

Risk Factors Comparison 2025-03-25 to 2024-03-07 Form: 10-K

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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 the Proposed BMS Transaction The proposed acquisition by BMS is subject to a number of conditions beyond our control. Failure to complete the proposed acquisition within the expected time frame, or at all, could have a material adverse effect on our business, operating results, financial condition and our stock price. On March 10, 2025, we entered into the BMS Merger Agreement, pursuant to which, and upon the terms and subject to the conditions thereof, Daybreak Merger Sub Inc. (a wholly-owned subsidiary of BMS) (“Merger Sub”) will commence a cash tender offer to acquire all of our issued and outstanding shares of common stock at a price per share of \$ 5.00 per share, without interest and subject to any withholding of taxes required by applicable law. In the event the tender offer conditions are satisfied and the tender offer is closed, upon the terms and subject to the conditions set forth in the BMS Merger Agreement, Merger Sub will merge with and into us, with our company continuing as the surviving corporation and as a wholly owned subsidiary of BMS. Upon completion of these transactions, we will no longer be a publicly traded company, and the listing of our common stock on Nasdaq will have been terminated. Refer to Note 20 to our Consolidated Financial Statements for a summary of the terms of the BMS Merger Agreement, the transactions provided for thereunder, and the various conditions to closing the transaction. As described in Note 20, the obligation of BMS and Merger Sub to consummate the tender offer is subject to certain conditions, including the condition that there be validly tendered and not withdrawn prior to the expiration of the offer a number of shares of common stock that, together with the shares of common stock then owned by BMS or its affiliates, represents at least one more than 50 % of the total number of shares of our common stock issued and outstanding at the time of expiration of the tender offer. The obligation of BMS to consummate the offer is also subject to other conditions, including the receipt of required clearances under applicable antitrust laws and other customary conditions. We cannot predict whether and when the conditions to closing will be satisfied. Until these conditions are satisfied and we complete proposed transaction, our business, operating results and financial condition are exposed to certain risks due to the effect of the pending transaction, including:

- the possibility of disruption to our business and operations, including diversion of management attention and resources;
- the inability to attract and retain key personnel, and the possibility that our current employees could be distracted, and their productivity decline as a result;
- the inability to pursue alternative business opportunities or make changes to our business pending the completion of the transaction, and other restrictions on our ability to conduct our business;
- the amount of the costs, fees, expenses, and charges related to the transaction;
- our inability to solicit other acquisition proposals; and
- the market price of our common stock could decrease if the proposed transaction is not completed or if there exists a market perception that the transaction will not be completed. If the transaction does not close, we would be exposed to additional risks, including:

- to the extent the current market price of our common stock reflects an assumption that the transaction will be completed, the price of our common stock could decrease if the transaction is not completed;
- investor confidence could decline, shareholder litigation could be brought against us, relationships with service providers, investors, and other business partners (including BMS as our collaboration partner on Abecma) may be adversely impacted, we may be unable to retain key personnel, and our financial condition may be adversely impacted due to costs incurred in connection with the pending transaction; and
- the requirement that we pay a termination fee of \$ 10,000,000 if the BMS Merger Agreement is terminated in certain circumstances, including if we terminate to accept and enter into an agreement with respect to a superior proposal.

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 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, 2023 was \$ 217.6 million, and our net losses for the years ended December 31, 2022-2024 and 2021-2023 were \$ 254.57, 2 million and \$ 292.217, 2.6 million, respectively. 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 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 has received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for Abecma in those markets. We expect to continue to incur significant expenses and continued operating losses in the near future. We anticipate that our expenses will increase if and as we:

- continue any additional clinical trials of Abecma, which we are co-developing with BMS;
- conduct commercialization activities for Abecma;
- obtain, build and expand manufacturing capacity, including capacity at third-party manufacturers;
- 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 for commercial sale **and we receive a 50 % share of all revenue from sales of Abecma in the United States pursuant to our collaboration with BMS**, 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 commercialize** 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 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, **2023-2024**, we held cash, cash equivalents and marketable securities of \$ **221-183.8-6** million. **We-If the merger with BMS does not close, we may require need to raise additional funding funds sooner than currently anticipated if we choose to continue to advance Abecma or** pursue additional indications for Abecma, **alone** or otherwise expand more rapidly than we presently anticipate **with strategic partners, through additional clinical studies**. 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 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 development programs for the commercialization of Abecma 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, **together with BMS**, have limited experience in the sales and marketing activities necessary for the commercialization of Abecma. 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 the Asset Sale closed on April 1, 2024. We also** entered into an asset purchase agreement with **Regeneron Novo** to sell substantially all of the assets related to our **solid tumor megaTAL platform** and other **the Novo Transaction** oncology and autoimmune cell therapy programs, or the Asset Sale. **The Asset Sale is expected to close closed in June** 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 **including reductions in the workforce**, 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.

Risks Related to the Discovery, Product Development and Regulatory Approval 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 ~~may not be able to successfully or our timely complete development and commercialization efforts on treatments for cancer. Our projections of both the number of people who have the these diseases~~ **Asset Sale**, which could materially impact the market price of our common stock, as well as **the subset of people with these diseases who have the potential to benefit from treatment with Abecma** ~~our~~ **or any** future ~~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 Abecma is 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~~ **There** is no guarantee that ~~our future~~ 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. **In April 2024** 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 **the** results from ~~of the~~ **KarMMA - 3 study**, ~~the~~ we are seeking FDA approval **approved** for Abecma as a ~~third line therapy in~~ **for the treatment of adult patients with relapsed and/or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti- CD38 monoclonal antibody.** 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. **If the marketing approval of Abecma and any future approved products is ultimately for more narrow indications than we expect, our business prospects, results of operations, and our financial condition would be adversely affected. Before obtaining marketing approval from regulatory authorities for the commercialization of Abecma in additional indications**, we must complete extensive clinical studies to demonstrate the safety, purity and potency, and efficacy, of the product candidate in humans in such indications, which is expensive, time-consuming ~~and~~, uncertain as to outcome and subject to a high failure rate. We cannot guarantee that any clinical studies 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 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;** • **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 cash flows~~ 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, and we may experience delays if we encounter difficulties in recruitment or enrollment. The **Asset Sale 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, or our clinical studies 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, as required by the FDA or our ongoing business 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 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 without limitation 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 follows: • we more products are reviewed by regulatory authorities, regulatory authorities may experience negative reactions from financial markets and 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, declined, terminated, or 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, 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 Abecma in additional indications. 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. Any future product candidates 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 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. 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 future clinical trials are inconclusive with respect to the safety and efficacy of product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with any product candidate, we may be prevented or delayed in obtaining marketing approval for such product candidates. If we encounter difficulties in recruiting or..... experience unexpected results in

the future. 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. 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 **future** 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 **adults with relapsed and refractory multiple myeloma who have received at least four prior lines of therapy, including and an immunomodulatory agent** the FDA approved this BLA in March 2021. **However, a proteasome inhibitor and an anti-CD38 (cyclic ADP ribose hydrolase) monoclonal antibody, obtaining** **Obtaining** one regulatory approval does not guarantee that the FDA will **approve a product** 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~~ **Clinical** studies may not ~~begin be completed~~ on schedule, and ~~our planned clinical studies~~ may not ~~begin be completed~~ 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. **Inadequate funding for the FDA, the SEC and other U. S. government agencies or the EMA or comparable foreign regulatory authorities, including from government shut downs, or other disruptions to these agencies' operations, including significant leadership, personnel, and policy changes, could prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA, the EMA or comparable foreign regulatory authorities to review and approve products, including additional indications, can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and enact statutory, regulatory and policy changes. Average review times at the FDA or other regulatory authorities have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, and those that fund research and development activities that is required by third parties we enter into agreements with, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, the EMA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. Currently, federal agencies in the U. S. are operating under a continuing resolution that is set to expire on September 30, 2025. In prior years the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. A prolonged government shutdown, significant leadership, personnel, and / or policy changes, or other substantial modification in agency activities (including due to global health concerns or geopolitical factors) could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our 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, **the** 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, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw or limit their approval of Abecma; • 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 is distributed or administered, conduct additional clinical trials or change the labeling for Abecma; • 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 from the marketplace; • we could be sued and held liable for injury caused to individuals exposed to or taking Abecma; and • our reputation may suffer. Negative public opinion and increased regulatory scrutiny of **cell and** gene therapy and genetic research may damage public perception of Abecma and any future products or adversely affect our ability to conduct our business or obtain and maintain marketing approvals for Abecma and our **future** product candidates. Public perception may be influenced by claims that **cell and** 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 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 future** 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 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 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 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.

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-partnering with BMS to develop~~ **develop** and ~~co-promoting~~ **promote** 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, 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 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 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 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, 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. 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 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. 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 existing contract manufacturers for Abecma, are subject to extensive regulation. Abecma 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 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 **any potential future** 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 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 **cell and** 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 **future** 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;
- obtain adequate pricing and reimbursement for any future products, if approved;
- 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 and commercialize Abecma or any future products, if approved, raise capital 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.

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 ourselves. In addition, we may fail to enter into arrangements with third parties to commercialize 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 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 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 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 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 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 **Abecma and our future** 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 **future** 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 this Annual Report 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 future product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, future products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize 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**

Abecma 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 this Annual Report 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 **the European Union , interaction between pharmaceutical companies,healthcare professionals,and patients are also governed by strict laws, regulations– regulation** ,industry self- regulation codes of conduct and physicians’ codes of professional ~~conduct–conduction~~ 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~~ **addition, we may 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 are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and / or adverse publicity and could negatively affect our operating results and business. We may be subject to patient and consumer 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, at the federal level, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act (the FTCA), 15 U. S. C § 45 (a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Regulators and legislators in the U. S. are also increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government- Related Data by Countries of Concern as implemented by Department of Justice regulations issued in December 2024, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and / or civil sanctions, and may result in exclusion from participation in federal and state programs. In addition, certain state laws govern privacy and security of personal information. For example, California recently enacted the California Consumer Privacy Act, or CCPA, which, effective January 1, 2023, creates created new individual privacy rights for California consumers (as defined in the law) and places placed increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require requires 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 (and amended the CCPA by creating additional obligations with respect to processing and storing personal information. These additional obligations have included expanding consumers' rights with respect to certain provisions having retroactive effect categories of sensitive personal information and by establishing the California Privacy Protection Act to enforce January 1, 2022). Additionally, some observers have noted that the CCPA, 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, numerous in the United States states, we including Virginia, Colorado, Connecticut, New Jersey, New Hampshire and others, have adopted comprehensive witnessed significant developments at the state level. For example, on March 2, 2021, Virginia enacted the Consumer Data Protection Act, or the CDPA, and, on July 8, 2021, Colorado's governor signed the Colorado Privacy Act, or the CPA, into law laws. The CDPA and the CPA both became effective January 1, 2023. While the these laws CDPA and CPA incorporate many similar concepts to those 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. There are also A number of other states that are specifically regulating health information. For example, Washington's My Health My Data Act, which became effective on March 31, 2024, regulates the collection and sharing of health information and has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have proposed new also passed similar laws regulating consumer health data. The existence of a patchwork of 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 will 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 Our operations may also be subject to European Union data privacy laws, interactions between pharmaceutical regulations and guidelines. The collection, use, storage, disclosure, transfer, or other processing of personal information regarding individuals in the EEA and UK, including personal health data, is subject to the EU General Data Protection Regulation, or EU GDPR, with respect to the EEA and the UK General Data Protection Regulation and UK Data Protection Act 2018 with respect to the UK, or UK GDPR, and collectively with the EU GDPR referred to as the “GDPR” in this document unless specified otherwise. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal information, including requirements relating to processing of special categories of personal information (such as healthcare health professionals data), relying on a legal basis or condition for processing personal information, where required obtaining consent of the individuals to whom the personal information relates, providing information to individuals regarding data processing activities, conducting privacy impact assessments for “high risk” processing, implementing safeguards to protect the security and patients are confidentiality of personal information, implementing limitations on the retention of personal information, providing mandatory notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes governed by strict rules on the transfer of personal information to countries outside the EEA and UK to non-adequate territories, including the United States in certain circumstances unless derogation exists or a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses, or SCCs, and the UK International Data Transfer Agreement / Addendum, or UK IDTA) have been put in place. Where relying on the SCCs / UK IDTA for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws, regulations, industry self-regulation..... world the alleged bribery activity occurs, which allow 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 public 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 authority access to personal information 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 the requirements could GDPR, and any supplemental EEA Member State or UK national data protection laws which may apply by virtue of the location of the individuals whose personal information we collect, may result in substantial penalties, including potential fines of up to € 20 million (£ 17. 5 million for the UK GDPR) or 4 % of annual global revenues for the preceding financial year, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR increases our responsibility and liability in relation to personal information that we process where such processing is subject to the GDPR, and requires us to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with risk, public reprimands, administrative penalties, fines or our imprisonment European activities.** 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 cell and 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 **for biologics**, 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 future** 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 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 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 this Annual Report 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. Risks Related to Our Business Operations Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints **and significant political, trade, or regulatory developments**. 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, or future public health events. 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. Significant political, trade, or regulatory developments such as those stemming from the change in U. S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U. S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, in February 2025, the U. S. imposed a 25 % tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10 % additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U. S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U. S. trade policies, could have a material adverse effect on our financial condition or results of** 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. For example, in March 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of Silicon Valley Bank and Signature Bank after each bank was unable to continue its operations. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by the financial institutions with which we have arrangements directly, or 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 financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial 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 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. 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 our existing collaboration and license agreements, including, in particular, our collaboration with 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, 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, 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. 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 **currently** 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. **07-235** billion or more; (ii) **December 31, 2026** ~~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 cybersecurity incidents **or data breaches**, which could result in a ~~material~~ disruption of our product candidates' development programs and have ~~an 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, cybersecurity incidents, **data breaches**, 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 **(including phishing attacks)** 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 ~~breaches and security~~ **cybersecurity** incidents. If we experience a ~~material~~ system failure, accident ~~or~~, cybersecurity incident **or data breach** 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, **data breach**, or 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, **data breaches**, or 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, cybersecurity incidents, cyberattacks and other related events, **including data breaches**. 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 ~~breaches, security incidents or other~~ **cybersecurity incidents, or other disruptions** that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, **may require us to notify relevant stakeholders (including affected individuals, regulators and investors) and** 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 ~~an a-material~~ adverse effect on our reputation, business, financial condition or results of operations. Moreover, **our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Data** security incidents and other security events can be difficult to detect, and any delay in identifying them may lead to increased harm. Because the techniques used by ~~those 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 **breaches, or security-cybersecurity** 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 **the current we will need to expend additional resources dedicated to protect protecting** our technology and information systems **may not suffice**. 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. 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:

- **the pendency of the proposed acquisition by BMS and the market perception thereof;**
- 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 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 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. 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. 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. 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.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key personnel, and substantial leadership, personnel, and policy changes or otherwise, could prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory,

and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, including substantial leadership, personnel, and policy changes, may also slow the time necessary for biological products or modifications to approved biological products to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U. S. market could be impacted.