relationships and Related Person Transactions—Agreements with bluebird bio."

General risks

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

If the estimates we make, or the assumptions on which we rely, in preparing our consolidated and combined financial statements are incorrect, our actual results may vary from those reflected in our projections and accruals.

Our consolidated and combined financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these consolidated and combined financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot assure you, however, that our estimates, or the assumptions underlying them, will be correct.

Further, from time to time we issue financial guidance relating to our expectations for our cash, cash equivalents, and marketable securities available for operations, which guidance is based on estimates and the judgment of management. If, for any reason, our expenses differ materially from our guidance or we utilize our cash more quickly than anticipated, we may have to adjust our publicly announced financial guidance. If we fail to meet, or if we are required to change or update any element of, our publicly disclosed financial guidance or other expectations about our business, our stock price could decline.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have established processes to assess risks from cybersecurity threats, monitor our information systems for potential vulnerabilities, and test those systems pursuant to our cybersecurity policies, processes, and practices, which are integrated into our overall risk management program. In an effort to protect our information systems from cybersecurity threats, we have implemented information security and incident response policies as well as operating procedures. We also use various security tools that are designed to help us identify risks from cybersecurity threats, and escalate, investigate, resolve, and recover from cybersecurity incidents in a timely manner. We have an informal risk oversight committee, which is comprised of representatives from our information technology and legal functions, in consultation with business operations, as needed. The committee assesses risks based on probability and potential impact to key business systems and processes. We have established a process for risks that are considered high, including risks from cybersecurity threats, to be incorporated into our overall risk management program and tracked as part of our overall risk management program overseen by the Audit Committee of our board of directors.

We also collaborate with third parties to assess the effectiveness of our cybersecurity prevention and response systems and processes. These third parties include cybersecurity assessors, consultants, and other external cybersecurity experts to assist in the identification, verification, and validation of cybersecurity risks, as well as to support associated mitigation plans when necessary. We leverage these third parties to provide virtual chief information security officer and, if necessary, cybersecurity incident response services as well as to perform periodic penetration testing and other vulnerability scans. We also maintain processes designed to proactively manage potential supply chain risks posed by third-party vendors. As part of our cybersecurity risk management program, we work with certain third-party vendors to assess the their cybersecurity processes, including a process for requesting that vendors who have access to our systems and data complete cybersecurity questionnaires prior to onboarding.

We face a number of cybersecurity risks in connection with our business. While cybersecurity threats, including those resulting from any previous cybersecurity incidents, have not materially affected, and we do not believe they are reasonably likely to materially affect, our Company, including our business strategy, results of operations, or financial condition, to date, we have, like other companies in our industry, from time to time, experienced threats and cybersecurity incidents relating to our, and our third-party vendors', data and information systems. Refer to the risk factor captioned "*Our computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer cybersecurity incidents, which could result in a material disruption of our product candidates' development programs and have a material adverse effect on our reputation, business, financial condition or results of operations*" in Part I, Item 1A. "Risk Factors" for additional description of cybersecurity risks and potential related impacts on our Company.

Governance

Our board of directors oversees our risk management process, including as it pertains to cybersecurity risks, directly and through its committees. The Audit Committee of the board oversees our risk management program, which focuses on the significant identified risks. Audit Committee meetings include discussions of specific risk areas throughout the year, including, among others, those relating to cybersecurity threats, as appropriate. The Audit Committee reviews our cybersecurity risk profile with management on a periodic basis, including reviewing assessments of our cybersecurity program and strategy for the prevention, detection, mitigation, and remediation of cybersecurity incidents.

We take a risk-based approach to cybersecurity and have implemented cybersecurity policies throughout our operations that are designed to address cybersecurity threats and incidents. The Company's VP of IT is responsible for the establishment and maintenance of our cybersecurity program, as well as the assessment and management of cybersecurity risks. The VP of IT meets periodically with the Company's leadership team to discuss the status of the Company's cybersecurity program and relevant updates, as appropriate. The current VP of IT and the Director of Operations, who is directly responsible for day-to-day cybersecurity program and security operations, have over 20 years of combined experience in information security. The VP of IT and the Director of Operations provide periodic updates on our cybersecurity risk profile to the Audit Committee of our board of directors.

Item 2. Properties

Below is a summary of our material owned and leased properties as of December 31, 2022 December 31, 2023:

Massachusetts

Our corporate headquarters is located at 60 Binney Street, Cambridge, Massachusetts where we occupy approximately 253,108 rentable square feet of office and laboratory space under a lease that was assigned to us by bluebird bio in October 2021 and will continue until March 31, 2034, unless terminated sooner. We have the option to extend the 60 Binney Street lease for two successive five-year terms.

Washington

We lease office and laboratory space at 188 East Blaine Street Suite 300, Seattle, Washington, totaling approximately 58,314 square feet. The lease was assigned to us by bluebird bio in October 2021 and will continue through April 2028. We have the option to extend the lease for one five-year term.

We believe that our existing facilities are adequate for our current needs needs.

In connection with the Asset Sale, Regeneron also agreed to sublease our facilities in Seattle, Washington, and that suitable additional space will be available as and when needed. a portion of our facilities in Cambridge, Massachusetts.

Item 3. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

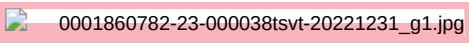
Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock trades under the symbol "TSVT" on The Nasdaq Global Market and has been publicly traded since November 5, 2021. Prior to this time, there was no public market for our common stock.

Performance Graph

Set forth below is a graph comparing the total returns of our company, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index. The graph assumes $100 is invested on November 5, 2021 in our common stock and each of the indices. Past performance is not indicative of future results.



Holders of Our Common Stock

As of March 8, 2023 February 29, 2024 there were approximately 13 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business*Abecma* and we do not

anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects and any other factors deemed relevant by our board of directors.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. Reserved

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K, or this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements." We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Overview

We are a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. We are led by an accomplished team with significant expertise and experience in this field, from discovery through clinical development to regulatory approval of *Abecma* (idecabtagene vicleucel, or ide-cel), the first chimeric antigen receptor, or CAR, T cell therapy approved by the U.S. Food and Drug Administration, or FDA, for multiple myeloma. Our approach combines our expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. We are advancing multiple clinical programs, including SC-DARIC33, for the treatment of pediatric patients with relapsed and refractory acute myeloid leukemia and bbT369, for the treatment of patients with B-cell non-Hodgkins lymphoma, as well as multiple preclinical programs, including bbT4015, an engineered CAR T cell therapy targeting MUC16. Additionally, together Together with our partner, Bristol Myers Squibb, or BMS, we are delivering *Abecma* to multiple myeloma patients in the United States following approval by the FDA of *Abecma* in March 2021 for the treatment of adults with multiple myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 (cyclic ADP ribose hydrolase) monoclonal antibody.

On January 29, 2024, we began undertaking a strategic realignment to focus on the development and commercialization of *Abecma.* In connection with the strategic realignment, we entered into an asset purchase agreement with Regeneron to sell to Regeneron substantially all of the assets related to our solid tumor and other oncology and autoimmune cell therapy programs, including the bbT369 program in B-NHL, SC-DARIC33 in AML, MUC16 in ovarian cancer, MAGE-A4, autoimmune, and several unnamed targets. Upon closing of the transaction, which is subject to customary closing conditions, Regeneron will assume all of the ongoing programs, infrastructure and personnel costs related to these programs. The transaction is expected to close in the first half of 2024.

We have never been profitable and have incurred net losses since inception. Our net losses for the years ended December 31, 2022 December 31, 2023, 2022 and 2021 were $217.6 million, $254.2 million and 2020 were $254.2 million, $292.2 million and $120.1 million, respectively. We expect to continue to incur expenses and operating losses for at least the next several years as we:

- advance our next-generation programs in B-NHL, AML, and multiple myeloma through the clinic;
- manufacture clinical study drug product and materials and establish the infrastructure necessary to support and develop manufacturing capabilities;
- we continue to develop and commercialize *Abecma* with our partner, BMS; BMS.
- seek regulatory approval for our product candidates and advance our preclinical programs into clinical development; and
- increase research and development-related activities for the discovery and development of product candidates and technologies in oncology.

In February 2023, we substantially completed the construction of our drug product manufacturing facility at our existing headquarters in Cambridge, Massachusetts for our future Phase 1 clinical trials. We anticipate the facility to be operational by mid-2023. In the meantime, all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize third-party contract research organizations, or CROs, to carry out our clinical development activities. As we continue to develop and seek to obtain regulatory approval for our *Abecma* in earlier lines of therapy, expand site footprint, educate physicians on treatment sequencing and the emerging data supporting the use of BCMA-directed CAR Ts before other BCMA-targeted therapies, competitively differentiate *Abecma*'s real-world

safety, efficacy and product candidates, reliability and predictability profile, continue to support the quality control of the LVV, manufacturing and the transition to suspension LVV, which will deliver additional efficiencies and cost savings, we expect to incur significant expenses. Accordingly, until we generate significant revenues from product sales, we will continue to seek to fund our operations through public or private equity or debt financings, strategic collaborations, or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates. and commercialize *Abecma*. Refer to sections *Liquidity and Capital Resources* and *Funding Requirements* below for further discussion.

As of December 31, 2022 December 31, 2023, we had cash, cash equivalents and marketable securities of $267.7 million $221.8 million. In January 2023, we entered into a Share Purchase Agreement with Regeneron pursuant to which we sold 1,114,827 shares of our common stock to Regeneron for an aggregate cash price of approximately $20.0 million. In March 2023, we sold 10.9 million shares of common stock through an underwritten public offering at a price per share of $11.50. This resulted in aggregate gross proceeds to us of approximately $125.0 million, before deducting underwriting discounts and commissions and offering expenses. Based on our current operating plans, including with respect to the ongoing commercialization of *Abecma*, and not taking into consideration our strategic realignment and the Asset Sale with Regeneron which is expected to close in the first half of 2024, we expect that our cash, cash equivalents and marketable securities, (including amounts received from the transactions discussed above), will be sufficient to fund current planned operations for at least the next twelve months from the date of filing this Annual Report on Form 10-K. Report. We may, in the future, pursue additional cash resources through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. This includes the potential sale of shares of our common stock of up to $150.0 million in gross proceeds under the at-the-market, ("ATM") or the ATM, facility established in November 2022 with Cowen and Company, LLC. No sales of common stock have occurred under this ATM as of the date of this Annual Report on Form 10-K. and we do not have any current plans to sell shares under the ATM.

Separation from bluebird bio, Inc.

We did not operate as a separate, stand-alone entity prior to our separation from bluebird bio on November 4, 2021. Our historical financial statements for periods prior to the separation have been prepared on a carve-out basis and are derived from bluebird bio's consolidated financial statements and accounting records. Our financial statements are presented in conformity with generally accepted accounting principles in the United States, or GAAP. See Note 2, *Summary of significant accounting policies and basis of presentation*, in the notes to the audited consolidated and combined financial statements for additional information on the preparation and basis of presentation of the financial statements. Our financial position, results of operations and cash flows historically operated as part of bluebird bio's financial position, results of operations and cash flows prior to and until the distribution of our common stock to bluebird bio's stockholders. The historical consolidated and combined financial statements may not be indicative of our future performance and do not necessarily reflect what our consolidated results of operations, financial condition and cash flows would have been had we operated as a separate, publicly traded company during the periods presented.

On November 4, 2021, bluebird bio completed the separation and spin-off of its oncology portfolio and programs into 2seventy bio, retaining its severe genetic disease portfolio and programs. In connection with the separation, certain assets and liabilities, including certain accounts receivables and accounts payables, included on the consolidated and combined balance sheets prior to the separation have been retained by bluebird bio post-separation and, therefore, were adjusted through net parent investment in our consolidated and combined financial statements. In addition, in connection with the separation, certain equity awards were converted in accordance with the Employee Matters Agreement, as further described in Note 13, *Stock-based compensation*. , in the notes to our audited consolidated and combined financial statements. As a result of the separation, our net parent investment balance was reclassified to additional paid-in capital.

Financial Operations Overview

Revenue

Our revenues have been derived from collaboration arrangements and out-licensing arrangements, primarily related to our collaboration arrangement with BMS as part of which we are jointly commercializing *Abecma* in the United States. States and our collaboration arrangement with Regeneron. To date, all revenue we have recognized relating to the sale of products has been the collaboration revenue derived from commercial sales of *Abecma* by BMS, and we have not recognized any revenue from the sale of products by us.

Revenue recognized under collaborative arrangements has been generated primarily from a collaboration arrangement between bluebird bio and BMS, which was assigned to and assumed by us in connection with the separation. The terms of the BMS collaboration arrangement with respect to ide-cel contain multiple promised goods or services, which included at inception: (i) research and development services, (ii) a license to ide-cel, and (iii) manufacture of vectors and associated payload for incorporation into ide-cel under the license. As of September 2017, the BMS collaboration also included the following promised goods or services with respect to bb21217: (i) research and development services, (ii) a

license to bb21217, and (iii) manufacture of vectors and associated payload for incorporation into bb21217 under the license. An agreement was entered into with BMS to co-develop and co-promote ide-cel in March 2018, which was subsequently amended in May 2020, as part of which both parties will share equally in U.S. costs and profits. Revenue from our collaborative arrangements is recognized as the underlying performance obligations are satisfied.

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements*, or ASC 808, which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For

collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606, *Revenue from Contracts with Customers*, or Topic 606 or ASC 606. For those elements of the arrangement that are accounted for pursuant to Topic 606, we apply the five-step model prescribed in Topic 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606. In arrangements where we do not deem our collaborator to be our customer, payments to and from our collaborator are presented in the consolidated and combined statements of operations and comprehensive loss based on the nature of the payments, as summarized in the table and further described below. The calculation of collaborative activity to be recognized is performed on a quarterly basis and is independent of previous quarterly activity. This may result in fluctuations between revenue and expense recognition period over period, depending on the varying extent of effort performed by each party during the period.

Nature of Payment	Statement of Operations Presentation
Our share of net profits in connection with commercialization of products	Collaborative arrangement revenue
Our share of net losses in connection with commercialization of products	Share of collaboration loss
Net reimbursement to us for research and development expenses	Collaborative arrangement revenue
Net reimbursement to the collaborator for research and development	Research and development expense

Where the collaborator is the principal in the product sales, we recognize our share of any profits or losses, representing net product sales less cost of goods sold and shared commercial and other expenses, in the period in which such underlying sales occur and costs are incurred by the collaborator. We also recognize our share of costs arising from research and development activities performed by collaborators in the period our collaborators incur such expenses.

Effective January 1, 2020, we adopted Accounting Standards Update, or ASU, No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, or ASU 2018-18, on a retrospective basis. As a result, prior periods are presented in accordance with the new standard. As we recognize revenue under our collaborative arrangements both within and outside the scope of Topic 606, we present revenue on our consolidated and combined statements of operations and comprehensive loss as follows: service revenue includes revenue from collaborative partners recognized within the scope of Topic 606 and collaborative arrangement revenue includes only revenue from collaborative partners recognized outside the scope of Topic 606.

Nonrefundable license fees are recognized as revenue upon delivery of the license provided there are no unsatisfied performance obligations in the arrangement. License revenue has historically been generated from out-license agreements, under which we may also recognize revenue from potential future milestone payments and royalties.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with CROs and clinical sites that conduct our clinical studies;
- costs related to acquiring and manufacturing clinical study materials;
- reimbursable costs to our partners for collaborative activities;

- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, information technology, insurance, and other supplies in support of research and development activities;
- costs associated with our research platform and preclinical activities;
- milestones and upfront license payments;
- costs associated with our regulatory, quality assurance and quality control operations; and
- amortization of certain intangible assets.

Our research and development expenses include expenses associated with the following activities:

- CRB-401 study – an open label, single-arm, multi-center, Phase 1 study, conducted by BMS, to examine the safety and efficacy of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- KarMMA study – an open label, single-arm, multi-center Phase phase 2 study conducted by BMS, to examine the efficacy and safety of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- KarMMa-2 study – a multi-cohort, open-label, multicenter Phase phase 2 study conducted by BMS, to examine the safety and efficacy of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma and in high-risk multiple myeloma. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- KarMMa-3 study – a multicenter, randomized, open-label Phase phase 3 study conducted by BMS, comparing the efficacy and safety of ide-cel versus standard triplet regimens in patients with relapsed and refractory multiple myeloma.The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- KarMMa-4 study – a multi-cohort, open-label, multicenter phase 1 study, conducted by BMS, intended to determine the optimal target dose and safety of ide-cel in subjects with newly-diagnosed multiple myeloma.

The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.

- KarMMa-7 study – an open label, multi-arm, multi-cohort phase 1/2 study, conducted by BMS, intended to determine the optimal target dose, safety and efficacy of ide-cel combinations in subjects with relapsed and/or refractory multiple myeloma. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- CRB-402 KarMMa-9 study – an open label, single-arm, a multicenter, Phase 1 randomized, open-label phase 3 study comparing the efficacy and safety of ide-cel with Lenalidomide maintenance versus Lenalidomide maintenance therapy alone in adult participants with newly diagnosed multiple myeloma who have suboptimal response after autologous stem cell transplantation. The costs incurred by BMS for this study are subject to examine the safety and efficacy cost-sharing provisions of the bb21217 product candidate in the treatment of patients with relapsed and refractory multiple myeloma. We have been winding down the study following our election to discontinue the development of bb21217 in 2022. BMS collaboration arrangement.
- CRC-403 study – an open-label, multi-site Phase 1/2 dose-escalation study to examine the safety and efficacy of bbT369 in relapsed and/or refractory B Cell Non-Hodgkin's Lymphoma, (NHL). or NHL.
- PLAT-08 study – an open-label Phase 1 study to examine the safety and efficacy of SC-DARIC33 in pediatric and young adult relapsed or refractory acute myeloid leukemia, (AML). or AML.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites. We cannot determine with certainty the duration and completion costs of the current or future clinical studies of our product candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may not succeed in achieving regulatory approval for all of our product candidates. The duration, costs, and timing of clinical studies and development of our product candidates will depend on a variety of factors, any of which could mean a significant change in the costs and timing associated with the development of our product candidates including:

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical studies and other research and development activities we undertake;
- future clinical study results;

- uncertainties in clinical study enrollment rates;

- new manufacturing processes or protocols that we may choose to or be required to implement in the manufacture of our lentiviral vector or drug product;
- regulatory feedback on requirements for regulatory approval, as well as changing standards for regulatory approval; and
- the timing and receipt of any regulatory approvals.

We expect our ongoing research and development expenses to be driven mainly by our advancement of SC-DARIC33 and bbT369 clinical programs through Phase 1 studies, funding our share of the costs of development of *Abecma*, including clinical expansion to earlier lines of therapy, through our collaboration with BMS, progressing new product candidates to IND, and manufacture of clinical study materials in support of our clinical studies. BMS.

Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to acquiring and manufacturing clinical study materials. We allocate salary and benefits, personnel-related discretionary bonus, and stock-based compensation costs directly related to specific programs. In the prior period disclosures, we did not allocate discretionary bonus and stock-based compensation. However, beginning in 2022, we have allocated these costs among specific programs and have conformed the prior period presentation to reflect this allocation. We do not allocate certain general research and platform personnel costs, certain laboratory and related expenses, rent expense, depreciation or other indirect costs that are deployed across multiple projects under

development and, as such, the costs are separately classified as other research and development expenses in the table below:

	Year ended December 31,		
	2022	2021	2020
ide-cel	$ 45,896	$ 71,958	$ 107,974
bb21217	3,734	10,001	24,257
bbT369	29,256	20,172	8,463
SC-DARIC33	3,985	8,307	744
Preclinical programs	60,590	36,436	44,313
Total direct research and development expense	143,461	146,874	185,751
General research and platform personnel costs	21,638	36,996	47,398
Unallocated laboratory and manufacturing expenses	16,792	14,341	14,381
Facility and other support costs	66,844	54,406	48,937
Total other research and development expenses	105,274	105,743	110,716
Total research and development expense	$ 248,735	$ 252,617	$ 296,467

The costs associated with our bbT369 and SC-DARIC33 programs were included in pre-clinical programs in prior year disclosures, however, as we initiated the clinical studies for bbT369 and SC-DARIC33 in the first quarter of 2022, we now present these programs separately and have conformed the prior period presentation to reflect this.

	Year ended December 31,		
	2023	2022	2021
ide-cel	$ 40,682	$ 45,896	$ 71,958
bb21217	1,086	3,734	10,001
bbT369	34,897	29,256	20,172
SC-DARIC33	2,330	3,985	8,307
Preclinical programs	47,502	60,590	36,436
Total direct research and development expense	126,497	143,461	146,874
General research and platform personnel costs	26,039	21,638	36,996
Unallocated laboratory and manufacturing expenses	13,435	16,792	14,341
Facility and other support costs	64,787	66,844	54,406

Total other research and development expenses	104,261	105,274	105,743
Total research and development expense	$ 230,758	$ 248,735	$ 252,617

Cost of Manufacturing for Commercial Collaboration

Cost of manufacturing for commercial collaboration consists of quality and other manufacturing costs incurred by us to support the manufacture of *Abecma* inventory sold by our collaborative partner, BMS, in both the U.S. and ex-U.S. regions. These costs are subject to the cost sharing arrangement under the terms of our collaboration agreement (the Amended Ide-cel CCPS) with BMS. For further information on the Amended Ide-cel CCPS, please refer to Note 10, *Collaborative arrangements and strategic partnerships,* in the notes to our audited consolidated and combined financial statements.

The reimbursement from BMS for their share of our U.S. quality and other manufacturing costs is recorded as collaborative arrangement revenue or share of collaboration loss in our consolidated and combined statements of operations and comprehensive loss. The reimbursement from BMS for our ex-U.S. quality and other manufacturing

costs is recorded as service revenue in our consolidated and combined statements of operations and comprehensive loss.

Restructuring expenses

In September 2023, we announced our restructuring plan, or Restructuring Plan, to conserve financial resources and better align our workforce with current business needs. As part of the Restructuring Plan, our workforce was reduced by approximately 40%. Substantially all of the reduction in personnel was completed by December 31, 2023. In connection with the Restructuring Plan, we incurred one-time costs in the third quarter of 2023 relating to severance and retention packages and related benefits. These costs were recorded as restructuring expenses in our consolidated statements of operations and comprehensive loss.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance, legal, business development, commercial, information technology, and human resource functions. Other selling, general and administrative expenses include facility-related costs, insurance, IT costs, professional fees for accounting, tax, legal and consulting services, directors' fees and expenses associated with obtaining and maintaining patents.

Share of Collaboration Loss

Share of collaboration loss represents our share of net loss arising from product sales less cost of goods sold and shared commercial costs and other expenses related to the commercialization of a product where the collaborator is the principal in the product sales. Refer to *Financial Operations Overview – Revenue* for further discussion of collaboration arrangements that are accounted for pursuant to ASC 808.

Cost of Royalty and Other Revenue

Cost of royalty and other revenue represents expenses associated with amounts owed to third-party licensors as a result of revenue recognized under our out-license arrangements.

Change in Fair Value of Contingent Consideration

On June 30, 2014, bluebird bio acquired Pregenen. All assets, liabilities and future obligations related to the Pregenen acquisition, including the resulting intangible assets, goodwill and contingent consideration, were assumed by us in connection with the separation. The agreement provided for up to $135.0 million in future contingent cash payments upon the achievement of certain preclinical, clinical and commercial milestones related to the Pregenen technology.

As of December 31, 2022 December 31, 2023, there were $99.9 million in future contingent cash payments related to commercial milestones. We estimate future contingent cash payments have a fair value of $2.2 million $2.4 million as of December 31, 2022 December 31, 2023, which are classified within other non-current liabilities on our consolidated balance sheet.

Goodwill Impairment Charge

As noted within "Change in Fair Value of Contingent Consideration" above, we assumed goodwill related to the Pregenen acquisition upon our separation from bluebird bio. As discussed further in Note 17, *Goodwill*, in the notes to our audited consolidated and combined financial statements, the sustained decline in the price of our common stock in part due to decreased external expectations for future *Abecma* sales resulting from increased competitive dynamics triggered an indicator of impairment during the third quarter of 2023. Upon completing a quantitative

goodwill impairment test, we recorded a non-cash impairment charge of $12.1 million, writing off our goodwill balance in its entirety.

Other Income, Net

Other income, net consists primarily of rental income resulting from the allocation of facility-related, depreciation and amortization expense to a third party, income recognized under our transition service agreements with bluebird bio, for its proportional use of assets that were assumed by us, as well as expense resulting and sublease income from the allocation of facility-related, depreciation and amortization expense to us for our proportional use of assets that were not assumed by us. Other income, net also includes immaterial rental income and gains and losses on disposal of assets. bluebird bio.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated and combined financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. Estimates and judgments are used in the following areas, among others: allocations of revenue, expenses, assets and liabilities from bluebird bio's historical consolidated financial statements to us for periods prior to the separation, future undiscounted cash flows and subsequent fair value estimates used to assess potential and measure any impairment of long-lived assets, including goodwill and intangible assets, the measurement of right-of-use assets and lease liabilities, contingent consideration, stock-based compensation expense, accrued expenses, income taxes, and the assessment of our ability to fund operations for at least the next twelve months from the date of issuance of our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

While our significant accounting policies are described in more detail in the notes to our audited consolidated and combined financial statements, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Revenue Recognition

Under Topic 606, *Revenue from Contracts with Customers,* an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity

determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. We assess if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying license relative to the option exercise price, including assumptions about technical feasibility and the probability of developing a candidate that would be subject to the option rights. The exercise of a material right is accounted for as a contract modification for accounting purposes.

We assess whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, we consider factors such as the license terms, the research, manufacturing and commercialization capabilities of the collaboration

partner and the availability of the associated expertise in the general marketplace. We also consider the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is determined and allocated to the identified performance obligations in proportion to their stand-alone selling prices, or SSP, on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, we consider applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. We validate the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, we estimate the amount of consideration to which we will be entitled in exchange for transferring the promised goods or services to a customer. We determine the amount of variable consideration by using the expected value method or the most likely amount method. The amount of variable consideration included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty related to the variable consideration is resolved. At the end of each subsequent reporting period, we re-evaluate the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or

the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

In determining the transaction price, we adjust consideration for the effects of the time value of money if the timing of payments provides us with a significant benefit of financing. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. We assessed each of our revenue generating arrangements in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of our arrangements.

We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and if over time recognition is based on the use of an output or input method.

We recognize revenue within the following financial statement captions:

Service Revenue

To date, our service revenue has primarily been generated from the elements of the collaboration arrangements with BMS and Novo Nordisk that are accounted for pursuant to Topic 606, using the five-step model described above. We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808 or Topic 606. For the elements of the arrangement which are more reflective of a vendor-customer relationship and therefore within the scope of Topic 606, we record the related revenue as service revenue on the consolidated and combined statement of operations and comprehensive income (loss). Refer to *Financial Operations Overview – Revenue* above for additional discussion around our policy for recognizing collaborative arrangement revenue and the determination of whether elements of a collaboration arrangement are within the scope of ASC 808 or Topic 606. For the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020, 2021, service revenue consisted of the following:

	Year Ended December 31,		
	2022	2021	2020
ide-cel ex-U.S. service revenue from BMS	$13,226	$16,895	$ 99,052

	Year Ended December 31,		
	2023	2022	2021
ide-cel ex-U.S. service revenue from BMS			

bb21717 license and manufacturing service revenue from BMS	bb21717 license and manufacturing service revenue from BMS	35,762	—	—
bb21217 phase 1 trial service revenue from BMS		—	—	12,400
Service revenue from December 2021 agreement with Novo Nordisk	Service revenue from December 2021 agreement with Novo Nordisk	6,501	—	—
Other	Other	—	4,486	—
Total service revenue	Total service revenue	$55,489	$21,381	$111,452

Collaborative Arrangement Revenue and Share of Collaboration Loss

To date, collaborative arrangement revenue has been primarily generated from the collaboration arrangements with BMS and Regeneron, as further described in Note 10, *Collaborative arrangements and strategic partnerships,* in the notes to our audited consolidated and combined financial statements. We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808 or Topic 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606. In arrangements where we do not deem our collaborator to be our customer, payments to and from our collaborator are presented in the consolidated and combined statements of operations and comprehensive loss based on the nature of the payments. Refer to *Financial Operations Overview – Revenue* above for additional discussion around our policy for recognizing collaborative arrangement revenue and

the determination of whether elements of a collaboration arrangement are within the scope of ASC 808 or Topic 606. For the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020, 2021, collaborative arrangement revenue consisted of the following:

	Year Ended December 31,		
	2022	2021	2020
U.S. *Abecma* collaboration with BMS	$12,781	$19,425	$108,196
Collaboration with Regeneron	19,577	7,496	7,398
Total collaborative arrangement revenue	$32,358	$26,921	$115,594

	Year Ended December 31,		
	2023	2022	2021
U.S. *Abecma* collaboration with BMS	$12,781	$19,425	$108,196
Collaboration with Regeneron	19,577	7,496	7,398
Total collaborative arrangement revenue	$32,358	$26,921	$115,594

To date, *Abecma* is our only commercial product where the collaborator is the principal in the product sales and thus, all amounts shown within our consolidated and combined statements of operations and comprehensive loss for share of collaboration loss relate to *Abecma*. The table below summarizes the impact of the *Abecma* U.S.

collaboration profit/loss share on our consolidated and combined statements of operations and comprehensive loss for the years ended December 31, 2022 December 31, 2023, 2022, and 2021, (in thousands). Amounts for 2020 are not shown, as *Abecma* was not commercially approved until March 2021.

	Three months ended				Year ended
***Abecma* U.S. Collaboration Profit/Loss Share**	**March 31, 2023**	**June 30, 2023**	**September 30, 2023**	**December 31, 2023**	**December 31, 2023**
Our share of profits (losses), net of our share of BMS costs for commercial activities	$ 21,581	$ 23,272	$ (582)	$ 1,366	$ 45,637
Reimbursement from BMS for our costs of commercial manufacturing and commercial activities	1,380	1,271	1,118	604	4,373
Collaborative arrangement revenue (1)	$ 22,961	$ 24,543	$ 536	$ 1,970	$ 50,010
Share of collaboration loss (1)	$ —	$ —	$ —	$ —	$ —
Costs of commercial manufacturing incurred by us, prior to BMS reimbursement	(2,583)	(2,389)	(2,167)	(1,136)	(8,275)
Costs of commercial activities incurred by us, prior to BMS reimbursement	(176)	(153)	(70)	(73)	(472)
Total impact of *Abecma* U.S. collaboration profit/loss share on our statement of operations	$ 20,202	$ 22,001	$ (1,701)	$ 761	$ 41,263

	Three months ended				Year ended
***Abecma* U.S. Collaboration Profit/Loss Share**	**March 31, 2022**	**June 30, 2022**	**September 30, 2022**	**December 31, 2022**	**December 31, 2022**
Our share of profits (losses), net of our share of BMS costs for commercial activities	$ (6,709)	$ (5,931)	$ 2,849	$ 7,286	$ (2,505)
Reimbursement from BMS for our costs of commercial manufacturing and commercial activities	1,357	1,641	1,215	1,431	5,644
Collaborative arrangement revenue (1)	$ —	$ —	$ 4,064	$ 8,717	$ 12,781
Share of collaboration loss (1)	$ (5,352)	$ (4,290)	$ —	$ —	$ (9,642)
Costs of commercial manufacturing incurred by us, prior to BMS reimbursement	(2,086)	(2,696)	(2,175)	(2,615)	(9,572)
Costs of commercial activities incurred by us, prior to BMS reimbursement	(628)	(587)	(256)	(246)	(1,717)
Total impact of *Abecma* U.S. collaboration profit/loss share on our statement of operations	$ (8,066)	$ (7,573)	$ 1,633	$ 5,856	$ (8,150)

	Three months ended				Year ended
***Abecma* U.S. Collaboration Profit/Loss Share**	**March 31, 2021**	**June 30, 2021**	**September 30, 2021**	**December 31, 2021**	**December 31, 2021**
Our share of profits (losses), net of our share of BMS costs for commercial activities	$ —	$ (11,766)	$ 9,762	$ 7,901	$ 5,897
Reimbursement from BMS for our costs of commercial manufacturing and commercial activities	—	1,695	845	917	3,457
Collaborative arrangement revenue (1)	$ —	$ —	$ 10,607	$ 8,818	$ 19,425
Share of collaboration loss (1)	$ —	$ (10,071)	$ —	$ —	$ (10,071)
Costs of commercial manufacturing incurred by us, prior to BMS reimbursement	—	(2,940)	(1,311)	(1,358)	(5,609)
Costs of commercial activities incurred by us, prior to BMS reimbursement	—	(449)	(379)	(476)	(1,304)
Total impact of *Abecma* U.S. collaboration profit/loss share on our statement of operations	$ —	$ (13,460)	$ 8,917	$ 6,984	$ 2,441

(1) This calculation is performed on a quarterly basis and consists of our share of profits, net of our share of BMS costs for commercial activities, offset by reimbursement from BMS for our commercial activities. The calculation is independent of previous activity, which may result in fluctuations between revenue and expense recognition period over period.

Collaborative arrangement revenue net of share of collaboration loss was $50.0 million, $3.1 million, and $9.4 million for the years ended December 31, 2022 December 31, 2023, 2022, and 2021, respectively.

The recognition of service revenue, collaborative arrangement revenue, and share of collaboration loss require management judgment due to the fact that the terms of our collaboration arrangements are complicated and the nature of the collaborative activities change over time. This process includes the identification of costs that we incur that relate to each particular collaboration arrangement, evaluating the nature of these costs (for example, whether the costs relate to a particular geography or territory or whether the costs relate to clinical or commercial activities), and applying the terms of the respective collaborative arrangement to determine the portion of such costs that are the responsibility of the collaboration partner, which in certain circumstances requires significant judgment.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time.

We recognize expenses related to clinical studies based on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period and adjust accordingly.

Other examples of estimated accrued research and development expenses include fees paid to:

- collaboration partners for research performed in connection with ongoing collaboration arrangements;
- investigative sites in connection with clinical studies;
- vendors in connection with preclinical development activities; and
- vendors related to the development, manufacturing, and distribution of clinical trial materials.

Stock-based compensation

Our share-based compensation expense relates to stock options, restricted stock units, restricted stock awards, and shares issued under our employee stock purchase plan. Grants are awarded to employees and non-employees, including our board of directors.

We account for our stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation—Stock Compensation*(", orASC 718"). 718. ASC 718 requires all stock-based payments, including grants of stock options and restricted stock units and modifications to existing stock options, to be recognized in the consolidated and combined statements of operations and comprehensive loss based on their fair values.

Our stock-based awards are subject to either service, performance-based, or market-based vesting conditions. Compensation expense related to awards with service-based vesting conditions is recognized on a straight-line basis

based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Compensation expense related to awards with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable.

We estimate the fair value of our option awards using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the calculation of expected term of the award, (iii) the risk-free interest rate, and (iv) expected dividends. Due to the lack of company specific historical and implied volatility data, we based our estimate of expected volatility on the estimate and expected volatilities of a representative group of publicly traded companies. For these analyses, we select companies with comparable characteristics to ours including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our

own stock price becomes available. For awards granted subsequent to the separation from bluebird bio, we have estimated the expected term of our employee stock options using the "simplified" method, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data. For stock options that were converted in accordance with the Employee Matters Agreement, as discussed above and as further described in Note 13, *Stock-based compensation*, to the consolidated and combined financial statements included elsewhere in this Annual Report on Form 10-K, we have estimated the expected term to be the remaining contractual term of the awards as of the date of the separation. The risk-free interest rates for periods within the expected term of the option are based on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. We have never paid, and do not expect to pay, dividends in the foreseeable future.

For performance-based restricted stock units that vest based on a total shareholder return metric, the vesting condition is considered a market condition as it vests based on the movement in share price of a company. The impact of the market condition is reflected in the award's fair value on the grant date, and the expense is recognized irrespective of whether the market condition is achieved as long as the required service is provided.

We account for forfeitures as they occur. Stock-based compensation expense recognized in the financial statements is based on awards for which performance or service conditions are expected to be satisfied.

Recently Issued Accounting Pronouncements

See Note 2, *Summary of significant accounting policies and basis of presentation,* in the notes to the audited consolidated and combined financial statements included elsewhere in this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

Results of Operations

Historically, for periods prior to the separation from bluebird bio, our operations were managed in the normal course of business as part of bluebird bio. Accordingly, for periods prior to the separation from bluebird bio certain shared costs have been allocated to us and reflected as expenses in the stand-alone consolidated and combined financial statements, as described in greater detail in the notes to the consolidated and combined financial statements. We considered the allocation methodologies used to be a reasonable and appropriate reflection of the historical bluebird bio expenses attributable to us for purposes of the stand-alone financial statements. The expenses reflected in the consolidated and combined financial statements may not be indicative of expenses that will be incurred by us in the future. The following discussion summarizes the key factors we believe are necessary for an understanding of our consolidated and combined financial statements.

Comparison of the years ended December 31, 2022 December 31, 2023 and 2021 2022

	Year ended December 31,			Year ended December 31,		
	2022	2021	Change	2023	2022	Change
Revenue:	Revenue:					
Service revenue						
Service revenue						
Service revenue	Service revenue	$ 55,489	$ 21,381	$34,108		
Collaborative arrangement revenue	Collaborative arrangement revenue	32,358	26,921	5,437		
Royalty and other revenue	Royalty and other revenue	3,649	6,220	(2,571)		
Total revenues	Total revenues	91,496	54,522	36,974		
Operating expenses:	Operating expenses:					
Research and development	Research and development	248,735	252,617	(3,882)		
Research and development						
Research and development						

Cost of manufacturing for commercial collaboration	Cost of manufacturing for commercial collaboration	14,851	9,320	5,531
Selling, general and administrative	Selling, general and administrative	79,450	93,506	(14,056)
Share of collaboration loss	Share of collaboration loss	9,642	10,071	(429)
Restructuring expenses				
Cost of royalty and other revenue	Cost of royalty and other revenue	1,726	2,517	(791)
Change in fair value of contingent consideration	Change in fair value of contingent consideration	232	439	(207)
Goodwill impairment charge				
Total operating expenses	Total operating expenses	354,636	368,470	(13,834)
Loss from operations	Loss from operations	(263,140)	(313,948)	50,808
Interest income, net	Interest income, net	2,932	88	2,844
Other income, net	Other income, net	6,055	21,647	(15,592)
Loss before income taxes	Loss before income taxes	(254,153)	(292,213)	38,060
Income tax expense	Income tax expense	—	—	—
Net loss	Net loss	$(254,153)	$(292,213)	$38,060

Revenue. Total revenue was $100.4 million for the year ended December 31, 2023, compared to $91.5 million for the year ended December 31, 2022, compared to $54.5 million for the year ended December 31, 2021. In 2022, 2023, revenue amounts consisted of our share of commercial profits from *Abecma* sales, collaboration revenue with our collaboration partners such as Regeneron, and service revenue from our collaboration and license agreement with Novo Nordisk, reimbursement by BMS related to our performance of services for *Abecma* that benefited ex-US geographies under our collaboration agreement, and the release royalty revenue recognized on net sales of deferred revenue related to bb21217, the development of which was discontinued in 2022. Breyanzi (lisocabtagene maraleucel) by BMS. We saw a large increase in service collaborative arrangement revenue in 2022 2023 primarily due to increased revenue from our share of commercial profits from *Abecma* in the first half of 2023. The decrease in service revenue was primarily driven by the release of $35.8 million of deferred revenue in 2022 in connection with our completion of bb21217 license and manufacturing services when BMS released us of our performance obligation to manufacture vector for bb21217.

Research and Development Expenses. Research and development expenses were $230.8 million for the year ended December 31, 2023, compared to $248.7 million for the year ended December 31, 2022, compared to $252.6 million for the year ended December 31, 2021. The overall decrease of $3.9 million $18.0 million was primarily attributable to the following:

- $15.1 11.7 million of decreased costs relatedincurred under our partnerships with Gritstone Oncology, Inc. and Seattle Children's Therapeutics relating to our share of start-up and initial patient advance costs in 2022, as well as a decrease in net research and development costs expenses recognized under our collaboration with BMS;
- $12.2 9.6 million of decreased employee compensation expenses, primarily due resulting from the 40% reduction to decreased our workforce announced in September 2023. The decrease was also driven by a decrease in stock-based compensation expense resulting from the completion of our employee retention plan at the end of 2021 and due to an overall decrease in the value of stock-based compensation awards. This was partially offset by increased employee salary expense;
- $2.4 million of decreased license outstanding awards and milestone fees associated with oncology research, the SC-DARIC33 program, and our collaboration with Novo; and September 2023 workforce reduction;

- $3.2 million of decreased lab expenses and other platform costs primarily related to lab consumables;
- $1.9 million of decreased amortization expense associated with the intangible asset acquired in our purchase of Pregenen in 2014. The amortization of this intangible asset was completed in the second quarter of 2022. 2022;
- $1.4 million of decreased IT and other facility-related costs; and
- $0.9 million of decreased consulting and professional service fees, mainly consisting of decreased contractor and consulting support for quality, regulatory, and manufacturing work.

These decreased costs were partially offset by:

- $15.2 million by $10.6 million of increased material production costs associated with CRC-403, the Phase 1/2 Study of bbT369, along with increased manufacturing activities of for suspension lentiviral vector for ide-cel development in the first half of 2023 and MAGE-A4 development; and
- $12.5 million increased starting materials in the second half of increased IT and other facility-related costs, mainly driven by higher rent charges under the assigned and amended 60 Binney Street lease. This increase is also attributable to a higher allocation of these costs to research and development expenses based on headcount and facility square footage.2023.

Cost of Manufacturing for Commercial Collaboration. Cost of manufacturing for commercial collaboration was $14.9 million $14.8 million for the year ended December 31, 2022 December 31, 2023, compared to $9.3 million $14.9 million for the year ended December 31, 2021 December 31, 2022. The increase of $5.5 million This was primarily due to an increase a slight decrease in quality testing performed by us on *Abecma* inventory manufactured in 2022 during 2023 compared to 2021, over which we performed quality testing. 2022. These costs primarily consist of the salaries and benefits for our quality employees and laboratory expenses incurred to support quality testing on *Abecma* inventory testing.

Restructuring Expenses. The increase in restructuring expenses is a result of the costs associated with the workforce reduction announced in September 2023.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $69.4 million for the year ended December 31, 2023, compared to $79.5 million for the year ended December 31, 2022, compared to $93.5 million for the year ended December 31, 2021. The decrease of $14.1 million $10.0 million was primarily due to the following:

- $8.7 8.9 million of million decreased employee compensation expenses, driven mainly by reduced headcount, reflectiveprimarily resulting from the 40% reduction to our workforce as part of efforts to streamline 2seventy's operating model; our restructuring, effective as of September 2023; and
- $5.9 1.2 million of decreased consulting and professional service fees in 2023 compared to 2022, associated with our spin-off from bluebird bio.

These decreased IT and other facility-related costs mainly driven were offset by a lower allocation $1.0 million of these costs to selling, general and administrative expense based on headcount and increased facility square footage. related expenses.

*Share of Collaboration Loss.*Share of collaboration loss for the year ended December 31, 2022, represents our share of net loss arising from the commercialization of *Abecma* under the BMS collaboration during both the first and second quarters half of 2022, as we recorded collaborative arrangement revenue related to this collaboration in the third and fourth quarters second half of 2022. Share of collaboration loss for the year ended December 31, 2021, represents our share of loss for only the second quarter of 2021, as *Abecma* was approved in the U.S. at the end of March 2021 and sales did not begin until April 2021, and we recorded collaborative arrangement revenue related to this collaboration in the third and fourth quarters of 2021. The decrease in share of collaboration loss period over period is attributable to increased net sales partially offset by increased vector manufacturing costs during 2022.

Cost of Royalty and Other Revenue. Cost of royalty and other revenue was $2.1 million for the year ended December 31, 2023, compared to $1.7 million for the year ended December 31, 2022, comparedand represents amounts owed to $2.5 million for the year ended December 31, 2021. third-party licensors on revenues recognized under our out-license arrangements. The decrease increase is attributable to increased royalty and other revenue in the termination same periods driven by sales of our license agreement with Novartis in March 2021, partially offset Breyanzi (lisocabtagene maraleucel) by an increase in cost of royalty revenue related to lisocabtagene maraleucel (marketed as Breyanzi) as a result of increased net sales period over period. BMS.

Change in Fair Value of Contingent Consideration. The change in fair value of contingent consideration was primarily due to the change in significant unobservable inputs used in the fair value measurement of contingent consideration, including the probabilities of successful achievement of clinical and commercial milestones and discount rates.

Goodwill Impairment Charge. During the third quarter of 2023 and more recently, we experienced a sustained decline in the price of our common stock in part due to decreased external expectations for future *Abecma* sales resulting from increased competitive dynamics, which was considered a triggering event. We performed a goodwill impairment test which resulted in a non-cash impairment charge of $12.1 million in the third quarter of 2023. Refer to Note 19, *Goodwill*, in the notes to our audited consolidated and combined financial statements for further discussion.

Other Income, Net. For the year ended December 31, 2022, other Other income, net primarily consisted consists of rental income, income recognized under our transition services service agreements with bluebird bio, and rental income. For the year ended December 31, 2021, other sublease income net consisted primarily of income resulting from the allocation of facility-related, depreciation and amortization expense to bluebird bio for its proportional use of assets that were assumed by us, as well as expense resulting from the allocation of facility-related, depreciation and amortization expense to us for our bio.

proportional use of assets that were not assumed by us. Other income, net also included rental income and gains and losses on disposal of assets along with a refund of license fees for the year ended December 31, 2021.

Liquidity and Capital Resources

Historically, for periods prior to the separation from bluebird bio, the primary source of liquidity for our business was cash flow allocated to us from bluebird bio. Prior to separation, transfers of cash to and from bluebird bio have been reflected in net parent investment in the historical consolidated and combined balance sheets, statements of cash flows and statements of equity (deficit). Accordingly, for periods prior to the separation we have not reported cash or cash equivalents. bluebird bio continued to fund our cash needs through the date of the separation. Upon separation, bluebird bio funded us with approximately $441.5 million of cash, cash equivalents, and marketable securities, of which $140.8 million was cash and cash equivalents, $267.7 million was marketable securities and $33.0 million was restricted cash. investments.

As of December 31, 2022 December 31, 2023, we had cash, cash equivalents and marketable securities of $267.7 million $221.8 million. In January 2023, we entered into a Share Purchase Agreement with Regeneron pursuant to which we sold 1,114,827 shares of our common stock to Regeneron for an aggregate cash price of approximately $20.0 million. In March 2023, we sold 10.9 million shares of common stock through an underwritten public offering at a price per share of $11.50. This resulted in aggregate gross proceeds to us of approximately $125.0 million, before deducting underwriting discounts and commissions and offering expenses. Based on our current operating plans, including with respect to the ongoing commercialization of *Abecma*, and not taking into consideration our strategic realignment and the Asset Sale to Regeneron which is expected to close in the first half of 2024, we expect that our cash, cash equivalents and marketable securities, (including amounts received from the transactions discussed above), will be sufficient to fund current planned operations for at least the next twelve months from the date of filing this Annual Report on Form 10-K. Report. We may, in the future, pursue additional cash resources through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. This includes the potential sale of shares of our common stock of up to $150.0 million in gross proceeds under the at-the-market, ("ATM") or the ATM, facility established in November 2022 with Cowen and Company, LLC. No sales of common stock have occurred under this ATM as of the date of this Annual Report on Form 10-K. and we do not have any current plans to sell shares under the ATM.

We have incurred losses and have experienced negative operating cash flows for all periods presented. During the year ended December 31, 2022 December 31, 2023, we incurred a loss of $254.2 million $217.6 million and used $237.1 million $166.9 million of cash in operations. We will continue to incur research and development and selling, general and administrative expenses and we expect to continue to generate operating losses and negative operating cash flows for the next few years. near future.

Cash Flows

The following table summarizes our cash flow activity:

	Year ended December 31,		
	2022	2021	2020
	(in thousands)		
Net cash used in operating activities	$ (237,134)	$ (207,034)	$ (67,793)
Net cash provided by (used in) investing activities	11,697	15,411	(22,261)
Net cash provided by financing activities	166,229	354,889	90,054
(Decrease) Increase in cash, cash equivalents and restricted cash	$ (59,208)	$ 163,266	$ —

	Year ended December 31,		
	2023	2022	2021
	(in thousands)		
Net cash used in operating activities	$ (166,858)	$ (228,140)	$ (206,855)
Net cash provided by (used in) investing activities	43,861	3,753	(17,586)

Net cash provided by financing activities	127,390	166,229	354,889
Increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents	$ 4,393	$ (58,158)	$ 130,448

Cash Flows from Operating Activities

Net cash used in operating activities was $237.1 million $166.9 million for the year ended December 31, 2023 and primarily consisted of a net loss of $217.6 million adjusted for non-cash items, including stock-based compensation of $32.2 million, goodwill impairment charges of $12.1 million, depreciation and amortization of $10.3 million, and the change in fair value of contingent consideration of $0.2 million, as well as the change in our net working capital.

Net cash used in operating activities was $228.1 million for the year ended December 31, 2022 and primarily consisted of a net loss of $254.2 million adjusted for non-cash items, including stock-based compensation of $41.0 million, $41.0 million, depreciation and amortization of $11.5 million, and the change in fair value of contingent consideration of $0.2 million, as well as the change in our net working capital.

Net cash used in operating activities was $207.0 million $206.9 million for the year ended December 31, 2021 and primarily consisted of a net loss of $292.2 million adjusted for non-cash items, including stock-based compensation of $54.6 million, depreciation and amortization of $16.4 million, and the change in fair value of contingent consideration of $0.4 million, as well as the change in our net working capital.

Net cash used in operating activities was $67.8 million for the year ended December 31, 2020 and primarily consisted of a net loss of $120.1 million adjusted for non-cash items, including stock-based compensation of $61.0 million, depreciation and amortization of $13.2 million, and the change in fair value of contingent consideration of $6.5 million, as well as the change in our net working capital.

Cash Flows from Investing Activities

Net cash provided by investing activities for the year ended December 31, 2022 December 31, 2023 was 11.7 million $43.9 million and was driven by $180.4 million $304.9 million of proceeds from maturities of marketable securities and $18.0 million of proceeds from maturities of restricted investments, which was offset by $145.9 million $246.7 million related to purchases of marketable securities, along with purchases of property, plant and equipment of $22.8 million $13.9 million, and the purchase of restricted investments of $18.4 million.

Net cash provided by investing activities for the year ended December 31, 2021 December 31, 2022 was $15.4 million $3.8 million and was driven by $35.0 $180.4 million of proceeds from maturities of marketable securities and proceeds from maturities of restricted investments of $2.0 million, which was offset by purchase of property, plant and equipment of $11.6 $30.8 million, and the purchase of intangible assets restricted investments of $8.0 $2.0 million.

Net cash used in investing activities for the year ended December 31, 2020 December 31, 2021 was $22.3 million $17.6 million and relates to purchases was driven by the purchase of restricted investments of $33.0 million, the purchase of property, plant, and equipment. equipment of $11.6 million, along with the purchase of intangible assets of $8.0 million. These were offset by $35.0 million of proceeds from maturities of marketable securities.

Cash Flows from Financing Activities

Prior Net cash provided by financing activities for the year ended December 31, 2023 was $127.4 million and was primarily due to net proceeds received of $117.0 million from the separation, bluebird bio managed our cash and financing arrangements. Accordingly, all excess cash generated through earnings was deemed remitted issuance of common stock in a public offering in March 2023 along with net proceeds of $9.9 million from the issuance of common stock to bluebird bio and all sources of cash were deemed funded by bluebird bio. Regeneron from the January 2023 Share Purchase Agreement.

Net cash provided by financing activities for the year ended December 31, 2022 was $166.2 million and was primarily due to net proceeds received of $165.5 million $165.5 million from the issuance of common stock in a private placement in March 2022.

Net cash provided by financing activities for the year ended December 31, 2021 was $354.9 million. The amount includes net cash transferred to us from bluebird bio based on changes in our cash used for operating and investing activities prior to the separation and the cash distributed to us upon separation.

Net cash provided by financing activities for Prior to the year ended December 31, 2020 was $90.1 million and was primarily due to cash transferred to us from separation, bluebird bio based on changes in managed our cash used for operating and investing activities. financing arrangements. Accordingly, all excess cash generated through earnings was deemed remitted to bluebird bio and all sources of cash were deemed funded by bluebird bio.

Funding Requirements

We intend to incur costs in support of the following activities:

- development of SC-DARIC33 and bbT369, including conducting PLAT-08, the Phase 1 study of SC-DARIC33 in pediatric and young adult relapsed or refractory AML and CRC-403, the Phase 1/2 Study of bbT369 in relapsed and/or refractory B Cell Non-Hodgkin's Lymphoma (NHL);

- advancement of the KarMMA trials to support the use of *Abecma* in into earlier lines of therapy and in support of the ongoing commercialization of *Abecma* pursuant to our cost sharing arrangements with BMS;
- development of our pipeline of early research programs;
- operationalizing our drug product manufacturing capabilities at our Cambridge, Massachusetts headquarters, which will enable rapid translational research in our clinical trials and the manufacture of drug product for preclinical and Phase 1 clinical development activities; and
- additional research discovery efforts, BMS, other capital expenditures, working capital requirements, and other general corporate activities.

Based on our current operating plans, including with respect to the ongoing commercialization of *Abecma*, we expect that our cash, cash equivalents and marketable securities will be sufficient to fund current planned operations for at least the next twelve months from the date of filing these financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, the development and commercialization of *Abecma* and future product candidates, we are unable to estimate the exact amount of our working capital requirements. The scope of our future funding requirements will depend on, and could increase significantly as a result of, many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review approvals for *Abecma* in earlier lines of our product candidates; therapy;
- the costs of future activities, including clinical trials, sales, marketing, medical affairs, manufacturing and distribution, for any of our product candidates for which we receive marketing approval; *Abecma*;
- the cost and timing of hiring new employees or contractors to support our continued growth; activities;
- the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on our current or future product candidates, *Abecma*, if any.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, positive operating cash flows, we expect may need to finance our cash needs operations through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, this could result in dilution and could adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in increased fixed payment obligations.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or any future product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market any future product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Lease Commitments

60 Binney Street Lease

In September 2015, bluebird bio entered into a lease agreement, which was assigned to us in connection with the separation, for office and laboratory space located at 60 Binney Street, Cambridge, Massachusetts. Under the terms of the lease, starting on October 1, 2016, we leased approximately 253,108 square feet of office and laboratory space at

$72.50 per square foot per year, or $18.4 million per year in base rent, which is subject to scheduled annual rent increases of 1.75% plus certain operating expenses and taxes. bluebird bio historically maintained a $13.8 million collateralized letter of credit which, subject to the terms of the lease and certain reduction requirements specified therein, including market capitalization requirements, could decrease to $9.2 million over time. The lease would continue until March 31, 2027. Pursuant to a work letter entered into in connection with the lease, the landlord contributed an aggregate of $42.4 million toward the cost of construction and tenant improvements for the building.

In October 2021, bluebird bio entered into a consent to assignment and amendment to its lease agreement for its 60 Binney Street lease, pursuant to which bluebird bio's interest in the lease was assigned to us. In November 2021, we executed a $25.0 million letter of credit related to this lease. Under the assigned and amended lease agreement, the lease term was extended through March 31, 2034 with the 2022 base rent being $90.00 per square foot per year,

or $22.8 million per year in base rent, subject to scheduled annual rent increases of 3.0% plus certain operating expenses and taxes. Starting April 1, 2026, the base rent will reset to $118.41 per square foot per year, or $30.0 million per year in base rent, subject to scheduled annual rent increases of 3.0% plus certain operating expenses and taxes. The lease amendment allowed for an additional tenant improvement allowance of $19.1 million to support the build out of the drug product manufacturing facility, substantially all of which has been incurred and fully reimbursed by the landlord.

Seattle, Washington Leases

In July 2018, bluebird bio entered into a lease agreement for office and laboratory space located in a portion of a building in Seattle, Washington. This lease was assigned to us in connection with the separation. The lease was amended in October 2018 to increase the total rentable space to approximately 36,126 square feet at $54.00 per square foot in base rent per year, which is subject to scheduled annual rent increases of 2.5% plus certain operating expenses and taxes. The lease commenced on January 1, 2019 and the lease term will continue through January 31, 2027. We moved into the facility in June 2019. The lease allowed for a tenant improvement allowance, of up to $215.00 per square foot, or approximately which we utilized $8.0 million. We utilized the $8.0 million tenant improvement allowance and it which has been fully reimbursed by the landlord.

In September 2019, bluebird bio entered into a second amendment to the lease, or the Second Amendment. The Second Amendment added approximately 22,188 square feet to the existing space and extended the lease term of the entire premises by 16 months, or until April 2028. Fixed monthly rent for the expanded space will be incurred at a rate of $62.80 per square foot per year beginning in January 2021, subject to annual increases of 2.5%. The Second Amendment includes a five-year option to extend the term. In September 2020, bluebird bio entered into a sublease agreement for the 22,188 square feet added under the Second Amendment at a fixed monthly rent of $62.80 per square foot per year beginning in January 2021, subject to annual increases of 2.5%. The sublease term will continue through April 2028.

In October 2021, bluebird bio entered into a consent to assignment and amendment to its lease agreement for office and laboratory space in Seattle, Washington and the related sublease that was executed in September 2020 for a portion of the space. The agreement reassigns bluebird bio's interest in the lease and the sublease to us. As part of the assignment, the sublease agreement associated with the expanded space was also assigned to us. In November 2021, we executed a $5.0 million letter of credit related to this lease.

In connection with the Asset Sale, Regeneron agreed to sublease our facilities in Seattle, Washington and a portion of our facilities in Cambridge, Massachusetts. The expected sublease income will cover a majority of the future minimum commitments through 2027. Please refer to Note 7, *Leases,* in the notes to the audited consolidated and combined financial statements included elsewhere in this Annual Report on Form 10-Kfor further information regarding our future minimum commitments under ASC 842 under our operating leases and Note 20, *Subsequent Events*, for further information on the terms of the Asset Sale to Regeneron.

Contingent Consideration Related to Business Combinations

In connection with the Pregenen acquisition, bluebird bio agreed to make contingent cash payments to the former equityholders equity holders of Pregenen. All assets and liabilities related to the Pregenen acquisition, including the

resulting goodwill and contingent consideration, was attributed to us in connection with the separation. In accordance with accounting guidance for business combinations, these contingent cash payments are recorded as a component of other non-current liabilities on our consolidated balance sheets at fair value. During the second quarter of 2017, a $5.0 million preclinical milestone was achieved, which resulted in a $5.0 million payment to the former equityholders equity holders of Pregenen during the third quarter of 2017. As of December 31, 2022 December 31, 2023, the aggregate remaining undiscounted amount of contingent consideration potentially payable is $99.9 million. As of December 31, 2022, December 31, 2023 and 2021, $2.2 2022, $2.4 million and $1.9 $2.2 million, respectively, is reflected as a non-current liability in the consolidated balance sheets, which represents the fair value of our contingent consideration obligations as of that date.

Contingent Milestone and Royalty Payments

We also have obligations to make future payments to third parties that become due and payable on the achievement of certain development, regulatory and commercial milestones (such as the start of a clinical trial, filing

of a BLA, approval by the FDA or product launch). We do not recognize these commitments in our financial statements until they become payable or have been paid.

Based on our development plans as of December 31, 2022 December 31, 2023, we may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products associated with our collaboration and license agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. Because the achievement of these milestones or sales had not occurred as of December 31, 2022 December 31, 2023, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments and sales-based royalties are not yet considered contractual obligations as they are contingent upon success.

- Under a license agreement with Biogen Inc., which was attributed to us in the separation, pursuant to which we license certain patents and patent applications related to ide-cel, we are required to make payments related to certain development milestone obligations and must report on our progress in achieving these milestones on a periodic basis. We may be obligated to pay up to $23.0 million in the aggregate for each licensed product upon the achievement of remaining milestones. Upon commercialization of *Abecma*, which is covered by the in-licensed intellectual property, we are obligated to pay a percentage of net sales as a royalty in the low single digits.

- Under a license agreement with the National Institutes of Health, or NIH, which was attributed to us in the separation, pursuant to which we license certain patent applications related to ide-cel, we have agreed to certain development and regulatory milestone obligations and must report on our progress in achieving these milestones on a periodic basis. We may be obligated to pay up to $9.7 million in the aggregate for a licensed product upon the achievement of these milestones. During the year ended December 31, 2022, we paid fees of $1.0 million to NIH upon milestones reached for products covered by in-licensed intellectual property. These milestone payments were subject to the cost-sharing provisions of the BMS collaboration arrangement. Upon commercialization of *Abecma*, which is covered by the in-licensed intellectual property, we are obligated to pay NIH a percentage of annual net sales as a royalty in the low single digits. The royalties payable under this license agreement are subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits.

- Under a license and collaboration agreement with Gritstone Oncology Inc., or Gritstone, which was attributed to us in the separation, we may utilize Gritstone's proprietary technology platform to identify and validate tumor-specific targets, among other activities under our research plan. We may be obligated to pay up to $129.0 million in the aggregate per therapy product and $27.5 million in the aggregate per target product for development, regulatory, and commercial milestones as well as low single-digit tiered royalty payments based on annual net sales.

- Under a license and collaboration agreement with Medigene Immunotherapies, GmbH, or Medigene, which was attributed to us in the separation, we may utilize Medigene's technology to research, develop and commercialize immune-oncology cell therapies including personalized T cell-based immunotherapies. We entered into an amendment to the agreement relating to the Collaboration Target MAGE-A4 in October 2022. According to the terms of the amendment, we may be obligated to pay up to $29 million in aggregate for development milestones, $39 million in aggregate for regulatory milestones for the first indication, and $19.5 million in aggregate for regulatory milestones for each additional indication. Under the amendment, we were required to pay a $3.0 million development milestone to Medigene in the first quarter of 2023. We may be subject to additional development and regulatory milestones relating to additional Collaboration Targets. We may be obligated to pay mid- to upper-single-digit tiered royalty payments, not exceeding 10%, base on annual net sales. Further, we may be obligated to pay up to $150 million in one-time aggregated sales milestones on a target-by-target basis. The royalties payable under this agreement are subject to reduction for any third-party payments required to be made, with a maximum reduction of fifty percent (50%) on net sales for any quarter.

- Under a license and collaboration agreement with Inhibrx, Inc., or Inhibrx, which was attributed to us in the separation, we will research, develop and commercialize chimeric antigen receptor, (CAR) or CAR, T cell therapies using Inhibrx's proprietary single domain antibody, (sdAb) or sdAb, platform to multiple cancer targets. We may be obligated to pay up to $51.5 million in the aggregate per target for development, regulatory, and commercial milestones as well as mid-single-digit tiered royalty payments based on annual net sales.

- Under a 2011 license agreement, Institut Pasteur granted a license to bluebird bio for certain patents relating to the use of DNA sequences, LVV and recombinant cells in the field of ex vivo gene therapy and CAR T cell-based therapy in a range of indications, excluding vaccinations, (the "Licensed or the Licensed Pasteur IP"). IP. In February 2023, we entered into a partial assumption and assignment agreement with bluebird bio and Institut Pasteur, by which bluebird bio assigned us its rights, obligations and interests under the 2011 license agreement, to any and all uses of the Licensed Pasteur IP in connection with the prevention, diagnosis or treatment of oncological diseases or disorders and hemophilia. We will pay Institut Pasteur an annual maintenance payment, a percentage of income received in the event of sublicensing arrangements and, upon commercialization of products covered by the Licensed Pasteur IP, a percentage of net sales as a royalty, which varies depending on the indication of the product. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of such license income varying from the low single digits to mid-range double digits depending on the nature of the sublicense and stage of development. Prior to entering into the partial assignment and assumption agreement, the

Licensed Pasteur IP was sublicensed by bluebird bio to us under the Intellectual Property License Agreement, dated as of November 3, 2021, entered into in connection with the Separation. After the expiration of the last valid patent covered by Licensed Pasteur IP, we terminated the agreement with Institut Pasteur, effective as of December 31, 2023.

- In connection with the separation, bluebird bio granted us a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, including with respect to patents licensed to bluebird bio by Research Development Foundation, or RDF and SIRION Biotech GmbH, or SIRION, sublicense) to certain intellectual property to allow us to use such intellectual property in connection with our ongoing and future research and development activities and product candidates. For already commercialized products and upon commercialization of our future products covered by the in-licensed intellectual property, we are and will be obligated to pay a percentage of net sales as a royalty in the low single digits. During the year ended December 31, 2022, we paid fees of $1.0 million to SIRION upon the initiation of a Phase 1 trial for bbT369.

- Concurrent with the sale of the manufacturing facility in Durham, North Carolina, bluebird bio also entered into a commercial supply agreement certain ancillary agreements, including two manufacturing agreements and a license agreement, or the Resilience License Agreement, among others, which are collectively referred to as the Ancillary Agreements. One of the manufacturing agreements, or the Development Manufacturing Supply Agreement, supports ongoing manufacturing for lentiviral vector for development candidates. The other manufacturing supply agreement for the future manufacturing of lentiviral vector for the commercial product marketed in collaboration with Resilience. BMS, *Abecma*, or the Commercial Supply Agreement, was assigned by us to BMS on June 23, 2023. Certain rights and obligations under the asset purchase agreement and certain of the ancillary agreements, including two manufacturing agreements, among others, Ancillary Agreements were assigned by bluebird bio to us on November 4, 2021 upon our separation of 2seventy bio from bluebird bio. The assignments under the asset purchase agreement and the development manufacturing supply agreement Ancillary Agreements commit us to reimburse Resilience for an amount equal to 50% of the net operating losses of and relating to the manufacturing facility incurred during the twelve-month period ending on the first anniversary of the closing of the transaction, as calculated in accordance with the asset purchase agreement, subject to a cap of $15.0 million. As During the second quarter of December 31, 2022, 2023, we have accrued $14.8 paid a total of $14.2 million representing our estimated to Resilience for its share of the net operating losses of Resilience. We anticipate settlement with Resilience in early 2023. losses. The disposition of the net assets of the manufacturing facility previously assigned to 2seventy bio has been us was reflected as a transfer to bluebird bio via a net parent investment as a result of bluebird bio's sale of such facility. 2seventy bio is facility in our 2021 Annual Report on Form 10-K for the year ended December 31, 2021. As a result of the separation, our net parent investment balance was reclassified to additional paid-in capital. We are not a party to the sale of the manufacturing facility and, therefore, did not recognize any gain or loss arising from the transaction.

Additionally, we are party to various contracts with contract research organizations and contract manufacturers that generally provide for termination on notice, with the exact amounts in the event of termination to be based on the timing of the termination and the terms of the agreement.

We have various manufacturing development and license agreements to support clinical and commercial product needs. The following table presents non-cancelable contractual obligations arising from these arrangements:

Years ended December 31,	Years ended December 31,	Purchase commitment	Years ended December 31,	Purchase commitment
2023		$ 16,008		
2024	2024	15,750		
2025		—		
2026 and thereafter		—		
2025 and thereafter				
Total purchase commitments	Total purchase commitments	$ 31,758		

Transactions with Related and Certain Other Parties

On November 3, 2021, in connection with the separation and distribution, we entered into certain agreements with bluebird bio relating and giving effect to the separation, including a separation agreement, two transition services agreements, a tax matters agreement, an intellectual property license agreement and an employee matters agreement. The terms of these agreements, including information on the business purpose of such agreements, transaction prices, related ongoing contractual commitments and any related special risks or contingencies are discussed in greater detail in Item 13. "Certain Relationships and Related Transactions, and Director Independence," included elsewhere in this Annual Report on Form 10-K.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest rate fluctuation risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2022 December 31, 2023, we had cash, cash equivalents and marketable securities of $267.7 million $221.8 million, primarily invested in U.S. government agency securities and treasuries, corporate bonds and commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points, or one percentage point, from levels at December 31, 2022 December 31, 2023, the net fair value of our interest-sensitive marketable securities would have resulted in a hypothetical decline of $0.7 million $1.0 million.

Foreign currency fluctuation risk

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. While we have not engaged in the hedging of our foreign currency transactions to date, we are evaluating the costs and benefits of initiating such a program and may in the future hedge selected significant transactions denominated in currencies other than the U.S. dollar as we expand our international operations and our risk grows.

Inflation fluctuation risk

Inflation generally affects us by increasing our cost of labor and operating expenses. Although we do not believe that inflation had a material effect on our business, financial condition or results of operations during the year ended December 31, 2022 December 31, 2023, we may experience some effect in the near future (especially if inflation rates rise) due to an impact on the costs to conduct clinical trials, labor costs we incur to attract and retain qualified personnel, and other operational costs.

Item 8. Financial Statements and Supplementary Data.

The financial statements and the report of our independent registered public accounting firm required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Management’s Evaluation of our Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2022 December 31, 2023, the end of the period covered by this Annual Report on Form 10-K. Based upon such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. generally accepted accounting principles, ("GAAP"). or GAAP. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer principal executive officer and Chief Financial Officer, principal financial officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

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

Management assessed our internal control over financial reporting as of December 31, 2022 December 31, 2023, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment, management has concluded that our internal controls over financial reporting were effective as of December 31, 2022 December 31, 2023 and provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with GAAP. We reviewed the results of management's assessment with the Audit Committee of our Board of Directors.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fourth quarter of 2022 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Internal Controls

In designing and evaluating the disclosure controls and procedures, management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Our management, including our Chief Executive Officer principal executive officer and Chief Financial Officer, principal financial officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud.

Item 9B. Other Information

(a) Not applicable.

(b) During the quarter ended December 31, 2023, none of our directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Except as set forth below, the information required by this Item 10 is incorporated by reference from our definitive proxy statement to be filed with the SEC with respect to our 2023 2024 Annual Meeting of the Stockholders within 120 days after the end of the fiscal year ended December 31, 2022 December 31, 2023.

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. The Code of Business Conduct and Ethics is posted on our website at https://ir.2seventybio.com/corporate-governance/governance-overview.

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of The Nasdaq Global Stock Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

Item 11. Executive Compensation.

The information required by this Item 11 is incorporated by reference from our definitive proxy statement to be filed with the SEC with respect to our 2023 2024 Annual Meeting of the Stockholders within 120 days after the end of the fiscal year ended December 31, 2022 December 31, 2023.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 is incorporated by reference from our definitive proxy statement to be filed with the SEC with respect to our 2023 2024 Annual Meeting of the Stockholders within 120 days after the end of the fiscal year ended December 31, 2022 December 31, 2023.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 is incorporated by reference from our definitive proxy statement to be filed with the SEC with respect to our 2023 2024 Annual Meeting of the Stockholders within 120 days after the end of the fiscal year ended December 31, 2022 December 31, 2023.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 is incorporated by reference from our definitive proxy statement to be filed with the SEC with respect to our 2023 2024 Annual Meeting of the Stockholders within 120 days after the end of the fiscal year ended December 31, 2022 December 31, 2023.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are included on pages F-1 through F-51 attached hereto and are filed as part of this Annual Report on Form 10-K:

(1) The following Report and Consolidated and Combined Financial Statements of the Company are included in this Annual Report on Form 10-K:

- Report of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets
- Consolidated and Combined Statements of Operations and Comprehensive Loss
- Consolidated and Combined Statements of Stockholders' Equity
- Consolidated and Combined Statements of Cash Flows
- Notes to Consolidated and Combined Financial Statements

(2) Financial Statement Schedules. All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits. The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Item 16. Form 10–K Summary

The Company has We have elected not to include summary information.

INDEX TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of 2seventy bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of 2seventy bio, Inc. (the Company) as of December 31, 2022 December 31, 2023 and 2021, 2022, the related consolidated and combined statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022 December 31, 2023, and the related notes (collectively referred to as the "consolidated and combined financial statements"). In our opinion, the consolidated and combined financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 December 31, 2023 and 2021, 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect

to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.

Boston, Massachusetts

March 16, 2023 7, 2024

2seventy bio, Inc.

Consolidated Balance Sheets
(in thousands)

	As of December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 71,032	$130,414
Marketable securities	195,238	134,643
Prepaid expenses	13,652	9,512
Receivables and other current assets	20,960	16,995
Total current assets	300,882	291,564
Property, plant and equipment, net	55,735	34,913
Marketable securities	1,414	97,124
Intangible assets, net	7,302	9,892
Goodwill	12,056	12,056

Operating lease right-of-use assets	Operating lease right-of-use assets	240,885	275,534
Restricted cash and other non-current assets		38,391	38,592
Restricted investments and other non-current assets			
Total assets	Total assets	$656,665	$759,675
Liabilities and Stockholders' Equity	**Liabilities and Stockholders' Equity**		
Current liabilities:	Current liabilities:		
Current liabilities:			
Current liabilities:			
Accounts payable			
Accounts payable			
Accounts payable	Accounts payable	$ 7,208	$ 6,024
Accrued expenses and other current liabilities	Accrued expenses and other current liabilities	54,678	55,410
Operating lease liability, current portion	Operating lease liability, current portion	11,164	9,769
Deferred revenue, current portion	Deferred revenue, current portion	3,000	5,000
Collaboration research advancement, current portion	Collaboration research advancement, current portion	3,744	22,185
Total current liabilities	Total current liabilities	79,794	98,388
Deferred revenue, net of current portion	Deferred revenue, net of current portion	5,000	25,762
Collaboration research advancement, net of current portion		—	1,135
Operating lease liability, net of current portion	Operating lease liability, net of current portion	259,008	272,446
Other non-current liabilities	Other non-current liabilities	2,397	2,122
Total liabilities	Total liabilities	346,199	399,853
Commitments and contingencies (Note 8)	Commitments and contingencies (Note 8)		Commitments and contingencies (Note 8)
Stockholders' equity:	Stockholders' equity:		

Preferred stock, $0.0001 par value; 10,000 shares authorized, 0 shares issued and outstanding at December 31, 2022 and December 31, 2021		—	—
Common stock, $0.0001 par value; 200,000 shares authorized, 37,928 and 23,585 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively		4	2
Preferred stock, $0.0001 par value; 10,000 shares authorized, 0 shares issued and outstanding at December 31, 2023 and December 31, 2022			
Preferred stock, $0.0001 par value; 10,000 shares authorized, 0 shares issued and outstanding at December 31, 2023 and December 31, 2022			
Preferred stock, $0.0001 par value; 10,000 shares authorized, 0 shares issued and outstanding at December 31, 2023 and December 31, 2022			
Common stock, $0.0001 par value; 200,000 shares authorized, 50,632 and 37,928 shares issued and outstanding at December 31, 2023 and December 31, 2022 respectively			
Additional paid-in capital	Additional paid-in capital	606,986	400,026
Accumulated other comprehensive loss	Accumulated other comprehensive loss	(2,877)	(712)
Accumulated deficit	Accumulated deficit	(293,647)	(39,494)
Total stockholders' equity	Total stockholders' equity	310,466	359,822
Total liabilities and stockholders' equity	Total liabilities and stockholders' equity	$656,665	$759,675

See accompanying notes to consolidated and combined financial statements.

2seventy bio, Inc.

Consolidated and Combined Statements of Operations and Comprehensive Loss
(in thousands)

	Year ended December 31,		
	2022	2021	2020
Revenue:			
Service revenue			
Service revenue	$ 55,489	$ 21,381	$ 111,452
Collaborative arrangement revenue	32,358	26,921	115,594
Royalty and other revenue	3,649	6,220	21,076
Total revenues	91,496	54,522	248,122
Operating expenses:			
Research and development	248,735	252,617	296,467
Research and development			
Cost of manufacturing for commercial collaboration	14,851	9,320	—
Selling, general and administrative	79,450	93,506	90,897
Share of collaboration loss	9,642	10,071	—
Restructuring expenses			
Cost of royalty and other revenue	1,726	2,517	5,396
Change in fair value of contingent consideration	232	439	(6,468)
Goodwill impairment charge			
Total operating expenses	354,636	368,470	386,292
Loss from operations	(263,140)	(313,948)	(138,170)

	Year ended December 31,		
	2023		
Revenue:			
Service revenue			
Service revenue			
Collaborative arrangement revenue			
Royalty and other revenue			
Total revenues			
Operating expenses:			
Research and development			
Research and development			
Cost of manufacturing for commercial collaboration			
Selling, general and administrative			
Share of collaboration loss			
Restructuring expenses			
Cost of royalty and other revenue			
Change in fair value of contingent consideration			
Goodwill impairment charge			
Total operating expenses			
Loss from operations			

	Year ended December 31,		
	2023	2022	2021
Revenue:			
Service revenue			
Service revenue			
Collaborative arrangement revenue			
Royalty and other revenue			
Total revenues			
Operating expenses:			
Research and development			
Research and development			
Cost of manufacturing for commercial collaboration			
Selling, general and administrative			
Share of collaboration loss			
Restructuring expenses			
Cost of royalty and other revenue			
Change in fair value of contingent consideration			
Goodwill impairment charge			
Total operating expenses			
Loss from operations			

Interest income, net	Interest income, net	2,932	88	—				
Other income, net	Other income, net	6,055	21,647	18,056				
Loss before income taxes	Loss before income taxes	(254,153)	(292,213)	(120,114)				
Income tax expense	Income tax expense	—	—	—				
Net loss	Net loss	$(254,153)	$(292,213)	$(120,114)				
Net loss per share - basic and diluted	Net loss per share - basic and diluted	$ (7.13)	$ (12.44)	$ (5.14)				
Weighted-average number of common shares used in computing net loss per share - basic and diluted	Weighted-average number of common shares used in computing net loss per share - basic and diluted	35,637	23,499	23,369	Weighted-average number of common shares used in computing net loss per share - basic and diluted	49,276	35,637	23,499
Other comprehensive loss:	Other comprehensive loss:							
Other comprehensive loss, net of tax benefit (expense) of $0.0 million, $0.0 million, and $0.0 million for the years ended December 31, 2022, 2021 and 2020, respectively.		$ (2,165)	$ (712)	$ —				
Other comprehensive income (loss), net of tax benefit (expense) of $0.0 million, $0.0 million, and $0.0 million for the years ended December 31, 2023, 2022 and 2021, respectively.								
Other comprehensive income (loss), net of tax benefit (expense) of $0.0 million, $0.0 million, and $0.0 million for the years ended December 31, 2023, 2022 and 2021, respectively.								
Other comprehensive income (loss), net of tax benefit (expense) of $0.0 million, $0.0 million, and $0.0 million for the years ended December 31, 2023, 2022 and 2021, respectively.								
Total other comprehensive loss	Total other comprehensive loss	$ (2,165)	$ (712)	$ —				
Comprehensive loss	Comprehensive loss	$(256,318)	$(292,925)	$(120,114)				

See accompanying notes to consolidated and combined financial statements.

2seventy bio, Inc.

Consolidated and Combined Statements of Stockholders' Equity
(in thousands)

	Common stock		Net parent investment	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount					
Balances at December 31, 2019	—	$ —	$ 43,692	$ —	$ —	$ —	$ 43,692
Stock-based compensation	—	—	60,997	—	—	—	60,997
Transfers from bluebird bio	—	—	90,054	—	—	—	90,054
Net loss	—	—	(120,114)	—	—	—	(120,114)

	Common stock						
	Shares						
Balances at December 31, 2020	—	$ —	$ 74,629	$ —	$ —	$ —	$ 74,629
Stock-based compensation - bluebird allocation	—	—	44,626	—	—	—	44,626
Transfers from bluebird bio	—	—	517,936	—	(230)	—	517,706
Consummation of spin-off transaction, which includes issuance of pre-funded warrants to purchase 757,575 shares of common stock (refer to Note 9, *Stockholders' equity*)	23,369	2	(384,472)	384,470	—	—	—
Vesting of restricted stock units	7	—	—	—	—	—	—
Stock-based compensation	—	—	—	9,012	—	—	9,012
Issuance of unrestricted stock awards to settle accrued employee compensation	209	—	—	6,544	—	—	6,544
Other comprehensive loss	—	—	—	—	(482)	—	(482)
Net loss	—	—	(252,719)	—	—	(39,494)	(292,213)
Balances at December 31, 2021	23,585	$ 2	$ —	$400,026	$ (712)	$ (39,494)	$ 359,822
Vesting of restricted stock units	374	—	—	—	—	—	—

	Common stock		Net parent investment	Additional paid-in capital	Accumulated other comprehensive loss	Acc
	Shares	Amount				

Exercise of stock options	Exercise of stock options	2	—	—	17	—	—	17
Issuance of common stock in private placement, net of issuance costs	Issuance of common stock in private placement, net of issuance costs	13,934	2	—	165,531	—	—	165,533
Stock-based compensation	Stock-based compensation	—	—	—	41,040	—	—	41,040
Purchase of common stock under ESPP	Purchase of common stock under ESPP	33	—	—	372	—	—	372
Other comprehensive loss	Other comprehensive loss	—	—	—	—	(2,165)	—	(2,165)
Net loss	Net loss	—	—	—	—	—	(254,153)	(254,153)
Balances at December 31, 2022	**Balances at December 31, 2022**	37,928	$ 4	$ —	$606,986	$ (2,877)	$ (293,647)	$ 310,466
Vesting of restricted stock units								
Exercise of stock options								
Issuance of common stock in public offering, net of issuance costs								
Issuance of common stock to Regeneron								
Stock-based compensation								
Purchase of common stock under ESPP								
Other comprehensive income								
Net loss								
Balances at December 31, 2023								

See accompanying notes to consolidated and combined financial statements.

2seventy bio, Inc.

Consolidated and Combined Statements of Cash Flows
(in thousands)

	Year ended December 31,		
	2022	**2021**	**2020**
Year ended December 31,			**Year ended December 31,**

2023		2023	2022	2021
Cash flows from operating activities:	**Cash flows from operating activities:**			
Net loss	Net loss			
Net loss	Net loss	$(254,153)	$(292,213)	$(120,114)
Adjustments to reconcile net loss to net cash used in operating activities:	Adjustments to reconcile net loss to net cash used in operating activities:			
Change in fair value of contingent consideration	Change in fair value of contingent consideration	232	439	(6,468)
Change in fair value of contingent consideration				
Change in fair value of contingent consideration				
Depreciation and amortization	Depreciation and amortization	11,533	16,350	13,188
Stock-based compensation expense	Stock-based compensation expense	41,040	54,629	60,997
Goodwill impairment charge				
Other non-cash items	Other non-cash items	85	430	73
Changes in operating assets and liabilities:	Changes in operating assets and liabilities:			
Prepaid expenses and other assets				
Prepaid expenses and other assets				
Prepaid expenses and other assets	Prepaid expenses and other assets	(8,356)	1,578	1,526
Operating lease right-of-use assets	Operating lease right-of-use assets	34,649	15,541	13,764
Accounts payable	Accounts payable	327	(6)	(13,240)
Accrued expenses and other liabilities	Accrued expenses and other liabilities	(8,110)	15,733	(7,479)
Operating lease liabilities	Operating lease liabilities	(12,042)	(16,199)	(10,960)
Deferred revenue	Deferred revenue	(22,762)	4,180	8,317
Collaboration research advancement	Collaboration research advancement	(19,577)	(7,496)	(7,397)
Net cash used in operating activities	Net cash used in operating activities	(237,134)	(207,034)	(67,793)
Cash flows from investing activities:	**Cash flows from investing activities:**			
Purchases of property, plant and equipment	Purchases of property, plant and equipment	(22,842)	(11,575)	(22,261)
Purchases of property, plant and equipment				
Purchases of property, plant and equipment				
Purchases of marketable securities	Purchases of marketable securities	(145,908)	—	—

Proceeds from maturities of marketable securities	Proceeds from maturities of marketable securities	180,447	34,986	—
Purchase of intangible assets	Purchase of intangible assets	—	(8,000)	—
Purchase of restricted investments				
Proceeds from maturities of restricted investments				
Net cash provided by (used in) investing activities	Net cash provided by (used in) investing activities	11,697	15,411	(22,261)
Cash flows from financing activities:	**Cash flows from financing activities:**			
Transfers from bluebird bio	Transfers from bluebird bio	—	354,889	90,054
Transfers from bluebird bio				
Transfers from bluebird bio				
Proceeds from issuance of common stock in public offering, net of issuance costs				
Proceeds from issuance of common stock to Regeneron, net of issuance costs				
Proceeds from issuance of common stock in private placement, net of issuance costs	Proceeds from issuance of common stock in private placement, net of issuance costs	165,533	—	—
Proceeds from exercise of stock options and ESPP contributions	Proceeds from exercise of stock options and ESPP contributions	696	—	—
Net cash provided by financing activities	Net cash provided by financing activities	166,229	354,889	90,054
Decrease in cash, cash equivalents and restricted cash		(59,208)	163,266	—
Cash, cash equivalents and restricted cash at beginning of year		163,266	—	—
Cash, cash equivalents and restricted cash at end of year		$ 104,058	$ 163,266	$ —
Reconciliation of cash, cash equivalents and restricted cash:				

Increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents				
Cash, cash equivalents and restricted cash and cash equivalents at beginning of year				
Cash, cash equivalents and restricted cash and cash equivalents at end of year				
Reconciliation of cash, cash equivalents and restricted cash and cash equivalents:				
Cash and cash equivalents	Cash and cash equivalents	$ 71,032	$ 130,414	$ —
Restricted cash included in restricted cash and other non-current assets		33,026	32,852	—
Total cash, cash equivalents and restricted cash		$ 104,058	$ 163,266	$ —
Cash and cash equivalents				
Cash and cash equivalents				
Restricted cash and cash equivalents included in restricted investments and other non-current assets				
Total cash, cash equivalents and restricted cash and cash equivalents				
Supplemental cash flow disclosures:	**Supplemental cash flow disclosures:**			
Purchases of property, plant and equipment included in accounts payable and accrued expenses	Purchases of property, plant and equipment included in accounts payable and accrued expenses	$ 10,896	$ 3,703	$ 2,039
Right-of-use assets obtained in exchange for operating lease liabilities		$ —	$ —	$ 4,989
Purchases of property, plant and equipment included in accounts payable and accrued expenses				
Purchases of property, plant and equipment included in accounts payable and accrued expenses				
Non-cash return of bRT-related assets to bluebird bio	Non-cash return of bRT-related assets to bluebird bio	$ —	$ 110,300	$ —
Increase of right-of-use asset and associated lease liability due to lease reassessment	Increase of right-of-use asset and associated lease liability due to lease reassessment	$ —	$ 174,618	$ —

Issuance of unrestricted stock awards to settle accrued employee compensation	Issuance of unrestricted stock awards to settle accrued employee compensation	$ —	$ 6,544	$ —

See accompanying notes to consolidated and combined financial statements.

2seventy bio, Inc.

Notes to Consolidated and Combined Financial Statements

For the Years Ended December 31, 2022 December 31, 2023, 2021 2022 and 2020 2021

1. Description of the business

2seventy bio, Inc. (the "Company" or "2seventy bio") is a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. The Company's approach combines its expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. The Company is advancing multiple preclinical and clinical programs in oncology and, together with Bristol Myers Squibb ("BMS"), BMS, delivering the first FDA-approved CAR T therapy in multiple myeloma, *Abecma* (idecabtagene vicleucel, or ide-cel), to patients in the United States. Please refer to Note 10, *Collaborative arrangements and strategic partnerships*, for further discussion of the collaboration with BMS.

2seventy bio Securities Corporation is a wholly-owned subsidiary of the Company which was incorporated in Massachusetts on December 13, 2021 and was granted securities corporation status in Massachusetts for the 2021 tax year. 2seventy bio Securities Corporation has no employees.

On January 29, 2024, the Company began undertaking a strategic realignment to focus on the development and commercialization of *Abecma.* In connection with the strategic realignment, the Company entered into an asset purchase agreement with Regeneron Pharmaceuticals, Inc., or Regeneron, to sell to Regeneron substantially all of the assets related to its oncology and autoimmune cell therapy programs. Upon closing of the transaction, which is subject to customary closing conditions, Regeneron will assume all of the ongoing program, infrastructure and personnel costs related to these programs. The transaction is expected to close in the first half of 2024.

The Company is subject to risks and uncertainties similar to other companies in the biotechnology industry. There can be no assurance that the Company's preclinical studies and clinical trials will be successfully completed, that it will maintain protection of proprietary technology, or that it will obtain the necessary government regulatory approvals for its*Abecma* or any future product candidates candidates. Even following approval, *Abecma* or those of its collaborators. Even if approved, these any future product candidates may not be commercially viable. The Company operates in an environment of rapid technological innovation and substantial competition from pharmaceutical and biotechnology companies. Additionally, the Company is dependent on key personnel and on third party organizations such as financial institutions, collaborators, and contract manufacturing organizations.

The separation from bluebird bio, Inc.

In January 2021, bluebird bio, Inc. ("bluebird bio") announced its plans to separate its oncology portfolio and programs from its severe genetic disease portfolio and programs, and spin off its oncology portfolio and programs into a separate, publicly traded company. In furtherance of this plan, 2seventy bio was incorporated as a Delaware corporation in April 2021, and in September 2021, bluebird bio's board of directors approved the distribution of all of the issued and outstanding shares of 2seventy bio common stock on the basis of one share of 2seventy bio common stock for every three shares of bluebird bio common stock issued and outstanding on October 19, 2021, the record date for the distribution. As a result of the distribution, which occurred on November 4, 2021, 2seventy bio became an independent, publicly traded company.

On November 3, 2021, the Company also entered into a separation agreement with bluebird bio, which is referred to in this annual report as the "Separation Agreement", as well as various other agreements with bluebird bio, including a tax matters agreement, an employee matters agreement, an intellectual property license agreement, a transition services agreement under which 2seventy bio temporarily receives certain services from bluebird bio, and a second transition services agreement under which 2seventy bio temporarily provides certain services to bluebird bio. These agreements also govern certain of 2seventy bio's relationships with bluebird bio after the separation. For additional information regarding the Separation Agreement and the other related agreements, refer to Note 14, *Related-party transactions.*

Going concern

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern*, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the consolidated and combined financial

statements are issued. The Company has incurred losses and has experienced negative operating cash flows for all historical periods presented. During the year ended December 31, 2022 December 31, 2023, the Company incurred a net loss of $254.2 million $217.6 million and used $237.1 million $166.9 million of cash in operations. The Company expects to continue to generate operating losses and negative operating cash flows for the next few years. The Company's continued operations are dependent on its ability to raise additional funding. near future.

As of December 31, 2022 December 31, 2023, the Company had cash, cash equivalents and marketable securities of $267.7 million $221.8 million. In January 2023, the Company entered into a Share Purchase Agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron") pursuant to which it sold 1,114,827 shares of its common stock to Regeneron for an aggregate cash price of approximately $20.0 million. In March 2023, the Company sold 10.9 million shares of common stock through an underwritten public offering at a price per share of $11.50. This resulted in aggregate gross proceeds to the Company of approximately $125.0 million, before deducting underwriting discounts and commissions and offering expenses. Based on its the Company's current operating plans, including with respect to the ongoing commercialization of *Abecma*, and not taking into consideration our strategic realignment and the Asset Sale to Regeneron which is expected to close in the first half of 2024, the Company expects that its cash, cash equivalents and marketable securities, (including amounts received from the transactions discussed above), will be sufficient to fund current planned operations for at least the next twelve months from the date of filing this Annual Report on Form 10-K. The Company may, in the future, pursue additional cash resources through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. This includes the potential sale of shares of its the Company's common stock of up to $150.0 million in gross proceeds under the at-the-market, ("ATM") or the ATM, facility established in November 2022 with Cowen and Company, LLC. No sales of common stock have occurred under this ATM as of the date of this Annual Report on Form 10-K. 10-K and the Company does not currently have any plans to sell shares under the ATM.

2. Summary of significant accounting policies and basis of presentation

Basis of presentation

The Company did not operate as a separate, stand-alone entity prior to its separation from bluebird bio. The Company's consolidated balance sheets as of December 31, 2022 December 31, 2023 and 2021, 2022, statement of operations and comprehensive loss for the year years ended December 31, 2022, December 31, 2023 and 2022, statement of stockholder's equity for the year years ended December 31, 2022 December 31, 2023 and 2022 and the statement of cash flows for the year years ended December 31, 2022 December 31, 2023 and 2022 consist of the consolidated balances of the Company as prepared on a stand-alone basis. The Company's consolidated and combined statements of operations and comprehensive loss, stockholders' equity and cash flows for the year ended December 31, 2021, have been prepared on a carve out basis, derived from bluebird bio's consolidated financial statements and accounting records, for the period prior to the separation on November 4, 2021 and on a stand-alone basis for the period following the separation through December 31, 2021. The Company's combined statements of operations and comprehensive loss, stockholders' equity and cash flows for the year ended December 31, 2020, have been prepared on a carve-out basis, derived from bluebird bio's consolidated financial statements and accounting records.

The accompanying consolidated and combined financial statements reflect the historical results of the operations, financial position and cash flows of the Company and have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as included in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB").

The historical results of operations, financial position and cash flows of 2seventy bio presented in these consolidated and combined financial statements may not be indicative of what they would have been had 2seventy bio been an independent stand-alone entity for each of the years presented prior to the separation, nor are they necessarily indicative of 2seventy bio's future results of operations, financial position and cash flows.

Prior to the separation, the Company was dependent upon bluebird bio for all of its working capital and financing requirements, as bluebird bio used a centralized approach to cash management and financing its operations. There were no cash amounts specifically attributable to the Company for the periods prior to the separation; therefore, cash and cash equivalents were not allocated to the Company for periods prior to the

separation. Financing transactions related to bluebird bio for periods prior to the separation are accounted for as a component of net parent investment in the consolidated and combined balance sheets and as a financing activity on the accompanying consolidated and combined statements of cash flows. In 2021, net cash transferred to us from bluebird bio of $354.9 million, as indicated in our consolidated and combined statements of cash flows, includes

both the net changes in our cash used for operating and investing activities prior to the separation and the cash and cash equivalents distributed to us upon separation.

Prior to the separation, the Company's combined financial statements included an allocation of expenses related to certain bluebird bio corporate functions, including senior management, legal, human resources, finance and information technology. In addition, prior to the separation the Company's combined financial statements include an allocation of certain research and development costs not directly attributable to individual programs. These expenses were allocated to the Company based on direct usage or benefit where specifically identifiable, with the remainder allocated based on employee time spent on projects, square footage or other measures that management believes are consistent and reasonable. These allocations may not be indicative of the actual expense that would have been incurred had the Company operated as an independent, publicly traded company for the periods prior to the separation. See Note 14, *Related-party transactions*, for a further description of the accounting for the separation from bluebird bio.

As 2seventy bio's operations were not historically held by a single legal entity or separate legal entities, net parent investment was shown in lieu of stockholder's equity in the combined financial statements for periods prior to the separation. As a result of the separation, the Company's net parent investment balance was reclassified to additional paid-in capital.

For periods prior to the separation, the taxable income (loss) of bluebird bio entities, including 2seventy bio, Inc. prior to the separation, was included in bluebird bio's consolidated tax returns. As such, separate income tax returns were not prepared for the entities included within the combined financial statements prior to separation.

In connection with the separation, certain assets and liabilities, including certain accounts receivables and accounts payables, included on the consolidated and combined balance sheets prior to the separation have been retained by bluebird bio post-separation and, therefore, were adjusted through net parent investment in the Company's consolidated and combined financial statements. In addition, in connection with the separation, certain equity awards were converted in accordance with the Employee Matters Agreement, as further described in Note 13, *Stock-based compensation*. Upon separation, bluebird bio contributed $384.5 million of net assets to the Company.

Amounts reported are computed based on thousands, except percentages or as otherwise noted. As a result, certain totals may not sum due to rounding.

Correction of immaterial error

During the first quarter of 2023, the Company identified two immaterial errors in its previously issued 2022 quarterly reports on Form 10-Q, and 2022 and 2021 annual reports on Form 10-K related to: 1) restricted investments previously presented as restricted cash on its consolidated balance sheets and consolidated statements of cash flows; and 2) cash outflows related to the purchase of property, plant and equipment previously presented within operating cash outflows instead of investing cash outflows in its 2022 annual consolidated statements of cash flows.

Based on the analysis of quantitative and qualitative factors in accordance with SEC Staff Accounting Bulletin (SAB) Topic 1.M "Assessing Materiality" and SAB Topic 1.N "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements", the Company concluded that these errors were immaterial, individually and in the aggregate, to its consolidated balance sheets and consolidated statements of cash flows as presented in its previously filed quarterly and annual financial statements. There was no impact to any other statements for any period presented.

To correct for the immaterial error related to restricted investments, the Company:

- changed the caption "Restricted cash and other non-current assets" to "Restricted investments and other non-current assets" on the balance sheet;
- included additional disclosures around the restricted investments within Note 3, *Marketable securities* and Note 4, *Fair value measurements*; and
- adjusted its previously filed consolidated statement of cash flows as follows:

	For the year ended December 31, 2022		
in thousands	As previously reported	Adjustment	As revised
Cash flows from operating activities:			
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	$ (8,356)	$ 1,024	$ (7,332)
Accrued expenses and other liabilities	$ (8,110)	$ 7,970	$ (140)
Net cash used in operating activities	$ (237,134)	$ 8,994	$ (228,140)
Cash flows from investing activities:			
Purchases of property, plant and equipment	$ (22,842)	$ (7,968)	$ (30,810)
Purchases of restricted investments	$ —	$ (1,976)	$ (1,976)
Maturities of restricted investments	$ —	$ 2,000	$ 2,000
Net cash provided by investing activities	$ 11,697	$ (7,944)	$ 3,753
Decrease in cash, cash equivalents and restricted cash and cash equivalents	$ (59,208)	$ 1,050	$ (58,158)
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	$ 163,266	$ (32,818)	$ 130,448
Cash, cash equivalents and restricted cash and cash equivalents at end of period	$ 104,058	$ (31,768)	$ 72,290

Reconciliation of cash, cash equivalents and restricted cash and cash equivalents			
Restricted cash and cash equivalents included in restricted investments and other non-current assets	$ 33,026	$ (31,768)	$ 1,258
Total cash, cash equivalents and restricted cash and cash equivalents	$ 104,058	$ (31,768)	$ 72,290

	For the year ended December 31, 2021		
in thousands	**As previously reported**	**Adjustment**	**As revised**
Cash flows from operating activities:			
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	$ 1,578	$ 179	$ 1,757
Net cash used in operating activities	$ (207,034)	$ 179	$ (206,855)
Cash flows from investing activities:			
Purchases of restricted investments	$ —	$ (32,997)	$ (32,997)
Net cash used in (provided by) investing activities	$ 15,411	$ (32,997)	$ (17,586)
Decrease in cash, cash equivalents and restricted cash and cash equivalents	$ 163,266	$ (32,818)	$ 130,448
Cash, cash equivalents and restricted cash and cash equivalents at end of period	$ 163,266	$ (32,818)	$ 130,448
Reconciliation of cash, cash equivalents and restricted cash and cash equivalents			
Restricted cash and cash equivalents included in restricted investments and other non-current assets	$ 32,852	$ (32,818)	$ 34
Total cash, cash equivalents and restricted cash and cash equivalents	$ 163,266	$ (32,818)	$ 130,448

The Company has corrected its prior period presentation for this error in the 2023 quarterly financial statements on Form 10-Q and 2023 annual report on Form 10-K.

To correct for the immaterial misclassification of cash outflows noted above, the Company has adjusted its 2022 statement of cash flows within its 2023 annual report on Form 10-K by reclassifying $8.0 million of cash outflows from net cash used in operating activities to net cash provided by investing activities.

Principles of consolidation and combination

Periods prior to separation

The accompanying combined financial statements included the attribution of certain assets and liabilities that were historically held by bluebird bio but which were specifically identifiable or attributable to the Company. All intercompany balances and transactions with bluebird bio were deemed to be effectively settled in the combined financial statements at the time the transaction was recorded. Expenses related to corporate allocations from bluebird bio to the Company were considered to be effectively settled for cash in the combined financial statements at the time the transaction was recorded.

Periods after the separation

The accompanying consolidated and combined financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany transactions and accounts within the Company have been eliminated. Certain amounts presented in the prior period have been reclassified to conform to the current period presentation.

As a standalone entity, the Company will file has filed tax returns on its own behalf, and tax balances and the effective income tax rate may differ have differed from the amounts reported in the historical periods. As of November 4, 2021 and in

connection with the separation, the Company adjusted its deferred tax balances and computed its related tax provision to reflect operations as a standalone entity.

Variable interest entities

The Company continually assesses whether it is the primary beneficiary of a variable interest entity as changes to existing relationships or future transactions may result in consolidation or deconsolidation of one or more collaborators or partners. In determining whether it is the primary beneficiary of an entity in which the Company has a variable interest, management applies a qualitative approach that determines whether the Company has both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements.

Estimates and judgments are used in the following areas, among others: allocations of revenue, expenses, assets and liabilities from bluebird bio's historical consolidated financial statements to the Company for periods prior to the separation, future undiscounted cash flows and subsequent fair value estimates used to assess potential and measure any impairment of long-lived assets, including goodwill and intangible assets, the measurement of right-of-use assets and lease liabilities, contingent consideration, stock-based compensation expense, accrued expenses, income taxes, and the assessment of the Company's ability to fund its operations for at least the next twelve months from the date of issuance of these financial statements. In addition, estimates and judgments are used in the Company's

accounting for its revenue-generating arrangements, in particular as it relates to determining the stand-alone selling price of performance obligations, evaluating whether an option to acquire additional goods and services represents a material right, estimating the total transaction price, including estimating variable consideration and the probability of achieving future potential development and regulatory milestones, assessing the period of performance over which revenue may be recognized, and accounting for modifications to revenue-generating arrangements.

Segment information

The Company operates in a single segment, focusing on researching, developing and commercializing potentially transformative treatments for cancer. Consistent with its operational structure, its chief operating decision maker manages and allocates resources for the Company at a consolidated level. Therefore, results of the Company's operations are reported on a consolidated basis for purposes of segment reporting. All material long-lived assets of the Company reside in the United States.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original final maturities of 90 days or less from the date of purchase to be cash equivalents. Cash equivalents may consist of marketable securities with maturities of less than 90 days when purchased. Cash equivalents are reported at fair value. There were no cash or cash equivalents specifically attributable to 2seventy bio for the historical periods presented prior to the separation.

Restricted cash investments

As of December 31, 2022 December 31, 2023 and 2021, 2022, restricted cash investments consists primarily of United States government agency securities and treasuries placed as collateral to letters of credit totaling $32.8 million and $30.0 million, respectively that are required to be maintained in connection with the Company's lease arrangements. The letters of credit are in the name of the Company's landlords landlord and are required to fulfill lease requirements in the event the Company should default on its lease obligations. As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company classified its restricted cash investments as non-current on the consolidated balance sheet based on the release dates of the restrictions. For further information on the Company's letters of credit, see Note 7, *Leases*.

Marketable securities

The Company's marketable securities are maintained by investment managers and consist of U.S. government agency securities and treasuries, corporate bonds and commercial paper. Debt securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity until realized. Any premium arising at purchase is amortized to the earliest call date and any discount arising at purchase is accreted to maturity. Amortization and accretion of premiums and discounts are recorded in interest income, net. Realized gains and losses on debt securities are determined using the specific identification method and are included in other income, net.

The Company classifies marketable securities with a remaining maturity when purchased of greater than three months as available-for-sale. Marketable securities with a remaining maturity date greater than one year are classified as non-current assets although these securities are available for use in the Company's current operations. There were no marketable securities specifically attributable to 2seventy bio for the historical periods presented prior to the separation.

Effective January 1, 2020, The Company assesses its available-for-sale debt securities under the Company adopted available-for-sale debt security impairment model in ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements* ("ASU 2016-13" or "ASC 326"), using the effective date method. As the Company had never recorded any other-than-temporary-impairment adjustments to its available-for-sale debt securities prior to the effective date, no transition provisions are applicable to the Company.

The Company assesses its available-for-sale debt securities under the available-for-sale debt security impairment model in ASC 326 as of each reporting date in order to determine if a portion of any decline in fair value below carrying value recognized on its available-for-sale debt securities is the result of a credit loss. The Company records credit

losses in the consolidated and combined statements of operations and comprehensive loss as credit loss expense within other income, net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale debt securities.

Accrued interest receivable related to the Company's available-for-sale debt securities is presented within receivables and other current assets on the Company's consolidated balance sheets. The Company has elected the practical expedient available to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivables associated with its marketable securities.

Concentrations of credit risk and off-balance sheet risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, available-for-sale securities, and accounts receivable. Deposits are maintained with banks in the United States and such amounts may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on such accounts, and does not believe it is exposed to any unusual credit risk beyond the normal credit risk currently associated with commercial banking relationships. Cash deposits are insured by the Federal Deposit Insurance Corporations (“FDIC”) up to $250,000. The Company has cash deposits in excess of the FDIC insured limit. The Company’s marketable securities, which primarily consist of U.S. government agency securities and treasuries, corporate bonds and commercial paper, potentially subject the Company to concentrations of credit risk.

The Company has adopted an investment policy that limits the amounts the Company may invest in any one type of investment and requires all investments held by the Company to be at least AA+/Aa1 rated, thereby reducing credit risk exposure. The Company’s accounts receivable balance primarily consists of amounts owed from collaborative arrangement partners and royalties receivable under out-license agreements with various third parties. The Company monitors economic conditions to identify facts or circumstances that may indicate that any of its accounts receivable are at risk of collection.

Fair value of financial instruments

The Company has certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements:

Level 1—Fair values are determined utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Fair values are determined utilizing quoted prices for identical assets or liabilities in non-active markets, quoted prices for similar assets or liabilities in active markets, or other market observable inputs such as interest rates, yield curves and foreign currency spot rates.

Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Items measured at fair value on a recurring basis include marketable securities (see Note 3, *Marketable securities*, and Note 4, *Fair value measurements*) and restricted cash and cash equivalents, restricted investments, and contingent consideration (see Note 4, *Fair value measurements*). The carrying amounts of accounts receivable, accounts payable and accrued expenses approximate their fair values due to their short-term nature.

Business combinations

Business combinations are accounted for using the acquisition method of accounting. Using this method, the tangible and intangible assets acquired and the liabilities assumed are recorded as of the acquisition date at their respective fair values. The Company evaluates a business as an integrated set of activities and assets that is capable of being managed for the purpose of providing a return in the form of dividends, lower costs or other economic benefits and consists of inputs and processes that provide or have the ability to provide outputs. In an acquisition of a business, the excess of the fair value of the consideration transferred over the fair value of the net assets acquired is recorded as goodwill. In an acquisition of net assets that does not constitute a business, no goodwill is recognized.

The consolidated and combined financial statements include the results of operations of an acquired business after the completion of the acquisition.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting. Goodwill is not amortized; rather, it is evaluated for impairment within the Company's single reporting unit on an annual basis, during the fourth quarter, or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the Company's reporting unit below its carrying amount. The Company performs a one-step quantitative test and records the amount of goodwill impairment, if any, as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The As noted within "Change in Fair Value of Contingent Consideration" above, the Company has not recognized any impairment charges assumed goodwill related to the Pregenen acquisition upon its separation from bluebird bio. As discussed further in Note 17, *Goodwill*, the sustained decline in the price of the Company's common stock in part due to decreased external expectations for future *Abecma* sales resulting from increased competitive dynamics triggered an indicator of impairment during the third quarter of 2023. Upon completing a quantitative goodwill to date.

impairment test, the Company recorded a non-cash impairment charge of $12.1 million, writing off its goodwill balance in it's entirety.

Intangible assets, net

Intangible assets, net primarily consist of acquired core technology, net of accumulated amortization. The Company amortizes its intangible assets using the straight-line method over their estimated economic lives and periodically reviews for impairment. The Company has not recognized any impairment charges related to intangible assets to date.

Contingent consideration

Each reporting period, the Company remeasures the contingent consideration obligations associated with business combinations to their fair value and records within operating expenses increases or decreases in their fair value as change in fair value of contingent consideration within the consolidated and combined statements of operations and comprehensive loss. Changes in contingent consideration result from changes in the assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones may be achieved, and the discount rate used to estimate the fair value of the liability. Contingent consideration may change significantly as development of the Company's programs in certain indications progress and additional data is obtained, impacting the Company's assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value. See Note 4, *Fair value measurements,* for additional information.

Property, plant and equipment

Property, plant and equipment is stated at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Depreciation and amortization is calculated using the straight-line method over the estimated useful lives of the assets, which are as follows:

Asset	Estimated useful life
Building	40 years
Computer equipment and software	3 years
Furniture and fixtures	2-5 years
Laboratory equipment	2-5 5-10 years
Leasehold improvements	Shorter of the useful life or remaining lease term

Impairment of long-lived assets

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the relevant facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable. The Company does not have material financing leases.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. To estimate its incremental borrowing

rate, a credit rating applicable to the Company is estimated using a synthetic credit rating analysis since the Company does not currently have a rating agency-based credit rating.

The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless it is reasonably certain that the Company will exercise its renewal option.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the stand-alone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

In accordance with ASC 842, components of a lease should be separated into lease components and non-lease components. The fixed and in-substance fixed contract consideration must be allocated based on the relative stand-alone prices to the lease components and non-lease components.

Entities may elect not to separate lease and non-lease components. Rather, entities would account for each lease component and related non-lease component together as a single lease component. The Company has elected to

account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only.

For purposes of distinguishing between operating and financing leases, ASC 842 allows for the use of judgment in determining whether the lease term is for a major part of the remaining economic life of the underlying asset and whether the present value of lease payments represents substantially all of the fair value of the underlying asset. The Company applies the bright line thresholds referenced in ASC 842-10-55-2 to assist in evaluating leases for appropriate classification. The aforementioned bright lines are applied consistently to the Company's entire portfolio of leases.

Common stock warrants

The Company's common stock warrants are evaluated pursuant to ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and ASC 815, *Derivatives and Hedging* ("ASC 815"). Management classifies its freestanding warrants as (i) liabilities, if the warrant terms allow settlement of the warrant exercise in cash, or (ii) equity, if the warrant terms only allow settlement in shares of common stock.

Revenue recognition

Under ASC Topic 606, *Revenue from Contracts with Customers* ("Topic 606"), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying good or service relative to the option exercise price. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the license terms, the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is determined and allocated to the identified performance obligations in proportion to their stand-alone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation,

the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The amount of variable consideration included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty related to the variable consideration is resolved. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assessed each of its revenue generating arrangements in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of its arrangements.

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and if over time recognition is based on the use of an output or input method.

The Company recognizes revenue within the following financial statement captions:

Service revenue

To date, the Company's service revenue has primarily been generated from the elements of its collaboration arrangements with BMS and Novo Nordisk that are accounted for pursuant to Topic 606, using the five-step model described above. As discussed further below, the Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") or Topic 606. For the elements of a collaboration arrangement which are more reflective of a vendor-customer relationship and therefore within the scope of Topic 606, the Company records the related revenue as service revenue on the consolidated and combined statement of operations and comprehensive loss. Refer below for additional discussion around the Company's policy for recognizing collaborative arrangement revenue and the determination of whether elements of a collaboration arrangement are within the scope of ASC 808 or Topic 606. For the years ending 2023, 2022 2021 and 2020, 2021, service revenue consisted of the following:

	Year Ended December 31,		
	2022	2021	2020

ide-cel ex-U.S. service revenue from BMS	$ 13,226	$ 16,895	$ 99,052
bb21717 license and manufacturing service revenue from BMS	35,762	—	—
bb21217 phase 1 trial service revenue from BMS	—	—	12,400
Service revenue from December 2021 agreement with Novo Nordisk	6,501	—	—
Other	—	4,486	—
Total service revenue	$ 55,489	$ 21,381	$ 111,452

	Year Ended December 31,		
	2023	2022	2021
ide-cel ex-U.S. service revenue from BMS	$ 14,751	$ 13,226	$ 16,895
bb21717 license and manufacturing service revenue from BMS	—	35,762	—
Service revenue from December 2021 agreement with Novo Nordisk	5,765	6,501	—
Other	3,628	—	4,486
Total service revenue	$ 24,144	$ 55,489	$ 21,381

Collaborative arrangement revenue

To date, the Company's collaborative arrangement revenue has been generated from its collaboration arrangements with BMS and Regeneron, as further described in Note 10, *Collaborative arrangements and strategic partnerships.* For the years ending 2023, 2022 2021 and 2020, 2021, collaborative arrangement revenue consisted of the following:

	Year Ended December 31,		
	2022	2021	2020
U.S. *Abecma* collaboration with BMS	$ 12,781	$ 19,425	$ 108,196
Collaboration with Regeneron	19,577	7,496	7,398
Total collaborative arrangement revenue	$ 32,358	$ 26,921	$ 115,594

	Year Ended December 31,		
	2023	2022	2021
U.S. *Abecma* collaboration with BMS	$ 12,781	$ 19,425	$ 108,196
Collaboration with Regeneron	19,577	7,496	7,398
Total collaborative arrangement revenue	$ 32,358	$ 26,921	$ 115,594

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of Topic 606 (refer above for further discussion of the Company's policy for recognizing service revenue pursuant to Topic 606). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606.

In arrangements where the Company does not deem its collaborator to be its customer, payments to and from its collaborator are presented in the consolidated and combined statements of operations and comprehensive loss based on the nature of the payments, as summarized in the table and further described below.

Nature of Payment	Statement of Operations Presentation
The Company's share of net profits in connection with commercialization of products	Collaborative arrangement revenue
The Company's share of net losses in connection with commercialization of products	Share of collaboration loss
Net reimbursement to the Company for research and development expenses	Collaborative arrangement revenue
Net reimbursement to the collaborator for research and development expenses	Research and development expense

Where the collaborator is the principal in the product sales, the Company recognizes its share of any profits or losses, representing net product sales less cost of goods sold and shared commercial and other expenses, in the period in which such underlying sales occur and costs are incurred by the collaborator. The Company also recognizes its share of costs arising from research and development activities performed by collaborators in the period its collaborators incur such expenses.

Royalty and other revenue

The Company enters into out-licensing agreements that are within the scope of Topic 606. The Company does not have any material license arrangements that contain more than one performance obligation. The terms of such out-license agreements include the license of functional intellectual property, given the functionality of the intellectual property is not expected to change substantially as a result of the licensor's ongoing activities, and typically include payment of one or more of the following: non-refundable up-front license fees; development and regulatory milestone payments and milestone payments based on the level of sales; and royalties on net sales of licensed products. Nonrefundable up-front license fees are recognized as revenue at a point in time when the licensed intellectual property is made available for the customer's use and benefit, which is generally at the inception of the arrangement. Development and regulatory milestone fees, which are a type of variable consideration, are recognized as revenue to the extent that it is probable that a significant reversal will not occur. The Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

For a complete discussion of accounting for collaboration and other revenue-generating arrangements, see Note 10, *Collaborative arrangements and strategic partnerships*, and Note 11, *Royalty and other revenue.*

Research and development expenses

Research and development costs are charged to expense as costs are incurred in performing research and development activities, including salaries and benefits, facilities costs, overhead costs, clinical study and related clinical manufacturing costs, license and milestone fees, contract services, manufacturing costs for pre-launch inventory that did not qualify for capitalization, and other related costs. Up-front fees and milestones paid to third parties in connection with technologies that have not reached technological feasibility and do not have an alternative future use are expensed as research and development expense as incurred. In circumstances where amounts have been paid in excess of costs incurred, the Company records a prepaid expense. The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations, clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Where amounts owed to a collaboration partner exceed the Company's collaborative arrangement revenues in each quarterly period, such amounts are classified as research and development expense.

Cost of Manufacturing for Commercial Collaboration

Cost of manufacturing for commercial collaboration consists of quality and other manufacturing costs incurred by the Company to support the manufacture of *Abecma* inventory sold by its collaborative partner, BMS, in both the U.S. and in ex-U.S. regions. These costs are subject to the cost sharing arrangement under the terms of the Company's collaboration agreement (the Amended Ide-cel CCPS) with BMS. For further information on the Amended Ide-cel CCPS, please refer to Note 10, *Collaborative arrangements and strategic partnerships*.

The reimbursement from BMS for their share of the Company's U.S. quality and other manufacturing costs is recorded as collaborative arrangement revenue or share of collaboration loss in the consolidated and combined statements of operations and comprehensive loss. The reimbursement from BMS for the Company's ex-U.S. quality and other manufacturing costs is recorded as service revenue in the consolidated and combined statements of operations and comprehensive loss.

Restructuring expenses

In September 2023, the Company announced its Restructuring Plan to conserve financial resources and better align its workforce with current business needs. As part of the Restructuring Plan, the Company's workforce was reduced by approximately 40%, with substantially all of the reduction in personnel completed by December 31, 2023. In connection with the Restructuring Plan, the Company incurred one-time costs in the third quarter of 2023

relating to severance and retention packages and related benefits. These costs were recorded as restructuring expenses in the consolidated statements of operations and comprehensive loss.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for the Company's employees in executive, operational, finance, legal, business development, commercial, information technology, and human resource functions. Other selling, general and administrative expenses include facility-related costs, insurance, IT costs, professional fees for accounting, tax, legal and consulting services, directors' fees and expenses associated with obtaining and maintaining patents.

Share of Collaboration Loss

Share of collaboration loss represents the Company's share of net loss arising from product sales less cost of goods sold and shared commercial costs and other expenses related to the commercialization of a product where the collaborator is the principal in the product sales. For a complete discussion of accounting for share of collaboration loss, see Note 10, *Collaborative arrangements and strategic partnerships.*

Cost of royalty and other revenue

Cost of royalty and other revenue represents expense associated with amounts owed to third parties as a result of revenue recognized under the Company's out-license arrangements.

Stock-based compensation

The Company's share-based compensation programs grant awards that include stock options, restricted stock units, restricted stock awards, and shares issued under an employee stock purchase plan. Grants are awarded to employees and non-employees, including the Company's board of directors.

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments, including grants of stock options and restricted stock units and modifications to existing stock options, to be recognized in the consolidated and combined statements of operations and comprehensive loss based on their fair values.

The Company's stock-based awards are subject to either service, performance-based, or market-based vesting conditions. Compensation expense related to awards with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Compensation expense related to awards with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable.

The Company estimates the fair value of its option awards using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the calculation of expected term of the award, (iii) the risk-free interest rate, and (iv) expected dividends. Due to the lack of company specific historical and implied volatility data, the Company bases its estimate of expected volatility on the estimate and expected volatilities of a representative group of publicly traded companies. For these analyses, the Company selects companies with comparable characteristics including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. It will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. The Company has estimated the expected term of its employee stock options using the "simplified" method, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data. For stock options that were converted in accordance with the Employee Matters Agreement, as further described in Note 13, *Stock-based compensation*, the Company estimated the expected term to be the remaining contractual term of the awards as of the date of the separation. The risk-free interest rates for periods within the expected term of the option are based on the U.S.

Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid, and does not expect to pay, dividends in the foreseeable future.

For performance-based restricted stock units that vest based on a total shareholder return metric, the vesting condition is considered a market condition as it vests based on the movement in share price of a company. The impact of the market condition is reflected in the award's fair value on the grant date, and the expense is recognized irrespective of whether the market condition is achieved as long as the required service is provided.

The Company accounts for forfeitures as they occur. Stock-based compensation expense recognized in the financial statements is based on awards for which performance or service conditions are expected to be satisfied.

Other income, net

For periods prior to the separation, other income, net consisted primarily of income resulting from the allocation of facility-related, depreciation and amortization expense to bluebird bio for its proportional use of assets that were attributed to the Company as well as expense resulting from the allocation of facility-related, depreciation and amortization expense to the Company for its proportional use of bluebird bio assets that were not attributed to the Company. Other income, net also includes immaterial gains and losses on disposal of assets. Following the separation, other income, net primarily consisted of rental income from third parties, income recognized under the Company's transition services agreements with bluebird bio and sublease income.

Net loss per share

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period, including the shares of common stock issuable upon the exercise of warrants that are exercisable for little or no consideration. Diluted net income per share is calculated by dividing the net income attributable to common stockholders by the weighted-average number of common equivalent shares outstanding for the period, including the shares of common stock issuable upon the exercise of warrants that are exercisable for little or no consideration as well as any dilutive effect from outstanding stock options, unvested restricted stock, restricted stock units, and employee stock purchase plan stock using the treasury stock method. Given that the Company recorded a net loss for each of the periods presented, there is no difference between basic and diluted net loss per share since the effect of common stock equivalents would be anti-dilutive and are, therefore, excluded from the diluted net loss per share calculation.

The Company follows the two-class method when computing net loss per share in periods when issued shares that meet the definition of participating securities are outstanding. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to received dividends as if all income for the period had been distributed. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders when participating securities are outstanding, losses are not allocated to the participating securities.

Prior to November 4, 2021, there were no shares of the Company outstanding. As such, the shares outstanding immediately after the distribution, including the shares of common stock issuable upon the exercise of warrants that are exercisable for little or no consideration, were used to calculate the basic and diluted net loss per share for the year ended December 31, 2020.

Income taxes

For periods prior to the separation, income taxes as presented in the combined financial statements of 2seventy bio attribute current and deferred income taxes of bluebird bio to 2seventy bio in a manner that is systematic, rational and consistent with the asset and liability method prescribed by FASB ASC Topic 740: Income Taxes ("ASC 740"). Accordingly, 2seventy bio's income tax provision for periods prior to the separation was prepared following the separate return method. The separate return method applies ASC 740 to the stand-alone financial statements of each member of the consolidated group as if each group member was a separate taxpayer and a stand-alone enterprise. The calculation of the Company's income taxes on a separate return basis requires a considerable

amount of judgment and use of both estimates and allocations. As a result, actual transactions included in the consolidated financial statements of bluebird bio may not be included in the separate combined financial statements

of 2seventy bio. Similarly, the tax treatment of certain items reflected in the combined financial statements of 2seventy bio may not be reflected in the consolidated financial statements and tax returns of bluebird bio. Therefore, items such as net operating losses, credit carryforwards and valuation allowances may exist in the Company's stand-alone financial statements that may or may not exist in bluebird bio's consolidated financial statements. As such, the income taxes of 2seventy bio as presented for periods prior to the separation may not be indicative of the income taxes that 2seventy bio will generate in the future.

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense.

In general, for periods prior to the separation, the taxable income (loss) of bluebird bio, including any taxable income (loss) attributed to 2seventy bio, was included in bluebird bio's consolidated tax returns. As such, separate income tax returns were not prepared for 2seventy bio prior to the separation. Consequently, for periods prior to the separation any income taxes currently payable by 2seventy bio are deemed to have been remitted to bluebird bio, in cash, in the period prior to the separation in which the liability arose, and income taxes currently receivable by 2seventy bio are deemed to have been received from bluebird bio in the period in which the receivable arose.

Comprehensive loss

Comprehensive loss is composed of net loss and other comprehensive income (loss). Other comprehensive income (loss) consists of unrealized gains and losses on debt securities.

Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. During the years ended December 31, 2022 December 31, 2023, 2022, and December 31, 2021, 2021, the Company did not adopt any new accounting pronouncements that had a material effect on its consolidated and combined financial statements. As

Not yet adopted

ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosure

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting(Topic 280: Improvements to Reportable Segment Disclosures)* ("ASU 2023-07"). The amendments in this update improve reportable segment disclosure requirements through enhanced disclosures about significant segment expenses. All disclosure requirements of December 31, 2022 the ASU are required for entities with a single reportable segment. The amendments are effective for fiscal years beginning after December 15, 2023, there are no additional pending accounting pronouncements that and interim periods within fiscal years beginning after

December 15, 2024, and should be applied on a retrospective basis to all periods presented. The Company is currently evaluating the impact of future adoption on its financial statements and related disclosures.

ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which is intended to enhance the transparency and decision usefulness of income tax disclosures. This new standard is effective for annual periods beginning after December 15, 2024. The Company plans to adopt in this standard following the future that would effective date and the Company does not expect ASU 2023-09 to have a material effect impact on its consolidated and combined the Company's financial statements.

Change in financial statement presentation

In connection with the preparation of its consolidated financial statements as of and for the year ended December 31, 2022, the Company changed the presentation of quality and other manufacturing costs incurred by the Company for the manufacture of *Abecma* inventory under its commercial collaboration with BMS from "research and development expenses" to "cost of manufacturing for commercial collaboration" within its consolidated and combined statements position or results of operations and comprehensive loss. This change in presentation has been applied retrospectively and does not change any previously reported subtotals or totals on the consolidated and combined statements of operations and comprehensive loss. upon adoption.

3. Marketable securities

The following table summarizes the marketable securities held at December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022 (in thousands):

	Amortized cost/ cost	Unrealized gains	Unrealized losses	Fair Value
	Amortized cost/ cost	Unrealized gains	Unrealized losses	Fair Value
December 31, 2023				
U.S. government agency securities and treasuries				

U.S. government agency securities and treasuries					
U.S. government agency securities and treasuries					
Commercial paper					
Total					
December 31, 2022	**December 31, 2022**				
U.S. government agency securities and treasuries					
U.S. government agency securities and treasuries					
U.S. government agency securities and treasuries	U.S. government agency securities and treasuries	$120,739	$ 3	$ (1,963)	$118,779
Corporate bonds	Corporate bonds	2,524	—	(26)	2,498
Commercial paper	Commercial paper	75,491	3	(119)	75,375
Total	Total	$198,754	$ 6	$ (2,108)	$196,652
December 31, 2021					
U.S. government agency securities and treasuries		$128,899	$ —	$ (507)	$128,392
Corporate bonds		49,368	—	(58)	49,310
Commercial paper		54,065	—	—	54,065
Total		$232,332	$ —	$ (565)	$231,767

No available-for-sale debt securities held as of December 31, 2022 December 31, 2023 or December 31, 2021 December 31, 2022 had remaining maturities greater than five years.

The following table summarizes available-for-sale debt securities in a continuous unrealized loss position for less than and greater than twelve months, and for which an allowance for credit losses has not been recorded at December 31, 2023 and December 31, 2022 (in thousands):

	Less than 12 months		12 months or greater		Total	
Description	**Fair value**	**Unrealized losses**	**Fair value**	**Unrealized losses**	**Fair value**	**Unrealized losses**
December 31, 2023						
U.S. government agency securities and treasuries	$ 45,850	$ (60)	$ 1,475	$ (25)	$ 47,325	$ (85)
Total	$ 45,850	$ (60)	$ 1,475	$ (25)	$ 47,325	$ (85)
December 31, 2022						
U.S. government agency securities and treasuries	$ 28,749	$ (159)	$ 86,176	$ (1,804)	$ 114,925	$ (1,963)
Corporate bonds	—	—	2,498	(26)	2,498	(26)
Commercial paper	62,636	(119)	—	—	62,636	(119)
Total	$ 91,385	$ (278)	$ 88,674	$ (1,830)	$ 180,059	$ (2,108)

As discussed further in Note 7, *Leases*, the Company maintains letters of credit related to its leases in Cambridge and Seattle. A portion of this collateral is classified as restricted investments and included within restricted investments and other non-current assets on the condensed consolidated balance sheets.

The following table summarizes restricted investments held at December 31, 2023 and December 31, 2022 (in thousands):

	Amortized cost/ cost	Unrealized gains	Unrealized losses	Fair Value
December 31, 2023				
U.S. government agency securities and treasuries	$ 33,072	$ 67	$ (365)	$ 32,774
Total	$ 33,072	$ 67	$ (365)	$ 32,774
December 31, 2022				
U.S. government agency securities and treasuries	$ 32,880	$ —	$ (1,112)	$ 31,768
Total	$ 32,880	$ —	$ (1,112)	$ 31,768

The following table summarizes restricted investments in a continuous unrealized loss position for less than and greater than twelve months, and for which an allowance for credit losses has not been recorded at December 31, 2023 and December 31, 2022 (in thousands):

	Less than 12 months		12 months or greater		Total	
Description	**Fair value**	**Unrealized losses**	**Fair value**	**Unrealized losses**	**Fair value**	**Unrealized losses**
December 31, 2023						
U.S. government agency securities and treasuries	$ 3,496	$ (4)	$ 13,266	$ (361)	$ 16,762	$ (365)
Total	$ 3,496	$ (4)	$ 13,266	$ (361)	$ 16,762	$ (365)
December 31, 2022						
U.S. government agency securities and treasuries	$ 1,942	$ (27)	$ 29,826	$ (1,085)	$ 31,768	$ (1,112)
Total	$ 1,942	$ (27)	$ 29,826	$ (1,085)	$ 31,768	$ (1,112)

Accrued interest receivable on the Company's available-for-sale debt securities totaled $0.3 $0.8 million and $0.4 0.3 million as of December 31, 2022 December 31, 2023 and 2021, 2022, respectively. No accrued interest receivable was written off during the twelve months ended December 31, 2022 December 31, 2023 or 2021. 2022.

The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to the earliest call date for premiums or to maturity for discounts. At December 31, 2022, December 31, 2023 and December 31, 2021 December 31, 2022, the balance in the Company's accumulated other comprehensive loss was composed primarily of activity related to the Company's available-for-sale debt securities. There were no material realized gains or losses recognized on the sale or maturity of available-for-sale debt securities during the years ended December 31, 2022 December 31, 2023 or December 31, 2021 December 31, 2022.

The following table summarizes available-for-sale debt securities in a continuous unrealized loss position for less than and greater than twelve months, and for which an allowance for credit losses has not been recorded at December 31, 2022 (in thousands):

	Less than 12 months		12 months or greater		Total	
Description	**Fair value**	**Unrealized losses**	**Fair value**	**Unrealized losses**	**Fair value**	**Unrealized losses**
December 31, 2022						
U.S. government agency securities and treasuries	$ 28,749	$ (159)	$ 86,176	$ (1,804)	$ 114,925	$ (1,963)
Corporate bonds	—	—	2,498	(26)	2,498	(26)
Commercial paper	62,636	(119)	—	—	62,636	(119)
Total	$ 91,385	$ (278)	$ 88,674	$ (1,830)	$ 180,059	$ (2,108)

December 31, 2021						
U.S. government agency securities and treasuries	$ 111,190	$ (507)	$ —	$ —	$ 111,190	$ (507)
Corporate bonds	48,940	(58)	—	—	48,940	(58)
Total	$ 160,130	$ (565)	$ —	$ —	$ 160,130	$ (565)

The Company determined that there was no material change in the credit risk of the above investments for the year ended December 31, 2022 December 31, 2023. As such, an allowance for credit losses was not recognized. As of December 31, 2022 December 31, 2023, the Company does not intend to sell such securities and it is not more likely than not that the Company will be required to sell the securities before recovery of their amortized cost bases.

4. Fair value measurements

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2022				
Assets:				
Cash and cash equivalents	$ 71,032	$ 71,032	$ —	$ —
Marketable securities:				
U.S. government agency securities and treasuries	118,779	—	118,779	—
Corporate bonds	2,498	—	2,498	—
Commercial paper	75,375	—	75,375	—

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2023				
Assets:				
Cash and cash equivalents				
Restricted cash and cash equivalents	1,725	1,725		—

Restricted investments					
Total assets	Total assets	$267,684	$ 71,032	$196,652	$ —
Liabilities:	Liabilities:				
Contingent consideration	Contingent consideration	$ 2,180	$ —	$ —	$ 2,180
Contingent consideration					
Contingent consideration					
Total liabilities	Total liabilities	$ 2,180	$ —	$ —	$ 2,180
December 31, 2021					
December 31, 2022					
Assets:	Assets:				
Assets:					
Assets:					
Cash and cash equivalents					
Cash and cash equivalents					
Cash and cash equivalents	Cash and cash equivalents	$130,414	$130,414	$ —	$ —
Marketable securities:	Marketable securities:				
U.S. government agency securities and treasuries	U.S. government agency securities and treasuries	128,392	—	128,392	—
U.S. government agency securities and treasuries					
U.S. government agency securities and treasuries					
Corporate bonds	Corporate bonds	49,310	—	49,310	—
Commercial paper	Commercial paper	54,065	—	54,065	—
Restricted cash and cash equivalents					
Restricted investments					
Total assets	Total assets	$362,181	$130,414	$231,767	$ —
Liabilities:	Liabilities:				
Contingent consideration	Contingent consideration	$ 1,948	$ —	$ —	$ 1,948
Contingent consideration					
Contingent consideration					
Total liabilities	Total liabilities	$ 1,948	$ —	$ —	$ 1,948

Marketable securities

Marketable securities classified as Level 2 within the valuation hierarchy generally consist of U.S. government agency securities and treasuries, corporate bonds, and commercial paper. The Company estimates the fair values of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These

pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. The Company validates the prices provided by its third-party pricing sources by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

Contingent consideration

In connection with bluebird bio's prior acquisition of Precision Genome Engineering, Inc. ("Pregenen"), the Company may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. Contingent consideration is measured at fair value and is based on significant unobservable inputs, which represents a Level 3 measurement within the fair value

hierarchy. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. Future changes in the fair value of contingent consideration related to updated assumptions and estimates are recognized within the consolidated and combined statements of operations and comprehensive loss. In the absence of new information related to the probability of milestone achievement, changes in fair value will reflect changing discount rates and the passage of time. Contingent consideration is included in other non-current liabilities on the consolidated balance sheets.

The table below provides a roll-forward of fair value of the Company's contingent consideration obligations that include Level 3 inputs (in thousands):

	Year ended December 31,	
	2022	2021
Beginning balance	$1,948	$1,509
Additions	—	—
Changes in fair value	232	439
Payments	—	—
Ending balance	$2,180	$1,948

Please refer to Note 8, *Commitments and contingencies,* for further information.

5. Property, plant and equipment, net

Property, plant and equipment, net, consists of the following (in thousands):

	As of December 31,	
	2022	2021
Computer equipment and software	5,670	5,260
Office equipment	6,159	6,080
Laboratory equipment	36,216	31,710

Leasehold improvements	Leasehold improvements	27,416	28,479
Construction-in-progress	Construction-in-progress	28,112	3,462
Total property, plant and equipment	Total property, plant and equipment	103,573	74,991
Less accumulated depreciation and amortization	Less accumulated depreciation and amortization	(47,838)	(40,078)
Property, plant and equipment, net	Property, plant and equipment, net	$55,735	$34,913

Depreciation and amortization expense related to property, plant and equipment was $8.9 million $9.6 million, $12.1 million $8.9 million, and $9.4 million $12.1 million for the years ended December 31, 2022 December 31, 2023, 2021, 2022, and 2020, 2021, respectively.

Cambridge, Massachusetts drug product manufacturing facility

In February 2022, the Company began construction of a drug product manufacturing facility within its Cambridge, Massachusetts headquarters. The facility will enable enables rapid translational research in clinical trials and the manufacture of drug product for use in Phase 1 clinical development activities. Construction-in-progress The facility became fully operational as of August 2023 and related construction-in-progress totaling $36.6 million related to the build-out of the facility was placed into service. As of December 31, 2022 includes, construction-in-progress included $27.0 million related to the ongoing build-out of the facility. The build out of the facility was completed in February 2023 and is anticipated to be operational by mid-2023.

North Carolina manufacturing facility

In November 2017, bluebird bio acquired a manufacturing facility in Durham, North Carolina for the future manufacture of lentiviral vectors for its gene therapies. This manufacturing facility was primarily dedicated to the Company's operations and, accordingly, prior to the sale of the facility as described below, was to be attributed to the Company in connection with the separation.

In July 2021, bluebird bio and National Resilience, Inc. ("Resilience") announced a strategic manufacturing collaboration aimed to accelerate the early research, development, and delivery of cell therapies. Agreements related to the collaboration were executed in September 2021. As part of the agreements, Resilience acquired bluebird bio's North Carolina manufacturing facility and retained all staff employed at the site. As a result, bluebird bio disposed of $111.2 million of net assets, primarily consisting of the building and laboratory equipment. Prior to its disposal by bluebird bio, the North Carolina manufacturing facility was to be attributed to the Company and, accordingly, the manufacturing facility was included within the Company's financial statements prior to its disposal. The disposition of the net assets of the North Carolina manufacturing facility has been reflected as a transfer to bluebird bio via net parent investment as a result of bluebird bio's sale of such facility. Please refer to Note 10, *Collaborative arrangements and strategic partnerships*, for further discussion.

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	As of December 31,	
	2022	2021

	As of December 31,	
	2023	2022
Royalties		
Collaboration research costs		
Employee compensation		

Manufacturing costs	Manufacturing costs	$17,962	$ 5,459
Employee compensation		14,845	24,655
Royalties		13,094	6,768
Clinical and contract research organization costs	Clinical and contract research organization costs	1,619	3,229
Collaboration research costs		2,005	2,576
Property, plant, and equipment	Property, plant, and equipment	1,498	2,241
Professional fees		239	1,688
Other	Other	3,416	8,794
Total accrued expenses and other current liabilities	Total accrued expenses and other current liabilities	$54,678	$55,410

Accrued manufacturing costs increased The decrease in accrued expenses as of December 31, 2022 December 31, 2023 compared to December 31, 2021. This increase was driven by increased material production costs associated December 31, 2022 is largely due to a decrease in accrued manufacturing costs. During 2022, the Company accrued $14.8 million representing its estimated share of the net operating losses of and relating to the manufacturing facility under the assignments pertinent to the asset purchase agreement and the Development Manufacturing Supply Agreement committing the Company to reimburse Resilience. The Company settled this amount with CRC-403, the Phase 1/2 Study of bbT369, along with increased manufacturing activities of suspension lentiviral vector for ide-cel and MAGE-A4 development. Resilience in early 2023. Refer to Note 8, *Commitments & Contingencies*. Accrued employee compensation expenses also significantly decreased as of December 31, 2022 December 31, 2023 compared to December 31, 2021 December 31, 2022 primarily due to the Company's bonus structure for payout of 2023 annual bonuses in December 2023, whereas 2022 which included a 6-month bonus payout halfway through 2022 and the remainder to be paid out in early 2023. For the year ended December 31, 2021, employee annual bonuses were accrued throughout the year as of December 31, 2022 and paid out in early 2022. Finally, there was an increase in accrued the first quarter of 2023. Accrued royalties driven by an increase decreased as of December 31, 2023 compared to December 31, 2022 due to a decline in *Abecma* sales. sales in the fourth quarter of 2023 compared to the fourth quarter of 2022.

7. Leases

The Company leases certain office and laboratory space that was attributed to it in connection with the separation.

60 Binney Street lease

In September, 2015, bluebird bio entered into a lease agreement, which was attributed to the Company in connection with the separation. This is the Company's corporate headquarters and includes office and laboratory space located in a building (the "Building") at 60 Binney Street, Cambridge, Massachusetts (the "60 Binney Street Lease"). Under the terms of the 60 Binney Street Lease, starting on October 1, 2016, bluebird bio leased approximately 253,108 square feet of office and laboratory space at $72.50 per square foot per year, or $18.4 million per year in base rent, which is subject to scheduled annual rent increases of 1.75% plus certain operating expenses and taxes. bluebird bio historically maintained a $13.8 million collateralized letter of credit which, subject to the terms of the lease and certain reduction requirements specified therein, including market capitalization requirements, may decrease to $9.2 million over time. As the Company did not have legal ownership over any bank accounts prior to the separation, there were no cash and cash equivalent balances specifically attributable to the Company for the periods prior to the separation and, accordingly, no restricted cash is reflected in the consolidated and combined financial statements related to the letter of credit for periods prior to the separation. Pursuant to a work letter entered into in connection with the 60 Binney Street Lease, the landlord contributed an aggregate of $42.4 million toward the cost of construction and tenant improvements for the Building. The lease would continue until March 31, 2027.

In October 2021, bluebird bio entered into a consent to assignment and amendment to its lease agreement for its 60 Binney Street lease, pursuant to which bluebird bio's interest in the lease was assigned to the Company. In November 2021, the Company executed a $25.0 million letter of credit related to this lease. Under the assigned and amended lease agreement, the lease term was extended through March 31, 2034 with the 2022 base rent being $90.00 per square foot per year, or $22.8 million per year in base rent, subject to scheduled annual rent increases of 3.0% plus certain operating expenses and taxes. Starting April 1, 2026, the base rent will reset to $118.41 per square

foot per year, or $30.0 million per year in base rent, subject to scheduled annual rent increases of 3.0% plus certain operating expenses and taxes. Pursuant to a work letter entered into in connection with the 60 Binney Street assignment and amended lease agreement, the landlord agreed to contribute up to an aggregate of $19.1 million toward the cost of tenant improvements for the leased space. As of December 31, 2022 December 31, 2023, the Company has spent $27.0 $36.6 million related to the build-out of the drug product manufacturing facility within its Cambridge, Massachusetts headquarters and has received $14.3 $18.7 million in reimbursements.

The Company has classified this lease as an operating lease and recorded a right-of-use asset and lease liability. The Company is recognizing rent expense on a straight-line basis throughout the remaining term of the lease.

Seattle, Washington leases

In July 2018, bluebird bio entered into a lease agreement for office and laboratory space located in a portion of a building in Seattle, Washington, and moved into the facility in June 2019. This lease was assigned to the Company in connection with the separation. The lease was amended in October 2018 to increase the total rentable space to approximately 36,126 square feet at $54.00 per square foot in base rent per year, which is subject to scheduled annual rent increases of 2.5% plus certain operating expenses and taxes. The lease commenced on January 1, 2019 and the lease term will continue through January 31, 2027. The Company has classified this lease as an operating lease and recorded a right-of-use asset and lease liability at lease commencement.

In September 2019, bluebird bio entered into a second amendment to the lease (the “Second Amendment”). The Second Amendment added approximately 22,188 square feet to the existing space and extended the lease term of the entire premises by 16 months, or until April 2028. Fixed monthly rent for the expanded space will be incurred at a rate of $62.80 per square foot per year beginning in January 2021, subject to annual increases of 2.5%. The Second Amendment includes a five-year option to extend the term.

The execution of the Second Amendment was deemed to be a lease modification representing two separate contracts under ASC 842. One contract is related to a new right-of-use for the expanded 22,188 square feet of space, which is to be accounted for as a new lease, and the other is related to the modification of term for the original 36,126 square feet of space. An additional right-of-use asset and lease liability was recognized upon lease commencement of the expanded space. In September 2020, bluebird bio entered into a sublease agreement for the 22,188 square feet added under the Second Amendment at a fixed monthly rent of $62.80 per square foot per year beginning in January 2021, subject to annual increases of 2.5%. The sublease term will continue through April 2028.

In October 2021, bluebird bio entered into a consent to assignment and amendment to its lease agreement for office and laboratory space in Seattle, Washington and the related sublease that was executed in September 2020 for a portion of the space. The agreement reassigns bluebird bio’s interest in the lease and the sublease to the Company. In November 2021, the Company executed a $5.0 million letter of credit related to this lease.

The Company is recognizing rent expense on a straight-line basis through the remaining extended term of the respective leases. The head lease and the sublease will be accounted for as two separate contracts with the income from the sublease presented separately from the lease expense on the head lease.

Summary of all lease costs recognized under ASC 842

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company’s operating leases for the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020 2021 (in thousands):

	For the year ended December 31,		
	2022	2021	2020
Lease cost (1)			
Operating lease cost			
Operating lease cost	$33,738	$24,838	$22,454
Total lease cost	$33,738	$24,838	$22,454
Other information			
Other information			
Operating cash flows used for operating leases			

	For the year ended December 31,	
	2023	2022
Lease cost (1)		
Operating lease cost		
Operating lease cost		
Total lease cost		
Other information		
Other information		
Operating cash flows used for operating leases		

	For the year ended December 31,
	2021
Lease cost (1)	
Operating lease cost	
Operating lease cost	
Total lease cost	
Other information	
Other information	
Operating cash flows used for operating leases	

Operating cash flows used for operating leases											
Operating cash flows used for operating leases	Operating cash flows used for operating leases	$27,140	$25,489	$19,632							
Weighted average remaining lease term	Weighted average remaining lease term	10.8 years	11.8 years	6.4 years	Weighted average remaining lease term	9.9 years	10.8 years		11.8 years		
Weighted average discount rate	Weighted average discount rate	5.47 %	5.47 %	6.72 %	Weighted average discount rate	5.48 %	5.47	%	5.47	%	

(1) Short-term lease costs and variable lease costs incurred by the Company for the twelve months ended December 31, 2022 December 31, 2023, 2021 2022 and 2020 2021 were immaterial.

Rent expense is calculated on a straight-line basis over the term of the lease. Rent expense recognized under all leases, including additional charges variable costs for utilities, parking, maintenance, and real estate taxes that are not included within lease costs in the table above, was $43.9 $43.4 million, $34.5 million $43.9 million, and $32.5 million $34.5 million for the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020, 2021, respectively.

As of December 31, 2022 December 31, 2023, future minimum commitments under ASC 842 under the Company's operating leases were as follows (in thousands):

Maturity of lease liabilities	Maturity of lease liabilities	As of December 31, 2022	Maturity of lease liabilities	As of December 31, 2023
2023		$ 27,861		
2024	2024	28,672		
2025	2025	29,498		
2026	2026	32,920		
2027 and thereafter		250,383		
2027				
2028 and thereafter				
Total lease payments	Total lease payments	369,334		
Less: imputed interest	Less: imputed interest	(99,162)		
Total operating lease liabilities	Total operating lease liabilities	$270,172		

Please refer to Note 20, *Subsequent Events*, for further information on the terms of the Asset Sale to Regeneron. In connection with the Asset Sale, Regeneron agreed to sublease the Company's facilities in Seattle, Washington and a portion of the Company's facilities in Cambridge, Massachusetts. The expected sublease income will cover a majority of the future minimum commitments through 2027.

8. Commitments and contingencies

Lease commitments

2seventy bio leases certain office and laboratory space. Refer to Note 7, *Leases*, for further information on the terms of these lease agreements.

Contingent consideration related to business combinations

On June 30, 2014, bluebird bio acquired Pregenen. All assets and liabilities related to the Pregenen acquisition, including the resulting goodwill and contingent consideration, were attributed to the Company in connection with the separation. The Company may be required to make up to an additional $99.9 million in remaining future contingent cash payments to the former equityholders of Pregenen upon the achievement of certain commercial milestones related to the Pregenen technology. In accordance with accounting guidance for business combinations,

contingent consideration liabilities are required to be recognized on the consolidated balance sheets at fair value. Estimating the fair value of contingent consideration requires the use of significant assumptions primarily relating to probabilities of successful achievement of certain clinical and commercial milestones, the expected timing in which these milestones will be achieved and discount rates. The use of different assumptions could result in materially different estimates of fair value.

Other funding commitments

Certain agreements that were assigned by bluebird bio to the Company in connection with the separation relate principally to licensed technology and may require future payments relating to milestones that may be met in subsequent periods or royalties on future sales of specified products. These agreements include the collaboration agreements entered into with BMS, Regeneron, Novo Nordisk and the agreements entered into with Resilience, all of which were assigned to the Company in connection with the separation. Additionally, to the extent an agreement relating to licensed technology was not attributed to the Company, bluebird bio entered into a sublicense with the Company, which may require future milestone and/or royalty payments. Please refer to Note 10, *Collaborative arrangements and strategic partnerships*, for further information on the BMS, Regeneron, and Resilience agreements and Note 11, *Royalty and other revenue*, for further information on license agreements.

Based on the Company's development plans as of December 31, 2022 December 31, 2023, the Company may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. When the achievement of these milestones or sales has not occurred, such contingencies are not recorded in the Company's financial statements. As further discussed in Note 10, *Collaborative arrangements and strategic partnerships*, BMS assumed responsibility for amounts due to licensors as a result of any future ex-U.S. sales of *Abecma*.

In July 2021, bluebird bio and National Resilience, Inc. ("Resilience") announced a strategic manufacturing collaboration aimed to accelerate the early research, development, and delivery of cell therapies. Agreements related to the collaboration were executed in September 2021. As part of the agreement, Resilience acquired bluebird bio's North Carolina manufacturing facility and retained all staff employed at the site. Concurrent with the sale of the manufacturing facility in Durham, North Carolina, bluebird bio entered into certain ancillary agreements, including two manufacturing agreements and a license agreement (the "Resilience License Agreement"), among others (together referred to as the "Ancillary Agreements"). One of the manufacturing agreements supports ongoing manufacturing for lentiviral vector for development candidates (the "Development Manufacturing Supply Agreement"). The other manufacturing agreement will support for the future manufacturing of lentiviral vector for the commercial product marketed in collaboration with BMS, *Abecma* (the "Commercial Supply Agreement"), while was assigned by the other will support ongoing manufacturing for lentiviral vector for development candidates (the "Development Manufacturing Supply Agreement") Company to BMS on June 23, 2023. Certain rights and obligations under these agreements the Ancillary Agreements were assigned by bluebird bio to 2seventy bio on November 4, 2021 upon the separation of 2seventy bio from bluebird bio. The assignments under the asset purchase agreement and the Development Manufacturing Supply Agreement commit the Company to reimburse Resilience for an amount equal to 50% of the net operating losses of and relating to the manufacturing facility's business incurred during the twelve-month period ending on the first anniversary of the closing of the transaction, as calculated in accordance with the asset purchase agreement, subject to a cap of $15.0 million. In exchange, under During the terms second quarter of the Development Manufacturing Supply Agreement, 2023, the Company was entitled paid a total of $14.2 million to receive up to eight batches of lentiviral vector during the twelve-month period ending on the first anniversary of the closing of the transaction. The Company therefore committed to a minimum purchase of at least the Company's 50% Resilience for its share of the net operating losses during the twelve-month period ending on the first anniversary of the closing of the transaction, which occurred in September 2022. During 2022, the Company accrued $14.8 million representing its estimated share of the net operating losses of and relating to the manufacturing facility. The Company anticipates settling this amount with Resilience in early 2023. losses. The disposition of the net assets of the manufacturing facility previously assigned to 2seventy bio has been was reflected as a transfer to bluebird bio via net parent investment as a result of bluebird bio's sale of such facility. facility in the Company's 2021 annual report on Form 10-K. As a result of the separation, the Company's net parent investment balance was reclassified to additional paid-in capital. 2seventy bio is not a party to the sale of the manufacturing facility and, therefore, did not recognize any gain or loss arising from the transaction.

The Company has various manufacturing development and license agreements to support clinical and commercial product needs. The following table presents non-cancelable contractual obligations arising from these arrangements:

Years ended December 31,	Years ended December 31,	Purchase commitment	Years ended December 31,	Purchase commitment
2023		$ 16,008		
2024	2024	15,750		
2025		—		
2026 and thereafter		—		
2025 and thereafter				
Total purchase commitments	Total purchase commitments	$ 31,758		

Litigation

From time to time, the Company expects to be party to various claims and complaints arising in the ordinary course of business. However, the Company is not currently a party to any litigation or legal proceedings that, in the opinion of its management, are probable of having a material adverse effect on its business. The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners. In addition, pursuant to the separation agreement, the Company indemnifies, holds harmless, and agrees to reimburse bluebird bio for its indemnification obligations with respect to the Company's business partners, relating to the Company's business or arising out of the Company's activities, in the past or to be conducted in the future. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Management does not believe that any ultimate liability resulting from any of these claims will have a material adverse effect on its results of operations, financial position, or liquidity. However, management cannot give any assurance regarding the ultimate outcome of any claims, and their resolution could be material to operating results for any particular period.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and by-laws. The term of the indemnification period will last as long as a director or officer may be subject to any proceeding arising out of acts or omissions of such director or officer in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company holds director and officer liability insurance.

9. Stockholders' equity

The Company is authorized to issue 200.0 million shares of common stock. Holders of common stock are entitled to one vote per share. Holders of common stock are entitled to receive dividends, if and when declared by the Company's board of directors, and to share ratably in the Company's assets legally available for distribution to the Company's shareholders in the event of liquidation. Holders of common stock have no preemptive, subscription, redemption or conversion rights. As of December 31, 2022 December 31, 2023, the Company had 37.9 50.6 million shares of common stock issued and outstanding. As of December 31, 2021 December 31, 2022, the Company had 23.6 37.9 million shares of common stock issued and outstanding.

In November 2021, the Company issued 23,368,988 shares of its common stock to bluebird bio in connection with the separation.

In November 2021, the Company issued to certain institutional investors (who previously purchased pre-funded warrants to purchase shares of bluebird bio common stock) pre-funded warrants to purchase 757,575 shares of the Company's common stock at an exercise price of $0.0001 per share. The pre-funded warrants can be exercised at any time or times on or after November 4, 2021, until exercised in full. The warrants have been evaluated to determine the appropriate accounting and classification pursuant to ASC 480 and ASC 815. Based on the terms of the pre-funded warrants, management concluded that they should be classified within stockholders' equity on the Company's consolidated balance sheets, with no subsequent remeasurement as long as the underlying warrant agreements are not modified or amended.

In March 2022, the Company entered into stock purchase agreements with certain investors, pursuant to which the Company agreed to sell and issue, in a private placement, an aggregate of 13,934,427 shares of the Company's common stock at a purchase price per share of $12.20. This resulted in aggregate net proceeds to the Company of $165.5 million, after deducting placement agent fees and other offering expenses payable by the Company.

In November 2022, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen") under which it may from time to time offer and sell shares of its common stock through Cowen for aggregate gross sales proceeds of up to $150.0 million (the "ATM facility"). The Company has not sold any shares of its common stock under the ATM Facility as of the date of this Annual Report on Form 10-K. 10-K and the Company does not currently have any plans to sell shares under the ATM.

In January 2023, the Company entered into a Share Purchase Agreement with Regeneron, pursuant to which it sold 1,114,827 shares of its common stock to Regeneron, subject to certain restrictions, for an aggregate cash price of approximately $20.0 million. The purchase price represents $9.9 million worth of common stock plus a $10.1 million

premium, which represents collaboration deferred revenue. Details regarding the recognition of this deferred revenue as revenue are included below in Note 10, *Collaborative arrangements and strategic partnerships.*

In March 2023, the Company sold 10,869,566 shares of common stock through an underwritten public offering at a price per share of $11.50. This resulted in aggregate net proceeds to the Company of approximately $117.0 million, after deducting underwriting fees and offering expenses. The underwriters did not exercise their option to purchase up to 1,630,434 additional shares of common stock and therefore no additional proceeds were received.

The Company is authorized to issue 10.0 million shares of preferred stock in one or more series and to fix the powers, designations, preferences and relative participating option or other rights thereof, including dividend rights, conversion rights, voting rights, redemption terms, liquidation preferences and the number of shares constituting any series, without any further vote or action by the Company's shareholders. As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company had no shares of preferred stock issued or outstanding.

Reserved for future issuance

The Company has reserved for future issuance the following number of shares of common stock (in thousands):

	As of December 31,	
	2022	2021
Options to purchase common stock (1)	2,562	1,490
Restricted stock units (1)	1,314	1,080
2021 Stock Option and Incentive Plan	1,621	2,125
2021 Employee Stock Purchase Plan	434	233
Pre-funded warrants to purchase common stock	758	758
	6,689	5,686

As of December 31,	As of December 31,	
2023	2023	2022
8,098		

(1) Outstanding stock options and restricted stock units include awards outstanding to employees of bluebird bio.

10. Collaborative arrangements and strategic partnerships

To date, the Company's service and collaborative arrangement revenue has been primarily generated from collaboration arrangements with BMS, Regeneron, and Novo, each as further described below.

Bristol Myers Squibb

BMS Collaboration Agreement

In March 2013, bluebird bio entered into a Master Collaboration Agreement (the "BMS Collaboration Agreement") with Celgene (now BMS following its acquisition of Celgene in November 2019) to discover, develop and commercialize potentially disease-altering gene therapies in oncology and a Platform Technology Sublicense

Agreement (the “Sublicense Agreement”) with BMS pursuant to which bluebird bio obtained a sublicense to certain intellectual property from BMS, originating under BMS’s license from Baylor College of Medicine, for use in the collaboration.

Under the terms of the BMS Collaboration Agreement, the Company received an up-front, non-refundable, non-creditable payment of $75.0 million. The Company was responsible for conducting discovery, research, and development activities through completion of Phase 1 clinical trials, if any, during the initial term of the BMS Collaboration Agreement, or three years.

Subsequently, bluebird bio and BMS executed various amendments, summarized as follows. These agreements were assumed by the Company in connection with the separation.

In June 2015, both parties amended and restated the BMS Collaboration Agreement (the “Amended BMS Collaboration Agreement”) to narrow the focus of the collaboration to exclusively work on anti-B-cell maturation antigen (“BCMA”) product candidates for a new three-year term. In connection with the Amended BMS

Collaboration Agreement, the Company received an up-front, non-refundable, non-creditable payment of $25.0 million to fund research and development under the collaboration.

On a product candidate-by-product candidate basis, up through a specified period following enrollment of the first patient in an initial Phase 1 clinical trial for such product candidate, BMS had an option to obtain an exclusive worldwide license to develop and commercialize such product. Following BMS’s license of each product candidate, the Company is entitled to elect to co-develop and co-promote each product candidate in the United States.

BMS Ide-cel related agreements

In February 2016, BMS exercised its option to obtain an exclusive worldwide license to develop and commercialize ide-cel, the first product candidate under the Amended BMS Collaboration Agreement, pursuant to an executed license agreement (“Ide-cel License Agreement”) and paid the Company the associated $10.0 million option fee. Pursuant to the Ide-cel License Agreement, BMS was responsible for development and related funding of ide-cel after the substantial completion of the Phase 1 clinical trial. The Company was responsible for the manufacture of vector and associated payload throughout development and, upon BMS’s request, throughout commercialization, the costs of which were reimbursable by BMS in accordance with the terms of the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement, as further described below. BMS was responsible for the manufacture of drug product throughout development and commercialization. Under the Ide-cel License Agreement, the Company was eligible to receive (i) U.S. milestones of up to $85.0 million for the first indication to be addressed by ide-cel and royalties for U.S. sales of ide-cel and (ii) ex-U.S. milestones of up to $55.0 million and royalties for ex-U.S. sales of ide-cel.

In March 2018, the Company elected to co-develop and co-promote ide-cel within the United States pursuant to the execution of the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement (“Ide-cel CCPS”), which replaced the Ide-cel License Agreement. As a result of executing the Ide-cel CCPS, the Company will share equally in all profits and losses relating to developing, commercializing and manufacturing ide-cel within the United States and has the right to participate in the development and promotion of ide-cel in the United States. BMS is responsible for the costs incurred to manufacture vector and associated payload for use outside of the United States, plus a markup. As a result of electing to co-develop and co-promote ide-cel within the United States, the milestones and royalties payable under the Ide-cel License Agreement were adjusted. Under the Ide-cel CCPS, the Company was eligible to receive a $10.0 million milestone related to the development of ide-cel in the United States and, for the first indication to be addressed by ide-cel, ex-U.S. regulatory and commercial milestones of up to $60.0 million. Under the Ide-cel CCPS, the $10.0 million milestone related to the development of ide-cel in the United States was achieved in the second quarter of 2019 and subsequently paid by BMS.

BMS bb21217 License Agreement

In September 2017, BMS exercised its option to obtain an exclusive worldwide license to develop and commercialize bb21217, an investigational BCMA-targeted CAR T cell therapy, the second product candidate under the Amended BMS Collaboration Agreement, pursuant to an executed license agreement (“bb21217 License

Agreement”) and paid the Company an option fee of $15.0 million. Pursuant to the bb21217 License Agreement, BMS is responsible for development and related funding of bb21217 after the substantial completion of the ongoing Phase 1 clinical trial. In 2019, the parties amended the protocol for the ongoing Phase 1 clinical trial to enroll additional patients for which the Company will be reimbursed based upon an agreed-upon amount per patient. Under the bb21217 License Agreement, the Company is eligible to receive U.S. milestones of up to $85.0 million for the first indication to be addressed by bb21217 and royalties for U.S. sales of bb21217. Additionally, the Company was eligible to receive ex-U.S. milestones of up to $55.0 million and royalties for ex-U.S. sales of bb21217.

May 2020 Amendments to Ide-cel and bb21217 agreements

In May 2020, the First Amendment to the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement (as amended, the "Amended Ide-cel CCPS") and the Second Amended and Restated License Agreement ("Amended bb21217 License Agreement" and, collectively with the Amended Ide-cel CCPS, the “May 2020 Amendments”),

which replaced the bb21217 License Agreement, was executed. Under the Amended Ide-cel CCPS, the parties will continue to share equally in all profits and losses related to developing, commercializing and

manufacturing ide-cel within the United States. However, the Amended Ide-cel CCPS changed the Company's responsibilities with respect to manufacturing activities. Under the Amended Ide-cel CCPS, BMS assumed the contract manufacturing agreements related to ide-cel adherent lentiviral vector. Over time, BMS is also assuming responsibility for manufacturing ide-cel suspension lentiviral vector outside of the United States, with the Company responsible for manufacturing ide-cel suspension lentiviral vector in the United States.

Under In June 2023, the Amended bb21217 License Company assigned its Commercial Supply Agreement over time, with Resilience to BMS, is resulting in BMS assuming responsibility for manufacturing all ide-cel suspension lentiviral vector outside of the United States, with the Company responsible for manufacturing suspension lentiviral vector in the United States. Under the Amended bb21217 License Agreement, expenses incurred by the Company associated with these activities are fully reimbursable by BMS at cost plus a mark-up. Throughout both development and commercialization, BMS is responsible for the manufacture of drug product. manufacturing.

The May 2020 Amendments relieved BMS of its obligations to pay the Company for future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217 in exchange for an up-front, non-refundable, non-creditable payment of $200.0 million, which represents the aggregate of the probability-weighted, net present value of the future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217. In addition, the parties are released from future exclusivity related to BCMA-directed T cell therapies. There are no remaining milestones or royalties under the Amended Ide-cel CCPS.

In March 2021, the FDA approved the marketing of Ide-cel as *Abecma* in the United States for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Under the Amended Ide-cel CCPS, BMS is primarily responsible for the commercialization of *Abecma* and the Company has concluded BMS is the principal for such activities for purposes of applying its ASC 808 accounting policy to the Amended Ide-cel CCPS. As previously described, under the collaboration arrangement with BMS, the Company has had an option to co-develop and co-promote bb21217 within the United States. However, following completion of the CRB-402 clinical trial, in January 2022 the Company, along with BMS, evaluated its plans with respect to bb21217. Based in part on the strength of *Abecma* clinical data and commercial sales to date, the Company and BMS elected to discontinue development of bb21217 and, as such, the Company did not exercise its option to co-develop and co-promote bb21217 within the United States. The Company is still eligible to receive U.S. milestones and royalties for U.S. sales of bb21217, if further developed by BMS. Additionally, pursuant to the terms of the collaboration agreement, because it did not exercise its option to co-develop and co-promote bb21217, the Company received an additional fee in the amount of $10.0 million from BMS during the second quarter of 2022.

Accounting Analysis

Amended Ide-cel CCPS and Amended bb21217 License Agreement

Prior to the Amended Ide-cel CCPS and Amended bb21217 License Agreement, the Company had constrained all variable consideration related to the remaining ex-U.S. milestones and royalties for ex-U.S. sales under the Ide-cel CCPS and bb21217 License Agreement, as these milestones and royalties for ex-U.S sales were not considered to be probable. As a result of the Amended Ide-cel CCPS and Amended bb21217 License Agreement, the uncertainty associated with the previously constrained variable consideration for future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217 was resolved in exchange for an up-front, non-refundable,

non-creditable payment of $200.0 million. The Amended Ide-cel CCPS and Amended bb21217 License Agreement were negotiated as a package with a single commercial objective and, as such, the Amended Ide-cel CCPS and Amended bb21217 License Agreement were combined for accounting purposes and treated as a single arrangement.

At the time of execution of the Amended Ide-cel CCPS and Amended bb21217 License Agreement, there was one remaining performance obligation under each agreements: a combined performance obligation of the ide-cel license and ide-cel vector manufacturing through development; and a combined performance obligation of the bb21217 license and bb21217 vector manufacturing through development, neither of which were fully satisfied. The Company concluded each performance obligation was distinct from each other as BMS can benefit from each license and associated manufacturing services separately and the respective licenses and manufacturing services do

not modify one another and are not interdependent. Accordingly, the Company continues to account for each performance obligation separately.

The Company allocated the $200.0 million up-front payment received in connection with the Amended Ide-cel CCPS and Amended bb21217 License Agreement to the remaining performance obligations described above based on the general allocation principles of Topic 606. The Company considered that a portion of the $200.0 million was specifically attributable to each remaining performance obligation as the amount represents the aggregate of the probability-weighted, net present value of the future ex-U.S.

milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217 and that each respective portion therefore (i) relates specifically to the Company's satisfaction of each of its remaining performance obligations and (ii) is representative of the amount of consideration the Company expects to be entitled to in exchange for satisfying the respective performance obligations. As such, the Company concluded that the portion of the $200.0 million up-front payment specifically attributable to each of ide-cel and bb21217 should be allocated to each respective performance obligation pursuant to the variable consideration allocation exception.

The Amended Ide-cel CCPS and Amended bb21217 License Agreement represent a contract modification to an existing contract under Topic 606 resulting in a reduction in scope of the Company's responsibilities under each performance obligation described above. This resulted in a change in the overall transaction price under the arrangement. The Amended Ide-cel CCPS and Amended bb21217 License Agreement did not include any additional promised goods and services.

The remaining goods and services to be provided to fully satisfy each performance obligation described above are not distinct from those previously provided with respect to each performance obligation. Therefore, for each performance obligation, the remaining goods and services are part of a single performance obligation that is partially satisfied at the date of the contract modification. Accordingly, the effect that the contract modification had on the transaction price and the measure of progress toward complete satisfaction of each respective performance obligation has been recognized on a cumulative catch-up basis. The accounting for any previously satisfied performance obligations as of the contract modification date are not affected by the modification.

The following table summarizes the total transaction price, the allocation of the total transaction price to the identified performance obligations under the arrangement (including those performance obligations that were completed as of the May 2020 contract modification date as of December 31, 2022) (in thousands):

	Transaction price as of December 31, 2022	
	Ide-cel	bb21217
Upfront non-refundable payments received prior to May 2020 contract modification (1)	$ 120,000	$ 15,000
Allocated portion of the upfront non-refundable payment received in connection with the Amended Ide-cel CCPS and bb21217 License Agreement (2)	184,029	15,971
bb21217 co-develop and co-promote opt-out payment received in 2022	—	10,000
Estimated variable consideration (3)	83,900	—
	$ 387,929	$ 40,971

(1) Composed of all up-front payments and fees and milestone payments received under the related agreements. This consideration was allocated to the performance obligations under the agreements based on a relative standalone selling price ("SSP") basis.

(2) This represents the portion of the $200.0 million up-front payment received under the Amended Ide-cel CCPS and Amended bb21217 License Agreement which was allocated to ide-cel and bb21217.

(3) Estimated variable consideration represents the estimated reimbursement from BMS for the manufacture of vectors and associated payload through development.

Ide-cel research and development services

The Company allocated $40.9 million of the ide-cel transaction price to the ide-cel research and development services. The research and development performance obligation was satisfied prior to the May 2020 Amendments and, as a result, the accounting for this previously satisfied performance obligation was not affected by the modification. The Company recognized no revenue related to ide-cel research and development services for the years ended December 31, 2022 December 31, 2023, 2021, 2022, and 2020, 2021.

Ide-cel license and manufacturing services

The Company allocated $347.0 million of the ide-cel transaction price to the combined unit of accounting which consists of the license and manufacture of vectors and associated payload for incorporation into ide-cel through development. As of December 31, 2022 December 31, 2023, there was no unsatisfied transaction price and the remaining deferred revenue as of December 31, 2020 related to the performance obligation was recognized when the performance obligation was satisfied during the first quarter of 2021, upon *Abecma* commercial approval.

The following table summarizes the net collaboration revenue recognized or expense incurred for the joint ide-cel development efforts in the U.S. under ASC 808, including revenue or expense related to the combined performance obligation for license and manufacturing of ide-cel in the U.S. for the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020 2021 (in thousands):

	For the years ended December 31,

		2022	2021	2020
		For the years ended December 31,		
	2023			
ASC 808 ide-cel license and manufacturing revenue - U.S. (1)(2)	ASC 808 ide-cel license and manufacturing revenue - U.S. (1)(2)	$—	$533	$108,196
ASC 808 ide-cel license and manufacturing expense - U.S. (1)	ASC 808 ide-cel license and manufacturing expense - U.S. (1)	$—	$ —	$ (41,599)

		For the years ended December 31,		
	2023	2023	2022	2021

(1) As noted above, the calculation of collaborative arrangement activity to be recognized for joint ide-cel efforts in the United States is performed on a quarterly basis. The calculation is independent of previous activity, which may result in fluctuations between revenue and expense recognition period over period, depending on the varying extent of effort performed by each party during the period.

(2) In the second quarter of 2020, the Company recognized $169.2 million as a cumulative catch-up adjustment to revenue recorded in connection with the Amended Ide-cel CCPS, a portion of which was recognized as ASC 808 research and development collaboration revenue.

Abecma

Subsequent to the satisfaction of the Company's combined performance obligation license and manufacturing of ide-cel in the U.S. under the collaboration agreement with BMS, the Company shares equally in the profit and loss related to the development and commercialization of ide-cel in the United States (marketed as *Abecma*). The Company has no remaining financial rights with respect to the development or commercialization of ide-cel outside of the United States. The Company accounts for its collaborative arrangement efforts with BMS in the United States within the scope of ASC 808 given that both parties are active participants in the activities and both parties are exposed to significant risks and rewards dependent on the commercial success of the activities. The calculation of collaborative activity to be recognized for joint *Abecma* efforts in the United States is performed on a quarterly basis and is independent of previous quarterly activity. This may result in fluctuations between revenue and expense recognition period over period, depending on the varying extent of effort performed by each party during the period. The Company recognizes revenue related to the combined unit of accounting for the ex-U.S. license and lentiviral vector manufacturing services under Topic 606.

Ide-cel U.S. Share of Collaboration Profit or Loss

The U.S. commercial and development activities under the Amended Ide-Cel CCPS are within the scope of ASC 808. On a quarterly basis, the Company determines its share of collaboration profit or loss for commercial activities (i.e., commercial sales of *Abecma* by BMS). The Company's share of any collaboration profit for commercial activities is recognized as collaborative arrangement revenue and its share of any collaboration loss for commercial activity is recognized as an operating expense and classified as share of collaboration loss on the Company's consolidated and combined statements of operations and comprehensive loss.

The Company is also responsible for equally sharing in the ongoing ide-cel research and development activities being conducted by BMS in the United States as BMS continues conducting ongoing clinical studies to support the use of *Abecma* in earlier lines of therapy. The net amount owed to BMS for research and development activities determined on a quarterly basis is classified as research and development expense on the statements of operations and comprehensive loss. If BMS is obligated to reimburse the Company because the Company's research and development costs exceeds BMS' research and development costs in a particular quarterly period, the net amount is recorded as collaborative arrangement revenue.

The following tables summarize the components utilized in the Company's quarterly calculation of collaborative arrangement revenue or share of collaboration loss under the BMS collaboration arrangement for the years ended December 31, 2022 December 31, 2023, 2022 and 2021 (in thousands). Amounts for 2020 are not shown, as *Abecma* was not commercially approved until March 2021. The amounts reported for these periods represent the Company's share of BMS' *Abecma* product revenue, cost of goods sold, and selling costs, along with reimbursement by BMS of commercial costs incurred by the Company, and exclude expenses related to ongoing development, which are separately reflected in the consolidated and combined statements of operations and comprehensive loss as described below.

Abecma U.S. Collaboration Profit/Loss Share	Three months ended March 31, 2023	Three months ended June 30, 2023	Three months ended September 30, 2023	Three months ended December 31, 2023	Year ended December 31, 2023
2seventy's share of profits (losses), net of 2seventy's share of BMS costs for commercial activities	$ 21,581	$ 23,272	$ (582)	$ 1,366	$ 45,637
Reimbursement from BMS for 2seventy costs of commercial manufacturing and commercial activities	1,380	1,271	1,118	604	4,373
Collaborative arrangement revenue (1)	$ 22,961	$ 24,543	$ 536	$ 1,970	$ 50,010
Share of collaboration loss (1)	$ —	$ —	$ —	$ —	$ —

Abecma U.S. Collaboration Profit/Loss Share	Three months ended March 31, 2022	Three months ended June 30, 2022	Three months ended September 30, 2022	Three months ended December 31, 2022	Year ended December 31, 2022
2seventy's share of profits (losses), net of 2seventy's share of BMS costs for commercial activities	$ (6,709)	$ (5,931)	$ 2,849	$ 7,286	$ (2,505)
Reimbursement from BMS for 2seventy costs of commercial manufacturing and commercial activities	1,357	1,641	1,215	1,431	5,644
Collaborative arrangement revenue (1)	$ —	$ —	$ 4,064	$ 8,717	$ 12,781
Share of collaboration loss (1)	$ (5,352)	$ (4,290)	$ —	$ —	$ (9,642)

Abecma U.S. Collaboration Profit/Loss Share	*Abecma* U.S. Collaboration Profit/Loss Share	Three months ended March 31, 2021	Three months ended June 30, 2021	Three months ended September 30, 2021	Three months ended December 31, 2021	Year ended December 31, 2021
2seventy's share of profits (losses), net of 2seventy's share of BMS costs for commercial activities	2seventy's share of profits (losses), net of 2seventy's share of BMS costs for commercial activities	$ —	$ (11,766)	$ 9,762	$ 7,901	$ 5,897
Reimbursement from BMS for 2seventy costs of commercial manufacturing and commercial activities	Reimbursement from BMS for 2seventy costs of commercial manufacturing and commercial activities	—	1,695	845	917	3,457
Collaborative arrangement revenue (1)	Collaborative arrangement revenue (1)	$ —	$ —	$ 10,607	$ 8,818	$ 19,425
Share of collaboration loss (1)	Share of collaboration loss (1)	$ —	$ (10,071)	$ —	$ —	$ (10,071)

(1) As noted above, the calculation is performed on a quarterly basis and consists of 2seventy's share of profits, net of 2seventy's share of BMS costs for commercial activities, offset by reimbursement from BMS for 2seventy commercial activities. The calculation is independent of previous activity, which may result in fluctuations between revenue and expense recognition period over period.

(2) In March 2021, *Abecma* (idecabtagene vicleucel; ide-cel) was approved by the FDA in the United States for the treatment of adults with multiple myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. The first sale of *Abecma* occurred in the second quarter of 2021.

Collaborative arrangement revenue net of share of collaboration loss was $50.0 million, $3.1 million and $9.4 million for the years ended December 31, 2022 December 31, 2023, 2022, and 2021, respectively.

The following table summarizes the amounts associated with the research activities under the collaboration included in research and development expense or recognized as collaborative arrangement revenue for each quarter during the years ended December 31, 2022 December 31, 2023, 2022, and 2021 (in thousands):

	Three months ended				Year ended
Abecma U.S. Collaboration Net R&D Expenses	March 31, 2022	June 30, 2022	September 30. 2022	December 31, 2022	
2seventy's obligation for its share of BMS research and development expenses	$ (8,118)	$ (7,418)	$ (10,672)	$ (8,197)	$ (34,405)
Reimbursement from BMS for 2seventy research and development expenses	1,225	1,955	1,420	1,960	6,560
Net R&D expense (1)	$ (6,893)	$ (5,463)	$ (9,252)	$ (6,237)	$ (27,845)

	Three months ended				Year ended
Abecma U.S. Collaboration Net R&D Expenses	March 31, 2022	June 30, 2022	September 30. 2022	December 31, 2022	December 31, 2022
2seventy's obligation for its share of BMS research and development expenses	$ (8,118)	$ (7,418)	$ (10,672)	$ (8,197)	$ (34,405)
Reimbursement from BMS for 2seventy research and development expenses	1,225	1,955	1,420	1,960	6,560
Net R&D expense (1)	$ (6,893)	$ (5,463)	$ (9,252)	$ (6,237)	$ (27,845)

	Three months ended				Year ended
Abecma U.S. Collaboration Net R&D Expenses	March 31, 2021	June 30, 2021	September 30. 2021	December 31, 2021	December 31, 2021
2seventy's obligation for its share of BMS research and development expenses	$ (22,110)	$ (11,559)	$ (9,398)	$ (8,780)	$ (51,847)
Reimbursement from BMS for 2seventy research and development expenses	4,752	2,366	3,738	945	11,801
Net R&D expense (1)	$ (17,358)	$ (9,193)	$ (5,660)	$ (7,835)	$ (40,046)

(1) As noted above, the calculation is performed on a quarterly basis and consists of 2seventy's obligation for its share of BMS research and development expenses, offset by reimbursement from BMS for 2seventy research and development expenses expenses.

Ide-cel ex-U.S. Service Revenue

The Company accounts for any ex-U.S. activities under the Amended Ide-cel CCPS pursuant to ASC 606. The following table summarizes the revenue recognized related to ide-cel ex-U.S. activities for the years ended December 31, 2022 December 31, 2023, 2021, 2022, and 2020 2021 (in thousands). These amounts are reflected in service revenue in the consolidated and combined statements of operations and comprehensive loss:

	For the years ended December 31,		
	2022	2021	2020
ASC 606 ide-cel license and manufacturing revenue – ex-U.S. (included as a component of service revenue) (1)(2)	$ 13,226	$ 16,895	$ 99,052

	For the years ended December 31,		
	2023	2022	2021
ASC 606 ide-cel license and manufacturing revenue – ex-U.S. (included as a component of service revenue) (1)	$ 14,751	$ 13,226	$ 16,895

(1) In the second quarter of 2020, the Company recognized $169.2 million as a cumulative catch-up adjustment to revenue recorded in connection with the Amended Ide-cel CCPS, a portion of which was recognized as ASC 606 license and manufacturing revenue.

(2) These amounts include reimbursements from BMS to the Company for the Company's ex-U.S. quality and other manufacturing costs associated with the manufacture of *Abecma* inventory.

bb21217 research and development services

The Company allocated $5.4 million of the bb21217 transaction price to the research and development services. The research and development performance obligation was satisfied prior to the May 2020 amendments, and as a result, the accounting for this previously satisfied performance obligation was not affected by the modification. The Company recognized no revenue related to bb21217 research and developments services for the years ended December 31, 2022 December 31, 2023, 2021, 2022, and 2020.

The agreement to expand the bb21217 Phase 1 trial that occurred in 2019 was previously treated as a separate contract for accounting purposes. The transaction price associated with these additional patients consists of variable consideration and is based upon an agreed-upon amount per patient which will be recognized as revenue as the patients are treated. The Company began fulfilling the performance obligation in the fourth quarter of 2019 and it was satisfied in the fourth quarter of 2020. In connection with treating additional patients in the Phase 1 trial, the Company recognized revenue of $0.0 million, $0.0 million, and $12.4 million for the years ended December 31, 2022, 2021, and 2020, respectively. 2021.

bb21217 license and manufacturing services

The Company allocated $35.5 million of the bb21217 transaction price to its combined performance obligation representing the bb21217 license and vector manufacturing services. Of this amount, $1.8 million was never received by the Company as it represented the estimated reimbursement from BMS for the manufacture of vectors and associated payload through development. As noted above, following completion of the CRB-402 clinical trial for bb21217, in January 2022 the Company, along with BMS, evaluated its plans with respect to bb21217. Based in part on the strength of *Abecma* clinical data and commercial sales to date, the Company and BMS elected to discontinue development of bb21217 and, as such, the Company did not exercise its option to co-develop and co-promote bb21217 within the United States. Additionally, pursuant to the terms of the collaboration agreement,

because it did not exercise its option to co-develop and co-promote bb21217, the Company received an additional fee in the amount of $10.0 million from BMS during the second quarter of 2022. Pursuant to the variable consideration allocation exception, the $10.0 million of consideration received was allocated to the combined

performance obligation for the bb21217 license and vector manufacturing services through development, described above.

In December 2022, BMS formally notified the Company that its license and vector manufacturing services for bb21217 will no longer be required, thus releasing it from the combined performance obligation for the bb21217 license and vector manufacturing services through development. As a result, the Company recognized the remaining deferred revenue of $35.8 million as a component of service revenue during the year ended December 31, 2022.

Contract assets and liabilities – ide-cel and bb21217

The Company receives payments from its collaborative partners based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until such time as the Company satisfies its performance obligations under these arrangements. A contract asset is a conditional right to consideration in exchange for goods or services that the Company has transferred to a customer. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

The following table presents changes in the balances of the Company's BMS receivables and contract liabilities during the twelve months ended December 31, 2022 December 31, 2023 (in thousands):

	Balance at December 31, 2021	Additions	Deductions	Balance at December 31, 2022
Receivables	$ 652	$14,537	$(10,652)	$ 4,537
Contract liabilities:				
Deferred revenue	$25,762	$10,000	$(35,762)	$ —

	Balance at December 31, 2022	Balance at December 31, 2022	Additions	Deductions	Balance at December 31, 2023
Receivables	Receivables				
Contract liabilities:	Contract liabilities:				
Deferred revenue	Deferred revenue				

Deferred revenue

Deferred revenue

The increase decrease in the receivables balance for the twelve months ended December 31, 2022 December 31, 2023 is driven by amounts owed to the Company from BMS in the period under the settlement terms of the collaboration agreement, offset by amounts collected from BMS in the period.

The Company recognized the $10.0 million payment received from BMS for opting out of co-developing and co-promoting bb21217 as deferred revenue during the second quarter of 2022. As discussed above, in the fourth quarter of 2022, the Company was released of its combined performance obligation for bb21217 license and vector manufacturing services through development. Thus, the remaining $35.8 million of deferred revenue associated with this performance obligation (including the $10.0 million bb21217 opt-out payment) was recognized as a component of service revenue.

Regeneron

Regeneron Collaboration Agreement

In August 2018, bluebird bio entered into a Collaboration Agreement (the "Regeneron Collaboration Agreement") with Regeneron pursuant to which the parties will apply their respective technology platforms to the discovery, development, and commercialization of novel immune cell therapies for cancer. In August 2018, following the completion of required regulatory reviews, the Regeneron Collaboration Agreement became effective. As noted above, the agreement will be was attributed to the Company in connection with the separation. Under the terms of the agreement, the parties will leverage Regeneron's proprietary platform technologies for the discovery and characterization of fully human antibodies, as well as T cell receptors directed against tumor-specific proteins and peptides and the Company will contribute its field-leading expertise in gene therapy.

In accordance with the Regeneron Collaboration Agreement, the parties jointly selected six initial targets and intend to equally share the costs of research up to the point of submitting an IND application for a potential gene

therapy product directed to a particular target. Additional targets may be selected to add to or replace any of the initial targets during the five-year research collaboration term as agreed to by the parties.

Regeneron will accrue a certain number of option rights exercisable against targets as the parties reach certain milestones under the terms of the agreement. Upon the acceptance of an IND for the first product candidate directed to a target, Regeneron will have the right to exercise an option for co-development/co-commercialization of product candidates directed to such target on a worldwide or applicable opt-in territory basis, with certain exceptions. Where Regeneron chooses to opt-in, the parties will share equally in the costs of development and commercialization, and will share equally in any profits or losses therefrom in applicable opt-in territories. Outside of the applicable opt-in territories, the target becomes a licensed target and Regeneron would be eligible to receive, with respect to any resulting product, milestone payments of up to $130.0 million per product and royalties on net sales outside of the applicable opt-in territories at a rate ranging from the mid-single digits to low-double digits. A target would also

become a licensed target in the event Regeneron does not have an option to such target, or Regeneron does not exercise its option with respect to such target.

Either party may terminate a given research program directed to a particular target for convenience, and the other party may elect to continue such research program at its expense, receiving applicable cross-licenses. The terminating party will receive licensed product royalties and milestone payments on the potential applicable gene therapy products. Where the Company terminates a given research program for convenience, and Regeneron elects to continue such research program, the parties will enter into a transitional services agreement. Under certain conditions, following its opt-in, Regeneron may terminate a given collaboration program and the Company may elect to continue the development and commercialization of the applicable potential gene therapy products as licensed products.

First Amendment to the Regeneron Collaboration Agreement

In January 2023, 2seventy bio and Regeneron announced an amendment to the Regeneron Collaboration Agreement (the "Amendment"), to amend and extend their current agreement, applying their respective technology platforms to the discovery, development and commercialization of novel immune cell therapies for cancer. Under the Amendment, the parties have identified four research targets to advance the next stage of research therapies. The parties will continue sharing costs for these activities in a manner largely consistent with the existing agreement, with Regeneron now covering 75% of eligible late-stage research costs to study combinations and 100% of the costs for the arms of clinical studies that include Regeneron agents through regulatory approval of two of the four targets. For other programs, cost-sharing will follow the existing 50/50 cost sharing agreement.

Additionally, Regeneron will make one-time milestone payments for each of the first Clinical Candidate directed to MUC16 and the first Clinical Candidate directed to a selected early stage research target to achieve the applicable milestones. Clinical Candidate milestone events and payments include:

- $2.0 million payment from Regeneron for Development Candidate Nomination;
- $3.0 million payment from Regeneron for IND Acceptance; and
- $5.0 million payment from Regeneron for the Earlier of (i) last patient dosed with a Monotherapy Regimen and (ii) dosing of the 10th patient in a Clinical Trial included in an Approved Research/ Development Plan.

The Development Candidate Nomination for MUC16 had already occurred as of the Amendment and will not be due until the Clinical Candidate milestone event (IND Acceptance) is achieved for MUC16, at which time the first milestone will be reduced to $1.0 million for a total amount due for the two milestones related to MUC16 of $4.0 million.

Regeneron Share Purchase Agreement Agreements

A Share Purchase Agreement ("SPA") was entered into by bluebird bio and Regeneron in August 2018. In August 2018, on the closing date of the transaction, bluebird bio issued Regeneron 0.4 million shares of bluebird bio's common stock, subject to certain restrictions, for $238.10 per share, or $100.0 million in the aggregate. Following the spin-off, Regeneron held approximately 0.1 million shares of 2seventy bio's common stock, subject to certain restrictions. The purchase price represents $63.0 million worth of common stock plus a $37.0 million premium, which represents a collaboration research advancement, or credit to be applied to Regeneron's initial 50 percent funding obligation for collaboration research, after which the collaborators will continue to fund ongoing research equally. The collaboration research advancement only applies to pre-IND research activities and is not refundable or creditable against post-IND research activities for any programs where Regeneron exercises its opt-in rights.

In connection with the Amendment, the Company entered into a Share Purchase Agreement with Regeneron pursuant to which the Company sold 1.1 million shares of its common stock, subject to certain restrictions, for $17.94 per share, to Regeneron for an aggregate cash price of approximately $20.0 million. The purchase price represents $9.9 million worth of common stock plus a $10.1 million premium, which represents deferred revenue.

Accounting analysis – 2018 Regeneron Collaboration Agreement

At the commencement of the arrangement, two units of accounting were identified, which are the issuance of 0.4 million shares of bluebird bio's common stock and joint research activities during the five year research collaboration term. The Company determined the total transaction price to be $100.0 million, which comprises $54.5 million attributed to the bluebird bio equity sold to Regeneron and $45.5 million attributed to the joint research activities. In determining the fair value of the bluebird bio common stock at closing, the Company considered the closing price of the bluebird bio common stock on the closing date of the transaction and included a lack of marketability discount because Regeneron received shares subject to certain restrictions.

The Company analyzed the joint research activities to assess whether they fall within the scope of ASC 808, and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the arrangement as outlined above, for the collaboration research performed prior to submission of an IND application for a potential gene therapy product, both parties are deemed to be active participants in the collaboration. Both parties are performing research and development activities and will share equally in these costs through IND. Additionally, Regeneron and the Company are exposed to significant risks and rewards dependent on the commercial success of any product candidates that may result from the collaboration. As such, the collaboration arrangement is deemed to be within the scope of ASC 808.

The $45.5 million attributed to the joint research activities includes the $37.0 million creditable against amounts owed to the Company by Regeneron. The collaboration research advancement will be reduced over time for amounts due to the Company by Regeneron as a result of the parties agreeing to share in the costs of collaboration research equally. The remainder of the amount $8.5 million will be attributed to the joint research activities will be and recognized over the five-year research collaboration term. As of December 31, 2022, $1.1 million of the premium remained to be recognized. Refer below to the accounting analysis for the Regeneron Amendment for treatment of the remaining premium as of December 31, 2023.

Consistent with its collaboration accounting policy, the Company will recognize collaboration revenue or research and development expense related to the joint research activities in future periods depending on the amounts incurred by each party in a given reporting period. That is, if the Company's research costs incurred exceed those research costs incurred by Regeneron in a given quarter, the Company will record collaboration revenue and reduce the original $37.0 million advance by the amount due from Regeneron until such advancement is fully utilized, after which the Company would record an amount due from Regeneron. If Regeneron's research costs incurred exceed those research costs incurred by the Company in a given quarter, the Company will record research and development expense and record a liability for the amount due to Regeneron. As of December 31, 2022 and 2021, , the Company has had $3.7 million and $23.3 million respectively, of the amount collaboration research advancement credit attributed to the joint research activities remaining still to be recognized recognized. The research credit was fully utilized in the first quarter of 2023.

Accounting analysis - Regeneron Amendment

At the commencement of the Amendment, the Company identified two units of accounting, including the issuance of 1.1 million shares of 2seventy bio common stock and joint research activities under the amended agreement. The Company determined the total transaction price to be $20.0 million, which is classified comprises $9.9 million of 2seventy bio equity sold to Regeneron and $10.1 million attributed to joint research activities. In determining the fair value of 2seventy bio common stock at closing, the Company considered the closing price of 2seventy bio common stock on the closing date of the transaction and included a lack of marketability discount because Regeneron received shares subject to certain restrictions.

Consistent with the original Regeneron Collaboration Agreement, the Company assessed whether the joint research activities under the Amendment fell within the scope of ASC 808 and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the amended arrangement as outlined above, for the collaboration research advancement, performed prior to submission of an IND application for a potential gene therapy product, both parties continue to be active participants in the collaboration. Both parties continue to perform research and development activities and will share in these costs through IND submission. Additionally, Regeneron and the Company continue to be exposed to significant risks and rewards

dependent on the commercial success of any product candidates that may result from the collaboration. As such, the collaboration arrangement is deemed to be within the scope of ASC 808. The Company continues to apply ASC 606 by analogy to determine the measurement and recognition of the consideration received from Regeneron.

The Company analogized to the contract modification guidance in ASC 606 to account for the scope and pricing changes contained in the Amendment. The Company concluded the four targets outlined in the joint research activities within the Amendment are now four distinct performance obligations. Based on this, the Company treated the modification as a termination of the existing contract and a creation of a new contract. The remaining premium of $1.1 million that had not been recognized as of December 31, 2022 was allocated with the $10.1 million premium attributed to joint research activities from the Amendment, for a total of $11.2 million. This amount is recognized through the filing of IND for each individual target, allocated among the four distinct performance obligations based on the stand-alone selling price of each target performance obligation. Future milestones continue to be fully constrained until such time as the achievement of such milestones are considered probable.

The Company concluded that it continues to satisfy its obligations over-time as Regeneron receives the benefit of the research activities as the activities are performed. The Company determined the most appropriate method to track progress towards completion of the four performance obligations is an input method that is based on costs incurred. There are significant judgments and estimates inherent in the determination of the costs to be incurred for the research and development activities related to the collaboration with Regeneron. These estimates and assumptions include a number of objective and subjective factors, including the likelihood that a target will be successfully developed through its IND filing and the estimated costs associated with such development, including the potential third-party costs related to each target's IND-enabling study. Any changes to these estimates will be recognized in the period in which they change as a cumulative catch-up.

As noted, the four targets represent four distinct performance obligations and as such, the Company has allocated the total transaction price of $11.2 million among the four performance obligations based on the stand-alone selling price of each target.

The following table summarizes the allocation of the transaction price to each performance obligation and the amount of the allocated transaction price that is unsatisfied or partially unsatisfied as of December 31, 2023, which the Company expects to recognize as revenue as the targets progress through each of the target's respective IND filing (in thousands):

Performance Obligation	Allocation of Transaction Price	Unsatisfied Portion of Transaction Price
MUC16 Mono/Combo & Next Gen Therapies	$ 1,905	$ 144
MAGE-A4	178	10
Early Research Target (1)	8,701	7,743
Early Research Target (2)	475	424
Total	$ 11,259	$ 8,321

As of December 31, 2023, approximately $8.3 million remains in collaboration deferred revenue, of which $4.4 million is included in deferred revenue, current portion and collaboration research advancement, $3.9 million is included in deferred revenue, net of current portion, on the condensed consolidated balance sheet. sheets.

The Company recognized $19.6 million $21.6 million, $7.5 million $19.6 million and $7.4 million $7.5 million of collaboration revenue from the Regeneron Collaboration Agreement during the years ended December 31, 2022 December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, amounts due from Regeneron total $4.6 million, included within receivables and 2020, respectively. other current assets on the condensed consolidated balance sheets.

JW Therapeutics

In October 2022, the Company entered into a strategic alliance with JW (Cayman) Therapeutics Co., Ltd. ("JW") to establish a translational and clinical cell therapy development platform designed to more rapidly explore T

cell-based immunotherapy therapy products in the Chinese mainland, Hong Kong (China), and Macao (China). The initial focus of the collaboration is the Company's MAGE-A4 TCR program in solid tumors which is being developed as part of its collaboration with Regeneron.

Under the terms of the agreement, the Company will grant JW a license for the MAGE-A4 cell therapy in the Chinese mainland, Hong Kong (China), and Macao (China). JW will be responsible for development, manufacturing, and commercialization of the Initial Product within China. The Company is eligible to receive milestones and royalties on product revenues in China. The Company and Regeneron will equally share all payments received from JW, including but not limited to all upfront, milestone and royalty payments made by JW to the Company. The Company and Regeneron will also equally share all costs for any eligible expenses incurred in accordance with the terms of the Regeneron Collaboration Agreement. Additionally, the Company may leverage the early clinical data generated under the collaboration to support development in other geographies.

Accounting Analysis - JW

The Company concluded JW is a customer, and as such, the arrangement falls within the scope of Topic 606. Two performance obligations were identified within the contract consisting of (i) a license for the MAGE-A4 cell therapy, including a transfer of technology as agreed upon by both parties and (ii) vector supply necessary to conduct a Phase 1

clinical trial. The Company has concluded the manufacturing and supply of vector is a distinct performance obligation from the license for MAGE-A4 cell therapy because there are other vendors that could provide the necessary supply.

At contract inception, the Company determined the unconstrained transaction price was $7.3 million, consisting of the $3.0 million up-front consideration and $4.3 million consisting of variable consideration for the reimbursement of vector supply. JW provided the Company with a $3.0 million upfront payment related to the granting of a license for MAGE-A4 cell therapy and the transfer of technology for the development of the Initial Product. However, as of December 31, 2022, Product in which the Company has not shared equally with Regeneron. During the first quarter of 2023, the Company completed the full transfer of the license of IP related to MAGEA4 cell therapy along with the technology transfer, and as such, this the upfront payment is included within short-term deferred revenue until the transfer of technology is fully complete. received from JW was recognized as service revenue. The transaction price of $4.3 million related to the supply of vector, consists of variable consideration based upon the estimated amount of vector needed in the development and commercialization for the initial Phase 1 clinical

trial. The manufacturing and transfer of vector to JW trial which the Company will likely occur in early 2023, and therefore also share equally with Regeneron. For the year ended December 31, 2023, the Company has not received any payments related transferred a total of $0.6 million of vector supply to this performance obligation as of December 31, 2022. JW.

Novo Nordisk

Novo Collaboration and License Agreement

In December 2021, the Company entered into a Collaboration and License Agreement (the “Novo Collaboration Agreement”) with Novo Nordisk A/S (“Novo”) for the discovery, development, and commercialization of a potential new gene therapy in hemophilia A. The Company and Novo have agreed to develop an initial research program with the goal of researching and developing a lead candidate directed to hemophilia A. The Company will provide Novo with research licenses to support the companies’ activities during the initial research program and an option to enable Novo to obtain an exclusive license to commercialize the product derived from or containing compounds developed during the initial research program.

Under the terms of the Novo Collaboration Agreement, Novo agreed to pay the Company:

- a non-refundable, non-creditable upfront payment of $5.0 million;
- $15.0 million upon achievement of certain scientific milestones during the initial research program, or $9.0 million should Novo decide to continue the initial research program without achieving the scientific milestones;
- up to $26.0 million of exclusive license fees for the development, manufacture, and commercialization of the product should Novo exercise its option; and,
- up to $72.0 million in development and commercialization milestones.

Novo also agreed to reimburse the Company for research costs incurred in connection with the initial research program up to a mutually agreed upon amount. If Novo exercises its option to obtain a license to commercialize the product developed during the initial research program, the Company is also eligible to receive mid-single digit royalties on product sales on a country-by-country and product-by-product basis, subject to certain royalty step-down provisions set forth in the agreement.

Accounting Analysis - Novo

The Company concluded that Novo is a customer, and as such, the arrangement falls within the scope of Topic 606. The Company identified two performance obligations consisting of (i) the research license and research and development services to be provided during the initial research program and (ii) a material right related to Novo’s option to obtain an exclusive license for the development, manufacture, and commercialization of the product developed during the initial research program. The Company determined that the research license and research and development services promises were not separately identifiable and were not distinct or distinct within the context of the contract due to the specialized nature of the services to be provided by 2seventy, specifically with respect to the Company’s expertise related to gene therapy and the interdependent relationship between the promises. The material right is considered a separate performance obligation pursuant to the provisions of Topic 606.

At contract inception, the Company determined the unconstrained transaction price was $11.7 million, consisting of the $5.0 million in up-front consideration and the $6.7 million in reimbursement for the research and development services. Variable consideration associated with the scientific milestones was fully constrained due to the uncertainty associated with the outcome of the research efforts under the initial research program. The Company allocated $6.7 million of the transaction price to the research services and $5.0 million to the material right using a relative selling price methodology. Management will re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur and adjust the transaction price as necessary.

In April 2023, the Company achieved positive proof of concept, preclinical data related to its joint research and development collaboration with Novo. This achievement triggered a $15.0 million milestone payment to the Company under the terms of the Novo Collaboration Agreement. Following the achievement of this milestone, Novo has elected to exercise an option to in-license technology from a third party in connection with the Novo Collaboration Agreement, for which the Company was responsible in making a $9.0 million payment to such third party. In November 2023, Novo exercised its option to in-license technology from a third party in connection with the Novo Collaboration Agreement, which triggered the

$9.0 million payment by the Company to such third party. The remaining $6.0 million, of the $15.0 million proof of concept milestone, is allocated to the material right alongside the $5.0 million upfront payment. The total $11.0 million is included in deferred revenue, current portion, as of December 31, 2023, and will be recognized when Novo exercises its option to obtain a license to commercialize the product developed.

Revenue associated with the research and development performance obligation will be recognized as services are provided and costs are incurred. The portion of the transaction price attributed to the material right will be

deferred and recognized as revenue upon Novo exercising its option to license the product. For the year years ended December 31, 2022, December 31, 2023 and 2022, the Company recognized $5.8 million and $6.5 million of revenue under this agreement. As the services under this agreement commenced in 2022, there was no revenue recognized in the prior years.

11. Royalty and other revenue bluebird bio has out-licensed intellectual property to various third parties. Under the terms of these agreements, some of which were assumed by the Company in connection with the separation, bluebird bio and the Company may be entitled to royalties and milestone payments.

The Company recognized $4.6 million, $3.6 million, $6.2 million, and $21.1 $6.2 million of royalty and other revenue in the years ended December 31, 2022 December 31, 2023, 2021, 2022, and 2020, 2021, respectively.

Novartis Pharma AG

In April 2017, bluebird bio entered into a worldwide license agreement with Novartis. Under the terms of the agreement, Novartis non-exclusively licensed certain patent rights related to lentiviral vector technology to develop and commercialize CAR T cell therapies for oncology, including Kymriah (formerly known as CTL19), Novartis's anti-CD19 CAR T therapy. The agreement was assumed by the Company in connection with the separation. Beginning in the fourth quarter of 2017, bluebird bio began receiving royalties from sales of tisagenlecleucel under the agreement. This license agreement was terminated effective March 2021, at which point in time Novartis was no longer required to make royalty or other payments on net sales of tisagenlecleucel or any future products. Royalty revenue recognized from sales of tisagenlecleucel is included within royalty and other revenue in the condensed consolidated and combined statement of operations and comprehensive loss.

Juno Therapeutics

In May 2020, bluebird bio entered into a non-exclusive license agreement with Juno Therapeutics, Inc. ("Juno"), a wholly-owned subsidiary of BMS, related to lentiviral vector technology to develop and commercialize CD-19-directed CAR T cell therapies. The agreement was assumed by the Company in connection with the separation. Upon regulatory approval of lisocabtagene maraleucel Breyanzi (lisocabtagene maraleucel) during the first quarter of 2021, bluebird bio received a $2.5 million milestone payment from Juno, which is included within royalty and other revenue in the Company's consolidated and combined financial statements. Royalty revenue recognized from sales of lisocabtagene maraleucel Breyanzi (lisocabtagene maraleucel) through August 2023, the end of the royalty term, is also included within royalty and other revenue in the consolidated and combined statement of operations and comprehensive loss.

12. Intangible assets

Intangible assets, net of accumulated amortization, are summarized as follows (in thousands):

	As of December 31, 2022			As of December 31, 2021		
	Cost	Accumulated amortization	Net	Cost	Accumulated amortization	Net
Developed technology	$30,100	$ (30,100)	$ —	$30,100	$ (28,218)	$1,882
In-licensed rights	8,500	(1,198)	7,302	8,500	(490)	8,010
Total	$38,600	$ (31,298)	$7,302	$38,600	$ (28,708)	$9,892

	As of December 31, 2023			As of December 31, 2022		
	Cost	Accumulated amortization	Net	Cost	Accumulated amortization	Net
Developed technology	$30,100	$ (30,100)	$ —	$30,100	$ (28,218)	$1,882
In-licensed rights	8,500	(1,198)	7,302	8,500	(490)	8,010
Total	$38,600	$ (31,298)	$7,302	$38,600	$ (28,708)	$9,892

Amortization expense for intangible assets was $2.6 $0.7 million, $4.3 million $2.6 million, and $3.8 $4.3 million for the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020, 2021, respectively.

Developed technology

The Company's developed technology was obtained through the acquisition in 2014 of Pregenen, a privately-held biotechnology company includes gene editing and cell signaling technology with a broad range of potential

therapeutic applications. The gene editing platform intangible asset was amortized on a straight-line basis over its expected useful life until it was fully amortized in the second quarter of 2022.

In-licensed rights

In-licensed rights consist of capitalized milestone payments made to third parties upon receiving regulatory approval of *Abecma* in the U.S. The in-licensed rights are being amortized on a straight-line basis over the remaining life of the related patents of approximately twelve years, as the life of the related patents reflects the expected time period that the Company will benefit from the in-licensed rights.

The following table summarizes the estimated future amortization for intangible assets for the next five years and thereafter (in thousands):

	As of December 31, 2022
2023	$ 708

As of December 31, 2023		As of December 31, 2023
2024	2024	708
2025	2025	708
2026	2026	708
2027	2027	708
2028 and thereafter		3,762
2028		
2029 and thereafter		
Total	Total	$ 7,302

13. Stock-based compensation

The Company's employees have historically participated in bluebird bio's various stock-based compensation plans.

In connection with 2seventy's separation from bluebird bio on November 4, 2021, under the provisions of the existing plans, the outstanding bluebird bio equity awards were adjusted in accordance with the terms of the Employee Matters Agreement (equitable adjustment) to preserve the intrinsic value of the awards immediately before and after distribution.

Upon the distribution, employees holding stock options, restricted stock units ("RSUs") and performance restricted stock units ("PRSUs") denominated in pre-distribution bluebird bio stock received a number of otherwise-similar awards either in post-distribution 2seventy stock or in a combination of post-distribution bluebird stock and 2seventy stock based on conversion ratios outlined for each group of employees in the Employee Matters Agreement that the Company entered into in connection with the distribution.

The equity awards that were granted prior to 2021 were converted under the shareholder method, wherein employees holding outstanding equity awards received equity awards in both bluebird and 2seventy. The conversion ratio for the shareholder method took into consideration a distribution ratio of one share of 2seventy common stock for every three shares of bluebird bio common stock. For equity awards granted in 2021, the number of awards that were outstanding at the time of the spin-off were proportionately adjusted to maintain the aggregate intrinsic value of the awards at the date of the spin-off. The conversion ratio was determined based on the volume weighted-average trading price for bluebird common stock for the five trading days before and the volume weighted-average trading price for 2seventy common stock for the five trading days after the spin.

These modified awards otherwise retained substantially the same terms and conditions, including term and vesting provisions. Due to the modification of the equity awards as a result of the distribution, the Company compared the fair value of the outstanding equity awards immediately before and after the distribution. The modification resulted in an incremental fair value of $1.5 million, of which $1.3 million was immediately recognized as of the distribution.

The Company will incur future compensation cost related to bluebird bio equity awards held by its employees but will not incur future compensation cost related to bluebird employees holding equity awards in 2seventy.

In October 2021, the Company's board of directors adopted its 2021 Stock Option and Incentive Plan ("2021 Plan"), which was subsequently approved by bluebird bio, then the Company's sole stockholders. The 2021 Plan

became effective on October 17, 2021, the day immediately prior to the effectiveness of the Company's Registration Statement on Form 10.

The 2021 Plan allows for the granting of incentive stock options, non-qualified stock options, RSUs, PRSUs, and restricted stock awards to 2seventy bio's employees, members of the board of directors, and consultants of 2seventy bio, including those of 2seventy bio who became employees of the Company in connection with the separation. All awards granted under the 2021 Plan consist of shares of 2seventy bio's common stock.

Stock-based compensation expense

For periods prior to the separation, stock-based compensation expense was allocated to the Company using a combination of specific identification and time spent on projects at various levels of the organization, which management believes are consistent and reasonable.

The Company recognized stock-based compensation expense totaling $32.2 million, $41.0 million, $54.6 million, and $61.0 $54.6 million during the years ended December 31, 2022 December 31, 2023, 2021, 2022, and 2020, 2021, respectively. Stock-based compensation expense recognized by award type is as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Stock options	$17,784	$26,185	$36,685
Restricted stock units	22,983	21,414	19,185
Employee stock purchase plan and other	273	7,030	5,127
	$41,040	$54,629	$60,997

	Year Ended December 31,		
	2023	2022	2021
Stock options	$		

Stock-based compensation expense by classification included within the consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Research and development	$18,333	$29,746	$30,935
Selling, general and administrative	22,707	24,883	30,062

	Year Ended December 31,		
	2023	2022	2021
Research and development	$		

	$41,040	$54,629	$60,997
$			

As of December 31, 2022 December 31, 2023, the Company had $17.9 million $14.6 million, $20.9 million $19.0 million, and $0.6 million $0.0 million of unrecognized compensation expense related to unvested stock options, RSUs, and PRSUs, (exclusive of those with service and performance conditions that have not yet been achieved), respectively, that is expected to be recognized over a weighted-average period of 2.3 2.4 years, 1.9 2.1 years, and 1.1 0.0 years, respectively.

Stock options

The fair value of each option issued to employees was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	Year ended December 31,
	2022
Expected volatility	78.9 %
Expected term (in years)	6.1
Risk-free interest rate	1.8 %
Expected dividend yield	0.0 %

	Year ended December 31,	Year ended December 31,
	2023	2022
Expected volatility	80.9 %	78.9 %
Expected term (in years)	5.9	6.1
Risk-free interest rate	4.2 %	1.8 %
Expected dividend yield	0.0 %	0.0 %

(a) In connection with 2seventy's separation from bluebird bio on November 4, 2021, all option awards granted prior to 2022 were converted as part of the separation.

The following table summarizes the stock option activity under the Company's equity awards award plans for 2seventy employees:

	Shares (in thousands)	Weighted-average exercise price per share	Weighted-average contractual life (in years)	Aggregate intrinsic value (a) (in thousands)
Outstanding at December 31, 2021	873	$ 129.60		
Granted	1,619	$ 13.78		
Exercised	—	$ —		
Canceled or forfeited	(207)	$ 61.05		
Outstanding at December 31, 2022	2,285	$ 53.72	7.9	$ 6
Exercisable at December 31, 2022	640	$ 143.31	5.0	$ 6
Vested and expected to vest at December 31, 2022	2,285	$ 53.72	7.9	$ —

	Shares (in thousands)	Weighted-average exercise price per share	Weighted-average contractual life (in years)	Aggregate intrinsic value (a) (in thousands)
Outstanding at December 31, 2022	2,285	$ 53.72		
Granted	2,024	$ 9.52		
Exercised	—	$ —		
Cancelled or forfeited	(830)	$ 75.11		
Outstanding at December 31, 2023	3,479	$ 22.88	8.3	$ 232

Exercisable at December 31, 2023	1,113	$ 47.51	6.8	$	—
Vested and expected to vest at December 31, 2023	3,479	$ 22.88	8.3	$	232

(a) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that were in the money at December 31, 2022 December 31, 2023.

Restricted stock units

The following table summarizes the restricted stock unit activity under the Company's equity award plans for 2seventy employees:

	Shares (in thousands)	Weighted-average grant date fair value
Unvested balance at December 31, 2021	970	$ 50.56

Shares (in thousands)		Shares (in thousands)	Weighted-average grant date fair value
Unvested balance at December 31, 2022			
Granted	Granted	853	14.20
Vested	Vested	(334)	62.61
Forfeited	Forfeited	(219)	37.48
Unvested balance at December 31, 2022		1,270	$ 28.31
Unvested balance at December 31, 2023			

The intrinsic value of RSUs vested during the year ended December 31, 2022 December 31, 2023 was $5.5 $4.5 million.

On February 1, 2021, the Company's CEO was granted 27,000 PRSUs by bluebird. Each PRSU related to one share of common stock of bluebird. The number of PRSUs earned and vested would be determined based on bluebird's total shareholder return ("TSR") compared against the median TSR of a peer group over the performance period January 1, 2021 through December 31, 2023. Upon spin-off, the PRSUs were converted to 17,387 2seventy PRSUs. The TSR was kept whole by treating the value of bluebird at spin as a dividend that is reinvested into 2seventy stock. For the years ended December 31, 2022 December 31, 2023, 2022, and 2021, the Company recognized $0.6 million, $0.6 million, and $0.4 million of expense, respectively, related to the PRSUs. As of December 31, 2022 December 31, 2023, $0.6 million all expense related to the PRSUs has been recognized. Based on the comparison of unrecognized expense is expected bluebird's TSR from January 1, 2021 to the spin-off date and 2seventy's TSR from the spin-off date to December 31, 2023 to the median TSR of the peer group, the number of PRSUs earned and vested during the performance period was determined to be recognized over the remaining duration of the award's life. zero.

Unrestricted stock awards

During the fourth quarter of 2021, the Company granted 0.2 million unrestricted stock awards to employees as part of its 2021 retention program which was designed to incentivize and retain employees through the spin-off. Under the retention program, employees were entitled to a one-time bonus payment, consisting of both a cash payment and unrestricted stock awards, with the condition that the employee remained employed through the end of 2021. Expense recognized on the unrestricted stock awards during the year ended December 31, 2021 totaled $6.5 million. The Company recognized immaterial expense associated with unrestricted stock awards during the

year ended December 31, 2022 and no expense associated with unrestricted stock awards during the year ended December 31, 2023.

Employee Stock Purchase Plan

In October 2021, the Company's board of directors adopted its 2021 Employee Stock Purchase Plan ("2021 ESPP"), which was subsequently approved by bluebird bio, then its sole stockholders. stockholder. The 2021 ESPP became effective on October 17, 2021, the day immediately prior to the effectiveness of the Company's Registration Statement on Form 10. The 2021 ESPP authorizes the initial issuance of a specified number of shares of the Company's common stock to participating employees. For During each of the year years ended December 31, 2023 and December 31, 2022, 0.1 million shares and less than 0.1 million shares of common stock were issued under the 2021 ESPP. ESPP, respectively.

14. Related-party transactions

Relationship with Bluebird Bio

Following the separation, bluebird bio is considered a related party.

In connection with the separation, the Company entered into a separation agreement (the "Separation Agreement") with bluebird bio, dated as of November 3, 2021, that, among other things, set forth bluebird bio's agreements with 2seventy bio regarding the principal actions to be taken in connection with the separation, including the distribution. The effective time of the distribution was 12:01 a.m. on November 4, 2021. The Separation Agreement identifies assets transferred to, liabilities assumed by and contracts assigned to 2seventy bio as part of the separation, and it provides for when and how these transfers, assumptions and assignments occur. The purpose of the Separation Agreement is to provide 2seventy bio and bluebird bio with assets to operate their respective businesses and retain or assume liabilities related to those assets. Each of 2seventy bio and bluebird bio agreed to releases, with respect to pre-separation claims, and cross indemnities with respect to post-separation claims, that are principally designed to place financial responsibility for the obligations and liabilities allocated to 2seventy bio under the Separation Agreement with 2seventy bio and financial responsibility for the obligations and liabilities allocated to bluebird bio under the Separation Agreement. bluebird bio Following the completion of the separation and 2seventy bio are also each subject to mutual 12-month employee non-solicit and non-hire restrictions, subject to certain customary exceptions. In accordance with the Separation Agreement with bluebird bio, there were certain other transactions and adjustments post-Separation between distribution, the Company and bluebird bio. bio have operated separately, each as an independent public company and bluebird bio no longer owns any shares of the Company's common stock. Therefore, starting in 2023, transactions under those agreements are no longer accounted for as related party transactions. The Company recorded other income of $2.8 million for the year ended December 31, 2022 and an expense of $0.2 million for the two months since separation through December 31, 2021, related to the Separation Agreement.

The Company and bluebird bio also entered into a tax matters agreement, dated as of November 3, 2021, governing bluebird bio's and 2seventy bio's respective rights, responsibilities and obligations with respect to taxes (including taxes arising in the ordinary course of business and taxes, if any, incurred as a result of any failure of the distribution and certain related transactions to qualify as tax-free for U.S. federal income tax purposes, tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings, and assistance and cooperation in respect of tax matters).

In connection with the separation, the Company also entered into an employee matters agreement with bluebird bio, dated as of November 3, 2021. The employee matters agreement allocates assets, liabilities and responsibilities relating to the employment, compensation and employee benefits of bluebird bio and 2seventy bio employees, and other related matters, in connection with the separation, including the treatment of outstanding bluebird bio incentive equity awards and certain retirement and welfare benefit obligations. The employee matters agreement generally provides that, unless otherwise specified, 2seventy bio is responsible for liabilities associated with employees who

transfer to 2seventy bio and employees whose employment terminated prior to the distribution but who primarily supported the 2seventy bio business, and bluebird bio is responsible for liabilities associated with other employees, including employees retained by bluebird bio. Included in the agreement are also specific clauses relating to liabilities assumed by bluebird bio for the costs incurred prior to the separation. The Company recorded a reduction to operating expense of $0.2 million for the year ended December, 31, 2022 December 31, 2022 and $1.8 million for the two months since separation through to December 31, 2021 for costs stipulated by the employee matters agreement.

The Company and bluebird bio also entered into an intellectual property license agreement on November 3, 2021, pursuant to which each party granted a license to certain intellectual property and technology to the other. bluebird bio granted 2seventy bio a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to certain intellectual property to allow 2seventy bio to use such intellectual property in connection with 2seventy bio's ongoing and future research and development activities and product candidates. 2seventy bio granted bluebird bio a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to certain intellectual property for use in bluebird bio's existing products and product

candidates. Such licenses between the parties generally allow current or future uses of the intellectual property in connection with each party's respective fields. Charges associated to the intellectual property license agreement will commenced in 2022. As part of this agreement, the Company directly contacts and coordinates with bluebird bio's third party licensors to make direct payments to the third parties.

The Company and bluebird bio entered into two transition services agreements on November 3, 2021, pursuant to which bluebird bio will provide 2seventy bio with corporate and shared services and resources related to corporate functions, and to which 2seventy bio will provide certain services to bluebird bio, each for an initial term of two years, unless

earlier terminated or extended according to the terms of the transition services agreement. For the year ended December, 31, 2022, December 31, 2022, the Company recorded $10.0 million in other income, net, reflecting services provided to bluebird bio and $1.0 million of operating expenses for services received from bluebird bio. For the two months since separation through December 31, 2021, the Company recorded $1.4 million in other income, net and $0.7 million of operating expenses for services provided and received from bluebird bio, respectively.

Additionally, under the transition services agreements, 2seventy bio was subleasing 30% of its headquarters at 60 Binney Street in Cambridge, Massachusetts to bluebird bio through the first quarter of 2022. Beginning in the second quarter of 2022, this percentage decreased to 23% for the remainder of the year. The Company recorded $4.9 million for the year ended December, 31, 2022 December 31, 2022 and $0.8 million for the year ended December 31, 2021 in other income, net related to sublease income from bluebird under this arrangement.

As of December 31, 2022, amounts due to bluebird bio under the above agreements were $0.1 million and are included in accrued expenses. As of December 31, 2022, amounts due from bluebird bio under the above agreements were $1.9 million and were included in receivables and other current assets.

On February 23, 2023, the Company entered into a Partial Assignment and Assumption Agreement (the “Assignment and Assumption Agreement”) with Institut Pasteur (“Institut Pasteur”) and bluebird bio. Pursuant to the Assignment and Assumption Agreement, bluebird bio assigned to the Company bluebird bio’s rights, obligations and interests under a license agreement with Institut Pasteur that were previously licensed to the Company by bluebird bio under the License Agreement. The Company will pay Institut Pasteur an annual maintenance payment, a percentage of income received in the event of sublicensing arrangements and, upon commercialization of certain products, a percentage of net sales as a royalty, which varies depending on the indication of the product.

Corporate allocations

Prior to the separation, the Company did not operate as a separate, stand-alone entity, but rather was managed and operated in the normal course of business under bluebird bio. Accordingly, certain shared costs have been allocated to the Company and reflected as expenses in the Company's stand-alone consolidated and combined financial statements for periods prior to the separation. The expenses reflected in the consolidated and combined financial statements may not be indicative of expenses that will be incurred by the Company in the future.

For periods prior to the separation, year ended December 31, 2021, the consolidated and combined financial statements reflect allocations of certain expenses from bluebird bio, including, but not limited to, general corporate expenses, such as senior management, legal, human resources, accounting, other financial services (such as treasury, audit and purchasing), tax, information technology, and corporate employee benefits, incentives and stock-based compensation included within selling, general and administrative expense.

These expenses have been allocated to the Company based on direct usage or benefit where specifically identifiable, with the remainder allocated based on employee time spent on projects, square footage or other measures that management believes are consistent and reasonable. Allocations for management costs and corporate

support services provided to the Company totaled $55.3 million, and $76.6 million for the years year ended December 31, 2021, and 2020 respectively. .

The financial information in these consolidated and combined financial statements for periods prior to the separation does not necessarily include all the expenses that would have been incurred by the Company had it been a separate, stand-alone entity. Actual costs that may have been incurred if the Company had been a stand-alone company would depend on a number of factors, including the chosen organization structure and functions outsourced or performed by employees. See Note 2, *Summary of significant accounting policies and basis of presentation*, for additional information on the preparation and basis of presentation of these consolidated and

combined financial statements, including the treatment of certain research and development costs not directly attributable to individual programs.

Usage of the Company's assets by bluebird bio and of bluebird bio's assets by the Company prior to the separation

Certain assets have been reflected in these consolidated and combined financial statements as the underlying assets were attributed to the Company; however, bluebird bio has historically utilized a portion of the underlying asset as part of its operations. Accordingly, the expense related to the underlying asset has been reflected in the combined financial statements. The Company has also recorded an imputed charge to bluebird bio to reflect the cost of bluebird bio's proportional usage. In addition, the Company has recorded as an expense an imputed charge to reflect the cost of the Company's proportional usage of certain underlying assets not reflected in the consolidated and combined financial statements but for which the Company has historically utilized a portion of the underlying asset as part of its operations. The income and expense recognized by the Company for periods prior to the separation resulting from these imputed charges was recorded as other income, net in the combined financial statements and was as follows:

	Year ended December 31,	
	2021	2020
Imputed charge to bluebird bio for leases	$ 14,833	$ 16,562
Imputed charge from bluebird bio for leases	(908)	(1,072)
Imputed charge to bluebird bio for property, plant and equipment	1,891	2,225

Imputed charge from bluebird bio for property, plant and equipment	(1,130)	(229)
Imputed charge to bluebird bio for intangible assets	82	199
Other	(1)	155
	$ 14,767	$ 17,840

	Year ended December 31,
	2021
Imputed charge to bluebird bio for leases	$ 14,833
Imputed charge from bluebird bio for leases	(908)
Imputed charge to bluebird bio for property, plant and equipment	1,891
Imputed charge from bluebird bio for property, plant and equipment	(1,130)
Imputed charge to bluebird bio for intangible assets	82
Other	(1)
	$ 14,767

Other components of other income, net, that are not shown in the table above include immaterial gains and losses on disposals of fixed assets.

Stock-based compensation

As discussed in Note 13, *Stock-based compensation*, prior to the separation, 2seventy bio's employees participated in bluebird bio's stock-based compensation plans, the costs of which have been allocated to 2seventy bio and recorded in research and development and selling, general and administrative expenses in the consolidated and combined statements of operations and comprehensive loss.

Retirement plans

As discussed in Note 15, *401(k) Savings plan*, prior to the separation, 2seventy bio's employees participated in bluebird bio's 401(k) Savings plan, the costs of which have been allocated to 2seventy bio and recorded in research and development and selling, general and administrative expenses in the consolidated and combined statements of operations and comprehensive loss.

Transaction costs

Prior to the separation, bluebird bio had incurred costs related to the separation of the Company. To the extent separation costs are incurred that will directly benefit the Company as a stand-alone company, such costs were allocated to the Company.

Centralized cash management

Prior to the separation, no separate cash accounts for 2seventy bio were maintained and, therefore, bluebird bio was presumed to have funded 2seventy bio's operating, investing and financing activities as necessary. As cash was disbursed and received by bluebird bio, for purposes of the consolidated and combined financial statements, funding of 2seventy bio's expenditures was reflected in the consolidated and combined financial statements as a component of net parent investment.

15. 401(k) Savings plan

Prior to the spin-off, all 2seventy employees were covered by bluebird bio's defined-contribution savings plan under Section 401(k) of the Internal Revenue Code ("bluebird 401(k) Plan"), which was established in 1997. Upon spin-off, 2seventy bio established a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code ("2seventy 401(k) Plan"), which covers all employees who meet defined minimum age and service requirements, including those who became employees of the Company, and allows participants to defer a portion of their annual compensation on a pretax basis. Expense related to the bluebird and 2seventy 401(k) Plans for 2seventy employees totaled $3.2 million $3.1 million, $2.4 million $3.2 million, and $2.2 million $2.4 million for the years ended December 31, 2022 December 31, 2023, 2021, 2022, and 2020, 2021, respectively.

16. Income taxes

The Company did not operate as a separate, stand-alone entity for periods prior to the separation. The Company's statement of operations for periods prior to separation have been prepared on a carve out basis. The Company's income tax provision for the year years ended December 31, 2023 and December 31, 2022 and for the period from November 4, 2021 through December 31, 2021 has been prepared on a stand-alone basis. The 2020 and 2021 components component of loss before income taxes and rate reconciliation

are is presented for the full year period of activity, including for the portion of each period prior to the separation. Accordingly, the amount and composition of its tax losses, credits, and other deferred tax assets included in the consolidated and combined financial statements has changed as the result of the Company's separation from bluebird bio.

The components of loss before income taxes were as follows (in thousands):

	Year ended December 31,		
	2022	2021	2020
Domestic	$(254,153)	$(292,213)	$(120,114)
Foreign	—	—	—
Total	$(254,153)	$(292,213)	$(120,114)

	Year ended December 31,		
	2023	2022	2021
Domestic	$(254,153)	$(292,213)	$(120,114)
Foreign	—	—	—
Total	$(254,153)	$(292,213)	$(120,114)

The Company has not recorded a provision for federal or state income taxes as it has had cumulative net operating losses since inception.

For the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020, 2021, the Company did not recognize any income tax expense (benefit) as the Company was subject to a full valuation allowance. A reconciliation of income tax expense

(benefit) computed at the statutory federal income tax rate to the Company's effective income tax rate as reflected in the financial statements is as follows:

	Year ended December 31,		
	2022	2021	2020
Federal income tax expense at statutory rate	21.0 %	21.0 %	21.0 %
State income tax, net of federal benefit	6.6 %	0.6 %	3.8 %
Permanent differences	(0.2)%	— %	0.3 %
Stock-based compensation	(2.5)%	0.3 %	(4.1)%
Research and development credit	3.2 %	0.2 %	13.8 %
Officer compensation limitation	(1.2)%	(0.4)%	(1.6)%
Uncertain tax positions	(0.2)%	— %	(1.1)%
Other	(0.6)%	(1.1)%	— %
Change in tax rate	1.3 %	— %	— %
Change in valuation allowance	(27.4)%	64.8 %	(32.1)%
Separation adjustment	— %	(85.4)%	— %

	Year ended December 31,		
	2023	2022	2021
Federal income tax expense at statutory rate	21.0 %	21.0 %	21.0 %
State income tax, net of federal benefit	6.0 %	6.6 %	0.6 %
Permanent differences	(0.2) %	(0.2) %	— %
Goodwill	(1.2) %	— %	— %
Stock-based compensation	(9.2) %	(2.5) %	0.3 %
Research and development credit	5.3 %	3.2 %	0.2 %
Officer compensation limitation	4.0 %	(1.2) %	(0.4) %
Uncertain tax positions	(0.4) %	(0.2) %	— %
Other	0.7 %	(0.6) %	(1.1) %
Change in tax rate	(1.8) %	1.3 %	— %
Change in valuation allowance	(24.2) %	(27.4) %	64.8 %
Separation adjustment	— %	— %	(85.4) %

Effective income tax rate (expense) benefit	Effective income tax rate (expense) benefit	— %	— %	— %	Effective income tax rate (expense) benefit	— %	— %	— %

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities are composed of the following (in thousands):

	Year ended December 31,	
	2022	2021
Deferred tax assets:		
U.S. net operating loss carryforwards (federal and state)		
U.S. net operating loss carryforwards (federal and state)	$ 27,251	$12,142
Tax credit carryforwards (federal and state)	10,071	466
Capitalized license fees and research and development expenses	11,888	11,905
Deferred revenue	3,237	13,724
Stock-based compensation	16,719	15,824
Lease liabilities	73,719	71,941
Accruals and other	3,857	5,395
Capitalized research and development expenses	55,719	—
Total deferred tax assets	202,461	131,397
Intangible assets	—	(476)
Right-of-use assets	(65,181)	(69,693)
Fixed assets	(9,266)	(2,958)
Less: valuation allowance	(128,014)	(58,270)

	Year ended December 31,	
	2023	2022
Deferred tax assets:		
U.S. net operating loss carryforwards (federal and state)		
U.S. net operating loss carryforwards (federal and state)		
U.S. net operating loss carryforwards (federal and state)		
Tax credit carryforwards (federal and state)		
Capitalized license fees and research and development expenses		
Deferred revenue		
Stock-based compensation		
Lease liabilities		
Accruals and other		
Capitalized research and development expenses		
Total deferred tax assets		
Intangible assets		
Right-of-use assets		
Fixed assets		
Less: valuation allowance		

Net deferred taxes	Net deferred taxes	$ —	$ —

As of December 31, 2022 December 31, 2023, the Company had U.S. federal net operating loss carryforwards of approximately $96.1 million $143.4 million, which may be available to offset future income tax liabilities and which will carryforward indefinitely. As of December 31, 2022 December 31, 2023, the Company also had U.S. state net operating loss carryforwards of approximately $113.5 million $139.6 million, which may be available to offset future income tax liabilities and expire at various dates through 2042. 2043.

As of December 31, 2022 December 31, 2023, the Company had federal research and development and orphan drug tax credit carryforwards of approximately $8.1 million $19.7 million, available to reduce future tax liabilities which expire at various dates through 2042. 2043. As of December 31, 2022 December 31, 2023, the Company also had U.S. state research and development carryforwards of approximately $3.3 million $8.9 million, which may be available to offset future income tax liabilities and expire at various dates through 2037. 2038. An analysis of the U.S. research and development and orphan drug credits has not yet been completed. Until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended (the “Internal Revenue Code”), and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percent over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company’s stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company’s otherwise recognizable net deferred tax assets. With respect to the period from separation through December 31, 2022 December 31, 2023, the valuation allowance increased on a net basis by approximately $69.7 million $52.7 million primarily due to capitalization of R&D expenses and current year losses generated.

On December 22, 2017, the Tax Cuts and Jobs Act (“The TCJA”) was signed into law. Under the TCJA provisions, effective with tax years beginning on or after January 1, 2022, taxpayers can no longer immediately expense qualified research and development expenditures, including all direct, indirect, overhead, and software development costs. Taxpayers are now required to capitalize and amortize these costs over five years for research conducted within the United States or 15 years for research conducted abroad. As a result, the Company capitalized $232.1 million $203.4 million of research and development expenses for the year ended December 31, 2022 December 31, 2023.

The Company has no history of tax audits on a standalone basis and will regularly assesses assess the outcome of potential examinations in each of the taxing jurisdictions when determining the adequacy of the amount of unrecognized tax benefit recorded.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Unrecognized tax benefits
Balance as of December 31, 2020	4,403
Increases (decreases) for tax positions related to current period December 31, 2021	36
Increases (decreases) for tax positions as part of separation adjustment	(4,403)
Balance as of December 31, 2021	$ 36
Increases (decreases) for tax positions related to current period	713
Increases (decreases) for tax positions as part of separation adjustment	—
Balance as of December 31, 2022	$ 749
Increases (decreases) for tax positions related to current period	1,051
Increases (decreases) for tax positions as part of separation adjustment	—
Balance as of December 31, 2023	$ 1,800

The unrecognized tax benefits at December 31, 2022 is December 31, 2023 are not material and, if recognized, would not affect the Company’s effective tax rate due to its full valuation allowance position. The Company does not anticipate that the

amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. The Company has elected to include interest and penalties related to uncertain tax positions as a component of its provision for income taxes. For the year ended December 31, 2022 December 31, 2023, the Company's accrued interest and penalties related to uncertain tax positions were not material.

17. Net loss per share

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect (in thousands):

	Year ended December 31,		
	2022	2021	2020
Outstanding stock options (1)	2,562	1,490	—
Restricted stock units (1)	1,314	1,080	—
Employee Stock Purchase Plan	35	—	—
	3,911	2,570	—

Year ended December 31,		
2023	2022	2021
5,998		

(1) Outstanding stock options and restricted stock units include awards outstanding to employees of bluebird bio.

18. Corporate restructuring

In August 2023, the Company's board of directors approved a restructuring plan (the "Restructuring Plan") to conserve financial resources and better align the Company's workforce with current business needs. As part of the Restructuring Plan, the Company's workforce was reduced by approximately 40% in September 2023. The Restructuring Plan is substantially complete as of December 31, 2023.

In connection with the Restructuring Plan, the Company incurred $8.6 million of one-time costs relating to severance and retention packages and related benefits. These costs were recognized in the third quarter of 2023, in accordance with ASC 420, *Exit and Disposal Activities,* and are included in Restructuring expenses in the consolidated statement of operations and comprehensive loss. The following table summarizes the accrued liabilities activity recorded in connection with the Restructuring Plan as of December 31, 2023:

	As of December 31, 2023
Beginning balance	$ —
Total estimated expenses	8,614
Expenses paid from inception through December 31, 2023	(6,253)
Reversal of excess accrual through December 31, 2023	—
Remaining accrual at December 31, 2023 (1)	$ 2,361

This balance is included within accrued expense and other current liabilities on the condensed consolidated balance sheets.

19. Goodwill impairment

On June 30, 2014, bluebird bio acquired Pregenen. All assets and liabilities related to the Pregenen acquisition, including the resulting goodwill and contingent consideration, were attributed to the Company in connection with the separation from bluebird bio. Prior to the impairment test described further below, the balance of the Company's goodwill was $12.1 million. The Company operates in a single segment, focusing on researching, developing and commercializing potentially transformative treatments for cancer. Consistent with its operational structure, its chief operating decision maker manages and allocates resources for the Company at a consolidated level. Additionally, the Company determined that its single operating segment is also its only reporting unit. As such, the Company has

allocated its entire goodwill balance to its single reporting unit and the goodwill impairment test is completed at this level.

During the third quarter of 2023 and more recently, the Company experienced a sustained decline in the price of its common stock in part due to decreased external expectations for future *Abecma* sales resulting from increased competitive dynamics, which was considered a triggering event. Management concluded it was more likely than not that the fair value of its reporting unit is less than its carrying amount. The Company then performed a one-step quantitative test and recorded the amount of goodwill impairment as the excess of the reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit.

At September 30, 2023, the Company estimated the fair value of the Company's single reporting unit using both a market approach and an income approach. Major assumptions were applied in the income approach, including (i) forecasted growth rates (ii) forecasted profitability and (iii) discount rate. Considerable management judgment is necessary to evaluate the impact of operating changes and business initiatives on estimated future growth rates and profitability in order to estimate future cash flows.

Upon completing the impairment test, the Company determined that the estimated fair value of the reporting unit was less than its carrying value, thus indicating an impairment. The Company recognized a goodwill impairment charge of $12.1 million during the third quarter of 2023, which represented the entire goodwill balance prior to impairment charge.

The following table summarizes the activity of goodwill for the twelve months ended December 31, 2023 (in thousands):

	Balance at December 31, 2022	Additions	Deductions	Balance at December 31, 2023
Goodwill	$ 12,056	$ —	$ (12,056)	$ —

20. Subsequent events

In January 2023, Regeneron Transaction

On January 29, 2024, the Company entered into a Share an asset purchase agreement (the "Purchase Agreement") with Regeneron.Subject to the terms and conditions of the Purchase Agreement, the Company has agreed to sell to Regeneron (the "Asset Sale") substantially all of the assets related to its solid tumor and other oncology and autoimmune cell therapy programs (collectively, the "Programs" and such assets, the "Transferred Assets").Pursuant to the Purchase Agreement, in consideration for the Transferred Assets, at the closing of the Asset Sale (the "Closing"), which is expected in the first half of 2024, Regeneron will make an upfront payment to the Company of $5.0 million in cash and also assume certain liabilities of the Company arising after Closing, including liabilities related to the conduct of the Programs, under transferred contracts and with respect to certain of the Company's employees (collectively, the "Assumed Liabilities").Regeneron also agreed to sublease the Company's facilities in Seattle, Washington and a portion of the Company's facilities in Cambridge, Massachusetts.In addition to the upfront consideration, Regeneron has agreed to pay the Company a one-time $10.0 million milestone payment upon receipt of regulatory approval for the first product candidate within the Transferred Assets in certain specified countries and agreed-upon royalty payments based on net sales of the product candidates if commercialized.

The Purchase Agreement contains customary representations, warranties and covenants of each of the Company and Regeneron.The Purchase Agreement further provides that, subject to certain limitations, the Company and Regeneron will each indemnify the other for certain losses arising from such breaches of representations, warranties and covenants and liabilities allocated to such party pursuant to which the terms of the Purchase Agreement.Effective as of the Closing, the Regeneron Collaboration Agreement will terminate.

The Closing is subject to customary closing conditions, including, among others: (a) the absence of laws enjoining, making illegal or otherwise prohibiting the Asset Sale; (b) the accuracy of the other party's representations and warranties, subject to certain customary materiality standards;(c) compliance in all material respects by the other party with its obligations under the Purchase Agreement; and (d) no Material Adverse Effect (as defined in the Purchase Agreement) having occurred with respect to the Transferred Assets and Assumed Liabilities, taken as a whole, since the date of the Purchase Agreement.Upon the Closing, the parties will enter into certain ancillary agreements, including a transition services agreement, a license agreement and sublease agreements for the Company's facilities as described above.

Corporate Restructuring

The Board approved a strategic realignment and workforce reduction of approximately 14% on January 29, 2024 in connection with the Asset Sale. The workforce reduction is expected to be substantially complete by the end of the second quarter of 2024. In connection with the workforce reduction and restructuring, the Company sold 1,114,827 shares of its common stock, par value $0.0001 per share, expects to Regeneron for an aggregate incur one-time cash price costs of approximately $20.0 million. In addition, $8.0 million to $10.0 million, primarily in the first half of 2024, relating to severance and retention packages and related benefits. Non-cash expenses associated with the restructuring are not yet estimable. The estimates of non-cash expenses and cash costs that the Company expects to incur, and the timing thereof, are subject to a number of assumptions and actual results may differ. The Company may also entered into an amendment incur additional costs not currently contemplated due to its collaboration with Regeneron events that will facilitate an expanded and accelerated development plan for novel cell therapy-based combinations for solid tumors. The collaboration will leverage the Company's platform for T cell therapy research and development with Regeneron's antibodies and bispecifics. The parties will continue sharing costs for these activities in may occur as a manner largely consistent result of, or that are associated with, the existing agreement, with Regeneron covering 75% of certain preclinical costs necessary to study combinations and 100% of the costs for the arms of clinical studies that include Regeneron agents through regulatory approval. For other programs, cost-sharing will follow the existing 50/50 cost sharing agreement. actions described above.

In March 2023, the Company sold 10.9 million shares of common stock through an underwritten public offering at a price of $11.50 per share for aggregate gross proceeds, before deducting underwriting discounts and commissions and offering expenses, of approximately $125.0 million, excluding any exercise of the underwriter's option to purchase additional shares. The underwriters have a 30-day option to purchase up to an additional 1,630,434 shares of common stock.

EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of 2seventy bio, Inc. (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed on November 4, 2021).
3.2*	Amended and Restated Bylaws of 2seventy bio, Inc. Inc. (incorporated by reference to Exhibit 3.2 to Annual Report on Form 10-K filed on March 16, 2023).
4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 10.7 to Current Report on Form 8-K filed on November 4, 2021).
4.2	Description of Securities (incorporated by reference to Exhibit 4.4 to Annual Report on Form 10-K filed on March 22, 2022).
10.1#	2seventy bio, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.2 to Form S-8 filed on November 1, 2021).
10.2#	2seventy bio, Inc. 2021 Stock Option and Incentive Plan and forms of award agreement thereunder (incorporated by reference to Exhibit 99.1 to Form S-8 filed on November 1, 2021).
10.3#	2seventy bio, Inc. Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.3 to Annual Report on Form 10-K filed on March 22, 2022).
10.4	2seventy bio, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.4 to Annual Report on Form 10-K filed on March 22, 2022).
10.5#	Form of Indemnification Agreement between 2seventy bio, Inc. and individual directors (incorporated by reference to Exhibit 10.6 to Form 10 filed on October 8, 2021).
10.6†	Lease, dated September 21, 2015, by and between bluebird bio, Inc. and ARE-MA Region No. 40 LLC (incorporated by reference to Exhibit 10.22 to Form 10 filed on October 8, 2021).
10.7	First Amendment to Lease, dated June 21, 2016, by and between bluebird bio, Inc. and ARE-MA Region No. 40 LLC (incorporated by reference to Exhibit 10.23 to Form 10 filed on October 8, 2021).
10.8	Second Amendment to Lease, dated November 14, 2016, by and between bluebird bio, Inc. and ARE-MA Region No. 40 LLC (incorporated by reference to Exhibit 10.24 to Form 10 filed on October 8, 2021).
10.9#	Executive Employment Agreement between 2seventy bio, Inc. and Nick Leschly, dated as of November 3, 2021 (incorporated by reference to Exhibit 10.8 to Current Report on Form 8-K filed on November 4, 2021).
10.10#	Executive Employment Agreement between 2seventy bio, Inc. and William Baird, dated as of November 3, 2021 (incorporated by reference to Exhibit 10.9 to Current Report on Form 8-K filed on November 4, 2021).
10.11#	Executive Employment Agreement between 2seventy bio, Inc. and Philip Gregory, dated as of November 3, 2021 (incorporated by reference to Exhibit 10.10 to Current Report on Form 8-K filed on November 4, 2021).
10.12 10.1#	Letter Agreement between 2seventy bio, Inc. and Nicola Heffron, dated as of November 8, 2021 (incorporated by reference to Exhibit 10.12 to Annual Report on Form 10-K filed on March 22, 2022).
10.13# 2†	Executive Employment Agreement between Globalization Partners Switzerland SA and Nicola Heffron, dated as of December 1, 2021 (incorporated by reference to Exhibit 10.13 to Annual Report on Form 10-K filed on March 22, 2022).
10.14#	Amendment to Executive Employment Agreement between Globalization Partners Switzerland SA and Nicola Heffron, dated as of December 8, 2021 (incorporated by reference to Exhibit 10.14 to Annual Report on Form 10-K filed on March 22, 2022).
10.15#	First Addendum Executive Employment Agreement between Globalization Partners Switzerland SA and Nicola Heffron, dated as of March 7, 2022 (incorporated by reference to Exhibit 10.15 to Annual Report on Form 10-K filed on March 22, 2022).
10.16#	Second Addendum to Executive Employment Agreement between Globalization Partners Switzerland SA and Nicola Heffron, dated as of March 25, 2022 (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed on May 12, 2022).
10.17*#	Severance Agreement between Globalization Partners Switzerland SA and Nicola Heffron, dated February 17, 2023.
10.18*#	Consulting Agreement between 2seventy bio, Inc. and Nicola Heffron, dated February 21, 2023.

10.19†	Patent License Agreement, dated August 31, 2015, by and between bluebird bio, Inc. and the National Institutes of Health (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed on May 12, 2022)
10.20† 10.13†	Amendment to License Agreement, dated April 25, 2022, by and between 2seventy bio, Inc. and the National Institutes of Health Amendment to License Agreement, dated April 25, 2022, by and between 2seventy bio, Inc. and the National Institutes of Health (incorporated (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed on May 12, 2022).
10.21 10.14†	Second Amendment to License Agreement, dated January 16, 2024, by and between 2seventy bio, Inc. and the National Institutes of Health.
10.15	Form of Registration Rights Agreement, dated March 15, 2022, by and between 2seventy bio, Inc. and purchasers in the March 2022 private placement (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed on March 16, 2022).
10.22 16†	Amended and Restated License Agreement by and between bluebird bio, Inc. and Celgene Corporation, dated February 16, 2016 (incorporated by reference to Exhibit 10.14 to Form 10 filed on October 8, 2021).
10.23 17†	Second Amended and Restated License Agreement by and between bluebird bio, Inc. and Celgene Corporation and Celgene European Investment Company LLC, dated May 8, 2020 (incorporated by reference to Exhibit 10.15 to Form 10 filed on October 8, 2021).

10.24 18†	License Agreement, dated August 13, 2014, by and between bluebird bio, Inc. and Biogen Idec MA Inc. (incorporated by reference to Exhibit 10.17 to Annual Report on Form 10-K filed on March 22, 2022).
10.25 19†	Assumption Agreement by and between 2seventy bio, Inc. and bluebird bio, Inc. with respect to Securities Purchase Agreement, dated September 7, 2021, by and among bluebird bio, Inc. and the institutional investors named therein, and Registration Rights Agreement, dated September 7, 2021, by and among bluebir bio, Inc. and the persons listed on the attached Schedule A thereto (incorporated by reference to Exhibit 10.21 to Form 10 filed on October 8, 2021).
10.26 10.20	Tax Matters Agreement, dated as of November 3, 2021, by and between bluebird bio, Inc. and 2seventy bio, Inc. (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on November 4, 2021). November 4, 2021).
10.27 10.21	Intellectual Property License Agreement, dated as of November 3, 2021, by and between bluebird bio, Inc. and 2seventy bio, Inc. (incorporated by reference to Exhibit 10.3 10.3 to Current Current Report on Form 8-K filed on November 4, 2021).
10.28 10.22	Employee Matters Agreement, dated as of November 3, 2021, by and between bluebird bio, Inc. and 2seventy bio, Inc. (incorporated by reference to Exhibit 10. to Current Report on Form 8-K filed on November 4, 2021).
10.29 10.23	Transition Services Agreement, dated as of November 3, 2021, by and between bluebird bio, Inc. and 2seventy bio, Inc. (incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K filed on November 4, 2021).
10.30 10.24	Transition Services Agreement, dated as of November 3, 2021, by and between 2seventy bio, Inc. and bluebird bio, Inc. (incorporated by reference to Exhibit 10.5 to Current Report on Form 8-K filed on November 4, 2021).
10.25†	License Agreement by and between bluebird bio, Inc. and Institut Pasteur, dated September 8, 2011, as amended (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed on May 10, 2023).
10.26	Second Amendment to Amended and Restated Co-Development, Co-Promote and Profit Share Agreement, between 2seventy bio, Inc., Celgene Corporation and Celgene Investment Company LLC, dated June 23, 2023 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed on August 14, 2023).
10.27#	Transitional Services Agreement between 2seventy bio, Inc. and Nick Leschly, dated as of January 29, 2024 (incorporated by reference to Exhibit 10.1 to Currer Report on Form 8-K filed on January 30, 2024).
10.28#	Executive Employment Agreement between 2seventy bio, Inc. and William Baird, dated as of January 29, 2024 (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed on January 30, 2024).
10.29#	Executive Employment Agreement between 2seventy bio, Inc. and Victoria Eatwell, dated as of January 29, 2024 (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed on January 30, 2024).
19.1*	Insider Trading Policy.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Compensation Recovery Policy, effective as of September 26, 2023.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document

101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 and 32.2 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

# Indicates a management contract or compensatory plan, contract or arrangement.

† Portions of this exhibit (indicated by asterisks) were omitted in accordance with the rules of the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 16, 2023 March 7, 2024

2seventy bio, Inc.

By: /s/ Nick Leschly

Nick Leschly

President and Chief Executive Officer

Each person whose individual signature appears below hereby authorizes and appoints Nick Leschly, William D. Baird, and Teresa Jurgensen, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on March 16, 2023 March 7, 2024.

SIGNATURE	TITLE
/s/ Nick Leschly Nick Leschly	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Chip William D. Baird William D .Baird, D. Baird, III	Chief Financial Operating Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ Daniel S. Lynch Daniel S. Lynch	DirectorChair of the Board
/s/ Sarah Glickman Sarah Glickman	Director
/s/ Ramy Ibrahim, M.D. Ramy Ibrahim, M.D.	Director
/s/ Denice Torres Denice Torres	Director
/s/ Marcela Maus, M.D., Ph.D. Marcela Maus, M.D., Ph.D.	Director
/s/ Wei Lin, M.D. Wei Lin, M.D.	Director

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

AMENDED AND RESTATED NATIONAL INSTITUTES OF HEALTH

BY-LAWS

OF

2SEVENTY BIO, INC.

(the "Corporation")

ARTICLE I

Stockholders SECOND AMENDMENT TO [***]

SECTION [***] No.: [***]

This is the second amendment ("**Second Amendment**") of the agreement by and between the National Institutes of Health ("**NIH**") within the Department of Health and Human Services ("**HHS**"), and 2seventy bio, Inc. ("**Licensee**") having an effective date of August 31, 2015, and having **NIH** Reference Number [***], together with the **First Amendment** having an effective date of April 25, 2022 (the "**Agreement**"), and having **NIH** Reference Number [***]. This **Second Amendment**, having **NIH** Reference Number [***], is made between the **NIH** through the Office of Technology Transfer, having an address at 6701 Rockledge Drive, Suite 700, MS 7788, Bethesda, Maryland 20892 and **Licensee** having an address at 60 Binney St., Cambridge, MA 02142. This **SecondAmendment** includes, in addition to the amendments made below, 1) a Signature Page, and 2) Attachment 1 (Royalty Payment Information).

WHEREAS, the **NIH** and the **Licensee** desire that the **Agreement** be amended a second time as set forth below in order to modify the terms that relate to royalty payments.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, the **NIH** and the **Licensee**, intending to be bound, hereby mutually agree to the following:

1) Appendix C, Section III (a) shall be amended and restated in its entirety as follows:

"The **Licensee** agrees to pay the **NIH** tiered royalties on annual **Net Sales** by or on behalf of the **Licensee** and its sublicensees, as follows:

(1) For annual **Net Sales** up to and including [***], the **Licensee** agrees to pay the **NIH** earned royalties of [***]; and

(2) For annual **Net Sales** more than [***] up to and including [***], the **Licensee** agrees to pay the **NIH** earned royalties of [***]; and

(3) For annual **Net Sales** more than [***] up to and including [***], the **Licensee** agrees to pay the **NIH** earned royalties of [***]; and

(4) For annual **Net Sales** more than [***], the **Licensee** agrees to pay the **NIH** earned royalties of [***].

1) Within sixty (60) days after its execution of this **Second Amendment**, the **Licensee** shall pay an additional royalty to the **NIH** in the amount of [***] for **Net Sales** made between the August 31, 2015 and September 30, 2023.

2) Within sixty (60) days after its execution of this **Second Amendment**,the **Licensee** shall pay the **NIH** an amendment issue royalty in the sum of [***], and payment options may be found in Attachment 1.

Annual Meeting 3) . In the event any provision(s) of the **Agreement** is/are inconsistent with Attachment 1, such provision(s) is/are hereby amended to the extent required to avoid such inconsistency and to give effect to the payment information in such Attachment 1.

4) All terms and conditions of the **Agreement** not herein amended remain binding and in effect.

5) The annual meeting terms and conditions of stockholders (any such meeting being this **SecondAmendment** shall, at the **NIH's** sole option, be considered by the **NIH** to be withdrawnfrom the **Licensee's** consideration and the terms and conditions of this **Second Amendment**,and the **SecondAmendment** itself, to be null and void,unless this **Second Amendment** is executedby the **Licensee** and a fully executed original is received by the **NIH** within sixty (60) days from the date of the **NIH's** signature found at the Signature Page.

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

6) This **SecondAmendment** is effective as October 1, 2023.

SIGNATURES BEGIN ON NEXT PAGE

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SECOND AMENDMENT TO [***]

SIGNATURE PAGE

In Witness Whereof, the parties have executed this **SecondAmendment** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the **NIH**:

/s/ Richard U. Rodriguez January 16, 2024
Richard U. Rodriguez, M.B.A. Date
Associate Director, Technology Transfer Center
National Cancer Institute
National Institutes of Health

Address for **Agreement** notices and reports:

E-mail: LicenseNotices_Reports@mail.nih.gov (preferred)

Mail: License Compliance and Administration
Monitoring & Enforcement
Office of Technology Transfer
National Institutes of Health
6701 Rockledge Drive, Suite 700, MS 7788
Bethesda, Maryland 20892
(For courier deliveries please check https://www.ott.nih.gov/licensing/license-noticesreports)

For the **Licensee** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in these By-laws this document are truthful and accurate.):

/s/ Teresa Jurgensen January 16, 2024
Teresa Jurgensen Date
SVP, General Counsel

I. Official and Mailing Address for **Agreement** notices:

[***]

2seventy bio, Inc.
60 Binney St.
Cambridge, MA 02142
Email Address: [***]
Phone: [***]

II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments):

[***]

2seventy bio, Inc.
60 Binney St.
Cambridge, MA 02142
Email Address: [***]

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Phone: [***]

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal

liability including fine(s) or imprisonment).

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ATTACHMENT 1 – ROYALTY PAYMENT OPTIONS
New Payment Options Effective March 2018

[***]

Agency Contacts:

[***]

INSIDER TRADING POLICY

PURPOSE

The policy of 2seventy bio, Inc. (the "**Company**") is that it will comply with all applicable laws and regulations in conducting its business. Each employee and each officer and director of the Company is expected to abide by this policy. This "**Insider Trading Policy**" covers the trading in the Company's securities and the disclosure and use of information concerning the Company and the trading of other companies' securities based on material nonpublic information gained in connection with a person's relationship with the Company. This Insider Trading Policy is designed to prevent insider trading or the appearance of impropriety, to satisfy the Company's obligation to reasonably supervise the activities of Company personnel, and to help the Company and Company personnel avoid the severe consequences associated with violations of insider trading laws. The Company has designated its General Counsel as its insider trading compliance officer (the "**Insider Trading Compliance Officer**"). It is your obligation to understand and comply with this Insider Trading Policy. Please contact Insider Trading Compliance Officer, c/o 2seventy bio, Inc., 60 Binney Street, Cambridge, MA 02142 if you have any questions regarding the policy.

WHO IS COVERED BY THIS INSIDER TRADING POLICY?

This Insider Trading Policy is applicable to the Company's directors, officers, employees (regardless of role or title), consultants, contract workers and temporary staff worldwide, and their affiliated persons described below (collectively, "**Insiders**"), and continues to apply following the termination of any such individual's service to or employment with the Company until any material nonpublic ("material" and "nonpublic" are each defined below) information possessed by such individual has become public or is no longer material. The same restrictions that apply to you also apply to the following "**Affiliated Persons**":

- Your spouse, child, parent, significant other or other family member, in each case, living in the same household;
- all trusts, family partnerships and other types of entities formed for your benefit or the benefit of your family members over which you have the ability to influence or direct investment decisions concerning securities;
- all persons who execute trades on your behalf; and
- all investment funds, trusts, retirement plans, partnerships, corporations, and other types of entities over which you have the ability to influence or direct investment decisions concerning securities.

You are responsible for ensuring compliance with this Insider Trading Policy by all your Affiliated Persons. Unless the context otherwise requires, references to "you" or to "Insiders" in this Insider Trading Policy refer collectively to you and your Affiliated Persons.

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T IS PROHIBITED INSIDER TRADING?

The U.S. securities laws regulate the sale and purchase of securities in the interest of protecting the investing public. U.S. securities laws give the Company, its officers and directors, and other employees the responsibility to ensure that information about the Company is not used unlawfully in the purchase and sale of securities. The general rule can be stated as follows: It is a violation of the U.S. securities laws for any person to buy or sell securities if he or she is in possession of material nonpublic information. Information is material if there is a substantial likelihood that a reasonable investor would consider it important in making an investment decision. It is nonpublic information if it has not been publicly disclosed in a manner making it available to investors generally or a broad-based non-exclusionary basis in accordance with the U.S. securities laws. Furthermore, it is illegal for any person in possession of material nonpublic information to provide such information to others who may trade on the basis of that information (referred to as "**tipping**"). In that the case of tipping, both parties may be held liable. These prohibited activities are commonly referred to as "insider trading".

When you know or are in possession of material nonpublic information about the Company, you are prohibited from the following activities (except as otherwise provided in this Insider Trading Policy):

- trading in the Company's securities, which includes common stock, options to purchase common stock, any other type of securities that the Company may issue (such as preferred stock, convertible debentures, warrants, exchange-traded options, or other derivative securities), and any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities;
- having others trade in the Company's securities for you;
- giving trading advice of any kind about the Company; and
- disclosing any material, nonpublic information about the Company to anyone else.

In addition, it is the policy of the Company that if you, in the course of working for the Company, learn of any material, nonpublic information about a company (e.g., a licensor, collaboration partner, supplier or other party with which the Company is negotiating a transaction, such as an "Annual Meeting") shall acquisition, investment or sale), you may not trade in that company's securities or disclose such information until the information becomes public or is no longer material.

As noted above, these prohibitions also apply to your Affiliated Persons. These prohibitions continue whenever and for as long as you know or are in possession of material, nonpublic information. Remember, anyone scrutinizing your transactions will be held at doing so after the hour, date fact, with the benefit of hindsight. As a practical matter, before engaging in any transaction, you should carefully consider how enforcement authorities and place within others might view the transaction in hindsight.

is meant by a "trade"?

This Insider Trading Policy applies to any and all transactions in the Company's securities or, in certain instances, the securities of other companies, including its common stock, options to purchase common stock, any other type of securities that a company may issue (such as preferred stock, convertible debentures, warrants, exchange-traded options or other derivative securities), and any derivative securities that provide the economic equivalent of ownership of any of a company's securities or an opportunity, direct or indirect, to profit from any change in the value of a company's securities.

Gifts are subject to the same restrictions as all other trades. No Insider may give or make any other transfer of securities without consideration (e.g., a gift) during a period when the United States which Insider is fixed not permitted to trade.

is material nonpublic information?

Material information. Information about the Company is "material" if it could reasonably be expected to affect the investment or voting decisions of a stockholder or investor, or if the disclosure of the information could reasonably be expected to significantly alter the total mix of information in the marketplace about the Company. In other words, material information is any type of information that could reasonably be expected to affect the market price of the Company's securities. Both positive and negative information may be material. While it is not possible to identify all information that would be deemed "material," the following items are types of information that should be considered carefully to determine whether they are material:

- information related to clinical trials or the expected timing of announcing the results of such trials;
- information related to decisions by regulatory authorities regarding the Company's product candidates;
- projections of future earnings or losses, or other earnings guidance;
- projections of future non-financial key business metrics;
- earnings or revenue that are inconsistent with the consensus expectations of the investment community;
- potential restatements of the Company's financial statements, changes in auditors or auditor notification that the Company may no longer rely on an auditor's audit report;
- pending or proposed mergers, acquisitions, tender offers, joint ventures, or dispositions of significant assets;
- changes in management or the Board of Directors which time, date (the "**Board of Directors**");
- actual or threatened litigation or governmental investigations or major developments in such matters;
- developments regarding product candidates, customers, suppliers, orders, contracts, or financing sources;
- changes in dividend policy, declarations of stock splits, or public or private sales of additional securities;
- potential defaults under the Company's credit agreements or indentures, or the existence of material liquidity deficiencies; and place may subsequently

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- bankruptcies or receiverships.

The Securities and Exchange Commission (the "**SEC**") has stated that there is no fixed quantitative threshold amount for determining materiality, and that even very small quantitative changes can be changed at any time by vote qualitatively material if they would result in a movement in the price of the Board Company's securities.

Nonpublic information. Material information is "nonpublic" if it has not been disseminated in a manner making it available to investors generally. To show that information is public, it is necessary to point to some fact that establishes that the information has become publicly available, such as the filing of Directors. If no Annual Meeting a report with the SEC, the distribution of a press release through a widely disseminated news or wire service, or by other means that are reasonably designed to provide broad public access. Before a person who possesses material, nonpublic information can trade, there also must be adequate time for the market as a whole to absorb the information that has been held for a period of thirteen (13) months after the Corporation's last Annual Meeting, a special meeting in lieu thereof may be held, and such special meeting shall have, for disclosed. For the purposes of this Insider Trading Policy, information will be considered public after the close of trading on the first full trading day following the Company's public release of the information. For example, if the Company announces material information of which you are aware before trading begins on a Tuesday, the first time you can buy or sell Company securities is the opening of the market on Wednesday. However, if the Company announces this material information after trading begins on that Tuesday, the first time that you can buy or sell Company securities is the opening of the market on Thursday.

Other companies' stocks. The prohibition on illegal insider trading in this Insider Trading Policy is not limited to trading in the Company's own securities. It also includes trading in the securities of other entities, such as material licensors, collaboration partners, and suppliers of the Company, and entities with which the Company may be negotiating major transactions, such as an acquisition, investment, or sale. Insiders should be aware that information that is not material to the Company may nevertheless be material to one of these By-laws or otherwise, all the force and effect other entities.

LOYEE BENEFIT PLANS

Exercise of Stock Options. The exercise of an Annual Meeting. Any option to purchase securities of the Company when payment of the exercise price is made in cash is not subject to trading restrictions under this Insider Trading Policy. However, the securities acquired upon the exercise of an option to purchase Company securities are subject to all of the requirements and applicable restrictions under this Insider Trading Policy. Moreover, this Insider Trading Policy applies to the use of outstanding Company securities to constitute part or all references hereafter of the exercise price of an option, any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option (whether net proceeds are received in these By-laws to an Annual Meeting cash or Annual Meetings also shall be deemed to refer to any special meeting(s) in lieu thereof. shares).

SECTION 2. Notice of Stockholder Business Restricted stock and Nominations similar awards.
(a) Annual Meetings of Stockholders.

(1) Nominations of persons for election to the Board of Directors of the Corporation The trading prohibitions and the proposal of other business to be considered by the stockholders may be brought before an Annual Meeting (i) by or at the direction of the Board of Directors or (ii) by any stockholder of the Corporation who was a stockholder of record at the time of giving of notice provided for in this By-law, who is entitled to vote at the meeting, who is present (in person or by proxy) at the meeting and who complies with the notice procedures restrictions set forth in this By-law Insider Trading Policy do not apply to the withholding by the Company of shares of restricted stock units upon vesting to satisfy applicable tax withholding requirements or any automatic sell-to-cover transaction in which the holder does not have any discretion as to the sale in accordance with the Company's payroll policy or otherwise.

Employee Stock Purchase Plan*.* Thetrading prohibitions and restrictions set forth in this Insider Trading Policy do not apply to periodic wage withholding contributions by the Company or employees of the Company which are used to purchase the Company's securities pursuant to

the employees' advance instructions under the Company's Employee Stock Purchase Plan. However, no Insider may: (a) elect to participate in the plan or alter his or her instructions regarding the level of withholding or purchase by the Insider of Company securities under such nomination plan; or business. For (b) make cash contributions to such plan (other than through periodic wage withholding) without complying with this Insider Trading Policy. Any sale of securities acquired under such plan is subject to the avoidance prohibitions and restrictions of doubt, this Insider Trading Policy.

CIAL BLACKOUTS, QUARTERLY BLACKOUTS AND PRECLEARANCE

ers may not trade during applicable blackout periods

Special blackout periods. There are times when Insiders may become aware of a potentially material, nonpublic development. Although an Insider may not know the foregoing clause (ii) specifics of such development, if an Insider engages in a trade before it is disclosed to the public or resolved, the Insider and the Company might be exposed to a charge of insider trading that could be costly and difficult to refute. Therefore, Insiders may not trade in Company securities if they are notified by the Insider Trading Compliance Officer of a "special blackout period" due to the existence of a potentially material, nonpublic development. The Insider Trading Compliance Officer will subsequently notify the affected Insiders once the potentially material, nonpublic development is disclosed to the public or resolved. While the Insider Trading Compliance Officer will undertake reasonable efforts to notify affected Insiders that they may be aware of material, nonpublic information, it is each Insider's individual duty to ensure that they do not make any trade in Company securities when material, nonpublic information exists. It is anticipated that there will be times when trading is restricted despite an Insider's not receiving prior notice of special blackout periods. Information within the Company which is judged to be material and non-public is likely to change from time to time and it is not intended that special blackout periods be initiated for every such instance when material nonpublic information exists.

Financial Insiders may not trade during quarterly blackout periods. To avoid the appearance of trading on the basis of material nonpublic information, Insiders who are designated "**Financial Insiders**" may not trade in the Company's securities during the period beginning fifteen (15) days before the close of each fiscal quarter and continuing until the close of trading on the first full trading day following the release of the Company's earnings for that quarter. Financial Insiders shall be notified of their status by the exclusive means Insider Trading Compliance Officer.

ricted Insiders are subject to preclearance

Restricted Insiders must preclear trades. Insiders who are designated "**Restricted Insiders**" , which will include all executive officers and directors, may only trade in Company securities if the trade has been approved by the Insider Trading Compliance Officer (or designee) using the attached preclearance form or through the equity plan administration website interface (currently Solium Shareworks). The Insider Trading Compliance Officer will receive approval for his/her own trades from the Company's Chief Executive Officer (the "**CEO**").

The existence of the preclearance approval procedures does not in any way obligate the Insider Trading Compliance Officer to approve any trade requested by an Insider. The Insider Trading Compliance Officer may reject any trading request at his or her sole discretion. From time to

time, an event may occur that is material to the Company and is known by only a stockholder few Insiders. So long as the event remains material and nonpublic, the Insider Trading Compliance Officer may determine not to bring nominations approve any transactions in Company securities. If Restricted Insider requests clearance to trade in the Company's securities during the pendency of such an event, the Insider Trading Compliance Officer may reject the trading request without disclosing the reason.

After receiving written clearance to engage in a trade signed by the Insider Trading Compliance Officer, an Insider must complete the proposed trade within two (2) business days or business properly before make a new preclearance request.

Pre-Approved Rule 10b5-1 Trading Plans. Transactions made pursuant to an Annual Meeting (other than matters properly brought under approved Rule 14a-8 (or any successor rule) under 10b5-1 Trading Plan (as defined below) will not be subject to our trading windows, retirement plan blackout periods or pre-clearance procedures, and Insiders are not required to complete a Preclearance Request Form for such transactions. Rule 10b5-1 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), and such stockholder must comply with provides an affirmative defense from insider trading liability under the notice and other procedures set forth in Article I, Section 2(a)(2) and (3) of this By-law to bring such nominations federal securities laws for trading plans, arrangements or business properly before an Annual Meeting. In addition to instructions that meet specified requirements. A trading plan, arrangement or instruction that meets the other requirements set forth in this By-law, for any proposal of business to be considered at an Annual Meeting, it must be a proper subject for action by stockholders of the Corporation under Delaware law. SEC's Rule 10b5-1 (a "**Rule 10b5-1 Trading Plan**") enables Insiders to trade in Company securities outside of our trading windows, even when in possession of material nonpublic information.

(2) For nominations or other business to be properly brought before an Annual Meeting by The Company has adopted a stockholder pursuant to clause (ii) of Article I, Section 2(a)(1) of this By-law, separate Rule 10b5-1 Trading Plan policy that sets forth the stockholder must (i) have given Timely Notice (as defined below) thereof requirements for putting in writing to the Secretary of the Corporation, (ii) have provided any updates or supplements to such notice at the times and in the forms required by this By-law and (iii) together with the beneficial owner(s), if any, on whose behalf the nomination or business proposal is made, have acted in accordance with the representations set forth in the Solicitation Statement (as defined below) required by this By-law. To be timely, place a stockholder's written notice shall be received by the Secretary at the principal executive offices of the Corporation not later than the close of business on the ninetieth (90th) day nor earlier than the close of business on the one hundred twentieth (120th) day prior to the

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one-year anniversary of the preceding year's Annual Meeting; provided, however, that in the event the Annual Meeting is first convened more than thirty (30) days before or more than sixty (60) days after such anniversary date, or if no Annual Meeting were held in the preceding year, notice by the stockholder to be timely must be received by the Secretary of the Corporation not later than the close of business on the later of the ninetieth (90th) day prior to the scheduled date of such Annual Meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made (such notice within such time periods shall be referred to as "Timely Notice"). Notwithstanding anything to the contrary provided herein, for the first Annual Meeting of the Corporation, a stockholder's notice shall be timely if received by the Secretary at the principal executive offices of the Corporation not later than the close of business on the later of the ninetieth (90th) day prior to the scheduled date of such Annual Meeting or the tenth (10th) day following the day on which public announcement of the date of such Annual Meeting is first made or sent by the Corporation. Such stockholder's Timely Notice shall set forth:

(A) as to each person whom the stockholder proposes to nominate for election or reelection as a director, all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to Regulation 14A under the Exchange Act (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected);

(B) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting, and any material interest in such business of each Proposing Person (as defined below);

(C) (i) the name and address of the stockholder giving the notice, as they appear on the Corporation's books, and the names and addresses of the other Proposing Persons (if any) and (ii) as to each Proposing Person, the following information: (a) the class or series and number of all shares of capital stock of the Corporation which are, directly or indirectly, owned beneficially or of record by such Proposing Person or any of its affiliates or associates (as such terms are defined in Rule 12b-2 promulgated under the Exchange Act), including any shares of any class or series of capital stock of the Corporation as to which such Proposing Person or any of its affiliates or associates has a right to acquire beneficial ownership at any time in the future, (b) all Synthetic Equity Interests (as defined below) in which such Proposing Person or any of its affiliates or associates, directly or indirectly, holds an interest including a description of the material terms of each such Synthetic Equity Interest, including without limitation, identification of the counterparty to each such Synthetic Equity Interest and disclosure, for each such Synthetic Equity Interest, as to (x) whether or not such Synthetic Equity Interest conveys any voting rights, directly or indirectly, in such shares to such Proposing Person, (y) whether or not such Synthetic Equity

Interest is required to be, or is capable of being, settled through delivery of such shares and (z) whether or not such Proposing Person and/or, to the extent known, the counterparty to such Synthetic Equity Interest has entered into other transactions that hedge or mitigate the economic effect of such Synthetic Equity Interest, (c) any proxy (other than a revocable proxy given in response to a public proxy solicitation made pursuant to, and in accordance with, the Exchange Act), agreement, arrangement, understanding or relationship pursuant to which such Proposing Person has or shares a right to, directly or indirectly, vote any shares of any class or series of capital stock of the Corporation, (d) any rights to dividends or other distributions on the shares of any class or series of capital stock of the Corporation, directly or indirectly, owned beneficially by such Proposing Person that are separated or separable from the underlying shares of the Corporation, and (e) any performance-related fees (other than an asset based fee) that such Proposing Person, directly or indirectly, is entitled to based on any increase or decrease in the value of shares of any class or series of capital stock of the Corporation or any Synthetic Equity Interests (the disclosures to be made pursuant to the foregoing clauses (a) through (e) are referred

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to, collectively, as “Material Ownership Interests”) and (iii) a description of the material terms of all agreements, arrangements or understandings (whether or not in writing) entered into by any Proposing Person or any of its affiliates or associates with any other person for the purpose of acquiring, holding, disposing or voting of any shares of any class or series of capital stock of the Corporation;

(D) (i) a description of all agreements, arrangements or understandings by and among any of the Proposing Persons, or by and among any Proposing Persons and any other person (including with any proposed nominee(s)), pertaining to the nomination(s) or other business proposed to be brought before the meeting of stockholders (which description shall identify the name of each other person who is party to such an agreement, arrangement or understanding), and (ii) identification of the names and addresses of other stockholders (including beneficial owners) known by any of the Proposing Persons to support such nominations or other business proposal(s), and to the extent known the class and number of all shares of the Corporation’s capital stock owned beneficially or of record by such other stockholder(s) or other beneficial owner(s); and

(E) a statement whether or not the stockholder giving the notice and/or the other Proposing Person(s), if any, will deliver a proxy statement and form of proxy to holders of, in the case of a business proposal, at least the percentage of voting power of all of the shares of capital stock of the Corporation required under applicable law to approve the proposal or, in the case of a nomination or nominations, at least the percentage of voting power of all of the shares of capital stock of the Corporation reasonably believed by such Proposing Person to be sufficient to elect the nominee or nominees proposed to be nominated by such stockholder (such statement, the “Solicitation Statement”).

For purposes of this Article I of these By-laws, the term “Proposing Person” shall mean the following persons: (i) the stockholder of record providing the notice of nominations or business proposed to be brought before a stockholders’ meeting, and (ii) the beneficial owner(s), if different, on whose behalf the nominations or business proposed to be brought before a stockholders’ meeting is made. For purposes of this Section 2 of Article I of these By-laws, the term “Synthetic Equity Interest” shall mean any transaction, agreement or arrangement (or series of transactions, agreements or arrangements), including, without limitation, any derivative, swap, hedge, repurchase or so-called “stock borrowing” agreement or arrangement, the purpose or effect of which is to, directly or indirectly: (a) give a person or entity economic benefit and/or risk similar to ownership of shares of any class or series of capital stock of the Corporation, in whole or in part, including due to the fact that such transaction, agreement or arrangement provides, directly or indirectly, the opportunity to profit or avoid a loss from any increase or decrease in the value of any shares of any class or series of capital stock of the Corporation, (b) mitigate loss to, reduce the economic risk of or manage the risk of share price changes for, any person or entity 10b5-1 Trading Plan with respect to any shares of any class or series of capital stock of the Corporation, (c) otherwise provide in any manner the opportunity to profit or avoid a loss from any decrease in the value of any shares of any class or series of capital stock of the Corporation, or (d) increase or decrease the voting power of any person or entity with respect to any shares of any class or series of capital stock of the Corporation. Company securities.

(3) A stockholder providing Timely Notice of nominations or business proposed to be brought before an Annual Meeting shall further update Reporting Obligations and supplement such notice, if necessary, so that the information (including, without limitation, the Material Ownership Interests information) provided or required to be provided in such notice pursuant to this By-law shall be true and correct as of the record date for the meeting and as of the date that is ten (10) business days prior to such Annual Meeting, and such update and supplement shall be received by the Short-Swing Transactions.

Secretary at the principal executive offices of the Corporation not later than the close of business on the fifth (5th) business day after the record date for the Annual Meeting (in the case of the update and supplement required to be made as of the record date), and not later than the close of business on the eighth (8th) business day prior to the date of the Annual Meeting (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting).

(4) Notwithstanding anything in the second sentence of Article I, Section 2(a)(2) of this By-law to the contrary, in the event that the number of directors to be elected to the Board of Directors of the Corporation is increased and there is no public announcement naming all of the nominees for director or specifying the size of the increased Board of Directors made by the Corporation at least ten (10) days before the last day a stockholder may deliver a notice of nomination in accordance with the second sentence of Article I, Section 2(a)(2), a stockholder's notice required by this By-law shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be received by the Secretary of the Corporation not later than the close of business on the tenth (10th) day following the day on which such public announcement is first made by the Corporation.

(b) General.

(1) Only such persons who are nominated in accordance with the provisions of this By-law shall be eligible for election and to serve as directors and only such business shall be conducted at an Annual Meeting as shall have been brought before the meeting in accordance with the provisions of this By-law or in accordance with Rule 14a-8 under the Exchange Act. The Board of Directors or a designated committee thereof shall have the power to determine whether a nomination or any business proposed to be brought before the meeting was made in accordance with the provisions of this By-law. If neither the Board of Directors nor such designated committee makes a determination as to whether any stockholder proposal or nomination was made in accordance with the provisions of this By-law, the presiding officer of the Annual Meeting shall have the power and duty to determine whether the stockholder proposal or nomination was made in accordance with the provisions of this By-law. If the Board of Directors or a designated committee thereof or the presiding officer, as applicable, determines that any stockholder proposal or nomination was not made in accordance with the provisions of this By-law, such proposal or nomination shall be disregarded and shall not be presented for action at the Annual Meeting.

(2) Except as otherwise required by law, nothing in this Article I, Section 2 shall obligate the Corporation or the Board of Directors to include in any proxy statement or other stockholder communication distributed on behalf of the Corporation or the Board of Directors information with respect to any nominee for director or any other matter of business submitted by a stockholder.

(3) Notwithstanding the foregoing provisions of this Article I, Section 2, if the nominating or proposing stockholder (or a qualified representative of the stockholder) does not appear at the Annual Meeting to present a nomination or any business, such nomination or business shall be disregarded, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Article I, Section 2, to be considered a qualified representative of the proposing stockholder, a person must be authorized by a written instrument executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such written instrument or electronic transmission, or a reliable reproduction of the written instrument or electronic transmission, to the presiding officer at the meeting of stockholders.

(4) For purposes of this By-law, "public announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news

service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act.

(5) Notwithstanding the foregoing provisions of this By-law, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations thereunder with respect to the matters set forth in this By-law. Nothing in this By-law shall be deemed to affect any rights of (i) stockholders to have proposals included in the Corporation's proxy statement pursuant to Rule 14a-8 (or any successor rule), as applicable, under the Exchange Act and, to the extent required by such rule, have such proposals considered and voted on at an Annual Meeting or (ii) the holders of any series of Undesignated Preferred Stock to elect directors under specified circumstances.

SECTION 3. Special Meetings. Except as otherwise required by statute and subject to the rights, if any, of the holders of any series of Undesignated Preferred Stock, special meetings of the stockholders of the Corporation may be called only by the Board of Directors acting pursuant to a resolution approved by the affirmative vote of a majority of the Directors then in office. The Board of Directors may postpone or reschedule any previously scheduled special meeting of stockholders. Only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders of the Corporation. Nominations of persons for election to the Board of Directors of the Corporation and stockholder proposals of other business shall not be brought before a special meeting of stockholders to be considered by the stockholders unless such special meeting is held in lieu of an annual meeting of stockholders in accordance with Article I, Section 1 of these By-laws, in which case such special meeting in lieu thereof shall be deemed an Annual Meeting for purposes of these By-laws and the provisions of Article I, Section 2 of these By-laws shall govern such special meeting.

SECTION 4. Notice of Meetings; Adjournments.

(a) A notice of each Annual Meeting stating the hour, date and place, if any, of such Annual Meeting and the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting, shall be given not less than ten (10) days nor more than sixty (60) days before the Annual Meeting, to each stockholder entitled to vote thereat by delivering such notice to such stockholder or by mailing it, postage prepaid, addressed to such stockholder at the address of such stockholder as it appears on the Corporation's stock transfer books. Without limiting the manner by which notice may otherwise be given to stockholders, any notice to stockholders may be given by electronic transmission in the manner provided in Section 232 of the Delaware General Corporation Law ("DGCL").

(b) Notice of all special meetings of stockholders shall be given in the same manner as provided for Annual Meetings, except that the notice of all special meetings shall state the purpose or purposes for which the meeting has been called.

(c) Notice of an Annual Meeting or special meeting of stockholders need not be given to a stockholder if a waiver of notice is executed, or waiver of notice by electronic transmission is provided, before or after such meeting by such stockholder or if such stockholder attends such meeting, unless such attendance is for the express purpose of objecting at the beginning of the meeting to the transaction of any business because the meeting was not lawfully called or convened.

(d) The Board of Directors may postpone and reschedule any previously scheduled Annual Meeting or special meeting of stockholders and any record date with respect thereto, regardless of whether any notice or public disclosure with respect to any such meeting has been sent or made pursuant to Section 2 of this Article I of these By-laws or otherwise. In no event shall the

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public announcement of an adjournment, postponement or rescheduling of any previously scheduled meeting of stockholders commence a new time period for the giving of a stockholder's notice under this Article I of these By-laws.

(e) When any meeting is convened, the presiding officer may adjourn the meeting if (i) no quorum is present for the transaction of business, (ii) the Board of Directors determines that adjournment is necessary or appropriate to enable the stockholders to consider fully information which the Board of Directors determines has not been made sufficiently or timely available to stockholders, or (iii) the Board of Directors determines that adjournment is otherwise in the best interests of the Corporation. When any Annual Meeting or special meeting of stockholders is adjourned to another hour, date or place, notice need not be given of the adjourned meeting other than an announcement at the meeting at which the adjournment is taken of the hour, date and place, if any, to which the meeting is adjourned and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting; provided, however, that if the adjournment is for more than thirty (30) days from the meeting date, or if after the adjournment a new record date is fixed for the adjourned meeting, notice of the adjourned meeting and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned

meeting shall be given to each stockholder of record entitled to vote thereat and each stockholder who, by law or under the Certificate of Incorporation of the Corporation (as the same may hereafter be amended and/or restated, the "Certificate") or these By-laws, is entitled to such notice.

SECTION 5. Quorum. A majority of the shares entitled to vote, present in person or represented by proxy, shall constitute a quorum at any meeting of stockholders. If less than a quorum is present at a meeting, the holders of voting stock representing a majority of the voting power present at the meeting or the presiding officer may adjourn the meeting from time to time, and the meeting may be held as adjourned without further notice, except as provided in Section 4 of this Article I. At such adjourned meeting at which a quorum is present, any business may be transacted which might have been transacted at the meeting as originally noticed. The stockholders present at a duly constituted meeting may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum.

SECTION 6. Voting and Proxies. Stockholders shall have one vote for each share of stock entitled to vote owned by them of record according to the stock ledger of the Corporation as of the record date, unless otherwise provided by law or by the Certificate. Stockholders may vote either (i) in person, (ii) by written proxy or (iii) by a transmission permitted by Section 212(c) of the DGCL. Any copy, facsimile telecommunication or other reliable reproduction of the writing or transmission permitted by Section 212(c) of the DGCL may be substituted for or used in lieu of the original writing or transmission for any and all purposes for which the original writing or transmission could be used, provided that such copy, facsimile telecommunication or other reproduction shall be a complete reproduction of the entire original writing or transmission. Proxies shall be filed in accordance with the procedures established for the meeting of stockholders. Except as otherwise limited therein or as otherwise provided by law, proxies authorizing a person to vote at a specific meeting shall entitle the persons authorized thereby to vote at any adjournment of such meeting, but they shall not be valid after final adjournment of such meeting. A proxy with respect to stock held in the name of two or more persons shall be valid if executed by or on behalf of any one of them unless at or prior to the exercise of the proxy the Corporation receives a specific written notice to the contrary from any one of them.

SECTION 7. Action at Meeting. When a quorum is present at any meeting of stockholders, any matter before any such meeting (other than an election of a director or directors) shall be decided by a majority of the votes properly cast for and against such matter, except where a larger vote is

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required by law, by the Certificate or by these By-laws. Any election of directors by stockholders shall be determined by a plurality of the votes properly cast on the election of directors.

SECTION 8. Stockholder Lists. The Secretary or an Assistant Secretary (or the Corporation's transfer agent or other person authorized by these By-laws or by law) shall prepare and make, at least ten (10) days before every Annual Meeting or special meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for a period of at least ten (10) days prior to the meeting in the manner provided by law. The list shall also be open to the examination of any stockholder during the whole time of the meeting as provided by law.

SECTION 9. Presiding Officer. The Board of Directors shall designate a representative to preside over all Annual Meetings or special meetings of stockholders, provide that if the Board of Directors does not so designate such a presiding officer, then the Chairman of the Board, if one is elected, shall preside over such meetings. If the Board of Directors does not so designate such a presiding officer and there is no Chairman of the Board or the Chairman of the Board is unable to so preside or is absent, then the Chief Executive Officer, if one is elected, shall preside over such meetings, provided further that if there is no Chief Executive Officer or the Chief Executive Officer is unable to so preside or is absent, then the President shall preside over such meetings. The presiding officer at any Annual Meeting or special meeting of stockholders shall have the power, among other things, to adjourn such meeting at any time and from time to time, subject to Sections 4 and 5 of this Article I. The order of business and all other matters of procedure at any meeting of the stockholders shall be determined by the presiding officer.

SECTION 10. Inspectors of Elections. The Corporation shall, in advance of any meeting of stockholders, appoint one or more inspectors to act at the meeting and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the presiding officer shall appoint one or more inspectors to act at the meeting. Any inspector may, but need not, be an officer, employee or agent of the Corporation. Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his or her

ability. The inspectors shall perform such duties as are required by the DGCL, including the counting of all votes and ballots. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of the inspectors. The presiding officer may review all determinations made by the inspectors, and in so doing the presiding officer shall be entitled to exercise his or her sole judgment and discretion and he or she shall not be bound by any determinations made by the inspectors. All determinations by the inspectors and, if applicable, the presiding officer, shall be subject to further review by any court of competent jurisdiction.

ARTICLE II

Directors

SECTION 1. Powers. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors except as otherwise provided by the Certificate or required by law.

SECTION 2. Number and Terms. The number of directors of the Corporation shall be fixed solely and exclusively by resolution duly adopted from time to time by the Board of Directors. The directors shall hold office in the manner provided in the Certificate.

SECTION 3. Qualification. No director need be a stockholder of the Corporation.

SECTION 4. Vacancies. Vacancies in the Board of Directors shall be filled in the manner provided in the Certificate.

SECTION 5. Removal. Directors may be removed from office only in the manner provided in the Certificate.

SECTION 6. Resignation. A director may resign at any time by giving written notice to the Chairman of the Board, if one is elected, the President or the Secretary. A resignation shall be effective upon receipt, unless the resignation otherwise provides.

SECTION 7. Regular Meetings. Regular meetings (including any annual meeting) of the Board of Directors may be held at such hour, date and place as the Board of Directors may by resolution from time to time determine and publicize by means of reasonable notice given to any director who is not present at the meeting at which such resolution is adopted.

SECTION 8. Special Meetings. Special meetings of the Board of Directors may be called, orally or in writing, by or at the request of a majority of the directors, the Chairman of the Board, if one is elected, or the President. The person calling any such special meeting of the Board of Directors may fix the hour, date and place thereof.

SECTION 9. Notice of Meetings. Notice of the hour, date and place of all special meetings of the Board of Directors shall be given to each director by the Secretary or an Assistant Secretary, or in case of the death, absence, incapacity or refusal of such persons, by the Chairman of the Board, if one is elected, or the President or such other officer designated by the Chairman of the Board, if one is elected, or the President. Notice of any special meeting of the Board of Directors shall be given to each director in person, by telephone, or by facsimile, electronic mail or other form of electronic communication, sent to his or her business or home address, at least twenty-four (24) hours in advance of the meeting, or by written notice mailed to his or her business or home address, at least forty-eight (48) hours in advance of the meeting. Such notice shall be deemed to be delivered when hand-delivered to such address, read to such director by telephone, deposited in the mail so addressed, with postage thereon prepaid if mailed, dispatched or transmitted if sent by facsimile transmission or by electronic mail or other form of electronic communications. A written waiver of notice signed before or after a meeting by a director and filed with the records of the meeting shall be deemed to be equivalent to notice of the meeting. The attendance of a director at a meeting shall constitute a waiver of notice of such meeting, except where a director attends a meeting for the express purpose of objecting at the beginning of the meeting to the transaction of any business because such meeting is not lawfully called or convened. Except as otherwise required by law, by the Certificate or by these By-laws, neither the business to be transacted at, nor the purpose of, any meeting of the Board of Directors need be specified in the notice or waiver of notice of such meeting.

SECTION 10. Quorum. At any meeting of the Board of Directors, a majority of the total number of directors shall constitute a quorum for the transaction of business, but if less than a quorum is present at a meeting, a majority of the directors present may adjourn the meeting from time to time, and the meeting may be held as adjourned without further notice. Any business which might have been transacted at the meeting as originally

noticed may be transacted at such adjourned meeting at which a quorum is present. For purposes of this section, the total number of directors includes any unfilled vacancies on the Board of Directors.

SECTION 11. Action at Meeting. At any meeting of the Board of Directors at which a quorum is present, the vote of a majority of the directors present shall constitute action by the Board of Directors, unless otherwise required by law, by the Certificate or by these By-laws.

SECTION 12. Action by Consent. Any action required or permitted to be taken at any meeting of the Board of Directors may be taken without a meeting if all members of the Board of Directors consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the records of the meetings of the Board of Directors. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form. Such consent shall be treated as a resolution of the Board of Directors for all purposes.

SECTION 13. Manner of Participation. Directors may participate in meetings of the Board of Directors by means of conference telephone or other communications equipment by means of which all directors participating in the meeting can hear each other, and participation in a meeting in accordance herewith shall constitute presence in person at such meeting for purposes of these By-laws.

SECTION 14. Presiding Director. The Board of Directors shall designate a representative to preside over all meetings of the Board of Directors, provided that if the Board of Directors does not so designate such a presiding director or such designated presiding director is unable to so preside or is absent, then the Chairman of the Board, if one is elected, shall preside over all meetings of the Board of Directors. If both the designated presiding director, if one is so designated, and the Chairman of the Board, if one is elected, are unable to preside or are absent, the Board of Directors shall designate an alternate representative to preside over a meeting of the Board of Directors.

SECTION 15. Committees. The Board of Directors, by vote of a majority of the directors then in office, may elect one or more committees, including, without limitation, a Compensation Committee, a Nominating & Corporate Governance Committee and an Audit Committee, and may delegate thereto some or all of its powers except those which by law, by the Certificate or by these By-laws may not be delegated. Except as the Board of Directors may otherwise determine, any such committee may make rules for the conduct of its business, but unless otherwise provided by the Board of Directors or in such rules, its business shall be conducted so far as possible in the same manner as is provided by these By-laws for the Board of Directors. All members of such committees shall hold such offices at the pleasure of the Board of Directors. The Board of Directors may abolish any such committee at any time. Any committee to which the Board of Directors delegates any of its powers or duties shall keep records of its meetings and shall report its action to the Board of Directors.

SECTION 16. Compensation of Directors. Directors shall receive such compensation for their services as shall be determined by a majority of the Board of Directors, or a designated committee thereof, provided that directors who are serving the Corporation as employees and who receive compensation for their services as such, shall not receive any salary or other compensation for their services as directors of the Corporation.

ARTICLE III

Officers

SECTION 1. Enumeration. The officers of the Corporation shall consist of a President, a Treasurer, a Secretary and such other officers, including, without limitation, a Chairman of the Board of Directors, a Chief Executive Officer and one or more Vice Presidents (including

Executive Vice Presidents or Senior Vice Presidents), Assistant Vice Presidents, Assistant Treasurers and Assistant Secretaries, as the Board of Directors may determine.

SECTION 2. Election. At the regular annual meeting of the Board of Directors following the Annual Meeting, the Board of Directors shall elect the President, the Treasurer and the Secretary. Other officers may be elected by the Board of Directors at such regular annual meeting of the Board of Directors or at any other regular or special meeting.

SECTION 3. Qualification. No officer need be a stockholder or a director. Any person may occupy more than one office of the Corporation at any time.

SECTION 4. Tenure. Except as otherwise provided by the Certificate or by these By-laws, each of the officers of the Corporation shall hold office until the regular annual meeting of the Board of Directors following the next Annual Meeting and until his or her successor is elected and qualified or until his or her earlier resignation or removal.

SECTION 5. Resignation. Any officer may resign by delivering his or her written resignation to the Corporation addressed to the President or the Secretary, and such resignation shall be effective upon receipt, unless the resignation otherwise provides.

SECTION 6. Removal. Except as otherwise provided by law, the Board of Directors may remove any officer with or without cause by the affirmative vote of a majority of the directors then in office.

SECTION 7. Absence or Disability. In the event of the absence or disability of any officer, the Board of Directors may designate another officer to act temporarily in place of such absent or disabled officer.

SECTION 8. Vacancies. Any vacancy in any office may be filled for the unexpired portion of the term by the Board of Directors.

SECTION 9. President. The President shall, subject to the direction of the Board of Directors, have such powers and shall perform such duties as the Board of Directors may from time to time designate.

SECTION 10. Chairman of the Board. The Chairman of the Board, if one is elected, shall have such powers and shall perform such duties as the Board of Directors may from time to time designate.

SECTION 11. Chief Executive Officer. The Chief Executive Officer, if one is elected, shall have such powers and shall perform such duties as the Board of Directors may from time to time designate.

SECTION 12. Vice Presidents and Assistant Vice Presidents. Any Vice President (including any Executive Vice President or Senior Vice President) and any Assistant Vice President shall have such powers and shall perform such duties as the Board of Directors or the Chief Executive Officer may from time to time designate.

SECTION 13. Treasurer and Assistant Treasurers. The Treasurer shall, subject to the direction Members of the Board of Directors and except Section 16 officers of the Company must comply with the reporting obligations and limitations on short-swing transactions set forth in Section 16 of the Exchange Act.

TIONAL GUIDANCE

No trading in options in Company securities

The insider trading prohibition also applies to trading in derivative securities of the Company, such as put and call options. Option trading is highly speculative and very risky. People who buy options are betting that the Board stock price will move rapidly. For that reason, if an Insider trades in options in the Company's stock, it may arouse suspicion in the eyes of Directors the SEC that the person was trading on the basis of insider information, particularly where the trading occurs before a Company announcement or major event. It is difficult for an Insider to prove that he or she did not know about the announcement or event. If the SEC or the Chief Executive Officer may otherwise provide, have general charge stock exchanges were to notice active options trading by one or more Insiders prior to an announcement, they would investigate. Such an investigation could be embarrassing to the Company (as well as expensive) and could result in severe penalties and expense for the persons involved. For all of these reasons, the financial affairs of Company prohibits its Insiders from trading in options on the Corporation and shall cause Company stock. This policy does not pertain to employee stock options granted by the Company which cannot be kept accurate books of account. The Treasurer shall have custody of all funds, securities, and valuable documents of the Corporation. He or she shall have such other duties and powers as traded to any extent.

No Company securities subject to margin calls or pledges.

Securities held in a margin account may be designated from time sold by a broker without the customer's consent if the customer fails to time by the Board of Directors or the Chief meet a margin call. Similarly, securities pledged (or hypothecated) as

Executive Officer. Any Assistant Treasurer shall collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because such a sale or foreclosure sale may occur at a time when an Insider has material, nonpublic information or is otherwise not permitted to trade in Company securities, the Company prohibits Insiders from purchasing Company securities on margin or holding Company securities in a margin account or otherwise pledging Company securities as collateral for a loan.

No hedging transactions with Company securities

Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit an Insider to continue to own Company securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Insider may no longer have such powers and perform such duties the same objectives as the Board of Directors or the Chief Executive Officer may Company's other shareholders. Therefore, Insiders are prohibited from time to time designate.

SECTION 14. Secretary and Assistant Secretaries. The Secretary shall record all the proceedings of the meetings of the stockholders and the Board of Directors (including committees of the Board of Directors) engaging in books kept for that purpose. In his or her absence from any such meeting, a temporary secretary chosen at transaction.

No short sales of Company securities

A "short sale" is one involving securities, which the meeting shall record the proceedings thereof. The Secretary shall have charge of the stock ledger (which may, however, be kept by any transfer or other agent of the Corporation). The Secretary shall have custody of the seal of the Corporation, and the Secretary, or an Assistant Secretary shall have authority to affix it to any instrument requiring it, and, when so affixed, the seal may be attested by his or her signature or that of an Assistant Secretary. The Secretary shall have such other duties and powers as may be designated from time to time by the Board of Directors or the Chief Executive Officer. In the absence of the Secretary, any Assistant Secretary may perform his or her duties and responsibilities. Any Assistant Secretary shall have such powers and perform such duties as the Board of Directors or the Chief Executive Officer may from time to time designate.

SECTION 15. Other Powers and Duties. Subject to these By-laws and to such limitations as the Board of Directors may from time to time prescribe, the officers of the Corporation shall each have such powers and duties as generally pertain to their respective offices, as well as such powers and duties as from time to time may be conferred by the Board of Directors or the Chief Executive Officer.

ARTICLE IV

Capital Stock

SECTION 1. Certificates of Stock. Each stockholder shall be entitled to a certificate of the capital stock of the Corporation in such form as may from time to time be prescribed by the Board of Directors. Such certificate shall be signed by the Chairman of the Board, the President or a Vice President and by the Treasurer or an Assistant Treasurer, or the Secretary or an Assistant Secretary. The Corporation seal and the signatures by the Corporation's officers, the transfer agent or the registrar may be facsimiles. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed on such certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he or she were such officer, transfer agent or registrar seller does not own at the

time of sale, or if owned, are not delivered within 20 days after the sale or deposited in the mail or other usual channels of transportation within five days after the sale. The Company prohibits Insiders from selling the Company's securities short.

of electronic bulletin boards, internet chat rooms and websites

While the Company encourages its issue. Every certificate for shares stockholders and potential investors to obtain as much information as possible about the Company, the Company believes that information should come from its publicly-filed SEC reports, press releases and external website or from a designated Company spokesperson, rather than from speculation or unauthorized disclosures by the Company's directors, officers,employees, contract workers, or temporary staff. For this reason, the Company has designated certain members of stock which management to respond to inquiries regarding the Company's business and prospects. This centralization of communication is designed to ensure that the information the Company discloses is accurate and considered in light of previous disclosures. Formal announcements are subject to any restriction on transfer generally reviewed by management and every certificate issued when the Corporation is authorized to issue more than one class or series of stock shall contain such legend with respect thereto as is required by law. Notwithstanding anything legal counsel before they are made public. Any communications that do not go through this review process create an increased risk to the contrary provided in these Bylaws, Company, as well as to the Board individual responsible for the communication, of Directors civil and criminal liability.

In addition, with the advent of the Corporation Internet, and the emergence of electronic bulletin boards and chat rooms, electronic discussions about companies and their business prospects have become common. Inappropriate communications disseminated on the Internet may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares (except that the foregoing shall not apply to shares represented by a certificate until such certificate is surrendered pose an inherently greater risk due to the Corporation), and by the approval and adoption of these Bylaws the Board of Directors has determined that all classes or series size of the Corporation's audience they can reach. These forums have the potential to move a stock price significantly, and very rapidly – even though the information disseminated through electronic bulletin boards and chat rooms often is unreliable, and in some cases, may be uncertificated, whether upon original issuance, re-issuance, or subsequent transfer.

SECTION 2. Transfers. Subject to any restrictions on transfer deliberately false. The SEC has investigated and unless otherwise provided by prosecuted a number of fraudulent schemes involving electronic bulletin boards and chat rooms. You may encounter information about the Board of Directors, shares of stock that are represented by a certificate may be transferred Company on the books Internet that you believe is harmful or inaccurate, or other information that you believe is true or beneficial for the Company. Although you may have a natural tendency to deny or confirm such information on an electronic bulletin board or in a chat room, any sort of the Corporation by the surrender response, even if it presents accurate information, could be considered improper disclosure, and could result in legal liability to you and/or to the Corporation or its transfer agent of the certificate theretofore properly endorsed or accompanied by a written assignment or power of attorney properly executed, with transfer stamps (if necessary) affixed, and with such proof of the authenticity of signature as the Corporation or its transfer agent may reasonably require. Shares of stock that are not represented by a certificate may be transferred on the books of the Company.

Corporation The Company is committed to preventing inadvertent disclosures of material, nonpublic information, preventing unwitting participation in Internet-based securities fraud, and avoiding the appearance of impropriety by submitting persons associated with the Company. Accordingly, this Insider Trading Policy prohibits you from discussing material, nonpublic information about the Company with anyone, including other employees, except as required in the performance of your duties. You should not under any circumstances provide information or discuss matters involving the Company with the news media, any broker-dealer, analyst, investment banker, investment advisor, institutional investment manager, investment company or stockholder, even if you are contacted directly by such persons, without express prior authorization. This restriction applies whether or not you identify yourself as associated with the Company.

ntial penalties for illegal insider trading or noncompliance with this Insider Trading Policy

Both the SEC and the national securities exchanges, through the Financial Industry Regulatory Authority ("**FINRA**"), investigate and are very effective at detecting insider trading. The SEC, together with the U.S. Attorney's Office, pursue insider-trading violations vigorously. For instance, cases have been successfully prosecuted against trading by employees in foreign accounts, trading by family members and friends, and trading involving only a small number of shares.

The penalties for violating insider trading or tipping rules can be severe and include:

- disgorgement of the profit made or loss avoided by the trading;
- payment of the loss suffered by the persons who, contemporaneously with the purchase or sale of securities that are subject of such violation, have purchased or sold, as applicable, securities of the same class;
- payment of criminal penalties of up to $5,000,000;
- payment of civil penalties of up to three times the profit made or loss avoided; and
- imprisonment for up to 20 years.

The Company and/or the supervisors of the person engaged in insider trading may also be required to pay civil penalties of up to the Corporation greater of $1,525,000 or its transfer agent three times the profit made or loss avoided, as well as criminal penalties of up to $25,000,000, and could under certain circumstances be subject to private lawsuits.

Violation of this Insider Trading Policy or any federal or state insider trading laws may subject the person violating such evidence of transfer and following such other procedures as the Corporation policy or its transfer agent may require.

SECTION 3. Record Holders. Except as may otherwise be required by law, laws to disciplinary action by the Certificate or by these By-laws, the Corporation shall be entitled Company up to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, and including the payment of dividends and termination. The Company reserves the right to vote with respect thereto, regardless determine, in its own discretion and on the basis of the information available to it, whether this Insider Trading Policy has been violated. The Company may determine that specific conduct violates this Insider Trading Policy, whether or not the conduct also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against the alleged violator before taking disciplinary action.

do I report a violation of this Insider Trading Policy?

If you violate this Insider Trading Policy or any federal or state laws governing insider trading, or know of any transfer, pledge such violation by any director, officer,employee, contract worker, or other disposition of such stock, until the shares have been transferred on the books temporary staff of the Corporation Company, you must report the violation immediately to the Insider Trading

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Compliance Officer. However, if the conduct in accordance question involves the Insider Trading Compliance Officer, if you have reported such conduct to person and do not believe that he or she has dealt with it properly, or if you do not feel that you can discuss the matter with the requirements of these By-laws.Insider Trading Compliance Officer, you may raise the matter with the Company's Chief Executive Officer.

SECTION 4. Record Date. In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof or entitled to receive payment

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A waiver of any dividend or other distribution or allotment provision of any rights, or entitled to exercise any rights this Insider Trading Policy in respect a specific instance may be authorize din writing by the Audit Committee of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date: (a) in any such waiver shall be reported to the case Company's Board of determination of stockholders entitled to vote Directors.

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The Company may at any meeting of stockholders, shall, unless otherwise required by law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting and (b) in the case of any other action, shall not be more than sixty (60) days prior to time change this Insider Trading Policy or adopt such other action. If no record date is fixed: (i) policies or procedures which it considers appropriate to carry out the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held; and (ii) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

SECTION 5. Replacement of Certificates. In case of the alleged loss, destruction or mutilation of a certificate of stock of the Corporation, a duplicate certificate may be issued in place thereof, upon such terms as the Board of Directors may prescribe.

ARTICLE V

Indemnification

SECTION 1. Definitions. For purposes of this Article: its policies regarding insider trading and the disclosure of Company information.

(a) "Corporate Status" describes the status of a person who is serving or has served (i) as a Director of the Corporation, (ii) as an Officer of the Corporation, (iii) as a Non-Officer Employee of the Corporation, or (iv) as a director, partner, trustee, officer, employee or agent of any other corporation, partnership, limited liability company, joint venture, trust, employee benefit plan, foundation, association, organization or other legal entity which such person is or was serving at the request of the Corporation. For purposes of this Section 1(a), a Director, Officer or Non-Officer Employee of the Corporation who is serving or has served as a director, partner, trustee, officer, employee or agent of a Subsidiary shall be deemed to be serving at the request of the Corporation. Notwithstanding the foregoing, "Corporate Status" shall not include the status of a person who is serving or has served as a director, officer, employee or agent of a constituent corporation absorbed in a merger or consolidation transaction with the Corporation with respect to such person's activities prior to said transaction, unless specifically authorized by the Board of Directors or the stockholders of the Corporation;

(b) "Director" means any person who serves or has served the Corporation as a director on the Board of Directors of the Corporation;

(c) "Disinterested Director" means, with respect to each Proceeding in respect of which indemnification is sought hereunder, a Director of the Corporation who is not and was not a party to such Proceeding;**PRECLEARANCE REQUEST FORM**

(d) "Expenses" means all attorneys' fees, retainers, court costs, transcript costs, fees of expert witnesses, private investigators and professional advisors (including, without limitation, accountants and investment bankers), travel expenses, duplicating costs, printing and binding costs, costs of preparation of demonstrative evidence and other courtroom presentation aids and devices, costs incurred in connection with document review, organization, imaging and computerization, telephone charges, postage, delivery service fees, and all other disbursements, costs or expenses of the type customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to

To be a witness in, settling or otherwise participating in, a Proceeding;

(e) "Liabilities" means judgments, damages, liabilities, losses, penalties, excise taxes, fines and amounts paid in settlement;

(f) "Non-Officer Employee" means any person who serves or has served as an employee or agent of the Corporation, but who is not or was not a Director or Officer;

(g) "Officer" means any person who serves or has served the Corporation as an officer of the Corporation appointed completed by the Board of Directors of the Corporation;

(h) "Proceeding" means any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, inquiry, investigation, administrative hearing or other proceeding, whether civil, criminal, administrative, arbitrative or investigative; and

(i) "Subsidiary" shall mean any corporation, partnership, limited liability company, joint venture, trust or other entity of which the Corporation owns (either directly or through or together with another Subsidiary of the Corporation) either (i) a general partner, managing member or other similar interest or (ii) (A) fifty percent (50%) or more of the voting power of the voting capital equity interests of such corporation, partnership, limited liability company, joint venture or other entity, or (B) fifty percent (50%) or more of the outstanding voting capital stock or other voting equity interests of such corporation, partnership, limited liability company, joint venture or other entity.

SECTION 2. Indemnification of Directors and Officers.

(a) Subject to the operation of Section 4 of this Article V of these By-laws, each Director and Officer shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), and to the extent authorized in this Section 2.

(1) Actions, Suits and Proceedings Other than By or In the Right of the Corporation. Each Director and Officer shall be indemnified and held harmless by the Corporation against any and all Expenses and Liabilities that are incurred or paid by such Director or Officer or on such Director's or Officer's behalf in connection with any Proceeding or any claim, issue or matter therein (other than an action by or in the right of the Corporation), which such Director or Officer is, or is threatened to be made, a party to or participant in by reason of such Director's or Officer's Corporate Status, if such Director or Officer acted in good faith and in a manner such Director or Officer reasonably believed to be in or not opposed to the best interests of the

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Corporation and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful.

(2) Actions, Suits and Proceedings By or In the Right of the Corporation. Each Director and Officer shall be indemnified and held harmless by the Corporation against any and all Expenses that are incurred by such Director or Officer or on such Director's or Officer's behalf in connection with any Proceeding or any claim, issue or matter therein by or in the right of the Corporation, which such Director or Officer is, or is threatened to be made, a party to or participant in by reason of such Director's or Officer's Corporate Status, if such Director or Officer acted in good faith and in a manner such Director or Officer reasonably believed to be in or not opposed to the best interests of the Corporation; provided, however, that no indemnification shall be made under this Section 2(a)(2) in respect of any claim, issue or matter as to which such Director or Officer shall have been finally adjudged by a court of competent jurisdiction to be liable to the Corporation, unless, and only to the extent that, the Court of Chancery or another court in which such Proceeding was brought shall determine upon application that, despite adjudication of liability, but in view of all the circumstances of the case, such Director or Officer is fairly and reasonably entitled to indemnification for such Expenses that such court deems proper.

(3) Survival of Rights. The rights of indemnification provided by this Section 2 shall continue as to a Director or Officer after he or she has ceased to be a Director or Officer and shall inure to the benefit of his or her heirs, executors, administrators and personal representatives.

(4) Actions by Directors or Officers. Notwithstanding the foregoing, the Corporation shall indemnify any Director or Officer seeking indemnification in connection with a Proceeding initiated by such Director or Officer only if such Proceeding (including any parts of such Proceeding not initiated by such Director or Officer) was authorized in advance by the Board of Directors of the Corporation, unless such Proceeding was brought to enforce such Officer's or Director's rights to indemnification or, in the case of Directors, advancement of Expenses under these By-laws in accordance with the provisions set forth herein.

SECTION 3. Indemnification of Non-Officer Employees. Subject to the operation of Section 4 of this Article V of these By-laws, each Non-Officer Employee may, in the discretion of the Board of Directors of the Corporation, be indemnified by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended, against any or all Expenses and Liabilities that are incurred by such Non-Officer Employee

or on such Non-Officer Employee's behalf in connection with any threatened, pending or completed Proceeding, or any claim, issue or matter therein, which such Non-Officer Employee is, or is threatened to be made, a party to or participant in by reason of such Non-Officer Employee's Corporate Status, if such Non-Officer Employee acted in good faith and in a manner such Non-Officer Employee reasonably believed to be in or not opposed to the best interests of the Corporation and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The rights of indemnification provided by this Section 3 shall exist as to a Non-Officer Employee after he or she has ceased to be a Non-Officer Employee and shall inure to the benefit of his or her heirs, personal representatives, executors and administrators. Notwithstanding the foregoing, the Corporation may indemnify any Non-Officer Employee seeking indemnification in connection with a Proceeding initiated by such Non-Officer Employee only if such Proceeding was authorized in advance by the Board of Directors of the Corporation.

SECTION 4. Determination. Unless ordered by a court, no indemnification shall be provided pursuant to this Article V to a Director, to an Officer or to a Non-Officer Employee unless a determination shall have been made that such person acted in good faith and in a manner such

person reasonably believed to be in or not opposed to the best interests of the Corporation and, with respect to any criminal Proceeding, such person had no reasonable cause to believe his or her conduct was unlawful. Such determination shall be made by (a) a majority vote of the Disinterested Directors, even though less than a quorum of the Board of Directors, (b) a committee comprised of Disinterested Directors, such committee having been designated by a majority vote of the Disinterested Directors (even though less than a quorum), (c) if there are no such Disinterested Directors, or if a majority of Disinterested Directors so directs, by independent legal counsel in a written opinion, or (d) by the stockholders of the Corporation.

SECTION 5. Advancement of Expenses to Directors Prior to Final Disposition.

(a) The Corporation shall advance all Expenses incurred by or on behalf of any Director in connection with any Proceeding in which such Director is involved by reason of such Director's Corporate Status within thirty (30) days after the receipt by the Corporation of a written statement from such Director requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by such Director and shall be preceded or accompanied by an undertaking by or on behalf of such Director to repay any Expenses so advanced if it shall ultimately be determined that such Director is not entitled to be indemnified against such Expenses. Notwithstanding the foregoing, the Corporation shall advance all Expenses incurred by or on behalf of any Director seeking advancement of expenses hereunder in connection with a Proceeding initiated by such Director only if such Proceeding (including any parts of such Proceeding not initiated by such Director) was (i) authorized by the Board of Directors of the Corporation, or (ii) brought to enforce such Director's rights to indemnification or advancement of Expenses under these By-laws.

(b) If a claim for advancement of Expenses hereunder by a Director is not paid in full by the Corporation within thirty (30) days after receipt by the Corporation of documentation of Expenses and the required undertaking, such Director may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim and if successful in whole or in part, such Director shall also be entitled to be paid the expenses of prosecuting such claim. The failure of the Corporation (including its Board of Directors or any committee thereof, independent legal counsel, or stockholders) to make a determination concerning the permissibility of such advancement of Expenses under this Article V shall not be a defense to an action brought by a Director for recovery of the unpaid amount of an advancement claim and shall not create a presumption that such advancement is not permissible. The burden of proving that a Director is not entitled to an advancement of expenses shall be on the Corporation.

(c) In any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that the Director has not met any applicable standard for indemnification set forth in the DGCL.

SECTION 6. Advancement of Expenses to Officers and Non-Officer Employees Prior to Final Disposition.

(a) The Corporation may, at the discretion of the Board of Directors of the Corporation, advance any or all Expenses incurred by or on behalf of any Officer or any Non-Officer Employee in connection with any Proceeding in which such person is involved by reason of his or her Corporate Status as an Officer or Non-Officer Employee upon the receipt by the Corporation of a statement or statements from such Officer or Non-Officer Employee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by such Officer or Non-Officer Employee and shall be preceded or accompanied by an undertaking

by or on behalf of such person to repay any Expenses so advanced if it shall ultimately be determined that such Officer or Non-Officer Employee is not entitled to be indemnified against such Expenses.

(b) In any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that the Officer or Non-Officer Employee has not met any applicable standard for indemnification set forth in the DGCL.

SECTION 7. Contractual Nature of Rights.

(a) The provisions of this Article V shall be deemed to be a contract between the Corporation and each Director and Officer entitled to the benefits hereof at any time while this Article V is in effect, in consideration of such person's past or current and any future performance of services for the Corporation. Neither amendment, repeal or modification of any provision of this Article V nor the adoption of any provision of the Certificate of Incorporation inconsistent with this Article V shall eliminate or reduce any right conferred by this Article V in respect of any act or omission occurring, or any cause of action or claim that accrues or arises or any state of facts existing, at the time of or before such amendment, repeal, modification or adoption of an inconsistent provision (even in the case of a proceeding based on such a state of facts that is commenced after such time), and all rights to indemnification and advancement of Expenses granted herein or arising out of any act or omission shall vest at the time of the act or omission in question, regardless of when or if any proceeding with respect to such act or omission is commenced. The rights to indemnification and to advancement of expenses provided by, or granted pursuant to, this Article V shall continue notwithstanding that the person has ceased to be a director or officer of the Corporation and shall inure to the benefit of the estate, heirs, executors, administrators, legatees and distributes of such person.

(b) If a claim for indemnification hereunder by a Director or Officer is not paid in full by the Corporation within sixty (60) days after receipt by the Corporation of a written claim for indemnification, such Director or Officer may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim, and if successful in whole or in part, such Director or Officer shall also be entitled to be paid the expenses of prosecuting such claim. The failure of the Corporation (including its Board of Directors or any committee thereof, independent legal counsel, or stockholders) to make a determination concerning the permissibility of such indemnification under this Article V shall not be a defense to an action brought by a Director or Officer for recovery of the unpaid amount of an indemnification claim and shall not create a presumption that such indemnification is not permissible. The burden of proving that a Director or Officer is not entitled to indemnification shall be on the Corporation.

(c) In any suit brought by a Director or Officer to enforce a right to indemnification hereunder, it shall be a defense that such Director or Officer has not met any applicable standard for indemnification set forth in the DGCL.

SECTION 8. Non-Exclusivity of Rights. The rights to indemnification and to advancement of Expenses set forth in this Article V shall not be exclusive of any other right which any Director, Officer, or Non-Officer Employee may have or hereafter acquire under any statute, provision of the Certificate or these By-laws, agreement, vote of stockholders or Disinterested Directors or otherwise.

SECTION 9. Insurance. The Corporation may maintain insurance, at its expense, to protect itself and any Director, Officer or Non-Officer Employee against any liability of any character asserted against or incurred by the Corporation or any such Director, Officer or Non-Officer Employee, or arising out of any such person's Corporate Status, whether or not the Corporation

would have the power to indemnify such person against such liability under the DGCL or the provisions of this Article V.

SECTION 10. Other Indemnification. The Corporation's obligation, if any, to indemnify or provide advancement of Expenses to any person under this Article V as a result of such person serving, at the request of the Corporation, as a director, partner, trustee, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount such person may collect as indemnification or advancement of Expenses from such other corporation, partnership, joint venture, trust, employee benefit plan or enterprise (the "Primary Indemnitor"). Any indemnification or advancement of Expenses under this Article V owed by the Corporation as a result of a person serving, at the request of the Corporation, as a director, partner, trustee, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall only be in excess of, and shall be secondary to, the indemnification or advancement of Expenses available from the applicable Primary Indemnitor(s) and any applicable insurance policies.

ARTICLE VI

Miscellaneous Provisions

SECTION 1. Fiscal Year. The fiscal year of the Corporation shall be determined by the Board of Directors.

SECTION 2. Seal. The Board of Directors shall have power to adopt and alter the seal of the Corporation.

SECTION 3. Execution of Instruments. All deeds, leases, transfers, contracts, bonds, notes and other obligations to be entered into by the Corporation in the ordinary course of its business without director action may be executed on behalf of the Corporation by the Chairman of the Board, if one is elected, the President or the Treasurer or any other officer, employee or agent of the Corporation as the Board of Directors or the executive committee of the Board may authorize.

SECTION 4. Voting of Securities. Unless the Board of Directors otherwise provides, the Chairman of the Board, if one is elected, the President or the Treasurer may waive notice of and act on behalf of the Corporation, or appoint another person or persons to act as proxy or attorney in fact for the Corporation with or without discretionary power and/or power of substitution, at any meeting of stockholders or shareholders of any other corporation or organization, any of whose securities are held by the Corporation.

SECTION 5. Resident Agent. The Board of Directors may appoint a resident agent upon whom legal process may be served in any action or proceeding against the Corporation.

SECTION 6. Corporate Records. The original or attested copies of the Certificate, By-laws and records of all meetings of the incorporators, stockholders and the Board of Directors and the stock transfer books, which shall contain the names of all stockholders, their record addresses and the amount of stock held by each, may be kept outside the State of Delaware and shall be kept at the principal office of the Corporation, at an office of its counsel, at an office of its transfer agent or at such other place or places as may be designated from time to time by the Board of Directors.

SECTION 7. Certificate. All references in these By-laws to the Certificate shall be deemed to refer to the Amended and RestatedCertificate of Incorporation of the Corporation, as amended and/or restated and in effect from time to time.

SECTION 8. Exclusive Jurisdiction of Delaware Courts or the United States Federal District Courts. Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of, or a claim based on, a breach of a fiduciary duty owed by any current or former director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or the Certificate or Bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim governed by the internal affairs doctrine. Unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Section 8.

SECTION 9. Amendment of By-laws.

(a) Amendment by Directors. Except as provided otherwise by law, these By-laws may be amended or repealed by the Board of Directors by the affirmative vote of a majority of the directors then in office.

(b) Amendment by Stockholders. These By-laws may be amended or repealed at any Annual Meeting, or special meeting of stockholders called for such purpose in accordance with these By-Laws, by the affirmative vote of at least seventy-five percent (75%) of the outstanding shares entitled to vote on such amendment or repeal, voting together as a single class; provided, however, that if the Board of Directors recommends that stockholders approve such amendment or repeal at such meeting of stockholders, such amendment or repeal shall only require the affirmative vote of the majority of the outstanding shares entitled to vote on such amendment or repeal, voting together as a single class. Notwithstanding the foregoing, stockholder approval shall not be required unless mandated by the Certificate, these By-laws, or other applicable law.

SECTION 10. Notices. If mailed, notice to stockholders shall be deemed given when deposited in the mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the Corporation. Without limiting the manner by which notice otherwise may be given to stockholders, any notice to stockholders may be given by electronic transmission in the manner provided in Section 232 of the DGCL.

SECTION 11. Waivers. A written waiver of any notice, signed by a stockholder or director, or waiver by electronic transmission by such person, whether given before or after the time of the event for which notice is to be given, shall be deemed equivalent to the notice required to be given to such person. Neither the business to be transacted at, nor the purpose of, any meeting need be specified in such a waiver.

Effective as of November 4, 2021.

Severance Agreement

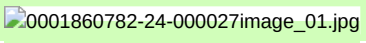
Between Restricted Insider

Globalization Partners Switzerland SA
Route de Frontenex
86bis
1208 Geneve
Switzerland

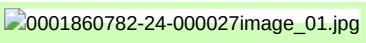
Pursuant to the Insider Trading Policy, I am seeking to preclear intended trades in the securities of 2seventy bio, Inc. (the "Company") as indicated below:

insider's name

(the **Employer**)



and requested trade date



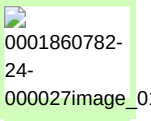
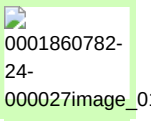
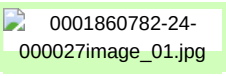
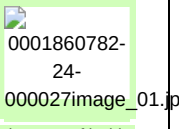
intent to purchase

Nicola Heffron
Dorfstrasse 20
Allenwinden
Zug 6319
Switzerland

type of transaction check all that apply

☐ cashless exercise of stock option(s) for shares

☐ open market acquisition of shares

		☐ other (please describe): 
intent to sell	type of transaction check all that apply	☐ sale of shares acquired through employee benefit plan (e.g., ESPP, exercise of stock option(s), vested RSUs) ☐ sale of shares acquired on the open market ☐ other (please describe): 
certification	I hereby certify that (1) I am not in possession of any material, nonpublic information concerning the Company, (2) to the best of my knowledge, the proposed trade(s) listed above does not violate the trading restrictions of Section 16 of the Securities Exchange Act of 1934, as amended, or Rule 144 under the Securities Act of 1933, as amended, and (3) the proposed trade(s) listed above do not violate the Insider Trading Policy in any other respect. I understand that, if I trade while possessing such information or in violation of such trading restrictions, I may be subject to severe civil and/or criminal penalties and may be subject to discipline by the Company.	
signature	 *date*	 *signature of insider*

(the **Employee)**

The Employer and the Employee are also referred to as **Party** or together as **Parties.**

Background

A. The Employee is employed To be completed by the Employer since December 1, 2021 and has been working for 2Seventy Bio (the **Client)** (the **Employment Relationship).** The Employment Relationship is regulated by a Main Employee Placement Contract dated December 1, 2021 and an Amendment to the Main Worker Placement Contract dated December 1, 2021 (the **Employment Contract).**

B. On February 7, 2023, the Employee terminated the Employment Contract by resignation as of March 10, 2023, waiving the contractually agreed notice period.

C. To facilitate an amicable situation and a mutually successful separation, the Parties have now agreed that the Employment Relationship shall terminate on the terms and conditions set forth in this agreement (the Severance Agreement).

1. Termination of the Employment Contract

The Employment Contract is terminated as of March 10, 2023 (the Termination Date). Any extension of the Employment Relationship, especially due to illness or accident, shall be expressly excluded.

The Employee confirms that no other employment relationship (than the one with the Employer), no mandate, no agency nor any other legal or contractual relationship

Insider Trading Compliance Officer (or designee)

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exists between the Employee and the Employer. If any such legal relationship would exist, the Parties agree to terminate such relationship as of today.

2. Continued Performance of Work

Until the Termination Date, the Employee will perform their normal duties under the Employment Contract or such duties the Employer or the Client might reasonably request.

3. Remuneration

From the signing of this Severance Agreement until the Termination Date, the Employer will continue to pay to the Employee the same base salary and allowances as before.

The Employer agrees to pay a pro-rated bonus amount of CHF 489,837 gross in relation to the performance of 2022, due for payment with Employee's regular scheduled salary payment for the month of February.

4. Severance

For the loss of the employment, for waiving the statutory termination protection due to illness and for all potential claims resulting from the Employment Relationship, the Employee will receive 6 months' salary as a non-statutory severance pay and 6 months of the allowances as detailed on the assignment schedule, on the final payroll cycle, subject to the standard payroll deductions, provided however, the Employee has:

a)fulfilled all the Employee's duties under this Severance Agreement;

b) not committed any breach prior to the payment date of the severance;

c)returned all the property to the Employer and/or the Client as referred to in Section 9 below on or prior to the Termination Date.

5. Deductions

From all payments the same deductions as in the past will be made, including, but not limited to social security contributions (AHV (Old-age and surviving dependents insurance)/IV (Disability insurance)/EO (Wage Compensation Order), ALV (Unemployment insurance)), UV (accidence insurance), premiums to pension funds (cp. regulations of the pension fund) and withholding taxes, if any.

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6. Accident Insurance. Daily Allowance Insurance and Pension Fund

The benefits coverage under the accident insurance will cease 30 days after the Termination Date. The Employer herewith informs the Employee that the Employee is obliged to notify their health insurer about the fact that the Employment Relationship will end and the Employee needs to include an accident insurance into their health insurance in order to secure sufficient insurance coverage. The Employee confirms that she has been informed regarding the possibility of entering into so-called single accord insurance(s) with the accident insurance provider and the daily sickness benefits allowance insurance provider of the Employer.

The benefits coverage under the pension fund (BVG) will cease on the Termination Date.

7. Unemployment Benefits

The Employer herewith informs the Employee that the Employee should get in contact with the responsible centre for unemployment *(regionales Arbeitsvermittlungszentrum (RAV))* within the next few days. If the Employee does not register the termination of the Employment Relationship this may lead to a reduction unemployment benefits. Pursuant to the law, the Employee is required to start to apply for new positions as soon as the Employee has signed this Severance Agreement.

8. Return of Employer and Client Property

On the Termination Date at the latest, or whenever requested by the Employer or the Client, the Employee shall return to the Employer and/or the Client all documents of a confidential nature (and copies thereof) belonging or relating to the Employer and/or the Client. In addition, the Employee shall return all property belonging to the Employer and/or the Client, including, but not limited to, files, calculations, books. documents, notes, business plans and forecasts, computers, laptops, mobile phones, credit cards, and keys, etc. Furthermore, the Employee shall destroy on his own all electronically stored confidential data belonging to the Employer and/or the Client.

9. Confidentiality

For the remainder of the Employment Relationship and thereafter the Employee shall keep strictly confidential and neither use for his own purposes or that of others nor make known to any third person any trade or business secret or any other confidential or proprietary information of the Employer or the Client received or created during the employment. These include in particular, but not exhaustively any products, improvements, designs, processes, customers, methods of distribution or methods of operation, sales, prices, profits, costs, contracts, suppliers, business prospects, business methods, techniques, research, trade secrets, or know-how or data obtained by the Employee during the Employment Relationship, regardless of whether

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such information is confidential or not, except if such information is already publicly known and in the public domain.

The Employee may not make any statement to the media, as far as she is not authorized to do so by the Employer or Client. The Employee is also reminded of and agrees to comply with their obligations regarding confidentiality pursuant to the Employment Contract. The Employee is aware that the Employee is bound by this obligation even after the Termination Date. The Parties also agree to keep the contents of this Severance Agreement confidential.

10. Loyalty

The Employee is reminded that their duty of loyalty towards the Employer and the Client will continue to apply until the Termination Date, meaning that they may not act in a manner that may harm the interests of the Employer or the Client.

11. Lawsuit Support

The Employee will support the Employer in any lawsuits, civil or public proceedings, inquiries, hearings or other formal procedures, including, but not limited to, provision of testimonies or witnessing. After the Termination Date, the Employer pays adequate compensation for such services of the Employee.

12. Non-Disparagement

The Employee agrees not to disparage the Employer or the Client as well as their directors, officers, employees, shareholders, agents and attorneys, in any manner likely to be harmful to them or their business, products, business reputation or personal reputation, provided that the Employee shall respond accurately and fully to any question, inquiry or request for information when required by law or court order.

13. Non-Representation

From the Termination Date onwards, the Employee will not hold herself out as an employee, director, officer, agent or attorney of the Employer.

14. Certificate of Reference

The Employee shall be entitled to an interim certificate of reference *(Zwischenzeugnis)* which will be handed out by March 31, 2023. In addition, the Employee shall be entitled

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to a certificate of reference *(Arbeitszeugnis)* to be executed and delivered by the Employer on the Termination Date or promptly thereafter.

15. Acknowledgement, Release and Waiver

The Employee acknowledges that she has no further rights or claims resulting from the Employment Relationship or the Employment Contract or arising from the services provided to the Client, except for the entitlements expressly mentioned in this Severance Agreement.

Upon execution and performance of this Severance Agreement neither Party shall have any further claims against the other Party resulting from the Employment Relationship and its termination.

The Parties hereby fully release and discharge each other from any and all claims and/or obligations including, but not limited to, claims, obligations and/or demands related to salary, stock options, shares, allowances. bonuses, commissions, thirteenth month payment, vacation, overtime, fringe benefits, expense reimbursements, severance pay, discrimination, harassment, fraud and defamation provisions.

The Employee hereby fully releases and discharges the Client from any and all claims and/or obligations including, but not limited to, claims. obligations and/or demands related to salary, stock options, shares, allowances, bonuses, commissions, thirteenth month payment, vacation, overtime, fringe benefits, expense reimbursements, severance pay, discrimination, harassment, fraud and defamation provisions.

This full settlement clause is applicable on known and unknown claims, irrespective of the nature of such claims or on claims which one of the Parties might not have known or which one of the Parties might not have thought of. The Parties are aware of the fact that with the signing of this Severance Agreement, they explicitly and irrevocably waive any claims which are not expressly stated within this Severance Agreement.

This acknowledgement, release and waiver also applies in relation to any rights or claims the Employee may have against the Client (genuine contract in favor of a third party - *echter Vertrag zu Gunsten Dritter)*.

16. Confirmation of Legal Advice

The Employee confirms that they had the opportunity to receive independent legal advice regarding this Severance Agreement and has done so or refused to do so of their own volition.

17. Miscellaneous

This Severance Agreement constitutes the complete agreement between the Parties regarding its subject matter and supersedes all prior oral and/or written agreements, representations and/or communications, concerning the subject matter hereof.

Any amendment and/or supplementation of this Severance Agreement shall require written form and shall only be valid if signed by both Parties.

T he Parties mutually agree not to publicly disclose the terms of this Severance Agreement except to the extent that disclosure is required by applicable law.

If the Employer does not impose sanctions on the Employee for breach of a provision of this Severance Agreement, such a non-sanctioning shall not be interpreted as a waiver of existing or future entitlements of the Employer.

Should any of the provisions of this Severance Agreement be or become legally invalid, such invalidity shall not affect the validity of the remaining other provisions. Any gap resulting from such invalidity shall be filled by a provision consistent with the spirit and purpose of the Severance Agreement. In the same way shall any gap that appears in the drafting of the contract be filled by a provision consistent with the spirit and purpose of the Severance Agreement.

The Employer has the right to set off any payment owed by the Employee to the Employer against any payment owed by the Employer to the Employee, regardless under which title this payment obligation arose. Notwithstanding anything to the contrary in this paragraph, the Employer's right to set off shall comply with article 323b(2) of the Swiss Code of Obligations.

18. Governing Law and Place of Jurisdiction

The terms of this Severance Agreement shall be construed in accordance with and governed in all respects by the laws of Switzerland (without giving effect to principles of conflicts of laws).

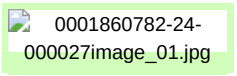
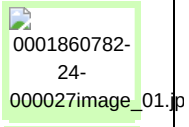
Any dispute, controversy or claim arising under, out of or in relation to this Severance Agreement, its valid conclusion, binding effects, interpretation, including tort claims, shall be referred and finally determined by the ordinary courts at the domicile of the defendant party or where the Employee normally had to perform their duties.

19. Execution

The Parties have duly executed this Severance Agreement in two originals.

Signatures

Globalization Partners:

United Kingdom authorized approval	 *date*  *signature of Insider Trading Compliance Officer (or designee)*

17 February 2023	/s/ Kathryn Barnes
Place, date	Kathryn Barnes Manager – Senior Employment Counsel - EMEA

Employee:

Nicola Heffron

16 February 2023	/s/ Nicola Heffron
Place, data	Nicola Heffron ACTIVE/123973265.4

CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (together with the attached **Business Terms Exhibit**, the "**Agreement**"), is made as of February 21, 2023 (the "**Effective Date**") by and between **2seventy bio, Inc.**, a Delaware corporation with a principal business address at 60 Binney Street, Cambridge, MA 02142 ("**2seventy bio**"), and Nicola Heffron("**Consultant**"). 2seventy bio desires to have the benefit of Consultant's knowledge and experience, and Consultant desires to provide services to 2seventy bio, all as provided in this Agreement.

1. **Services and Termination of Side Letter.** 2seventy bio retains Consultant, and Consultant agrees to provide, consulting and advisory services to 2seventy bio as 2seventy bio may from time to time reasonably request and as specified in the attached Business Terms Exhibit(the "**Consulting Services**"). Any changes to the Consulting Services (and any related compensation adjustments) must be agreed to in writing between Consultant and 2seventy bio prior to

implementation of the changes. 2seventy and Consultant agree that the Side Letter entered into between 2seventy bio and Consultant on November 8, 2021 is hereby terminated effective as of the date of this Agreement.

2. **Compensation.** As full consideration for Consulting Services provided under this Agreement, 2seventy bio agrees to pay Consultant and reimburse expenses as described in the Business Terms Exhibit.

3. **Performance.** Consultant agrees to provide the Consulting Services to 2seventy bio, or to its designee, in accordance with all applicable laws and regulations and the highest professional standards. Consultant represents and warrants that Consultant has not been, and is not under consideration to be (a) debarred from providing services pursuant to Section 306 of the United States Federal Food Drug and Cosmetic Act, 21 U.S.C. § 335a; (b) excluded, debarred or suspended from, or otherwise become ineligible to participate in, any federal or state health care program or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. §1320a-7b(f)); (c) disqualified by any government or regulatory agencies from performing specific services, and is not subject to a pending disqualification proceeding; or (d) convicted of a criminal offense related to the provision of health care items or services, or under investigation or subject to any such action that is pending.

4. **Compliance with Obligations to Third Parties.** Consultant represents and warrants to 2seventy bio that the terms of this Agreement and Consultant's performance of Consulting Services do not and will not conflict with any of Consultant's obligations to any third parties. Consultant agrees not to use any trade secrets or other confidential information of any other person, firm, corporation, institution or other entity in connection with any of the Consulting Services. If Consultant is or becomes an employee of another company or institution, Consultant represents and warrants that Consultant is permitted to enter into and continue to perform under this Agreement pursuant to such company's or institution's policies concerning professional consulting and additional workload. Consultant agrees not to make any use of any funds, space, personnel, facilities, equipment or other resources of a third party in performing the Consulting Services, nor take any other action that would result in a third party asserting ownership of, or other rights in, any Work Product (defined in Section 5), unless agreed upon in writing in advance by 2seventy bio.

5. **Work Product.** Consultant will promptly and fully disclose in confidence to 2seventy bio all inventions, discoveries, improvements, ideas, concepts, designs, processes, formulations, products, computer programs, works of authorship, databases, mask works, trade secrets, know-how, information, data, documentation, reports, research, creations and other products arising from or made in the performance of (solely or jointly with others) the Consulting Services (whether or not patentable or subject to copyright or trade secret protection) (collectively, the "**Work Product**"). Consultant assigns and agrees to assign to 2seventy bio all rights in the United States and throughout the world to Work Product. Consultant will keep and maintain adequate and current written records of all Work Product, and such records will be available to and remain the sole property of 2seventy bio at all times. For purposes of the copyright laws of

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the United States, Work Product will constitute "works made for hire," except to the extent such Work Product cannot by law be "works made for hire". Consultant represents and warrants that Consultant has and will have the right to transfer and assign to 2seventy bio ownership of all Work Product. Consultant will execute all documents, and take any and all actions needed, all without further consideration, in order to confirm 2seventy bio's rights as outlined above. In the event that Consultant should fail or refuse to execute such documents within a reasonable time, Consultant appoints 2seventy bio as attorney to execute and deliver any such documents on Consultant's behalf.

6. **Confidentiality.** "**Confidential Information**" means (a) any scientific, technical, business or financial information or trade secrets in whatever form (written, oral or visual) that is furnished or made available to Consultant by or on behalf of 2seventy bio, (b) all information contained in or comprised of 2seventy bio Materials (defined in Section 8); and (c) all Work Product. Confidential Information is, and will remain, the sole property of 2seventy bio. During the Term (defined in the Business Terms Exhibit) and for a period of seven (7) years thereafter, Consultant agrees to (i) hold in confidence all Confidential Information, and not disclose Confidential Information without the prior written consent of 2seventy bio; (ii) use Confidential Information solely in connection with the Consulting Services; (iii) treat Confidential Information with no less than a reasonable degree of care; and (iv) reproduce Confidential Information solely to the extent necessary to provide the Consulting Services, with all such reproductions being considered Confidential Information. Notwithstanding the foregoing, the non-disclosure and non-use obligations imposed by this Agreement with respect to trade secrets included in the Confidential Information will continue for as long as 2seventy bio continues to treat such Confidential Information as a trade secret. Consultant will not have obligations of non-disclosure and non-use under this Agreement with respect to any Confidential Information that Consultant can demonstrate, by competent proof:

(a) is generally known to the public at the time of disclosure or becomes generally known through no wrongful act on the part of Consultant;

(b) is in Consultant's possession at the time of disclosure other than as a result of Consultant's breach of any legal obligation;

(c) becomes known to Consultant on a non-confidential basis through disclosure by sources other than 2seventy bio having the legal right, to Consultant's knowledge, to disclose such Confidential Information; or

(d) is independently developed by Consultant without reference to or reliance upon Confidential Information.

If Consultant is required by a governmental authority or by order of a court of competent jurisdiction to disclose any Confidential Information, Consultant will give 2seventy bio prompt written notice thereof and Consultant will take all reasonable and lawful actions to avoid or minimize the degree of such disclosure. Consultant will cooperate reasonably with 2seventy bio in any efforts to seek a protective order.

7. **2seventy bio Materials.** All documents, data, records, materials, compounds, apparatus, equipment and other physical property furnished or made available by or on behalf of 2seventy bio to Consultant in connection with this Agreement ("**2seventy bio Materials**") are and will remain the sole property of 2seventy bio. Consultant will use 2seventy bio Materials only as necessary to perform the Consulting Services and will not transfer or make available to any third party the 2seventy bio Materials without the express prior written consent of 2seventy bio. Consultant will return to 2seventy bio any and all 2seventy bio Materials upon request.

8. **Publication; Publicity.** Consultant may not publish or refer to Work Product, in whole or in part, without the prior express written consent of 2seventy bio.

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9. **Expiration/Termination.** This Agreement will commence on the Effective Date and continue for the Term specified in the Business Terms Exhibit, unless sooner terminated pursuant to the provisions of this Section 9 or extended by mutual written agreement of the parties. 2seventy bio may terminate this Agreement for breach by Consultant at any time. Consultant may terminate this Agreement at any time upon ten (10) days' written notice. The Parties may terminate this Agreement at any time by mutual consent. Any expiration or termination of this Agreement shall be without prejudice to any obligation of either party that has accrued prior to the effective date of expiration or termination. Upon expiration or termination of this Agreement, neither Consultant nor 2seventy bio will have any further obligations under this Agreement, except that (a) Consultant will terminate all Consulting Services in progress in an orderly manner as soon as practicable and in accordance with a schedule agreed to by 2seventy bio, unless 2seventy bio specifies in the notice of termination that Consulting Services in progress should be completed; (b) Consultant will deliver to 2seventy bio all Work Product made through expiration or termination; (c) 2seventy bio will pay Consultant any monies due and owing Consultant, up to the time of termination or expiration, all authorized expenses actually incurred; (d) Consultant will immediately return to 2seventy bio all 2seventy bio Materials and other Confidential Information and copies thereof provided to Consultant under this Agreement; and (e) the terms, conditions and obligations under Sections 5, 6, 7, 8, 9 and 10 will survive expiration or termination of this Agreement.

10. **Miscellaneous.**

(a) **Independent Contractor.** The parties understand and agree that Consultant is an independent contractor and not an agent or employee of 2seventy bio. Consultant has no authority to obligate 2seventy bio by contract or otherwise. Consultant will not be eligible for any employee benefits of 2seventy bio and expressly waives any rights to any employee benefits. Unless otherwise provided in this Agreement, Consultant will bear sole responsibility for paying and reporting Consultant's own applicable federal and state income taxes, social security taxes, unemployment insurance, workers' compensation, and health or disability insurance, retirement benefits, and other welfare or pension benefits, if any, and indemnifies and holds 2seventy bio harmless from and against any liability with respect to such taxes, benefits and other matters.

(b) **Entire Agreement.** This Agreement contains the entire agreement of the parties with regard to its subject matter, and supersedes all prior or contemporaneous written or oral representations, agreements and understandings between the parties relating to that subject matter. This Agreement may be changed only by a writing signed by Consultant and an authorized representative of 2seventy bio.

(c) **Assignment and Binding Effect.** The Consulting Services to be provided by Consultant are personal in nature. Consultant may not assign or transfer this Agreement or any of Consultant's rights or obligations hereunder. In no event will Consultant assign or delegate responsibility for actual performance of the Consulting Services to any third party. 2seventy bio may transfer or assign this Agreement, in whole or in part, without the prior written consent of Consultant. Any purported assignment or transfer in violation of this Section is void. This Agreement will be binding upon and inure to the benefit of the parties and their respective legal representatives, heirs, successors and permitted assigns.

(d) **Notices.** All notices required or permitted under this Agreement must be in writing and must be given by directing the notice to the address for the receiving party set forth in this Agreement or at such other address as the receiving party may specify in writing under this procedure. Notices to 2seventy bio will be marked "Attention: Chief Legal Officer". All notices must be given (i) by personal delivery, with receipt acknowledged, (ii) by prepaid certified or registered mail, return receipt requested, or (iii) by prepaid recognized next business day delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

(e) **Governing Law.** This Agreement and any disputes relating to or arising out of this Agreement will be governed by, construed, and interpreted in accordance with the internal laws of the Commonwealth of Massachusetts, without regard to any choice of law principle that would require the application of the law of another jurisdiction. The parties agree to submit to the exclusive jurisdiction of the state and federal courts located in the Commonwealth of Massachusetts and waive any defense of inconvenient forum to the maintenance of any action or proceeding in such courts.

(f) **Severability; Reformation.** Each provision in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable because any other provision is found by a proper authority to be invalid or unenforceable in whole or in part. If any provision of this Agreement is found by such an authority to be invalid or unenforceable in whole or in part, such provision shall be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision and the intent of the parties, within the limits of applicable law.

(g) **Headings.** The section headings are included solely for convenience of reference and will not control or affect the meaning or interpretation of any of the provisions of this Agreement.

(h) **Waivers**. Any delay in enforcing a party's rights under this Agreement, or any waiver as to a particular default or other matter, will not constitute a waiver of such party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by Consultant and an authorized representative of the waiving party, as applicable.

(i) **Remedies.** Consultant agrees that (i) 2seventy bio may be irreparably injured by a breach of this Agreement by Consultant; (ii) money damages would not be an adequate remedy for any such breach; (iii) as a remedy for any such breach 2seventy bio will be entitled to seek equitable relief, including injunctive relief and specific performance; and (iv) such remedy will not be the exclusive remedy for any breach of this Agreement.

(j) **Counterparts.** This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. A facsimile or portable document format (".pdf") copy of this Agreement, including the signature pages, will be deemed an original.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

2seventy bio, Inc. **Nicola Heffron**

By: /s/ Nick Leschly /s/ Nicola Heffron

Name: Nick Leschly

Title: Chief Executive Officer

BUSINESS TERMS EXHIBIT

Consulting Agreement with Nicola Heffron

1. Consulting Services:

Consultant will provide the following Consulting Services to 2seventy bio:

Consulting with respect to Consultant's areas of expertise in commercial, operations, as directed by Nick Leschly, Chief Executive Officer, or his designee.

Consultant will provide Consulting Services on a schedule and at a location or locations indicated above or as otherwise mutually agreed between Consultant and Nick Leschly. In addition, Consultant will be available for a reasonable number of telephone and/or written consultations.

2. Compensation:

Outstanding Equity Grants: For purposes of this Section on Outstanding Equity Grants, the terms of any outstanding option grants and restricted stock unit grants to you ("**Outstanding Equity Grants**") are set forth in and governed by the applicable stock option agreement(s), applicable restricted stock unit agreement(s), and applicable stock option plans, including the 2seventy bio, Inc. 2021 Stock Option and Incentive Plan (the "**Stock Plan**") (the option agreement(s), the restricted stock unit agreement(s) and Stock Plan, together, constitute the "**Equity Documents**"). Notwithstanding anything to the contrary in the Equity Documents:

(a) during the period between the Effective Date and the end of the Term (the "**Extended Vesting Period**"), Consultant's Outstanding Equity Grants shall continue to vest in accordance with the schedule set forth in the Equity Documents and subject to the Stock Plan, and Consultant's change in status from employee of the Company on the Effective Date to a consultant under this Agreement has not caused a termination of his Service Relationship (as defined in the Stock Plan) with the Company on the Effective Date;

(b) on the last day of the Extended Vesting Period, any then-unvested Outstanding Equity Grants shall lapse and be of no further effect;

(c) Consultant will be permitted to exercise his vested options until the three (3) month anniversary of the date of termination of this Agreement, or the original applicable expiration date of each option, if earlier;

(d) In the event of a Sale Event (as such term is defined in the Stock Plan) and in the event that the Sale Event provides for the vesting of unvested shares, then in such case only such unvested shares that would otherwise vest during the Extended Vesting Period shall vest.

Expenses: 2seventy bio will reimburse Consultant for any pre-approved expenses actually incurred by Consultant in connection with the provision of Consulting Services. Requests for reimbursement will be in a form reasonably acceptable to 2seventy bio, will include supporting documentation and will accompany Consultant's invoices.

Invoicing: No later than the last day of each calendar month, Consultant will invoice 2seventy bio for Consulting Services rendered and related expenses incurred during the preceding month. Invoices should reference this Agreement and should be submitted to 2seventy bio by email to: invoices@2seventybio.com. Invoices will contain such detail as 2seventy bio may reasonably require and will be payable in U.S. Dollars. Undisputed payments will be made by 2seventy bio within thirty (30) days after 2seventy bio's receipt of Consultant's invoice, request for reimbursement and all supporting documentation.

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3. Term:

This Agreement will be for an initial term expiring on February 5, 2024,beginning on the Effective Date (the "**Term**").

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Name of Subsidiary	Jurisdiction of Formation
2seventy bio Securities Corporation	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) 1. Registration Statement (Form S-3 No. 333-268222) of 2seventy bio, Inc.,
(2) 2. Registration Statement (Form S-3 S-8 No. 333-264544) 333-260669) pertaining to the 2021 Stock Option and Incentive Plan and 2021 Employee Stock Purchase Plan of 2seventy bio, Inc.,
(3) 3. Registration Statement (Form S-8 No. 333-263853) pertaining to the 2021 Stock Option and Incentive Plan and 2021 Employee Stock Purchase Plan of 2seventy bio, Inc., and
(4) 4. Registration Statement (Form S-8 No. 333-260669) 333-270660) pertaining to the 2021 Stock Option and Incentive Plan and 2021 Employee Stock Purchase Plan of 2seventy bio, Inc., and
5. Registration Statement (Form S-8 No. 333-276403) pertaining to the 2021 Stock Option and Incentive Plan and 2021 Employee Stock Purchase Plan of 2seventy bio, Inc.

of our report dated March 16, 2023 March 7, 2024, with respect to the consolidated and combined financial statements of 2seventy bio, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2022 December 31, 2023.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 16, 2023 7, 2024

Exhibit 31.1

CERTIFICATION

CERTIFICATION

PURSUANT TO RULE 13a-14(a) AND RULE 15d-14(a)

UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED
RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Nick Leschly, certify that:

1. I have reviewed this Annual Report on Form 10-K of 2seventy bio, Inc.;

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 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) (Paragraph intentionally omitted 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 SEC Release Nos. 34-47986 and 34-54942);generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's 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 registrant's internal control over financial reporting that occurred during the registrant's registrant's most recent fiscal quarter (the registrant's 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 registrant's internal control over financial reporting; and

5. The registrant's 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 registrant's auditors and the audit committee of the registrant's 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 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 registrant's internal control over financial reporting.

Dated: March 16, 2023 March 7, 2024

/s/ Nick Leschly
Nick Leschly

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

CERTIFICATION
PURSUANT TO RULE 13a-14(a) AND RULE 15d-14(a)

UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED
RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Chip William D. Baird, certify that:

1. I have reviewed this Annual Report on Form 10-K of 2seventy bio, Inc.;

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 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) (Paragraph intentionally omitted 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 SEC Release Nos. 34-47986 and 34-54942);generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's 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 registrant's internal control over financial reporting that occurred during the registrant's registrant's most recent fiscal quarter (the registrant's 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 registrant's internal control over financial reporting; and

5. The registrant's 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 registrant's auditors and the audit committee of the registrant's 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 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 registrant's internal control over financial reporting.

Dated: March 16, 2023 March 7, 2024

/s/ Chip William D. Baird
Chip
William D. Baird

Chief Financial Operating Officer
(Principal Financial Officer and
Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of 2seventy bio, Inc. (the "Company") for the year ended December 31, 2022 December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to his knowledge, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 16, 2023 March 7, 2024

/s/ Chip William D. Baird

Chip William D. Baird

Chief Financial Operating Officer

(Principal Financial Officer and Principal Accounting Officer)

Dated: March 16, 2023 March 7, 2024

/s/ Nick Leschly

Nick Leschly

Chief Executive Officer

(Principal Executive Officer)

2SEVENTY BIO, INC.

COMPENSATION RECOVERY POLICY

Adopted as of September 26, 2023

2seventy bio, Inc., a Delaware corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below. This Policy supersedes and replaces the Company's Policy for Recoupment of Incentive Compensation, dated as of September __, 2021 (the "Prior Policy") with respect to Incentive Compensation received after the Effective Date (as defined below).

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any Executive Officer and any other person designated by the Board or the Committee as being subject to this Policy, as listed in Schedule A attached hereto, which schedule may be updated from time to time by the Committee. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered

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Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means September 26, 2023.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules.Incentive-Based Compensation is deemed received, earned, or vested when the Financial Reporting Measure is attained, not when the actual payment, grant, or vesting occurs.

h. "Exchange" means the Nasdaq Stock Market LLC.

i. "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation such person received during service in such role: the president, principal financial officer, principal accounting officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy making function, or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure and any equity-based compensation provided by the Company or any of its subsidiaries, including, without limitation, stock options, restricted stock awards, restricted stock units, and stock appreciation rights, regardless of whether such equity-based compensation is granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure.

l. "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

m. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board, a committee of the Board or the officer or officers of the Company authorized to take such action if Board action is not required concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Recovery from Participating Employees.

In addition to (and without limiting) the provisions of paragraph 2 above, in the event the Company is required to prepare a Financial Restatement after the Effective Date, the Company may recover from any current or former employee of the Company who is not a Covered Person (each a "Participating Employee") and who received Incentive-Based Compensation from the Company during the three completed fiscal years immediately preceding the date on which the Board, a committee of the Board or the officer or officers of the Company authorized to take such action if Board action is not required concludes that the Company is required to prepare a Financial Restatement, the amount that exceeds what would have been paid to the Participating Employee under the Financial Restatement; provided that, this paragraph 5 will apply only to the extent the Board (or a duly established committee thereof), in its sole discretion, determines that the Participating Employee committed any act or omission that materially contributed to the circumstances requiring the Financial Restatement and such act or omission involved any of the following: (i) misconduct, wrongdoing or a violation of any of the Company's rules or of any applicable legal or regulatory requirements in the course of the Participating Employee's employment by the Company; or (ii) a breach of a fiduciary duty to the Company or its stockholders by the Participating Employee.

6.Recovery Where Intentional Misconduct.

In addition to (and without limiting) the provisions of paragraphs 2 and 5 above, in the event the Company is required to prepare a Financial Restatement after the Effective Date and the Board (or a duly established committee thereof), in its sole discretion, determines that a Covered Person's or a Participating Employee's act or omission contributed to the circumstances requiring the Financial Restatement and such act or omission involved any of the following: (i) willful, knowing or intentional misconduct or a willful, knowing or intentional violation of any of the Company's rules or any applicable legal or regulatory requirements in the course of the

Covered Person's or the Participating Employee's employment by the Company or (ii) fraud in the course of the Covered Person's or the Participating Employee's employment by the Company, the Company may recover from such Covered Person or Participating Employee up to 100% (as determined by the Board or a duly established committee thereof in its sole discretion) of the Incentive-Based Compensation received by such Covered Person or Participating Employee from the Company during the three fiscal years preceding the date on which the Company determined that it is required to prepare a Financial Restatement.

7. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

8. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other offset;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

9. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

10. Policy Administration

This Policy shall be administered by the Committee. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding, and conclusive.

11. Compensation Recovery Repayments Not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any claim or losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.

Schedule A

Nick Leschly, Chief Executive Officer

William Baird, Chief Operating Officer

Steven Bernstein, Chief Medical Officer

Philip Gregory, Chief Scientific Officer

Susan Abu-Absi, Chief Technology Officer

Teresa Jurgensen, General Counsel

Kathy Wilkinson, Chief People Officer

Kerri Jensen, VP, Talent & Experience

Jenn Snyder, SVP Corporate Communications

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