Confidential draft submission submitted to the Securities and Exchange Commission on May 11, 2021.
This draft registration statement has not been filed publicly with the Securities and Exchange Commission and all information contained herein remains confidential.

File No. 001-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10

GENERAL FORM FOR REGISTRATION OF SECURITIES
PURSUANT TO SECTION 12(b) OR 12(g) OF
THE SECURITIES EXCHANGE ACT OF 1934

2seventy bio, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	86-3658454
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
60 Binney Street Cambridge, Massachusetts (Address of principal executive offices)	02142 (Zip Code)

(339) 499-9300
(Registrant's telephone number, including area code)

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

Title of Each Class to be so Registered	Name of Each Exchange on which each class is to be registered
Common Stock, par value $0.0001 per share	The Nasdaq Stock Market LLC

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

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

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

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

2seventy bio, Inc.

INFORMATION REQUIRED IN REGISTRATION STATEMENT
CROSS-REFERENCE SHEET BETWEEN INFORMATION STATEMENT
AND ITEMS OF FORM 10

Certain information required to be included in this Form 10 is incorporated by reference to specifically identified portions of the body of the information statement filed with this Form 10 as Exhibit 99.1. None of the information contained in the information statement shall be incorporated by reference in this Form 10 or deemed to be a part of this Form 10 unless such information is specifically incorporated by reference.

Item 1. Business.

The information required by this item is contained under the sections of the information statement entitled “Information Statement Summary,“ “Risk Factors,” “Cautionary Statement Concerning Forward-Looking Statements,” “Unaudited Pro Forma Combined Financial Statements,” “Management's Discussion and Analysis of Financial Condition and Results of Operations,” “Business,” “Certain Relationships and Related Person Transactions,” “Where You Can Find More Information” and “Index to Combined Financial Statements” and the financial statements referenced in the information statement. Those sections are incorporated herein by reference.

Item 1A. Risk Factors.

The information required by this item is contained under the section of the information statement entitled “Risk Factors.” That section is incorporated herein by reference.

Item 2. Financial Information.

The information required by this item is contained under the sections of the information statement entitled “Summary Historical and Unaudited Pro Forma Combined Financial Information,” “Unaudited Pro Forma Combined Financial Statements,” “Capitalization” and “Management's Discussion and Analysis of Financial Condition and Results of Operations.” Those sections are incorporated herein by reference.

Item 3. Properties.

The information required by this item is contained under the section of the information statement entitled “Business—Facilities.” That section is incorporated herein by reference.

Item 4. Security Ownership of Certain Beneficial Owners and Management.

The information required by this item is contained under the section of the information statement entitled “Security Ownership by Certain Beneficial Owners and Management.” That section is incorporated herein by reference.

Item 5. Directors and Executive Officers.

The information required by this item is contained under the section of the information statement entitled “Management.” That section is incorporated herein by reference.

Item 6. Executive Compensation.

The information required by this item is contained under the section of the information statement entitled “Executive Compensation.” That section is incorporated herein by reference.

Item 7. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is contained under the sections of the information statement entitled “Management,” “Executive Compensation” and “Certain Relationships and Related Person Transactions.” Those sections are incorporated herein by reference.

Item 8. Legal Proceedings.

The information required by this item is contained under the section of the information statement entitled “Business.” That section is incorporated herein by reference.

Item 9. Market Price of, and Dividends on, the Registrant's Common Equity and Related Stockholder Matters.

The information required by this item is contained under the sections of the information statement entitled “Risk Factors,” “Dividend Policy,” “Capitalization,” “The Separation and Distribution” and “Description of 2seventy bio's Capital Stock.” Those sections are incorporated herein by reference.

Item 10. Recent Sales of Unregistered Securities.

The information required by this item is contained under the section of the information statement entitled “Description of 2seventy bio's Capital Stock —Sale of Unregistered Securities.” That section is incorporated herein by reference.

Item 11. Description of Registrant's Securities to be Registered.

The information required by this item is contained under the sections of the information statement entitled “Risk Factors,” “Dividend Policy,” “Capitalization,” “The Separation and Distribution” and “Description of 2seventy bio's Capital Stock.” Those sections are incorporated herein by reference.

Item 12. Indemnification of Directors and Officers.

The information required by this item is contained under the section of the information statement entitled “Executive Compensation—Limitations on Liability and Indemnification Maters.” That section is incorporated herein by reference.

Item 13. Financial Statements and Supplementary Data.

The information required by this item is contained under the section of the information statement entitled “Index to Combined Financial Statements” and the financial statements referenced therein. That section is incorporated herein by reference.

Item 14. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 15. Financial Statements and Exhibits.

(a) Financial Statements

The information required by this item is contained under the section of the information statement entitled “Index to Combined Financial Statements” and the financial statements referenced therein. That section is incorporated herein by reference.

(b) Exhibits

The following documents are filed as exhibits hereto:

Exhibit Number	Exhibit Description
2.1*	Form of Separation Agreement by and between bluebird bio, Inc. and 2seventy bio, Inc.
3.1*	Form of Certificate of Incorporation of 2seventy bio, Inc.
3.2*	Form of Bylaws of 2seventy bio, Inc.
10.1*	Form of Transition Services Agreement by and between bluebird bio, Inc. and 2seventy bio, Inc.
10.2*	Form of Transition Services Agreement by and between 2seventy bio, Inc. and bluebird bio, Inc.
10.3*	Form of Tax Matters Agreement by and between bluebird bio, Inc. and 2seventy bio, Inc.
10.4*	Form of Employee Matters Agreement by and between bluebird bio, Inc. and 2seventy bio, Inc.
10.5*	Form of Intellectual Property License Agreement by and between bluebird bio, Inc. and 2seventy bio, Inc.
10.6*+	Form of Indemnification Agreement between2seventy bio, Inc. and individual directors and officers
10.7*+	Form of 2seventy bio, Inc. 2021 Employee Stock Purchase Plan
10.8*+	Form of 2seventy bio, Inc. 2021 Stock Option and Incentive Plan and forms of award agreement thereunder
99.1	Information Statement of 2seventy bio, Inc., preliminary and subject to completion, dated May 11, 2021
99.2*	Form of Notice of Internet Availability of Information Statement Materials

*To be filed by amendment.
+Management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

2seventy bio, Inc.

By: _____

Name:

Title:

Date: , 2021

Exhibit 99.1

Dear bluebird bio, Inc. Stockholder:

In January 2021, we announced a transformative milestone for bluebird bio, Inc.—our intent to separate our oncology portfolio and programs from our severe genetic disease portfolio and programs, thereby creating two independent, publicly traded companies. The strategic objectives of the separation are to unlock value, enhance operational performance and strategic flexibility and tailor the capital structures to best serve these distinct businesses.

We believe the best way to realize the full potential of this separation is for bluebird bio, Inc. and 2seventy bio, Inc. to operate independently, with distinct management teams and boards of directors dedicated to their unique business strategies. Through this separation, we have the potential to create two focused, durable businesses that are well-positioned with the resources, talent and foundation to be industry leaders in their respective fields.

Going forward, bluebird bio, Inc. intends to focus primarily on its programs in severe genetic disease, including betibeglogene autotemcel (beti-cel; formerly LentiGlobin gene therapy for β-thalassemia), LentiGlobin gene therapy for sickle cell disease, and elivaldogene autotemcel (eli-cel; formerly Lenti-D gene therapy for cerebral adrenoleukodystrophy). 2seventy bio, Inc. plans to focus primarily on the discovery and development of novel engineered cell therapies for cancer, including chimeric antigen receptor (CAR) and T cell receptor (TCR) T cell therapies. 2seventy bio, Inc. expects to commercialize idecabtagene vicleucel (ide-cel; being commercialized as Abecma) in the United States and develop bb21217 through its collaboration arrangement with Bristol-Myers Squibb.

Upon completion of the separation, 2seventy bio, Inc. will be spun out of bluebird bio, Inc. and established as an independent, publicly traded company. The separation is anticipated to be tax-free to bluebird bio, Inc. stockholders. Under the terms of the distribution, each bluebird bio, Inc. stockholder will receive one share of 2seventy bio, Inc. common stock for every shares of bluebird bio, Inc. common stock held of record on , 2021, the record date for the distribution. You do not need to take any action to receive the common stock of 2seventy bio, Inc. to which you are entitled as a bluebird bio, Inc. stockholder as of the record date.

Please read the attached information statement, which is being shared with all bluebird bio, Inc. stockholders as of the record date for the distribution. It describes the separation in detail and contains important information about bluebird bio, Inc. and 2seventy bio, Inc.

We thank you for your continued support of bluebird bio, Inc.

Sincerely,

Daniel S. Lynch
Chairman of the Board
bluebird bio, Inc.

Dear Future 2seventy bio, Inc. Stockholder:

On behalf of the entire future 2seventy bio, Inc. team, I am pleased to welcome you as a future stockholder of our new company.

2seventy bio, Inc. will be a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. Its programs will be based on chimeric antigen receptor (CAR) technology and T cell receptor technology. At launch, 2seventy bio, Inc.'s programs will include idecabtagene vicleucel; ide-cel, or Abecma, and bb21217, CAR-T cell product candidates for the treatment of multiple myeloma, which are partnered under a collaboration arrangement with Bristol-Myers Squibb. We believe our team's expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies will enable us to develop a pipeline of highly innovative, targeted cellular therapies for patients with cancer.

We intend to apply to have our common stock listed on the Nasdaq Global Market under the symbol "TSVT" in connection with the distribution of our company's common stock by bluebird bio, Inc.

I invite you to learn more about 2seventy bio, Inc. by reviewing the enclosed information statement. We look forward to our future as an independent company, and to your support as a 2seventy bio, Inc. stockholder as we begin this new and exciting chapter.

Sincerely,

Nick Leschly
Chief Executive Officer
2seventy bio, Inc.

Information contained herein is subject to completion or amendment. A Registration Statement on Form 10 relating to these securities has been filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

PRELIMINARY AND SUBJECT TO COMPLETION, DATED MAY 11, 2021

INFORMATION STATEMENT

2seventy bio, Inc.

This information statement is being furnished to you as a holder of common stock of bluebird bio, Inc. ("bluebird bio") in connection with the distribution of shares of common stock of 2seventy bio, Inc., or 2seventy bio. 2seventy bio, which is currently a wholly owned subsidiary of bluebird bio, will hold, directly or indirectly, assets and liabilities related to bluebird bio's oncology portfolio and programs. To implement the distribution, bluebird bio will distribute all of the outstanding shares of 2seventy bio common stock on a pro rata basis to holders of bluebird bio common stock in a manner that is intended to be tax-free to bluebird bio stockholders for U.S. federal income tax purposes.

You will receive shares of 2seventy bio common stock for every shares of bluebird bio common stock held of record by you as of the close of business on , 2021, the record date for the distribution. Holders of bluebird bio common stock will receive cash in lieu of any fractional shares of 2seventy bio common stock that those holders would have received after application of the above ratio. As discussed under "The Separation and Distribution—Trading Between the Record Date and Distribution Date," if you sell your shares of bluebird bio common stock in the "regular way" market after the record date and before the distribution, you also will be selling your right to receive shares of 2seventy bio common stock in connection with the distribution. 2seventy bio expects that shares of its common stock will be distributed by bluebird bio to you on , 2021. The date of distribution of 2seventy bio common stock is referred to in this information statement as the "distribution date."

No vote of bluebird bio stockholders is required for the distribution. Therefore, you are not being asked for a proxy, and you are requested not to send bluebird bio a proxy, in connection with the distribution. You do not need to pay any consideration, exchange or surrender your existing shares of bluebird bio common stock or take any other action to receive your shares of 2seventy bio common stock.

There is no current trading market for 2seventy bio common stock. 2seventy bio expects that a limited market, commonly known as a "when issued" trading market, will develop on or shortly before the record date for the distribution, and that "regular way" trading of 2seventy bio common stock will begin on the first trading day following the completion of the distribution. 2seventy bio intends to apply for listing of its common stock on the Nasdaq Global Market under the symbol "TSVT".

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we will be subject to reduced public company reporting requirements.

In reviewing this information statement, you should carefully consider the matters described under the caption "*Risk Factors*" beginning on page 19.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this information statement is truthful or complete. Any representation to the contrary is a criminal offense.

This information statement does not constitute an offer to sell or the solicitation of an offer to buy any securities.

A Notice of Internet Availability of Information Statement Materials containing instructions for how to access this information statement is first being mailed to bluebird bio stockholders on or about , 2021.

This information statement will be mailed to bluebird bio stockholders who previously elected to receive a paper copy of bluebird bio's materials.

The date of this information statement is , 2021.

TABLE OF CONTENTS

PRESENTATION OF INFORMATION	1
QUESTIONS AND ANSWERS ABOUT THE SEPARATION AND DISTRIBUTION	3
INFORMATION STATEMENT SUMMARY	10
SUMMARY HISTORICAL AND UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION	18
RISK FACTORS	19
CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS	71
DIVIDEND POLICY	73
CAPITALIZATION	74
UNAUDITED PRO FORMA COMBINED FINANCIAL STATEMENTS	75
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	79
BUSINESS	98
MANAGEMENT	134
EXECUTIVE COMPENSATION	138
CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS	149
SECURITY OWNERSHIP BY CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	152
THE SEPARATION AND DISTRIBUTION	153
MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES	158
DESCRIPTION OF 2SEVENTY BIO'S CAPITAL STOCK	162
WHERE YOU CAN FIND MORE INFORMATION	166
INDEX TO COMBINED FINANCIAL STATEMENTS	F-1

PRESENTATION OF INFORMATION

Except as otherwise indicated or unless the context otherwise requires, the information included in this information statement about 2seventy bio assumes the completion of all of the transactions referred to in this information statement in connection with the separation and distribution.

Unless the context otherwise requires, references in this information statement to the following terms shall have the following respective meanings:

- "bluebird bio" refers to bluebird bio, Inc., a Delaware corporation, and its consolidated subsidiaries;
- "distribution" refers to the distribution by bluebird bio to bluebird bio stockholders of record as of the record date of all of the outstanding shares of 2seventy bio, as further described in this information statement;
- "separation" refers to the separation of bluebird bio's oncology portfolio and programs from bluebird bio's severe genetic disease portfolio and programs, and the creation, as a result of the distribution, of an independent, publicly traded company, 2seventy bio, that holds the oncology portfolio and programs, as further described in this information statement; and
- "2seventy bio," "we," "us," "our," "our company" and "the company" refer to 2seventy bio, Inc., a Delaware corporation, together with its subsidiaries, as the context requires, in each case as they will exist, assuming the completion of all the transactions referred to in this information statement in connection with the separation and the distribution.

This information statement describes the portfolio and programs to be transferred to 2seventy bio by bluebird bio in the separation as if the transferred portfolio and programs were 2seventy bio's portfolio and programs for all historical periods described. References in this information statement to 2seventy bio's historical assets, liabilities, products, businesses or activities of 2seventy bio's portfolio and programs are generally intended to refer to the historical assets, liabilities, products, businesses or activities of the transferred portfolio and programs as they were conducted as part of bluebird bio prior to the separation.

You should not assume that the information contained in this information statement is accurate as of any date other than the date set forth on the cover. Changes to the information contained in this information statement may occur after that date, and we undertake no obligation to update the information, except in the normal course of our public disclosure obligations or as required by applicable law.

Websites described in this information statement and the content therein or connected thereto shall not be deemed incorporated into this information statement.

Trademarks, Trade Names and Service Marks

2seventy bio owns and has rights to use the trademarks, service marks and trade names that it uses in conjunction with the operation of its business, including 2seventy bio, 2seventybio, and 2seventy. In addition, 2seventy bio's trademarks are undergoing examination and registration in the United States and other jurisdictions. 2seventy bio's trademark rights may be limited to select markets. Each trademark, trade name or service mark of any other company appearing in this information statement is, to 2seventy bio's knowledge, owned by such other company.

Industry and Other Data

This information statement contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

QUESTIONS AND ANSWERS ABOUT THE SEPARATION AND DISTRIBUTION

What is 2seventy bio and why is bluebird bio separating 2seventy bio's portfolio and programs and distributing 2seventy bio's common stock?

2seventy bio, which is currently a wholly owned subsidiary of bluebird bio, was formed to hold bluebird bio's oncology portfolio and programs. The separation of 2seventy bio from bluebird bio and the distribution of 2seventy bio common stock are intended to provide you with equity investments in two separate, independent public companies, each of which is able to focus on its respective business strategies. bluebird bio and 2seventy bio believe the separation will enable each business to pursue focused growth and investment strategies in its respective therapeutic areas of expertise resulting in the enhanced long-term performance of each business, as discussed in "The Separation and Distribution—Overview" and "The Separation and Distribution—Reasons for the Separation."

Why am I receiving this document?

bluebird bio is delivering this information statement to you because you are a holder of record of shares of bluebird bio common stock. If you remain a holder of shares of bluebird bio common stock as of the close of business on , 2021, you will be entitled to receive one share of 2seventy bio common stock for every shares of bluebird bio common stock that you held of record at the close of business on such date. This information statement will help you understand how the separation will affect your investment in bluebird bio and your investment in 2seventy bio after the distribution.

How will the separation of 2seventy bio from bluebird bio work?

To accomplish the separation, bluebird bio will distribute all of the outstanding shares of 2seventy bio common stock to bluebird bio stockholders on a pro rata basis.

Why is the separation of 2seventy bio structured as a distribution?

bluebird bio believes that a tax-free distribution for U.S. federal income tax purposes of shares of 2seventy bio common stock to the bluebird bio stockholders is an efficient way to separate its oncology portfolio and programs in a manner that will create long-term value for bluebird bio, 2seventy bio and their respective stockholders. For more information, see "The Separation and Distribution—Conditions to the Distribution."

What is the record date for the distribution?

The record date for the distribution will be , 2021.

When will the distribution occur?

It is expected that all of the shares of 2seventy bio common stock will be distributed by bluebird bio on , 2021, to holders of record of bluebird bio common stock as of the close of business on , 2021. We refer to the date on which shares of 2seventy bio common stock are distributed as the "distribution date."

What do stockholders need to do to participate in the distribution?

Nothing. **Stockholders of bluebird bio as of the record date will not be required to take any action to receive 2seventy bio common stock, but are urged to read this entire information statement carefully**. No stockholder approval of the distribution is required or sought. **Therefore, you are not being asked for a proxy to vote on the separation, and you are requested not to send us a proxy.** You will neither be required to pay anything for the shares of 2seventy bio common stock nor be required to surrender any shares of bluebird bio common stock to participate in the distribution. **Please do not send in your bluebird bio stock certificates.**

The distribution will not affect the number of outstanding shares of bluebird bio common stock or any rights of bluebird bio stockholders, although it will affect the market value of each outstanding share of bluebird bio common stock. See "Questions and Answers about the Separation and Distribution—Will the distribution affect the market price of my bluebird bio common stock?" for more information.

How will bluebird bio distribute shares of 2seventy bio common stock?

Registered stockholders: If you are a registered stockholder (meaning you hold physical bluebird bio stock certificates or you own your shares of bluebird bio common stock directly through an account with bluebird bio's transfer agent, American Stock Transfer & Trust), the distribution agent will credit the number of whole shares of 2seventy bio common stock you receive in the distribution to your book-entry account on or shortly after the distribution date, and the distribution agent will mail you a check for any cash in lieu of fractional shares you are entitled to receive.

"*Street name" or beneficial stockholders:* If you own your shares of bluebird bio common stock beneficially through a bank, bluebird bio or other nominee, your bank, broker or other nominee will credit your account with the number of whole shares of 2seventy bio common stock you receive in the distribution on or shortly after the distribution date. Please contact your bank, broker or other nominee for further information about your account.

We will not issue any physical stock certificates to any stockholders receiving shares in the distribution, even if requested. See "The Separation and Distribution—When and How You Will Receive the Distribution" for more information.

How many shares of 2seventy bio common stock will I receive in the distribution?

bluebird bio will distribute to you one share of 2seventy bio common stock for every shares of bluebird bio common stock you hold of record as of the close of business on , 2021, the record date. Based on approximately shares of bluebird bio common stock outstanding as of , 2021, , a total of approximately shares of 2seventy bio common stock will be distributed. For more information, see "The Separation and Distribution—The Number of Shares of 2seventy bio Common Stock You Will Receive."

Will 2seventy bio issue fractional shares in the distribution?

2seventy bio will not distribute fractional shares of its common stock in the distribution. Instead, all fractional shares that bluebird bio registered stockholders would otherwise have been entitled to receive will be aggregated into whole shares and sold in the open market by the distribution agent. We expect the distribution agent, acting on behalf of bluebird bio, to take about after the distribution date to fully distribute the aggregate net cash proceeds of these sales on a pro rata basis (based on the fractional share such holder would otherwise be entitled to receive) to those stockholders who would otherwise have been entitled to receive fractional shares. Recipients of cash in lieu of fractional shares will not be entitled to any interest on the amounts of payment made in lieu of fractional shares. For more information, see "The Separation and Distribution—The Number of Shares of 2seventy bio Common Stock You Will Receive."

What are the conditions to the distribution?

The distribution is subject to the satisfaction (or waiver by bluebird bio in its sole discretion) of a number of conditions to be set forth in the separation agreement, including, among others, that bluebird bio will have received a private letter ruling from the Internal Revenue Service, or the IRS, and an opinion from Goodwin Procter LLP, both satisfactory to bluebird bio's board of directors, together confirming that the distribution, together with certain related transactions, generally is tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended, or the Code.

bluebird bio and 2seventy bio cannot assure you that any or all of these conditions will be met, and bluebird bio may waive any of these conditions to the distribution. In addition, bluebird bio can determine, at any time, not to proceed with the distribution. For more information, see "The Separation and Distribution—Conditions to the Distribution."

What is the expected date of completion of the distribution?

The completion and timing of the distribution are dependent upon a number of conditions. It is expected that the shares of 2seventy bio common stock will be distributed by bluebird bio on , 2021 to the holders of record of shares of bluebird bio common stock as of the close of business on the record date. However, no assurance can be provided as to the timing of the distribution or that all conditions to the distribution will be met.

Can bluebird bio decide to cancel the distribution of 2seventy bio common stock even if all the conditions have been met?

Yes, until the distribution has occurred, bluebird bio has the right to terminate the distribution, even if all of the conditions are satisfied. See "The Separation and Distribution—Conditions to the Distribution" for more information.

What if I want to sell my bluebird bio common stock or my 2seventy bio common stock?

You should consult with your advisors, such as your broker, bank or tax advisor.

What is "regular way" and "ex-distribution" trading of bluebird bio stock?

Beginning on or shortly before the record date and continuing up to and including the distribution date, it is expected that there will be two markets in shares of bluebird bio common stock: a "regular way" market and an "ex-distribution" market. Shares of bluebird bio common stock that trade in the "regular way" market will trade with an entitlement to shares of 2seventy bio common stock distributed pursuant to the distribution. Shares that trade in the "ex-distribution" market will trade without an entitlement to shares of 2seventy bio common stock distributed pursuant to the distribution.

If you hold shares of bluebird bio common stock on the record date and you decide to sell any shares of bluebird bio common stock before the distribution date, you should make sure your broker, bank or other nominee understands whether you want to sell your shares of bluebird bio common stock with or without your entitlement to receive 2seventy bio common stock pursuant to the distribution. See "The Separation and Distribution—Trading Between the Record Date and Distribution Date" for more information.

Where will I be able to trade shares of 2seventy bio common stock?

Currently, there is no public market for 2seventy bio common stock. 2seventy bio intends to apply to have its common stock authorized for listing on the Nasdaq Global Market under the symbol "TSVT".

2seventy bio anticipates that trading in shares of its common stock will begin on a "when issued" basis on or shortly before the record date for the distribution and will continue up to and including the distribution date. "When issued" trading in the context of a separation refers to a sale or purchase made conditionally on or before the distribution date because the securities of the separated entity have not yet been distributed. "When issued" trades generally settle within two weeks after the distribution date. On the first trading day following the distribution date, any "when issued" trading of our common stock will end and "regular way" trading will begin. "Regular way" trading refers to trading after the security has been distributed and typically involves a trade that settles on the second full trading day following the date of the trade. See "The Separation and Distribution—Trading Between the Record Date and Distribution Date" for more information. We cannot predict the trading prices for our common stock before, on or after the distribution date.

What will happen to the listing of shares of bluebird bio common stock?

Shares of bluebird bio common stock will continue to trade on the Nasdaq Global Select Market after the distribution.

Will the number of shares of bluebird bio common stock that I own change as a result of the distribution?

No. The number of shares of bluebird bio common stock that you own will not change as a result of the distribution.

Will the distribution affect the market price of my bluebird bio common stock?

Yes. As a result of the distribution, bluebird bio expects the trading price of shares of bluebird bio common stock immediately following the distribution to be lower than the "regular way" trading price of such shares immediately prior to the distribution because the trading price will no longer reflect the value of the oncology portfolio and programs. Furthermore, as the market assesses bluebird bio following the separation, the trading price of shares of bluebird bio common stock may fluctuate. There can be no assurance that, following the distribution, the combined trading prices of bluebird bio common stock and 2seventy bio common stock will equal or exceed what the trading price of bluebird bio common stock would have been in the absence of the separation, and it is possible the post-distribution combined equity value of bluebird bio and 2seventy bio will be less than bluebird bio's equity value prior to the distribution.

What are the material U.S. federal income tax consequences of the distribution?

It is a condition to the distribution that bluebird bio receive a private letter ruling from the IRS and an opinion from Goodwin Procter LLP, both satisfactory to bluebird bio's board of directors, together confirming that the distribution, together with certain related transactions, generally is tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code. Assuming that the distribution, together with certain related transactions, so qualifies, for U.S. federal income tax purposes, no gain or loss will be recognized by you and no amount will be included in your income upon receipt of shares of 2seventy bio common stock pursuant to the distribution. You will, however, recognize gain or loss for U.S. federal income tax purposes with respect to cash received in lieu of a fractional share of 2seventy bio common stock.

You should consult your own tax advisor as to the particular consequences of the distribution to you, including the applicability and effect of any U.S. federal, state and local tax laws, as well as non-U.S. tax laws. For more information regarding the material U.S. federal income tax consequences of the distribution, see "Material U.S. Federal Income Tax Consequences."

How will I determine my tax basis in the shares of 2seventy bio common stock I receive in the distribution?

For U.S. federal income tax purposes, your aggregate basis in the common stock that you hold in bluebird bio and the new 2seventy bio common stock received in the distribution (including any fractional share interest in 2seventy bio common stock for which cash is received) will equal the aggregate basis in the shares of bluebird bio common stock held by you immediately before the distribution, allocated between your shares of bluebird bio common stock and 2seventy bio common stock (including any fractional share interest in 2seventy bio common stock for which cash is received) you receive in the distribution in proportion to the relative fair market value of each on the distribution date.

	You should consult your own tax advisor as to the particular consequences of the distribution to you, including the application of the tax basis allocation rules and the application of state, local and non-U.S. tax laws.
What will 2seventy bio's relationship be with bluebird bio following the distribution?	To effect a decisive and efficient separation into two thriving companies, 2seventy bio intends to enter into a separation agreement and certain other agreements with bluebird bio, including a tax matters agreement, an employee matters agreement, an intellectual property license agreement, a transition services agreement under which we will temporarily receive certain services from bluebird bio and a second transition services agreement under which we will temporarily provide certain services to bluebird bio. These agreements will provide for the separation between bluebird bio and 2seventy bio of the assets, employees, liabilities and obligations (including investments, property and employee benefits) of bluebird bio attributable to periods prior to, at and after the distribution and will govern the relationship between bluebird bio and 2seventy bio subsequent to the completion of the distribution. For additional information regarding the separation agreement and other transaction agreements, see “Risk Factors—Risks Related to the Separation” and “Certain Relationships and Related Person Transactions—Agreements with bluebird bio.”
Who will manage 2seventy bio after the distribution?	2seventy bio will benefit from having in place a management team with a substantial background in the biotechnology business. 2seventy bio's management team possesses deep knowledge of and experience in its industry. 2seventy bio's management team is expected to include Nick Leschly, bluebird bio’s president and chief executive officer who is expected to be 2seventy bio's president and chief executive officer after the distribution, William D. Baird, bluebird bio’s chief financial officer who is expected to be 2seventy bio's chief financial officer after the distribution, and Philip Gregory who is expected to be 2seventy bio’s chief scientific officer after the distribution. For more information regarding bluebird bio’s expected management team and leadership structure, see “Management.”
Are there risks associated with owning 2seventy bio common stock?	Yes. Ownership of 2seventy bio common stock is subject to both general and specific risks related to 2seventy bio’s business, the industry in which it operates, its ongoing relationships with bluebird bio and its status as a separate, publicly traded company. Ownership of 2seventy bio common stock is also subject to risks related to the separation. These risks are described in the “Risk Factors” section of this information statement beginning on page 19. You are encouraged to read that section carefully.
Does 2seventy bio plan to pay dividends?	2seventy bio does not expect to pay a regular cash dividend following the distribution. The payment of any dividends in the future, and the timing and amount thereof, is within the discretion of 2seventy bio's board of directors. See “Dividend Policy.”

Who will be the distribution agent, transfer agent and registrar for the 2seventy bio common stock?

The distribution agent, transfer agent and registrar for 2seventy bio common stock will be American Stock Transfer & Trust Company. For registered holders with questions relating to the transfer or mechanics of the stock distribution, you should contact:

Address:
Tel:
E-mail:

How can I contact bluebird bio or 2seventy bio with any questions?

Before the distribution, if you have any questions relating to bluebird bio or 2seventy bio's business performance, you should contact:

bluebird bio, Inc.
Investor Relations Department
60 Binney Street
Cambridge, MA 02142
Tel: 617-245-2107
E-mail: investor@bluebirdbio.com

After the distribution, 2seventy bio stockholders who have any questions relating to 2seventy bio's business performance should contact 2seventy bio at:

2seventy bio, Inc.
Investor Relations Department
Address:
Tel:
E-mail:

INFORMATION STATEMENT SUMMARY

The following is a summary of material information discussed in this information statement. This summary may not contain all the details concerning the separation or other information that may be important to you. To better understand the separation and 2seventy bio's business and financial position, you should carefully review this entire information statement, including the risks discussed under "Risk Factors."

Except as otherwise indicated or unless the context otherwise requires, the information included in this information statement assumes the completion of all of the transactions referred to in this information statement in connection with the separation. Some of the statements in this summary constitute forward-looking statements. See "Cautionary Statement Concerning Forward-Looking Statements."

Overview

2seventy bio is a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. We are led by an accomplished team with significant expertise and experience in this field, from discovery through clinical development to regulatory approval of Abecma (idecabtagene vicleucel, or ide-cel), the first FDA-approved chimeric antigen receptor technology (CAR T) cell therapy for multiple myeloma. Our approach combines our expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. We are advancing multiple preclinical and clinical programs in oncology and, together with our partner Bristol-Myers Squibb (BMS), delivering Abecma to multiple myeloma patients in the United States.

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

While medicines such as Abecma have highlighted the power of first-generation CAR T cell therapy by achieving previously unobtainable levels of efficacy in the late line setting, we believe that to be broadly successful in the treatment of cancer, a combination therapy approach is necessary, and that our multiplex approach to next-generation autologous cellular therapy, which allows multiple encoded mechanisms of action to be delivered within a single drug product, represents an attractive solution. Based on our experience in the research and development of Abecma, we believe we can develop next-generation, engineered cell therapies to bring new options to patients suffering from a broad range of different tumor types.

In designing our next-generation product candidates, we aim to address the limitations of first-generation T cell therapies by augmenting them with additional technologies. Our approach is to create multiplex engineered cell therapies by combining: (1) CAR and T cell receptor technology, which programs T cells to recognize and kill cancer cells based on the cell surface expression or presentation of intracellular protein targets, respectively; (2) dual-targeting CAR architecture for multi-target tumor cell recognition; (3) our core lentiviral gene transfer technology which delivers these genetic cargos (and more) to program a patient's own T cells to the kill the cancer cells; (4) our megaTAL-based gene editing technology which allows us to perform site specific gene addition or deletion from the genome to improve the properties of the T cell; and (5) genetically encoded technologies for engineering T cells to enhance the cytotoxic activity and reprogram the tumor microenvironment for more effective anti-tumor responses.

Our Strategy

Our strategy is to apply our broad range of technologies to design multiplex product candidates that address the key treatment challenges in cancer. Unlike other oncology-focused companies in our space, we believe our breadth of technology enables us to develop tailored products focused on the specific areas of cancer biology we have identified. We selectively combine the relevant features and components from our range of tools and technologies to address the defined attributes of a cellular therapy necessary for anti-tumor effect.

To execute on our strategy, we plan to:

- Commercialize Abecma and develop bb21217 through our collaboration with BMS, the learnings from which allow us to leverage our clinical experience and product revenue stream to further invest in our next-generation proprietary programs.

- Leverage our leadership position in autologous CAR T therapies to advance into the clinic our next-generation programs in B cell non-Hodgkin's lymphoma, acute myeloid leukemia, and multiple myeloma.

- Apply our multiplex approach to the discovery and design of transformative cell and gene therapy products for the treatment of solid tumors.

- Seek to extend our approach to other cell types beyond T cells and to include allogeneic approaches, as we gain additional experience in our autologous T cell programs.

- Build upon our existing internal lentiviral vector manufacturing know-how and experience through selective investments in manufacturing collaborations and expanding our internal capabilities over time, with the objectives of enabling rapid iteration on clinical learnings into research and development, increasing the efficiency of manufacturing processes, and improving the overall patient and healthcare professional experience.

Our Technologies

Our oncology programs use a lentiviral vector to deliver the genetic cargo necessary to program a patient's own T cells to recognize specific proteins or protein fragments on the surface of cancer cells to kill the cancer cells. Our current programs are based on CAR technology to program T cells to recognize cancer cells based on expression of specific cell surface antigens, and T cell receptor technology to program T cells to recognize cancer cells based on protein fragments derived from either intracellular or extracellular proteins displayed on the tumor cell surface. The genetically engineered T cells are designed to supplement a patient's immune system and may be further engineered to overcome immune evasion mechanisms employed by cancer cells. Our approach is to create multiplex engineered cell therapies by combining our foundational lentiviral vector and CAR/T cell receptor (TCR) technology with next-generation tools to address the challenges in existing cancer treatments.

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

- **DARIC.** We have developed a pharmacologically-regulated split antigen receptor architecture, which we refer to as DARIC, that comprises separate antigen targeting and signal transduction componentry. DARIC receptors become poised for anti-tumor function only when the two components are brought together as heterodimers, a process that is strictly dependent on the bridging function of the drug rapamycin. This technology enables pharmacological, 'on-demand' control of engineered T cell responses. Controlling the

‘on’ and ‘off’ states of engineered T cells also creates opportunities to pursue cancers and cancer targets with disease characteristics and expression profiles that are incompatible with constitutively responsive antigen receptors.

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

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

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

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

- **Cellular chassis**. Beyond genetic modifications we are also developing approaches aimed at selecting for or enriching distinct cell types for tumor targeting that may be broadly applicable to both autologous and allogeneic settings. For instance, our bb21217 program utilizes a PI3K-inhibiting small molecule to enrich for memory-like T cells with the goal of extending the durability of action of our CAR T cells for multiple myeloma. In addition, we have developed approaches for the selection, transduction and expansion of gamma delta T cells. We believe gamma delta T cells may be useful in the allogeneic setting due to the absence of alloreactivity or graft-versus-host disease while demonstrating potent anti-tumor activity.

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

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

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

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

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

Summary of Risk Factors

An investment in 2seventy bio’s common stock is subject to a number of risks, including risks related to our business, risks related to the separation and risks related to our common stock. The following list of risk factors is not exhaustive. Please read the information in the section captioned “Risk Factors” for a more thorough description of these and other risks.

Risks Related to Our Business

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

- Our business has incurred significant losses and we anticipate that we will continue to incur significant losses for the foreseeable future.

- We will need to raise additional funding to advance our product candidates, which may not be available on acceptable terms, or at all.

- 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.
- If we encounter difficulties in enrolling subjects in our clinical studies, we could be delayed or prevented from proceeding with clinical trials of our product candidates.
- If the market opportunities for our approved product, Abecma, or any future 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 cannot predict when or if we will obtain marketing approval to commercialize our product candidates, and the marketing approval of our product and any future products may ultimately be for more narrow indications than we expect.
- Delays in the commencement and completion of clinical trials could increase costs and delay or prevent regulatory approval and commercialization of our product candidates.
- If our product candidates are ultimately not approved for any reason, our business, prospects, results of operations and financial condition would be adversely affected.
- Patients receiving T cell-based immunotherapies, such as Abecma or bb21217 in ongoing clinical trials, may experience serious adverse events, including neurotoxicity and cytokine release syndrome.
- Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our product and any future product candidates.
- We may not be successful in our efforts to identify or discover additional product candidates.
- We are dependent on BMS for the successful commercialization of Abecma and successful development of bb21217.
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.
- 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 may not be successful in obtaining or maintaining necessary rights to gene therapy product components and processes for our development pipeline through acquisitions and in-licenses.
- We have limited experience as a commercial company and the marketing and sale any future approved drugs may be unsuccessful or less successful than anticipated.
- 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.
- Even if we obtain regulatory approval for our product candidates, our product candidates may not achieve broad market acceptance by patients, physicians, healthcare payors or others in the medical community, which would limit the revenue that we generate from their sales.
- 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 our product and any future products.

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

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

Risks Related to the Separation

- We may not achieve some or all of the expected benefits of the separation, and the separation could harm our business, prospects, financial condition and results of operations.

- We have no history of operating as an independent company, and we expect to incur increased administrative and other costs following the separation by virtue of our status as an independent public company.

- The separation may impede our ability to attract and retain key personnel, which could materially harm our business.

- The separation may result in disruptions to, and harm our relationships with, our strategic business partners.

- If the distribution, together with certain related transactions, does not qualify as a transaction that is 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.

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

- Our agreements with bluebird bio may not reflect terms that would have resulted from negotiations with unaffiliated third parties.

- The combined post-separation value of bluebird bio and our common stock may not equal or exceed the pre-separation value of bluebird bio common stock.

- If the distribution occurs and you do not want to receive our common stock in the distribution, your sole recourse will be to divest yourself of your bluebird bio common stock prior to the record date.

The Separation and Distribution

In January 2021, bluebird bio announced its plans to separate its oncology portfolio and programs from its severe genetic disease portfolio and programs, and spin off its oncology portfolio and programs into a separate publicly traded company. The distribution is generally intended to be tax-free for U.S. federal income tax purposes to bluebird bio stockholders. See “The Separation and Distribution —Conditions to the Distribution” for more information.

In furtherance of this plan, on , 2021, bluebird bio’s board of directors approved the distribution of all of the issued and outstanding shares of 2seventy bio common stock on the basis of shares of 2seventy bio common stock for every shares of bluebird bio common stock issued and outstanding on , 2021, the record date for the distribution. As a result of the distribution, 2seventy bio will become an independent, publicly traded company.

Immediately following the distribution, we estimate that shares of 2seventy bio common stock will be issued and outstanding based on the number of shares of bluebird bio common stock outstanding as of , 2021. The actual number of shares of 2seventy bio common stock issued in the distribution will be determined on , 2021, the record date.

2seventy bio's Post-Distribution Relationship with bluebird bio

2seventy bio intends to enter into a separation agreement with bluebird bio, which is referred to in this information statement as the "separation agreement," and various other agreements with bluebird bio, including a tax matters agreement, an employee matters agreement, an intellectual property license agreement, a transition services agreement under which we will temporarily receive certain services from bluebird bio and a second transition services agreement under which we will temporarily provide certain services to bluebird bio. These agreements will effectuate the separation and govern 2seventy bio's relationship with bluebird bio after the distribution. These agreements will provide for the allocation between bluebird bio and 2seventy bio of bluebird bio's assets, employees, liabilities and obligations (including investments, property and employee benefits and tax-related assets and liabilities) attributable to periods prior to and after 2seventy bio's separation from bluebird bio. These agreements will also govern certain relationships between bluebird bio and 2seventy bio after the separation. For additional information regarding the separation agreement and the other related agreements, see "Risk Factors—Risks Related to the Separation" and "Certain Relationships and Related Person Transactions—Agreements with bluebird bio."

Reasons for the Separation

The bluebird bio board of directors believes that separating its oncology portfolio and programs from its severe genetic disease portfolio and programs is in the best interests of bluebird bio and its stockholders for a number of reasons, including that:

- the separation will allow each business to pursue its own operational and strategic priorities and more quickly respond to trends, developments and opportunities in its respective markets;
- the separation will create two separate and distinct management teams focused on each business's unique strategic priorities, target markets and corporate development opportunities;
- the separation will give each business opportunity and flexibility by pursuing its own investment, capital allocation and growth strategies consistent with its long-term objectives;
- the separation will enable the boards and management teams of each business to better align corporate performance goals with the specific vision, strategy, and objectives of each business; and
- the separation will allow investors to separately value each business based on the unique merits, performance and future prospects of each business, providing investors with two distinct investment opportunities.

The bluebird bio board of directors considered a number of other factors in evaluating the separation, including risks relating to the creation of a stand-alone company and possible increased overall costs as well as one-time separation costs, but concluded that the potential benefits of the separation outweighed these factors. For more information, see "The Separation and Distribution—Reasons for the Separation" and "Risk Factors" included elsewhere in this information statement.

Corporate Information

2seventy bio, Inc. was incorporated in the State of Delaware on April 26, 2021 for the purpose of holding bluebird bio's oncology portfolio and programs in connection with the separation described in this information statement. The contribution of the oncology portfolio and programs to 2seventy bio is occurring over a period of time prior to the distribution, and 2seventy bio will have no operations prior to such contribution. At the time of the distribution, the address of 2seventy bio's principal executive offices will be . 2seventy bio's telephone number will be . 2seventy bio will also maintain a website at .

Reason for Furnishing this Information Statement

This information statement is being furnished solely to provide information to stockholders of bluebird bio who will receive shares of 2seventy bio common stock in the distribution. It is not, and is not to be construed as, an inducement or encouragement to buy or sell any of 2seventy bio's securities.

Implications of Being an Emerging Growth Company

2seventy bio qualifies as an "emerging growth company" as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other obligations that are otherwise applicable generally to public companies. These may include the following:

- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
- exemption from the requirements for holding a non-binding advisory vote on executive compensation or golden parachute arrangements;
- extended transition period for complying with new or revised accounting standards; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total gross annual revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the distribution; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

SUMMARY HISTORICAL AND UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION

The following table presents our summary historical and unaudited pro forma combined financial information. We derived the summary historical combined financial data as of December 31, 2020 and 2019 and for the years ended December 31, 2020, 2019 and 2018 from our audited combined financial statements included elsewhere in this information statement.

The summary historical combined financial data includes certain expenses of bluebird bio that were allocated to us for certain corporate functions, including senior management, legal, human resources, finance and information technology. These costs may not be representative of the future costs we will incur as an independent, publicly traded company. In addition, our historical financial information does not reflect changes that we expect to experience in the future as a result of our separation from bluebird bio, including changes in our cost structure, personnel needs, tax structure, capital structure, financing and business operations.

The following unaudited pro forma combined statement of operations for the year ended December 31, 2020 gives effect to the separation as if it had occurred on January 1, 2020. The following unaudited pro forma combined balance sheet as of December 31, 2020 gives effect to the separation as if it had occurred on December 31, 2020. The unaudited pro forma adjustments are based on assumptions that management believes are reasonable under the circumstances and given the information available at this time. Refer to the notes to the unaudited pro forma combined financial statements included elsewhere in this information statement for a discussion of adjustments reflected in the unaudited pro forma combined financial statements. Consequently, the financial information included here may not necessarily reflect our financial position, results of operations and cash flows in the future or what our financial position, results of operations and cash flows would have been had we been an independent, publicly traded company during the periods presented.

For a better understanding of the financial information included here, this section should be read in conjunction with the discussion in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the "Unaudited Pro Forma Combined Financial Statements" and corresponding notes, and the audited combined financial statements and corresponding notes included elsewhere in this information statement.

	Year ended December 31,			
(in thousands)	**Pro Forma 2020**	**2020**	**2019**	**2018**
Statement of Operations:				
Total revenues		$ 248,122	$ 44,296	$ 54,579
Research and development expense		296,467	297,645	200,490
Selling, general and administrative expense		90,897	81,646	53,631
Net loss		(120,114)	(320,594)	(199,749)

	As of December 31,		
(in thousands)	**Pro Forma 2020**	**2020**	**2019**
Balance Sheet:			
Total assets		$ 312,620	$ 314,949
Total current liabilities		75,868	103,397
Total liabilities		237,991	271,257

RISK FACTORS

You should consider carefully the following risks and conditions, together with all the other information in this information statement, including our financial statements and notes thereto, when evaluating our common stock. The impact from these risks and conditions may be materially adverse to our business, prospects, financial condition and results of operations. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial also may materially harm our business, prospects, financial condition and results of operations. As a result, the trading price of our common stock could decline, which could decrease the value of the shares you hold.

Our business may be materially and adversely affected by the ongoing COVID-19 pandemic. The COVID-19 pandemic has had, and will likely continue to have, an impact on various aspects of our business and that of third parties on which we rely. The extent to which the COVID-19 pandemic impacts our business will depend in part on future developments, which are uncertain and unpredictable in nature.

In December 2019, a novel strain of coronavirus (COVID-19) was reported and in March 2020, the World Health Organization characterized COVID-19 as a pandemic. The COVID-19 pandemic, which has continued to spread, and the related adverse public health developments, including orders to shelter-in-place, travel restrictions, and the imposition of additional requirements on businesses, have adversely affected workforces, organizations, healthcare communities, economies, and financial markets globally, leading to an economic downturn and increased market volatility. It has also disrupted the normal operations of businesses across industries, including ours. As a result of the COVID-19 pandemic, we are experiencing disruptions in our operations and business, and those of third parties upon whom we rely. We cannot reasonably assess or predict at this time the full extent of the negative impact that the COVID-19 pandemic and related effects may have on our business, financial condition, results of operations and cash flows. We expect to continue experiencing these disruptions in our operations and those of our third parties for an unknown period of time, as the trajectory of the COVID-19 pandemic remains uncertain and continues to evolve in the United States and globally. These impacts, which may materially and adversely affect our business, include the following:

- We currently rely on BMS to continue to develop, manufacture, and commercialize Abecma, including conducting ongoing clinical studies. The COVID-19 pandemic has had, and will likely continue to have, an impact on various aspects of BMS's development and commercialization efforts. For example, policies at various clinical sites and federal, state, local and foreign laws, rules and regulations are continuing to evolve, including through the implementation of quarantines and travel restrictions, and direction of healthcare resources toward pandemic response efforts. Additionally, BMS and third parties in its supply chain may be subject to restrictions in operations arising from the COVID-19 pandemic and have experienced operational disruptions, which may affect activities necessary for the continued research, development, and commercialization efforts. Uncertainty as to when normal clinical study enrollment and patient treatment activities will resume may continue to affect BMS's operations. It is unknown how long these disruptions could continue.

- Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or lack resources to continue to monitor our clinical studies or to engage in other activities related to review of regulatory submissions in drug development. As a result, review, inspection, and other timelines may be materially delayed for an unknown period of time.

- We have implemented policies at our locations to mitigate the risk of exposure to COVID-19 by our personnel, including restrictions on the number of staff in any given research and development laboratory or manufacturing facility, a work-from-home policy applicable to the majority of our personnel, and a phased approach to bringing personnel back to our locations over time. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business

operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical study sites and other important agencies and contractors. Furthermore, since the onset of the COVID-19 pandemic, our employees and contractors conducting research and development activities have been limited in the activities that they may conduct, and will continue to be subject to policies restricting access to our laboratories for an extended period of time. As a result, this could delay timely completion of preclinical activities, including completing Investigational New Drug-enabling studies or our ability to select future development candidates, and initiation of additional clinical trials for our development programs.

- The trading prices for shares of biopharmaceutical companies have been highly volatile as a result of the economic volatility and uncertainty caused by the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of shares of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the COVID-19 pandemic will materially and adversely affect our business, the value of our common stock, and our ability to operate under our operating plan and execute our strategy.

The extent of the impacts described above will depend on numerous evolving factors that we may not be able to accurately predict, including:

- the duration, severity, and scope of the pandemic in the United States and globally;
- the effectiveness of governmental, business and individuals' protocols and actions that have been and continue to be taken in response to the pandemic;
- the impact of the pandemic on economic activity and actions taken in response;
- the effect on patients, healthcare providers and business partners;
- demand for our products, including as a result of reduced patient visits to healthcare providers, travel restrictions, social distancing, quarantines and other containment measures;
- the ability to obtain or deliver sufficient and timely supplies, given the disruptions to the production capabilities of manufacturers and suppliers of Abecma, particularly with respect to the priority given to the development and manufacture of COVID-19 vaccines;
- our access to the debt and equity markets on satisfactory terms, or at all;
- disruptions in regulatory oversight and actions, as a result of significant and unexpected resources expended to address the COVID-19 by regulators and industry professionals; and
- any closures of our and our partners' offices, operations and facilities.

The ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments which are difficult to predict, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and other actions taken to contain or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our commercialization efforts, our clinical studies, our research programs, healthcare systems or the global economy, and if the ultimate impact of the COVID-19 pandemic and the resulting uncertain economic and healthcare environment is more severe than we anticipated, we may not be able to execute on our current operating plan or on our strategy. If the duration of the COVID-19 pandemic and the associated period of business and social restrictions and economic uncertainty is longer than we anticipated, our cash, cash equivalents, and marketable securities may not be sufficient to fund the activities under our operating plan for the time period that we anticipated, and we may be required to revise our operating plan. To the extent the COVID-19 pandemic

adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

Risks Related to Our Financial Position and Capital Needs

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

We were incorporated in April 2021. Although our business was conducted within bluebird bio prior to that time, we have no history as an independent company. We are developing an oncology pipeline of cell and gene therapies for cancer, the first of which, Abecma (ide-cel), was approved by FDA in March 2021. FDA granted approval of Abecma to Bristol Myers Squibb, bluebird bio’s co-development partner, and although we intend to jointly commercialize this product with Bristol Myers Squibb through our co-development and co-promotion arrangement, we have never recognized revenue from product sales. 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 conducting a clinical trial of our most advanced product candidate, investigational B-cell maturation antigen (BCMA) directed chimeric antigen receptor (CAR) T cell therapy, bb21217.

To date, we have not engaged, on our own or through a third party, in commercial scale manufacturing of the lentiviral vector for Abecma, or conducted significant sales and marketing activities necessary for the commercialization of Abecma or obtained marketing approval of any of our other product candidates. Our short operating history offers limited insight into our prospects for success or even viability and we expect our operating results to be subject to frequent fluctuations. We will encounter challenges frequently experienced by early-stage 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.

Our business has incurred significant losses and we anticipate that we will continue to incur significant losses for the foreseeable 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 losses (on a carve-out basis) for the years ended December 31, 2019 and 2020 were $320.6 million and $120.1 million, respectively. We expect to incur significant losses for several years, as we continue our research activities and conduct development of, and seek regulatory approvals for, our product candidates.

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

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

- continue our research and preclinical and clinical development of our product candidates, including any additional clinical trials of Abecma, which we are co-developing with BMS;
- conduct commercialization activities for Abecma, which we are co-promoting with BMS;
- obtain, build and expand manufacturing capacity, including capacity at third-party manufacturers;

- initiate additional research, preclinical, clinical or other programs as we seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- experience any delays or encounter issues with any of the above.

We expect to continue to incur significant losses for the foreseeable future. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Even though Abecma has been approved by the FDA, and even if one or more of the product candidates that we develop is approved for commercial sale, we may never recognize revenue in amounts sufficient to achieve and maintain profitability. The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

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

Following the completion of the separation, we expect that our cash and cash equivalents will be $ million. Our management believes that our cash and cash equivalents at the time of separation will be sufficient to fund our current operating plan through .

We will require significant additional funding to advance our product candidates, alone or with strategic partners, through clinical studies and to seek marketing approval, as well as to continue advancing our research and development efforts with our other product candidates. We may also need to raise additional funds sooner than currently anticipated if we choose to pursue additional indications or geographies for our product candidates, identify additional product candidates to advance through clinical development or otherwise expand more rapidly than we presently anticipate. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our approved product and product candidates. 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 our debt or equity financing, our agreements and obligations under the tax matters agreement with bluebird bio may limit our ability to issue stock. See "—Risks Related to the Separation."

If we are unable to obtain funding on a timely basis, or if revenues from collaboration arrangements or product sales are less than we have projected, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates 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.

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

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

Our business depends heavily on successful clinical development, regulatory approvals and commercialization of Abecma and our product candidate, bb21217. Our current product candidates,other than bb21217 are still in preclinical development. Our current product candidates, as well as any we may discover in the future, will require substantial additional development and testing, as well as regulatory approvals, prior to commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical and clinical studies that our product candidates are both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate benefit-risk profile for its intended use in its intended patient population. 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 promising preclinical testing and earlier clinical studies. 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 we encounter difficulties in enrolling subjects in our clinical studies, we could be delayed or prevented from proceeding with clinical trials of our product candidates.

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

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

We focus our research and development efforts on treatments for cancer. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product or any future 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 our product and any future products may be limited or may not be amenable to treatment with our products.

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

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

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

Before obtaining marketing approval from regulatory authorities for the commercialization of our product candidates, we must conduct extensive clinical studies to demonstrate the safety, purity and potency, and efficacy, of the product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. There is a high failure rate for drugs and biologics proceeding through clinical studies. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical studies even after achieving promising results in earlier stage clinical studies. We cannot guarantee that any clinical studies will 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:

- delays in reaching a consensus with regulatory agencies on study design;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical study operations or study sites or due to unforeseen safety issues;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites;
- failure to obtain sufficient cells from patients to manufacture enough drug product or achieve target cell doses;

- delays in having patients complete participation in a study or return for post-treatment follow-up;
- clinical study sites or patients dropping out of a study;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Furthermore, the timing of our clinical studies depends on the speed at which we can recruit eligible patients to participate in testing our product candidates. The conditions for which we plan to evaluate our current product candidates in severe genetic diseases are rare disorders with limited patient pools from which to draw for clinical studies. The eligibility criteria of our clinical studies will further limit the pool of available study participants, and the process of finding and diagnosing patients may prove costly. Patients may be unwilling to participate in our studies because of negative publicity from adverse events in the biotechnology or gene therapy industries or for other reasons, including competitive clinical studies for similar patient populations. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical studies in a timely manner. We have experienced delays in some of our clinical studies in the past, and we may experience similar delays in the future.

Results from previous or ongoing studies are not necessarily predictive of our future clinical study results, and initial or interim results may not continue or be confirmed upon completion of the study. There is limited data concerning long-term safety and efficacy following treatment with our engineered cell therapy product candidates. These data, or other positive data, may not continue or occur for these patients or for any future patients in our ongoing or future clinical studies, and may not be repeated or observed in ongoing or future studies involving our product candidates. Furthermore, our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical studies. There can be no assurance that any of these studies will ultimately be successful or support further clinical advancement or marketing approval of our product candidates. For instance, patients with relapsed and refractory multiple myeloma who have been treated with Abecma or the bb21217 product candidate in clinical trials have experienced disease progression. We have experienced unexpected results in the past, and we may experience unexpected results in the future.

Even if our product candidates demonstrate safety and efficacy in clinical studies, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. We may experience delays or rejections based upon additional government regulation from future legislation or administrative action, changes in regulatory agency policy, or additional regulatory feedback or guidance during the period of product development, clinical studies and the review process. The field of engineered cell therapy is evolving, and as more products are reviewed by regulatory authorities, regulatory authorities may impose additional requirements that were not previously anticipated. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested 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 treatment 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 licensing 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.

If our product candidates are ultimately not approved for any reason, our business, prospects, results of operations and financial condition would be adversely affected.

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

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

- negative preclinical data;
- delays in receiving the required regulatory clearance from the appropriate regulatory authorities to commence clinical trials or amend clinical trial protocols, including any objections to our INDs or protocol amendments from the FDA;
- delays in reaching, or a failure to reach, a consensus with regulatory authorities on study design;
- delays in reaching, or failure to reach, agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulties in obtaining IRB approval at each site;
- challenges in recruiting suitable patients to participate in a trial;
- the inability to enroll a sufficient number of patients in clinical trials to ensure adequate statistical power to detect statistically significant treatment effects;
- difficulties in having patients complete a trial or return for post-treatment follow-up;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a clinical trial;
- unforeseen safety issues, including occurrence of treatment emergent adverse events associated with the product candidate that are viewed to outweigh the product candidate's potential benefits;
- difficulties in adding new clinical trial sites;
- ambiguous or negative interim results;
- lack of adequate funding to continue the clinical trial;
- difficulties in manufacturing sufficient quantities of acceptable product candidate for use in clinical trials in a timely manner, or at all; or
- the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other 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 protocols, inspection of the clinical trial operations or trial site by the FDA or other 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 our product candidate development and approval process and jeopardize our ability to commence product sales and recognize revenues. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, 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 and complexity 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. We have not requested or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain

In September 2020, the FDA accepted for Priority Review the BLA submitted by BMS for Abecma (ide-cel) as a treatment for relapsed and refractory multiple myeloma and the FDA approved this BLA in March 2021. However, obtaining one regulatory approval does not guarantee that the FDA will conclude that the information BMS may submit for additional or expanded indications for Abecma will be sufficient to support approval and BMS may fail to obtain additional regulatory approvals in the United States for Abecma. Additionally, certain factors beyond our and BMS' control may impact the timeliness of the regulatory reviews of our submissions or any applications for approval.

If our product candidates are ultimately not approved for any reason, our business, prospects, results of operations and financial condition would be adversely affected.

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

- the FDA or other regulatory bodies 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 contract research organizations, or 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 may disagree with our clinical study design and 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 treatment candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the use of any approved product, which will limit its prospects for commercialization, which could have a material and adverse effect on our business, prospects, financial condition and results of operations.

Patients receiving T cell-based immunotherapies, such as Abecma or the bb21217 product candidate may experience serious adverse events, including neurotoxicity and cytokine release syndrome. If our product or any of our product candidates are revealed to have high and unacceptable severity and/or prevalence of side effects or unexpected characteristics, its clinical development, marketing approval, and commercial potential will be negatively impacted, which will significantly harm our business, financial condition and prospects.

Abecma and the bb21217 product candidate are chimeric antigen receptor, or CAR, T cell-based immunotherapies. In previous and ongoing clinical studies involving CAR T cell products, including those involving ide-cel and the bb21217 product candidate, 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 pressor 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 or the bb21217 product candidate, other CAR T product candidates targeting 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 a more restrictive label or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authorities. 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. 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.

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

Public perception may be influenced by claims that gene therapy, including gene editing technologies, is unsafe or unethical, and research activities and adverse events in the field, even if not ultimately attributable to us or our product or 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 potential products, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our 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 or the FDA may impose additional preclinical studies and clinical study requirements. Amendments or changes to our clinical study protocols would require resubmission to the FDA and IRBs for review and approval, which may increase the cost or delay the timing or successful completion of clinical studies. Similarly, amendments to our preclinical studies may increase the cost or delay the timing or successful completion of those preclinical studies. If we experience delays completing, or if we terminate, any of our preclinical or clinical studies, or if we are required to conduct additional preclinical or clinical studies, the commercial prospects for our product candidates may be harmed and our ability to recognize product revenue will be delayed.

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

We are dependent on BMS for the successful development and commercialization of Abecma and bb21217. If BMS does not devote sufficient resources to the commercialization and further development of Abecma and the development of bb21217, is unsuccessful in its efforts, or chooses to terminate its agreements with us, our business will be materially harmed.

We are co-developing and co-promoting ide-cel, being marketed as Abecma in the United States, with BMS under our amended and restated co-development and co-promotion agreement with BMS, or the Ide-cel CCPS. Under the Ide-cel CCPS, we and BMS share the obligation to develop and commercialize ide-cel in the United States, and we will be solely dependent on BMS to develop and commercialize ide-cel outside of the United States. In addition, we have exclusively licensed to BMS the right to develop and commercialize the bb21217 product candidate, and we retain an option to co-develop and co-promote bb21217 in the United States under our license agreement with BMS. With respect to bb21217, we are responsible for completing the ongoing CRB-402 study, but BMS is responsible for further clinical development and commercialization costs, unless we choose to exercise our option to co-develop and co-promote bb21217 in the United States. If we exercise our option to co-develop and co-promote bb21217 in the United States, we and BMS will share the obligation to develop and commercialize bb21217 in the United States, and we will be solely dependent on BMS to develop and commercialize bb21217 outside of the United States.

In our partnership with BMS, BMS is obligated to use commercially reasonable efforts to develop and commercialize ide-cel and bb21217. BMS may determine however, that it is commercially reasonable to de-prioritize or discontinue the development of ide-cel and bb21217. 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 and bb21217), results from clinical trials or because of unfavorable regulatory feedback. Further, on review of the safety and efficacy data, the FDA may impose requirements on one or both of the programs that render them commercially nonviable. In addition, under our agreements with BMS, BMS has certain decision-making rights in determining the development and commercialization plans and activities for the programs. 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 or bb21217 to narrower indications than we would pursue. More broadly, if BMS elects to discontinue the development of ide-cel or bb21217, we may be unable to advance the product candidate ourselves.

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 development milestones, and 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, bb21217 and other product candidates that are the subject of its collaboration with us.

- BMS may develop and commercialize, either alone or with others, products that are similar to or competitive with ide-cel, bb21217 and other product candidates that are the subject of its collaboration with us. 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 a 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 our product candidates 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 requirements, or may fail 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 rights back to the relevant product candidates. If we were to terminate an agreement with BMS due to BMS's breach or BMS terminated the agreement without cause, the development and commercialization of ide-cel or bb21217 product candidates that are the subject of its collaboration with us 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 the programs under the strategic partnership with us. 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 our programs and/or cause the respective collaboration with us to terminate. The acquisition of Celgene by BMS in 2019 may result in organizational and personnel changes, shifts in business focus or other developments that may have a material adverse effect on our collaboration.

We expect to 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 expect to rely on CROs and clinical study sites to ensure our clinical studies are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be 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' 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. 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 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 GMP as applied in the relevant jurisdictions.

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

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

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities;
- the risk that these activities are not conducted in accordance with our study plans and protocols;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

We may be forced to manufacture lentiviral vector and drug product ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer, which we may not be able to do on reasonable terms, 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 our product or any future products. Some of these events could be the basis for FDA 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 will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop product candidates or commercialize our 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 our product and product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product and product candidates, are subject to extensive regulation. Some components of a finished therapeutic product approved for commercial sale or used in late-stage 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 our product and product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA or MAA on a timely basis and where required, must adhere to the FDA's or other regulator's good laboratory practices, or GLP, and GMP regulations enforced by the FDA or other regulator 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 of our product and potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our products 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 a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, 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 our product 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 or we could lose potential revenues.

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

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

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

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

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

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

- partners have significant discretion in determining the efforts and resources that they will apply to collaborations;
- a partner with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could

jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- collaboration and license arrangements may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;

- partners may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;

- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaboration or license arrangements; and

- a partner's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Related to Our Intellectual Property Rights

If we are unable to obtain or protect intellectual property rights related to our 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 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 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 product candidates, third parties 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 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 product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our 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 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. Furthermore, if third parties have filed such patent applications, an interference 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 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 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, is currently considering 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, oppositions, ex parte reexaminations, post-grant review, and inter partes review proceedings before the U.S. Patent and Trademark Office, or U.S. PTO, and corresponding foreign 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 are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our 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 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 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 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 the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

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

Presently we have rights to the intellectual property, through licenses from third parties 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 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.

We may need to obtain licenses from third parties to advance the development of our product candidates or allow commercialization of our approved product, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, 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 may also 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 question, 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 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 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 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 any future approved drugs 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 there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. To execute our business plan, in addition to successfully marketing and selling any future drugs 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 our drugs and any future drugs;
- obtain adequate pricing and reimbursement for any future drugs, if approved;
- gain regulatory acceptance for the development and commercialization of the drug candidates in our pipeline;
- develop and maintain successful strategic alliances; and
- manage our spending as costs and expenses increase due to clinical trials, marketing approvals, and commercialization.

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

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

To date, we have not recognized any revenue from commercial sales of Abecma, and we do not know when, or if, we will recognize any revenue from commercial sales of Abecma. BMS is primarily responsible for the launch and commercialization of Abecma, and there can be no guarantee that BMS will be able to launch and commercialize Abecma successfully.

We do not expect to recognize significant revenue until BMS begins to sell Abecma. Our ability to recognize revenue 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 a commercial sales force team for Abecma;
- obtain third-party coverage or adequate reimbursement for Abecma;
- achieve market acceptance of Abecma, in the medical community and with third-party payors; and
- including placement in accepted clinical guidelines for the conditions for which Abecma is intended to target.

We expect to incur significant sales and marketing costs as we and our partner BMS prepare for the commercialization of Abecma pursuant to our co-development and co-promotion agreement. Even if we expend

these costs, Abecma may not be commercially successful. We may not recognize significant, or any, revenue from Abecma. If we are unable to recognize product revenue, we may be unable to continue operations without additional funding, which may be dilutive to our stockholders.

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

Even if we obtain regulatory approval for our product candidates, our product candidates 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 future commercial success of our product candidates, if approved by the FDA or other applicable regulatory authorities outside the United States, will depend upon the awareness and acceptance of our product candidates among the medical community, including patients, physicians, and healthcare payors. If any of our product candidates are approved but 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 our product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy and safety of our approved product candidates as demonstrated in clinical trials;
- the clinical indications for which our product candidates are approved;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or other applicable regulatory authorities;
- any restrictions on the use of our products together with other medications or restrictions on the use of our products in certain types of patients;
- the prevalence and severity of any adverse effects associated with our product candidates;
- 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 approved product candidates compared to other available therapies;
- 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 effectiveness of our sales and marketing strategies; or
- publicity concerning our products or competing products and treatments.

If our product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not recognize sufficient revenue from our product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our product candidates, 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 our product candidates may require significant resources and may never be successful.

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

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Market acceptance and sales of any approved product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors and government authorities and may be affected by existing and future health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. 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.

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

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

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

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

Even if we or 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. For example, the FDA typically advises that patients treated with gene therapy undergo follow-up observations for potential adverse events for a 15-year period. 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 good manufacturing practices, or 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.

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

- 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; 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 the use of 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 any product candidates for which we or our collaborators obtain marketing approval. 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 current product candidates and any future product candidates, 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 any of our current products and any current or future product candidates, 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. Our operations are directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations including but not limited to: the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties. On December 2, 2020, the Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 19, 2021. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. We continue to evaluate what effect, if any, the rule will have on our business;

- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or

control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, 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, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the U.S. federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, 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 April 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 marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. 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. Most recently, 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 that offer benefits for patients. Several investigations into these programs have resulted in significant civil and criminal settlements.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert the attention of our management from operating our business.

In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions In addition to HIPAA, as amended by HITECH, and their respective implementing regulations, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General was able to commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

In the European Union, interactions between pharmaceutical companies, healthcare professionals, and patients are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU member states. The provision of benefits or advantages to healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. Also, direct-to-consumer advertising of prescription-only medicinal products is prohibited at the European Union level and in the individual member states. In addition, the UK Bribery Act applies to any company incorporated in or "carrying on business" in the UK, irrespective of where

in the world the alleged bribery activity occurs, which could have implications for our interactions with physicians both in and outside of the UK. Infringement of these laws could result in substantial fines and imprisonment.

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

EU member states, Switzerland and other countries have also adopted data protection laws and regulations, which impose significant compliance obligations. In the European Union, the collection and use of personal health data is currently governed by the provisions of the General Data Protection Regulation, or the GDPR. The GDPR, together with the national legislation of the individual EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals for the consent to be considered valid, the transfer of personal data out of the European Economic Area, security breach notifications, the use of third-party processors in connection with the processing of the personal data, confidentiality of the personal data, as well as substantial potential fines for breaches of the data protection obligations. Data protection authorities from the different EU member states may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the European Union. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, 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. Compliance with the GDPR is 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 any activities falling within the scope of the GDPR. Further, Brexit has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated.

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 our product 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 our product or any future products, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

We are engaged in the development of gene therapies for cancer and this field is competitive and rapidly changing. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. 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 potential products 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 and bb21217 have been granted orphan drug status by the FDA and EMA, there are limitations to the exclusivity. In the United States, the exclusivity period for orphan drugs is seven years, while 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 if it consents to a second orphan drug application or 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. 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 any of our product candidates and, if approved, our products harms patients, or is perceived to harm patients even when such harm is unrelated to such product candidate or product, our marketing approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval 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 our product candidates or any 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 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 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.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Affordable Care Act or ACA, was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, expanded the types of entities eligible for the 340B drug discount program, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Various portions of the Affordable Care Act are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court. It is unclear whether the Affordable Care Act will be overturned, repealed, replaced, or further amended. We cannot predict what effect further changes to the Affordable Care Act would have on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2025 unless Congress takes additional action. These reductions were extended through 2030 through subsequent legislative amendments. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

The former Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the former Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the former Trump administration also previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

In 2020, former President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. In response FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the

MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

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 recognize revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop product candidates.

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

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

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

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

Risks Related to Our Business Operations

Our 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, scientific and medical personnel, including our chief executive officer, chief financial officer, and chief scientific officer. Despite our efforts to retain valuable employees, members of our management, 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 or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the

industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we may be able to offer. We also experience competition for the hiring of scientific personnel from universities and research institutions. The failure to succeed in preclinical or clinical studies may make it more challenging to recruit and retain qualified personnel. In addition, in order to induce employees to continue their employment with us, we have provided equity awards that vest over time and the value to our employees of such equity awards may be significantly affected by movements in our stock price that are beyond our control and may be at any time insufficient to counteract more lucrative offers from other companies. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

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

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

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

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

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

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

As of , we had full-time employees. As we mature, we expect to expand our full-time employee base and to hire more consultants and contractors. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than

expected, our ability to recognize and/or grow revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We will incur increased costs as a result of operating as a public company. 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.

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

We will, however, be immediately 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. This will require, among other things, annual management assessments of the effectiveness of our internal control over financial reporting beginning in our second annual report filed after the distribution and a report by our independent registered public accounting firm addressing these assessments. These and other obligations will place significant demands on our management, administrative and operational resources, including accounting and information technology resources. To comply with these requirements, we anticipate that we will need to further upgrade our systems, including duplicating computer hardware infrastructure, implement additional financial and management controls, reporting systems and procedures and hire additional accounting, finance and information technology staff. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. If we are unable to do this in a timely and effective fashion, 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.

Unfavorable global economic conditions could harm our business, prospects, financial condition and results of operations.

Our results of operations could be harmed by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business, prospects, financial condition and results of operations.

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

Our computer systems and those of our current or future third-party collaborators, service providers, contractors and consultants may fail and are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The size and complexity of our information technology systems, and those of our collaborators, service providers, contractors and consultants, and the large amounts of information stored on those systems make those systems vulnerable to service interruptions, security breaches, or other failures, resulting from inadvertent or intentional actions by our employees or those of third-party business partners, or from cyber-attacks by malicious third parties. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized groups and individuals with a wide range of motives and expertise. In addition to extracting sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The prevalent use of mobile devices also increases the risk of data security incidents. If we experience a material system failure, accident or security breach that causes interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in significant reputational, financial, legal, regulatory, business or operational harm. For example, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach 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, we rely on third-party service providers for management of the manufacture and delivery of drug product to patients in the commercial context, including for chain of identity and chain of custody. We also rely on third-party service providers for aspects of our internal control over financial reporting and such service providers may experience a material system failure or fail to carry out their obligations in other respects, which may impact our ability to produce accurate and timely financial statements, thus harming our operating results, our ability to operate our business, and our investors' view of us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to material failures, security breaches, cyberattacks and other related 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 security incidents or other security breaches that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us. These events could cause third parties to lose trust in us or could result in claims by third parties asserting that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable foreign regulators, provide accurate information to the FDA and applicable foreign regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately and/or disclose unauthorized activities to us. In particular, research and development, sales, marketing and business arrangements in the healthcare industry are subject to considerable laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict, regulate or prohibit a wide range of activities pertaining to clinical trials including the informed consent process, data integrity, and conducting the study in accordance with the investigational plan, and for approved products, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Prior to effecting the distribution of any approved products, we will adopt 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 the Separation

We may not achieve some or all of the expected benefits of the separation, and the separation could harm our business, prospects, financial condition and results of operations.

We may not be able to achieve some or all of the anticipated strategic, financial, operational, marketing or other benefits expected to result from the separation, or such benefits may be delayed or not occur at all. These actions may not provide the benefits we currently expect, and could lead to disruption of our operations, loss of or inability to recruit, key personnel needed to operate and grow our businesses following the separation, weakening of our internal standards, controls or procedures and impairment of our key collaborations and supplier relationships. In addition, completion of the separation has and will continue to require significant amounts of management's time and effort, which may divert management's attention from operating and growing our businesses.

By separating from bluebird bio, we may become more susceptible to market fluctuations and other adverse events than we would have been if we were still a part of the current bluebird bio organizational structure. As part of bluebird bio, we have been able to benefit from bluebird bio's experience and expertise as a commercial-stage company developing multiple products, and opportunities to pursue integrated strategies with bluebird bio's other business activities. We have also benefited from bluebird bio's strategic advantages as an established market participant, including its improved negotiating power and historical partnerships. Additionally, as part of bluebird bio, we benefited from bluebird bio's market reputation, historical performance and brand identity when operating our business. As a newly formed, independent, publicly traded company, we will not have, and may never develop, a comparable market reputation, performance or brand identity of our own, which may limit our ability to recruit and retain personnel, pursue and negotiate strategic transactions, and access the capital markets to finance our operations. If we fail to achieve some or all of the benefits that we expect to achieve as an independent company, or do not achieve them in the time we expect, our business, prospects, financial condition and results of operations may be materially harmed.

The spin-off may not be successful and as an independent, publicly traded company, we will not enjoy the same benefits that we did as a portfolio business within bluebird bio.

Upon completion of the spin-off, we will be a stand-alone public company. The process of becoming a stand-alone public company may distract our management from focusing on our business and strategic priorities. Further, we may not be able to issue debt or equity on terms acceptable to us or at all and we may not be able to attract and retain employees as desired. We also may not fully realize the anticipated benefits of the separation and of being a stand-alone public company, or the realization of such benefits may be delayed, if any of the risks identified in this "Risk Factors" section, or other events, were to occur.

As a separate public company, we will be a smaller and less diversified company than bluebird bio, and we may not have access to financial and other resources comparable to those available to bluebird bio prior to the spin-off or enjoy certain other benefits that we did while part of bluebird bio. We cannot predict the effect that the spin-off will have on our relationship with partners or employees or our relationship with government regulators. We may also be unable to obtain goods, technology and services at prices and on terms as favorable as those available to us prior to the spin-off. Furthermore, as a less diversified company, we may be more likely to be negatively impacted by changes in global market conditions, regulatory reforms and other industry factors, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

We may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as an independent company, and we will be reliant on bluebird bio for the provision of certain services for a period of time.

We have historically operated as part of bluebird bio's corporate organization, and bluebird bio has assisted us by providing various corporate and other business functions. Following the separation, bluebird bio will have no obligation to assist our operations or growth strategy, other than providing certain services pursuant to agreements described under "Certain Relationships and Related Person Transactions—Agreements with bluebird bio." For a

period of time following the separation, we will be substantially reliant on bluebird bio to provide these limited services, and if bluebird bio is unable or unwilling to satisfy its obligations under these agreements, we could incur operational difficulties or losses that could have a material and adverse effect on our business, prospects, financial condition and results of operations.

Furthermore, the services to be provided by bluebird bio under this agreement do not include every service or all of the information and technology systems that we have received from bluebird bio in the past or that are necessary to successfully operate our business, and bluebird bio is only obligated to provide these services for limited periods of time from the distribution date. Accordingly, following the separation, we will need to develop internal capabilities to perform these services, or obtain from other third parties services we currently receive from bluebird bio. If we are unable to efficiently implement our own systems and services, or if we are unable to negotiate agreements with third-party providers of these services in a timely manner or on terms and conditions as favorable as those we receive from bluebird bio, we may not be able to operate our business effectively and our financial condition may decline. Furthermore, if we fail to develop high-quality internal capabilities, or obtain comparable services from third-party providers, in a cost-effective manner, we may be unable to operate our existing business or execute our strategic priorities successfully and efficiently, and our operating results and financial condition may be materially harmed.

We have no history of operating as an independent company and we expect to incur increased administrative and other costs following the separation by virtue of our status as an independent public company. Our historical and pro forma financial information is not necessarily representative of the results that we would have achieved as a separate, publicly traded company and should not be relied upon as an indicator of our future results.

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

- our historical combined financial data does not reflect the separation;
- our historical financial data reflects expense allocations for certain support functions that are provided on a centralized basis within bluebird bio, such as expenses for corporate administrative services, including information technology, research and development, finance, legal, insurance, compliance and human resources activities, that may be lower than the comparable expenses we would have actually incurred, or will incur in the future, as a stand-alone company;
- our cost of debt and our capital structure will be different from that reflected in our historical combined financial statements;
- significant increases may occur in our cost structure as a result of becoming a stand-alone public company, including costs related to public company reporting, investor relations and compliance with the Sarbanes-Oxley Act; and
- the separation may have a material effect on our relationships with our suppliers, collaborators and other business relationships.

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

Our ability to operate our business effectively may suffer if we do not, quickly and cost effectively, establish our own administrative and support functions necessary to operate as a stand-alone public company.

In connection with our separation from bluebird bio, we are creating our own financial, administrative, corporate governance, and listed company compliance and other support systems, including for the services bluebird bio had historically provided to us, or expect to contract with third parties to replace bluebird bio systems that we are not establishing internally. We expect this process to be complex, time consuming and costly. In addition, we are also establishing or expanding our own tax, treasury, internal audit, investor relations, corporate governance, and listed company compliance and other corporate functions. These corporate functions fall beyond the scope of the operational service domains formerly provided by bluebird bio and will require us to develop new stand-alone corporate functions. We may need to make significant investments to replicate, or will need to outsource from other providers, these corporate functions to replace these additional corporate services that bluebird bio historically provided us prior to the separation. bluebird bio will continue to provide support for certain of our key business functions after the spin-off for a limited period of time, pursuant to the Transition Services Agreement and certain other agreements we will enter into with bluebird bio. Any failure or significant downtime in our own financial, administrative or other support systems or in the bluebird bio financial, administrative or other support systems during the transitional period in which bluebird bio provides us with support could negatively impact our results of operations or prevent us from paying our suppliers and employees, executing business combinations and foreign currency transactions or performing administrative or other services on a timely basis, which could negatively affect our results of operations.

Further, as a stand-alone public company, we will incur significant legal, accounting and other expenses that we did not incur as part of bluebird bio. The provisions of SOX, as well as rules subsequently adopted by the SEC and Nasdaq, have imposed various requirements on public companies, including changes in corporate governance practices. For example, SOX requires, among other things, that we maintain and periodically evaluate our internal control over financial reporting and disclosure controls and procedures. In particular, we and our managers will have to perform system and process evaluation and testing of our and their internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of SOX.

Although bluebird bio has historically tested, and currently tests, its internal controls over financial reporting on a regular basis, we have never done so as a stand-alone entity. Doing so for ourselves will require our management and other personnel to devote a substantial amount of time to comply with these requirements and will also increase our legal and financial compliance costs. In particular, compliance with Section 404 of SOX will require a substantial accounting expense and significant management efforts. We cannot be certain at this time that all of our controls will be considered effective and our internal control over financial reporting may not satisfy the regulatory requirements when they become applicable to us.

The separation may impede our ability to attract and retain key personnel, which could materially harm our business.

Our success depends in large part upon the leadership and performance of our management team and other key employees. Operating as an independent company will demand a significant amount of time and effort from our management and other employees and may give rise to increased employee turnover. If we lose the services of members of our management team or other key employees, we may not be able to successfully manage our business or achieve our business objectives.

Following the separation, we will need to continue to attract and retain qualified key personnel in a highly competitive environment. Our ability to attract, recruit and retain such talent will depend on a number of factors, including the hiring practices of our competitors, the performance of our development programs, our compensation and benefits, work location and work environment and economic conditions affecting our industry generally. If we cannot effectively hire and retain qualified employees, our business, prospects, financial condition and results of operations could suffer.

The separation may result in disruptions to, and harm our relationships with, our strategic business partners.

Uncertainty related to the separation may lead the suppliers, research organizations, and other parties with which we currently do business or may do business in the future to terminate or attempt to negotiate changes in our existing business relationships, or cause them to delay entering into business relationships with us or consider entering into business relationships with parties other than us. These disruptions could have a material and adverse effect on our business, prospects, financial condition and results of operations. The effect of such disruptions could be exacerbated by any delays in the completion of the separation.

If the distribution, together with certain related transactions, does not qualify as a transaction that is 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.

It is a condition to the distribution that bluebird bio receive a private letter ruling from the IRS, and an opinion from Goodwin Procter LLP, both satisfactory to bluebird bio's board of directors, together confirming that the distribution, together with certain related transactions, generally is tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code. Any opinion of Goodwin Procter LLP and any IRS private letter ruling will be 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, any IRS private letter ruling and any tax opinion may be invalid. Accordingly, notwithstanding receipt of an IRS private letter ruling and an opinion of Goodwin Procter LLP, 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 any such IRS private letter ruling or on which any such opinion was based are false or have been violated. In addition, an opinion of Goodwin Procter LLP represents the judgment of Goodwin Procter LLP, which is not binding on the IRS or any court, and any IRS private letter ruling will not address all of the issues that are relevant to determining whether the distribution, together with certain related transactions, qualifies as a transaction that is generally tax-free for U.S. federal income tax purposes. Accordingly, notwithstanding receipt by bluebird bio of the tax opinion referred to above and an IRS private letter ruling, the IRS could assert that the distribution and certain related transactions do 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 receive 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. For more information, see "Material U.S. Federal Income Tax Consequences of the Distribution."

In connection with the distribution, we and bluebird bio will enter into a tax matters agreement pursuant to which we will be responsible for certain liabilities and obligations following the distribution. In general, under the terms of the tax matters agreement, if the distribution, together with certain related transactions, were to fail to qualify as a transaction that is generally tax-free, for U.S. federal income tax purposes, under Sections 355 and 368(a)(1)(D) of the Code, and if and to the extent that such failure results from a prohibited change of control in bluebird bio under Section 355(e) of the Code or an acquisition of bluebird bio stock or assets or certain actions, omissions or failures to act, by bluebird bio, then bluebird bio will bear any resulting taxes, interest, penalties and other costs. If and to the extent that such failure results from a prohibited change of control in 2seventy bio under Section 355(e) of the Code or an acquisition of our stock or assets or certain actions by us, then we will indemnify bluebird bio for any resulting taxes, interest, penalties and other costs, including any reductions in bluebird bio's net operating loss carryforwards or other tax assets. If such failure does not result from a prohibited change of control in bluebird bio or 2seventy bio under Section 355(e) of the Code and both we and bluebird bio are responsible for such failure, liability will be shared according to relative fault. If neither we nor bluebird bio is responsible for such

failure, bluebird bio will bear any resulting taxes, interest, penalties and other costs. For a discussion of the tax matters agreement, see “Certain Relationships and Related Person Transactions—Agreements with bluebird bio —Tax Matters Agreement.” Our indemnification obligations to bluebird bio under the tax matters agreement are not expected to be limited in amount or subject to any cap. If we are required to pay any taxes or indemnify bluebird bio and its subsidiaries and their respective officers and directors under the circumstances set forth in the tax matters agreement, we may be subject to substantial liabilities.

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

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

In connection with the separation, we will assume and agree 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 intend to enter into with bluebird bio, we will assume and agree 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 Combined Financial Statements—Notes to 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 will agree to indemnify us for liabilities of the bluebird bio business, but such indemnity from bluebird bio may not be sufficient to protect us against the full amount of such liabilities, and bluebird bio may not fully satisfy its indemnification obligations. Moreover, even if we ultimately succeed in recovering from bluebird bio any amounts for which we are held liable, we may be temporarily required to bear these losses ourselves. Each of these risks could harm our business, prospects, financial condition and results of operations

Our agreements with bluebird bio may not reflect terms that would have resulted from negotiations with unaffiliated third parties.

The agreements related to the separation, including, among others, the separation agreement, the employment matters agreement, the tax matters agreement, the intellectual property license agreement, the transition services agreement and the development agreement, will have been entered into in the context of the separation while we are still controlled by bluebird bio. Until the distribution occurs, bluebird bio will effectively have the sole and absolute discretion to determine and change the terms of the separation, including the terms of any agreements between bluebird bio and us and the establishment of the record date and distribution date. As a result, any changes could be unfavorable to us and may not reflect terms that would have resulted from negotiations between unaffiliated third

parties. In addition, bluebird bio may decide at any time not to proceed with all or any part of the separation. For a more detailed description, see "Certain Relationships and Related Person Transactions—Agreements with bluebird bio."

bluebird bio may compete with us.

bluebird bio will not be restricted from competing with us in the development or commercialization of products treating the same indications as our product candidates. Although bluebird bio has informed us it has no current intention to compete with us or our product candidates, if bluebird bio in the future decides to engage in the type of business we conduct, it may have a competitive advantage over us, which may cause our business, prospects, financial condition and results of operations to be materially harmed.

Certain of our directors and officers may have actual or potential conflicts of interest relating to bluebird bio.

Certain of our directors and officers may own shares of bluebird bio common stock or other equity awards as a result of their prior service as bluebird bio directors or officers. For certain of these individuals, their holdings of bluebird bio common stock or equity awards may be significant compared to their total assets. Additionally, Nick Leschly, our chief executive officer, is expected to serve as executive chair of bluebird bio following the separation. Mr. Leschly's leadership positions at both our company and bluebird bio, as well as the ownership of any bluebird bio equity or equity awards by certain of our directors and officers creates, or may create the appearance of, conflicts of interest when Mr. Leschly or our other directors or officers are faced with decisions that could have different implications for bluebird bio than for us.

The combined post-separation value of bluebird bio and our common stock may not equal or exceed the pre-separation value of bluebird bio common stock.

As a result of the distribution, bluebird bio expects the trading price of bluebird bio common stock immediately following the distribution to be lower than the trading price of such common stock immediately prior to the distribution because the trading price will no longer reflect the value of our business held by bluebird bio. Furthermore, following the distribution, the trading price of our common stock may not reflect the full value of our business and assets, due to market inefficiencies in the initial trading of our shares or variations in investor views regarding our business and prospects, among other market forces. The aggregate market value of bluebird bio common stock and our common stock following the separation may be higher or lower than the market value of bluebird bio common stock immediately prior to the separation, and may fluctuate, particularly during the period immediately following the distribution.

No vote of bluebird bio stockholders is required in connection with this distribution. As a result, if the distribution occurs and you do not want to receive our common stock in the distribution, your sole recourse will be to divest yourself of your bluebird bio common stock prior to the record date.

No vote of the bluebird bio stockholders is required in connection with the distribution. Accordingly, if the distribution occurs and you do not want to receive our common stock in the distribution, your only recourse will be to divest yourself of your bluebird bio common stock prior to the record date for the distribution.

Risks Related to Ownership of Our Common Stock

There is no existing market for our shares of common stock and an active trading market may not develop for our shares. Once our shares of common stock begin trading, the market price of these shares may fluctuate widely.

There is currently no public market for our shares of common stock. It is anticipated that on or prior to the record date for the distribution, trading of our shares of common stock will begin on a "when issued" basis and will continue up to and including through the distribution date. However, there can be no assurance that an active trading market for our shares of common stock will develop as a result of the distribution or be sustained in the future.

We cannot predict the prices at which our shares of common stock may trade after the distribution. The market price of our shares of common stock may fluctuate widely, depending upon many factors, some of which are beyond our control, including the following:

- a relatively low-volume trading market for our shares of common stock may result, which could cause trades of small blocks of shares to have a significant impact on the price of our shares of common stock;
- results and timing of preclinical studies and clinical studies of our product candidates;
- the commercial performance of our products, if approved, as well as the costs associated with such activities;
- results of clinical studies of our competitors' products;
- failure to adequately protect our trade secrets;
- our inability to raise additional capital 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 market 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.

Substantial sales of shares of our common stock may occur immediately following the distribution which could cause the market price of shares of our common stock to decline.

It is possible that many of bluebird bio's stockholders will sell the shares of our common stock that they receive in the distribution immediately in the public market because our business profile or market capitalization does not fit their investment objectives, because the shares are not included in certain indices or for other reasons. The sale of significant amounts of our shares or the perception in the market that this will occur may result in the lowering of the market price of our shares. We can offer no assurance that bluebird bio's stockholders will continue to hold the shares they receive in the distribution.

The combined post-spin-off value of our shares and the bluebird bio shares may not equal or exceed the aggregate pre-spin-off value of the bluebird bio shares and our shares.

After the spin-off, the bluebird bio shares will continue to be listed and traded on the Nasdaq Global Select Market. Our shares will be traded under the symbol "TSVT" on the Nasdaq Global Market. We have no current plans to apply for listing on any additional stock exchanges. As a result of the spin-off, bluebird bio expects the trading prices of bluebird bio shares at market open on , 2021 to be lower than the trading prices at market close on , 2021, because the trading prices will no longer reflect the value of our business. There can be no assurance that the aggregate market value of the bluebird bio shares and our shares following the spin-off will be higher than, equal to or lower than the market value of the bluebird bio shares if the spin-off did not occur. This means, for example, that the combined trading prices of one bluebird bio share and one share of our common stock after market open on , 2021 may be equal to, greater than or less than the trading price of one bluebird bio share before , 2021. In addition, following the close of business on , 2021 but before the commencement of trading on , 2021, your bluebird bio shares will reflect an ownership interest solely in bluebird bio and will not include the right to receive any of our shares in the spin-off, but may not yet accurately reflect the value of such bluebird bio shares excluding our business.

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 will be 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 the equity incentive plans that we intend to adopt prior to the distribution, 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 the equity incentive plans that we intend to adopt prior to the distribution. 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, our amended and restated certificate of incorporation will authorize us 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. See "Description of 2seventy bio's Capital Stock."

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. 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 will 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 will 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 will 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 will 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 will 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.

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. For example, on March 27, 2020, President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security Act" or the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 pandemic, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. On December 27, 2020, President Trump signed into law the "Consolidated Appropriations Act", which included additional stimulus relief for the COVID-19 pandemic in the form of modifications to the refundable employee retention credit under the CARES Act and credit extenders, and spending bill for the 2021 fiscal year. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. 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 combined financial statements are incorrect, our actual results may vary from those reflected in our projections and accruals.

Our 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 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.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This information statement and other materials we have filed or will file with the SEC include, or will include, forward-looking statements. All statements in this information statement, in other materials we have filed or will file with the SEC and in related comments by our management, other than statements of historical facts, including statements about future events, future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations, are forward-looking statements that involve certain risks and uncertainties. Use of the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "seeks," "intends," "evaluates," "pursues," "anticipates," "continues," "designs," "impacts," "affects," "forecasts," "target," "outlook," "initiative," "objective," "designed," "priorities," "goal" or the negative of those words or other similar expressions may identify forward-looking statements that represent our current judgment about possible future events, but the absence of these words does not necessarily mean that a statement is not forward-looking.

Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, by their nature, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. As a result, our actual results may differ materially from those contemplated by the forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:

- the completion and timing of the separation, the business and operations of 2seventy bio following the separation and any benefits or costs of the separation, including the tax treatment;
- our post-separation relationships with bluebird bio, third parties, collaborators and our employees;
- our ability to operate as a stand-alone company and execute our strategic priorities;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching, and commercializing our product candidates;
- our plans with respect to the development, manufacture or sale of our product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies;
- the safety profile and related adverse events of our product candidates;
- the efficacy and perceived therapeutic benefits of our product candidates and the potential indications and market opportunities therefor;
- U.S. and foreign regulatory requirements for our product candidates, including any post-approval development and regulatory requirements, and the ability of our product candidates to meet such requirements;
- our ability to attract and retain key employees needed to execute our business plans and strategies and our expectations regarding our ability to manage the impact of any loss of key employees;
- our ability to obtain and maintain intellectual property protection for our product candidates and the strength thereof;
- our future financial performance, revenues, expense levels, payments, cash flows, profitability, tax obligations, capital raising and liquidity sources, real estate needs and concentration of voting control, as well as the timing and drivers thereof, and internal control over financial reporting;

- our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;
- the status of government regulation in the life sciences industry, particularly with respect to healthcare reform;
- potential indemnification liabilities 2seventy bio may owe to bluebird bio after the separation;

  the tax treatment of the distribution and the limitations imposed on 2seventy bio under the tax matters agreement that 2seventy bio will enter into with bluebird bio; and
- trends and challenges in our potential markets.

See “Risk Factors” for a further description of these and other factors. Although we have attempted to identify important risk factors, there may be other risk factors not presently known to us or that we presently believe are not material that could cause actual results and developments to differ materially from those made in or suggested by the forward-looking statements contained in this information statement. If any of these risks materialize, or if any of the above assumptions underlying forward-looking statements prove incorrect, actual results and developments may differ materially from those made in or suggested by the forward-looking statements contained in this information statement. For the reasons described above, we caution you against relying on any forward-looking statements, which should also be read in conjunction with the other cautionary statements that are included elsewhere in this information statement. Any forward-looking statement made by us in this information statement speaks only as of the date thereof. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update or to revise any forward-looking statement, whether as a result of new information, future developments, or otherwise, except as may be required by law.

DIVIDEND POLICY

We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects and any other factors deemed relevant by our board of directors.

CAPITALIZATION

The following table sets forth 2seventy bio's capitalization as of December 31, 2020 on a historical basis and on a pro forma basis to give effect to the pro forma adjustments included in 2seventy bio's unaudited pro forma combined financial information. The information below is not necessarily indicative of what 2seventy bio's capitalization would have been had the separation and distribution been completed as of December 31, 2020. In addition, it is not indicative of 2seventy bio's future capitalization. This table should be read in conjunction with "Unaudited Pro Forma Combined Financial Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Summary Historical and Unaudited Pro Forma Combined Financial Information" and the audited combined financial statements and corresponding notes included elsewhere in this information statement.

	As of December 31, 2020	
(in thousands)	**Actual**	**Pro Forma**
	(unaudited)	
Cash and cash equivalents	$ —	
Debt:		
Long-term debt	$ —	
Total debt	—	
Equity:		
Common stock	—	
Additional paid-in capital	—	
Net parent investment	74,629	
Total Capitalization	$ 74,629	$ —

UNAUDITED PRO FORMA COMBINED FINANCIAL STATEMENTS

The unaudited pro forma combined financial data of 2seventy bio consists of an unaudited pro forma combined statement of operations for the year ended December 31, 2020 and an unaudited pro forma combined balance sheet as of December 31, 2020 that have been prepared by management in accordance with Article 11, *Pro Forma Financial Information*, under Regulation S-X of the Exchange Act, and are for illustrative and informational purposes only. The unaudited pro forma combined financial data reported below should be read in conjunction with “Management's Discussion and Analysis of Financial Condition and Results of Operations,” “Summary Historical and Unaudited Pro Forma Combined Financial Information” and the audited combined financial statements and corresponding notes included elsewhere in this information statement.

The following unaudited pro forma combined financial data is subject to assumptions and adjustments described in the accompanying notes. 2seventy bio's management believes these assumptions and adjustments are reasonable under the circumstances and given the information available at this time. However, these adjustments are subject to change as bluebird bio and 2seventy bio finalize the terms of the separation, including the separation agreement and related transaction agreements. The unaudited pro forma combined financial data does not purport to represent what 2seventy bio's financial position and results of operations actually would have been had the separation occurred on the dates indicated, or to project 2seventy bio's financial performance for any future period following the separation.

The unaudited pro forma combined statement of operations for the year ended December 31, 2020 gives effect to the separation as if it had occurred on January 1, 2020. The unaudited pro forma balance sheet as of December 31, 2020 gives effect to the separation as if it had occurred on December 31, 2020. The unaudited pro forma combined financial data includes adjustments to reflect the following:

- the contribution by bluebird bio to 2seventy bio, pursuant to the separation agreement, of all the assets and liabilities that comprise 2seventy bio's business;

- the expected transfer to 2seventy bio, upon completion of the separation, of certain assets and liabilities that were not included in 2seventy bio's historical combined financial statements; and

- the impact of the separation agreement, tax matters agreement, employee matters agreement, transition services agreements and other agreements between 2seventy bio and bluebird bio.

2seventy bio's historical financial information, which was the basis for the unaudited pro forma combined financial statements, was prepared on a carve-out basis as 2seventy bio was not operated as a separate, independent company for the periods presented. Accordingly, such historical financial information reflects an allocation for certain business and support functions that are provided on a centralized basis within bluebird bio, including senior management, legal, human resources, finance and information technology. These historical allocations may not be indicative of 2seventy bio's future cost structure.

2seventy bio

Unaudited Pro Forma Combined Statement of Operations

Year Ended December 31, 2020

(in thousands)

	2seventy bio As Reported	Transaction Accounting Adjustments	Notes	Pro Forma
Revenue:				
Service revenue	$ 111,452			$ 111,452
Collaborative arrangement revenue	115,594			115,594
Royalty and other revenue	21,076			21,076
Total revenues	248,122	—		248,122
Operating expenses:				
Research and development	296,467			296,467
Selling, general and administrative	90,897			90,897
Cost of royalty and other revenue	5,396			5,396
Change in fair value of contingent consideration	(6,468)			(6,468)
Total operating expenses	386,292	—		386,292
Loss from operations	(138,170)	—		(138,170)
Other income, net	18,056			18,056
Loss before income taxes	(120,114)	—		(120,114)
Income tax (expense) benefit	—			—
Net loss	$ (120,114)	$ —		$ (120,114)
Net loss per share - basic and diluted	N/A		(E, F)	
Weighted-average number of common shares - basic and diluted	N/A		(E, F)	

See Notes to Unaudited Pro forma Combined Financial Data.

2seventy bio

Unaudited Pro Forma Combined Balance Sheet

As of December 31, 2020

(in thousands)

	2seventy bio As Reported	Transaction Accounting Adjustments	Notes	Pro Forma
Assets:				
Current assets:				
Cash and cash equivalents	$ —		(A)	$ —
Prepaid expenses	14,413			14,413
Receivables	10,691			10,691
Total current assets	25,104	—		25,104
Property, plant and equipment, net	144,025			144,025
Intangible assets, net	5,644			5,644
Goodwill	13,128			13,128
Operating lease right-of-use assets	116,456			116,456
Other non-current assets	8,263			8,263
Total assets	$ 312,620	$ —		$ 312,620
Liabilities and Equity:				
Current liabilities:				
Accounts payable	$ 7,152			$ 7,152
Accrued expenses and other current liabilities	43,347			43,347
Operating lease liability, current portion	15,313			15,313
Deferred revenue, current portion	820			820
Collaboration research advancement, current portion	9,236			9,236
Total current liabilities	75,868	—		75,868
Deferred revenue, net of current portion	25,762			25,762
Collaboration research advancement, net of current portion	21,581			21,581
Operating lease liability, net of current portion	112,290			112,290
Other non-current liabilities	2,490			2,490
Total liabilities	237,991	—		237,991
Equity:				
Common stock	—		(D)	—
Additional paid-in capital	—		(A, D)	—
Net parent investment	74,629		(D)	74,629
Total equity	74,629	—		74,629
Total liabilities and equity	$ 312,620	$ —		$ 312,620

See Notes to Unaudited Pro forma Combined Financial Data.

Notes to Unaudited Pro Forma Combined Financial Data

(A) Reflects the impact of the initial cash contribution of $ million from bluebird bio to 2seventy bio in connection with the separation.

(B) Reflects the impact of assets, liabilities and related expenses that we expect to assume from bluebird bio that were not included in our audited combined financial statements. There may be additional assets, liabilities or related expenses transferred to us in the separation for which the transfer has not been finalized.

(C) Reflects the tax effects of the pro forma adjustments at the applicable effective income tax rate of % for the year ended December 31, 2020. The effective tax rate of 2seventy bio could be different (either higher or lower) depending on activities subsequent to the separation. The impact of pro forma adjustments on long-term deferred tax assets and liabilities were offset against existing long-term deferred tax assets and liabilities reflected in our historical combined balance sheet, all of which are offset by valuation allowance in full.

(D) Reflects the distribution of 2seventy bio common stock to bluebird bio stockholders, calculated based on shares of bluebird bio common stock outstanding on , and a distribution ratio of shares of 2seventy bio common stock for every shares of bluebird bio common stock. This amount is allocated between common stock and additional paid-in capital based on the number of shares of 2seventy bio common stock outstanding on the distribution date.

(E) The number of shares of 2seventy bio common stock used to compute basic earnings per share is based on the number of shares of 2seventy bio common stock assumed to be outstanding on the distribution date, after giving effect to the distribution, calculated based on shares of bluebird bio common stock outstanding on , and a distribution ratio of shares of 2seventy bio common stock for every shares of bluebird bio common stock.

(F) The number of shares of 2seventy bio common stock used to compute diluted earnings per share is based on the number of shares of 2seventy bio common stock as described in Note (E) above, plus incremental shares assuming exercise of dilutive options, restricted stock units and other common stock equivalents issued in connection with the separation. This calculation may not be indicative of the dilutive effect that will actually result from 2seventy bio's share-based awards issued in connection with the adjustment of outstanding bluebird bio share-based awards or the grant of new share-based awards. The number of dilutive shares of common stock underlying 2seventy bio's share-based awards issued in connection with the adjustment of outstanding bluebird bio share-based awards will not be determined until the distribution date or shortly thereafter.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with "Unaudited Pro Forma Combined Financial Statements," "Summary Historical and Unaudited Pro Forma Combined Financial Information" and the audited combined financial statements and corresponding notes included elsewhere in this information statement.

In addition to historical information, this report contains forward-looking statements that involve risks and uncertainties which may cause our actual results to differ materially from plans and results discussed in forward-looking statements. We encourage you to review the risks and uncertainties discussed in the sections captioned "Risk Factors" and "Forward-Looking Statements", included elsewhere in this information statement. The risks and uncertainties can cause actual results to differ significantly from those forecast in forward-looking statements or implied in historical results and trends.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

2seventy bio is a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. We were incorporated in April 2021 and are led by an accomplished team with significant expertise and experience in this field, from discovery through clinical development to regulatory approval of Abecma. Our approach combines our expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. We are advancing multiple preclinical and clinical programs in oncology and, together with our partner, delivering Abecma to multiple myeloma patients in the United States.

Separation from bluebird bio, Inc.

In January 2021, bluebird bio announced its plans to separate its oncology portfolio and programs from its severe genetic disease, or SGD, portfolio and programs through a pro rata distribution of our common stock to stockholders of bluebird bio. As a part of the separation, bluebird bio intends to transfer the assets, liabilities and operations of its oncology portfolio and programs to us, pursuant to the terms of a separation agreement to be entered into between us and bluebird bio. On the distribution date, each bluebird bio stockholder will receive shares of our common stock for every shares of bluebird bio common stock held of record at the close of business on the record date for the distribution. Registered stockholders will receive cash in lieu of any fractional shares of our common stock that they would have received as a result of the application of the distribution ratio. Following the distribution, we will operate as a separate, independent, publicly traded company. The distribution of our common stock as described in this information statement is subject to the satisfaction or waiver by bluebird bio of certain conditions. For a more detailed description of these conditions, see the section of this information statement captioned "The Separation and Distribution—Conditions to the Distribution."

Our historical financial statements have been prepared on a carve-out basis and are derived from bluebird bio's consolidated financial statements and accounting records. Our financial statements are presented in conformity with generally accepted accounting principles in the United States, or GAAP. See Note 2, *Summary of significant accounting policies and basis of presentation*, in the notes to the combined financial statements appearing elsewhere in this information statement for additional information on the preparation and basis of presentation of the combined financial statements. Our financial position, results of operations and cash flows historically operated, and will continue to operate, as part of bluebird bio's financial position, results of operations and cash flows prior to and until

the distribution of our common stock to bluebird bio's stockholders. The historical combined financial statements may not be indicative of our future performance and do not necessarily reflect what our combined results of operations, financial condition and cash flows would have been had we operated as a separate, publicly traded company during the periods presented. We expect that changes will occur in our operating structure and our capitalization as a result of the separation from bluebird bio. See the section of this information statement captioned "The Separation and Distribution" for additional detail.

Financial Operations Overview

Revenue

To date, we have not recognized any revenues from the sale of products. Our revenues have been derived from collaboration arrangements and out-licensing arrangements.

Revenue recognized under collaborative arrangements has been generated primarily from a collaboration arrangement with BMS that will be attributed to us in connection with the separation. The terms of the arrangement with respect to ide-cel contain multiple promised goods or services, which include at inception: (i) research and development services, (ii) a license to ide-cel, and (iii) manufacture of vectors and associated payload for incorporation into ide-cel under the license. As of September 2017, the collaboration also included the following promised goods or services with respect to bb21217: (i) research and development services, (ii) a license to bb21217, and (iii) manufacture of vectors and associated payload for incorporation into bb21217 under the license. An agreement was entered into with BMS to co-develop and co-promote ide-cel in March 2018, which was subsequently amended in May 2020, as part of which both parties will share equally in U.S. costs and profits. Revenue from our collaborative arrangements is recognized as the underlying performance obligations are satisfied.

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606, *Revenue from Contracts with Customers* ("Topic 606" or "ASC 606"). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606. Amounts that are owed to collaboration partners are recognized as an offset to collaborative arrangement revenues as such amounts are incurred by the collaboration partner. Where amounts owed to a collaboration partner exceed our collaborative arrangement revenues in a quarterly period, such amounts in excess are classified as research and development expense. For those elements of the arrangement that are accounted for pursuant to Topic 606, we apply the five-step model prescribed in Topic 606.

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

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

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

Research and Development Expenses

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

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with clinical research organizations ("CROs") and clinical sites that conduct our clinical studies;
- reimbursable costs to our partners for collaborative activities;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, information technology, insurance, and other supplies in support of research and development activities;
- costs associated with our research platform and preclinical activities;
- milestones and upfront license payments;
- costs associated with our regulatory, quality assurance and quality control operations; and
- amortization of certain intangible assets.

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

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical studies and other research and development activities we undertake;
- future clinical study results;
- uncertainties in clinical study enrollment rates;
- new manufacturing processes or protocols that we may choose to or be required to implement in the manufacture of our lentiviral vector or drug product;
- regulatory feedback on requirements for regulatory approval, as well as changing standards for regulatory approval; and
- the timing and receipt of any regulatory approvals.

We plan to increase our research and development expenses for the foreseeable future as we continue to conduct research and development activities and fund our share of the costs of development of Abecma and bb21217 (if we exercise our option to co-develop and co-commercialize this product candidate) in collaboration with BMS. Our research and development expenses include expenses associated with the following activities:

- CRB-401 study – an open label, single-arm, multi-center, phase 1 study to examine the safety and efficacy of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma.

- KarMMA study – an open label, single-arm, multi-center phase 2 study to examine the efficacy and safety of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma.

- KarMMa-2 study – a multi-cohort, open-label, multicenter phase 2 study to examine the safety and efficacy of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma and in high-risk multiple myeloma.

- KarMMa-3 study – a multicenter, randomized, open-label phase 3 study comparing the efficacy and safety of ide-cel versus standard triplet regimens in patients with relapsed and refractory multiple myeloma.

- KarMMa-4 study – a multi-cohort, open-label, multicenter phase 1 study intended to determine the optimal target dose and safety of ide-cel in subjects with newly-diagnosed multiple myeloma.

- CRB-402 study – an open label, single-arm, multicenter, phase 1 study to examine the safety and efficacy of the bb21217 product candidate in the treatment of patients with relapsed and refractory multiple myeloma.

- We will continue to incur costs related to the manufacture of clinical study materials in support of our clinical studies.

We expect that the timing of investment in our ongoing clinical studies will reflect COVID-19 related delays in these studies.

Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to acquiring and manufacturing clinical study materials. We allocate salary and benefit costs directly related to specific programs. We do not allocate personnel-related discretionary bonus or stock-based compensation costs, laboratory and related expenses, certain license and other collaboration costs, depreciation or other indirect costs that are

deployed across multiple projects under development and, as such, the costs are separately classified as other research and development expenses in the table below:

	Year ended December 31,		
	2020	2019	2018
ide-cel	$ 105,240	$ 121,182	$ 75,667
bb21217	23,511	19,827	15,624
Preclinical programs	52,778	48,505	50,115
Total direct research and development expense	181,529	189,514	141,406
Employee- and contractor-related expenses	22,008	21,128	12,820
Stock-based compensation expense	30,935	33,853	21,846
Laboratory and related expenses	2,292	2,721	831
License and other collaboration expenses	12,089	4,333	3,726
Facility expenses	46,402	44,661	18,948
Other expenses	1,212	1,435	913
Total other research and development expenses	114,938	108,131	59,084
Total research and development expense	$ 296,467	$ 297,645	$ 200,490

Selling, General and Administrative Expenses

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

Cost of Royalty and Other Revenue

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

Change in Fair Value of Contingent Consideration

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

As of December 31, 2020, there were $120.0 million in future contingent cash payments, of which $20.1 million relates to clinical milestones and $99.9 million relates to commercial milestones. We estimate future contingent cash payments have a fair value of $1.5 million as of December 31, 2020, which are classified within other non-current liabilities on our combined balance sheet.

Interest Expense

For the year ended December 31, 2018, interest expense consisted primarily of the financing lease obligation for our headquarters at 60 Binney Street in Cambridge, Massachusetts. Upon adoption of ASU 2016-02, *Leases (Topic 842)*, on January 1, 2019, we de-recognized the financing lease obligation and, as a result, no longer recognize interest expense associated with the financing lease obligation.

Other Income, Net

Other income, net consists primarily of income resulting from the allocation of facility-related, depreciation and amortization expense to bluebird bio for its proportional use of assets that will be attributed to us, as well as expense resulting from the allocation of facility-related, depreciation and amortization expense to us for our proportional use of assets that will not be attributed to us. Other income, net also includes immaterial gains and losses on disposal of assets.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Revenue Recognition

Revenue Recognition

Under Topic 606, *Revenue from Contracts with Customers*, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

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

probability of developing a candidate that would be subject to the option rights. The exercise of a material right is accounted for as a contract modification for accounting purposes.

We assess whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, we consider factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. We also consider the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

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

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

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

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

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

each of our revenue generating arrangements in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of our arrangements.

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

We recognize revenue within the following financial statement captions:

Service Revenue

To date, our service revenue has primarily been generated from the elements of the collaboration arrangement with BMS that are accounted for pursuant to Topic 606, using the five-step model described above. As discussed further in *Collaborative arrangement revenue* below, we analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* (“ASC 808”) or Topic 606. For the elements of the arrangement which are more reflective of a vendor-customer relationship and therefore within the scope of Topic 606, we record the related revenue as service revenue on the combined statement of operations and comprehensive loss. Refer to —*Collaborative arrangement revenue* below for additional discussion around our policy for recognizing collaborative arrangement revenue and the determination of whether elements of a collaboration arrangement are within the scope of ASC 808 or Topic 606.

Collaborative Arrangement Revenue

To date, collaborative arrangement revenue has been primarily generated from the collaboration arrangements with BMS and Regeneron Pharmaceuticals, Inc. ("Regeneron"), as further described in Note 8, *Collaborative arrangements*, in the notes to our combined financial statements appearing elsewhere in this information statement.

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808 to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of Topic 606 (refer above for further discussion of our policy for recognizing service revenue). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606. Amounts that are owed to collaboration partners are recognized as an offset to collaborative arrangement revenues as such amounts are incurred by the collaboration partner. Where amounts owed to a collaboration partner exceed our collaborative arrangement revenues in each quarterly period, such amounts are classified as research and development expense.

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

Leases

Effective January 1, 2019, we adopted ASU 2016-02, *Leases (Topic 842)*, (“ASU 2016-02” or “ASC 842”), using the required modified retrospective approach and utilizing the effective date as the date of initial application. As a result, prior periods are presented in accordance with the previous guidance in ASC 840, *Leases* (“ASC 840”).

At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the relevant facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. We do not have material financing leases.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, we utilize our incremental borrowing rate to discount lease payments, which reflects the fixed rate at which we could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. To estimate our incremental borrowing rate, a credit rating applicable to us is estimated using a synthetic credit rating analysis since we do not currently have a rating agency-based credit rating.

We have elected not to recognize leases with an original term of one year or less on the balance sheet. We typically only includes an initial lease term in our assessment of a lease arrangement. Options to renew a lease are not included in our assessment unless there is reasonable certainty that we will renew.

Assumptions that we made at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the stand-alone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

ASC 842 Transition Practical Expedients and Application of Transition Provisions to Leases at the Transition Date

We elected the following practical expedients, which must be elected as a package and applied consistently to all of our leases at the transition date (including those for which we are a lessee or a lessor): i) we did not reassess whether any expired or existing contracts are or contain leases; ii) we did not reassess the lease classification for any expired or existing leases (that is, all existing leases that were classified as operating leases in accordance with ASC 840 are classified as operating leases, and all existing leases that were classified as capital leases in accordance with ASC 840 are classified as finance leases); and iii) we did not reassess initial direct costs for any existing leases.

For leases that existed prior to the date of initial application of ASC 842 (which were previously classified as operating leases), a lessee may elect to use either the total lease term measured at lease inception under ASC 840 or the remaining lease term as of the date of initial application of ASC 842 in determining the period for which to measure its incremental borrowing rate. In transition to ASC 842, we utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

Application of ASC 842 Policy Elections to Leases Post Adoption

We have made certain policy elections to apply to our leases executed post adoption, or subsequent to January 1, 2019, as further described below.

In accordance with ASC 842, components of a lease should be split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Entities may elect not to separate lease and non-lease components. Rather, entities would account for each lease component and related non-lease component together as a single lease component. We have elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only.

ASC 842 allows for the use of judgment in determining whether the assumed lease term is for a major part of the remaining economic life of the underlying asset and whether the present value of lease payments represents substantially all of the fair value of the underlying asset. We apply the bright line thresholds referenced in ASC 842-10-55-2 to assist in evaluating leases for appropriate classification. The aforementioned bright lines are applied consistently to our entire portfolio of leases.

Accrued Research and Development Expenses

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

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

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

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

Recent Accounting Pronouncements

See Note 2, *Summary of significant accounting policies and basis of presentation*, in the notes to the combined financial statements appearing elsewhere in this information statement for a description of recent accounting pronouncements applicable to our business.

Results of Operations

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

Comparison of the Years Ended December 31, 2020 and 2019:

	Year ended December 31,		
	2020	2019	Change
	(in thousands)		
Revenue:			
Service revenue	$ 111,452	$ 30,351	$ 81,101
Collaborative arrangement revenue	115,594	5,740	109,854
Royalty and other revenue	21,076	8,205	12,871
Total revenues	248,122	44,296	203,826
Operating expenses:			
Research and development	296,467	297,645	(1,178)
Selling, general and administrative	90,897	81,646	9,251
Cost of royalty and other revenue	5,396	2,978	2,418
Change in fair value of contingent consideration	(6,468)	2,747	(9,215)
Total operating expenses	386,292	385,016	1,276
Loss from operations	(138,170)	(340,720)	202,550
Other income, net	18,056	20,126	(2,070)
Loss before income taxes	(120,114)	(320,594)	200,480
Income tax (expense) benefit	—	—	—
Net loss	$ (120,114)	$ (320,594)	$ 200,480

Revenue. Total revenue was $248.1 million for the year ended December 31, 2020, compared to $44.3 million for the year ended December 31, 2019. The increase of $203.8 million was primarily attributable to a cumulative catch-up adjustment to revenue recorded in connection with the May 2020 BMS contract modification, as well as an increase in royalty and other revenue primarily attributable to revenue recognized under an out-license agreement.

Research and Development Expenses. Research and development expenses were $296.5 million for the year ended December 31, 2020, compared to $297.6 million for the year ended December 31, 2019. The decrease of $1.2 million was primarily attributable to $26.5 million of decreased material production and other platform costs, primarily due to BMS assuming the contract manufacturing agreements relating to ide-cel adherent lentiviral vector under the May 2020 contract modification.

These decreased costs were partially offset by the following increases:

- $14.0 million of increased collaboration research funding costs, primarily due to an increase in collaboration costs incurred by BMS, of which we pay a portion, as a result of BMS assuming the contract manufacturing agreements relating to ide-cel adherent lentiviral vector under the May 2020 contract modification;
- $7.3 million of increased license and milestone fees;
- $3.2 million of increased consulting fees; and
- $1.5 million of increased research and development related IT and facility-related costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $90.9 million for the year ended December 31, 2020, compared to $81.6 million for the year ended December 31, 2019. The increase of $9.3 million was primarily due to the following:

- $7.5 million of increased employee compensation, benefit, and other headcount related expenses, which is primarily driven by an increase in headcount to support overall growth, including an increase of $1.9 million in stock-based compensation expense;
- $2.6 million of increased IT and facility-related costs; and
- $1.8 million of increased costs related to commercial activities.

These increased costs were partially offset by a $2.4 million decrease in consulting costs.

Cost of Royalty and Other Revenue. Cost of royalty and other revenue was $5.4 million for the year ended December 31, 2020, compared to $3.0 million for the year ended December 31, 2019. The increase is attributable to increased royalty revenue in the same periods.

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

Other Income, Net. The decrease in other income, net was primarily related to a decrease of $2.3 million in other income resulting from the allocation of facility-related and depreciation expense to bluebird bio for its proportional use of assets that will be attributed to us.

Comparison of the Years Ended December 31, 2019 and 2018:

	Year ended December 31,		
	2019	2018	Change
	(in thousands)		
Revenue:			
Service revenue	$ 30,351	$ 44,533	$ (14,182)
Collaborative arrangement revenue	5,740	7,820	(2,080)
Royalty and other revenue	8,205	2,226	5,979
Total revenues	44,296	54,579	(10,283)
Operating expenses:			
Research and development	297,645	200,490	97,155
Selling, general and administrative	81,646	53,631	28,015
Cost of royalty and other revenue	2,978	885	2,093
Change in fair value of contingent consideration	2,747	2,999	(252)
Total operating expenses	385,016	258,005	127,011
Loss from operations	(340,720)	(203,426)	(137,294)
Interest expense	—	(15,486)	15,486
Other income, net	20,126	19,163	963
Loss before income taxes	(320,594)	(199,749)	(120,845)
Income tax benefit (expense)	—	—	—
Net loss	$ (320,594)	$ (199,749)	$ (120,845)

Revenue. Total revenue was $44.3 million for the year ended December 31, 2019, compared to $54.6 million for the year ended December 31, 2018. The decrease of $10.3 million was primarily attributable to a decrease in service revenue recognized for the ide-cel license and manufacturing services under the BMS agreement. This decrease was partially offset by an increase in royalty and other revenue.

Research and Development Expenses. Research and development expenses were $297.6 million for the year ended December 31, 2019, compared to $200.5 million for the year ended December 31, 2018. The increase of $97.2 million was primarily attributable to the following:

- $32.0 million of increased laboratory expenses, material production, and other platform costs;
- $30.9 million of increased employee compensation, benefit, and other headcount related expenses, which is primarily driven by an increase in research and development headcount to support overall growth, including an increase of $12.0 million in stock-based compensation expense;
- $26.3 million of increased collaboration research funding costs;
- $25.9 million of increased research and development related IT and facility related costs, which includes the impact of adopting ASU 2016-02; and
- $1.7 million of increased consulting and market research costs.

These increased costs were partially offset by $18.3 million of decreased license and milestone fees and $1.5 million of decreased clinical trial costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $81.6 million for the year ended December 31, 2019, compared to $53.6 million for the year ended December 31, 2018. The increase of $28.0 million was primarily due to the following:

- $21.1 million of increased employee compensation, benefit, and other headcount related expenses, which is primarily driven by an increase in selling, general, and administrative headcount to support overall growth, including an increase of $9.2 million in stock-based compensation expense;
- $5.0 million of increased consulting fees;
- $1.2 million of increased IT and facility related costs; and
- $0.8 million of increased costs related to commercial-readiness activities.

Cost of Royalty and Other Revenue. Cost of royalty and other revenue was $3.0 million for the year ended December 31, 2019, compared to $0.9 million for the year ended December 31, 2018. The increase is attributable to increased royalty revenue in the same periods.

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

Interest Expense. The decrease in interest expense was due to the de-recognition of the financing lease obligation associated with our corporate headquarters at 60 Binney Street related to the adoption of ASU 2016-02 on January 1, 2019.

Other Income, Net. The increase in other income, net was primarily related to $2.6 million in additional income resulting from the allocation of facility-related expense to bluebird bio for its proportional use of assets that will be

attributed to us, partially offset by a decrease of $0.9 million in other income resulting from the allocation of depreciation expense to bluebird bio for its proportional use of equipment that will be attributed to us and an increase of $0.7 million in other expense resulting from the allocation of facility-related and depreciation expense to us for our proportional use of bluebird bio assets.

Liquidity and Capital Resources

We have historically participated in bluebird bio's centralized approach to cash management, and, therefore, there were no cash amounts specifically attributable to us for the historical periods presented. Historically, the primary source of liquidity for our business was cash flow allocated to us from bluebird bio. Prior to separation, transfers of cash to and from bluebird bio have been reflected in net parent investment in the historical combined balance sheets, statements of cash flows and statements of equity. We have not reported cash or cash equivalents for the periods presented in the combined balance sheets. We expect bluebird bio to continue to fund our cash needs through the date of the separation.

Going Concern

Our ability to fund our operations and capital needs will depend on our ongoing ability to generate cash from operations and access to capital markets and other sources of capital, as further described below. We have incurred losses and have experienced negative operating cash flows for all historical periods presented. During the year ended December 31, 2020, we incurred a loss of $120.1 million and used $67.8 million of cash in operations. As bluebird bio manages our cash and financing arrangements, excess cash generated, if any, is deemed remitted to bluebird bio and all sources of cash are deemed funded by bluebird bio. We expect to continue to generate operating losses and negative operating cash flows for the next few years. Our continued operations are dependent on our ability to raise additional funding. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned research or development programs or be unable to expand our operations. Based on our recurring losses from operations incurred, expectation of continuing operating losses for the next few years, and the need to raise additional funding to finance our future operations, as of May 11, 2021, the issuance date of the combined financial statements for the year ended December 31, 2020, we have concluded that there is substantial doubt about our ability to continue as a going concern for a period of one year from the date that our combined financial statements are issued. See Note 1, *Description of the business*, to our combined financial statements appearing elsewhere in this information statement.

Cash Flows

The following table summarizes our cash flow activity:

	Year ended December 31,		
	2020	2019	2018
	(in thousands)		
Net cash used in operating activities	$ (67,793)	$ (207,957)	$ (146,215)
Net cash used in investing activities	(22,261)	(59,765)	(50,827)
Net cash provided by financing activities	90,054	267,722	197,042
Increase (decrease) in cash, cash equivalents and restricted cash	$ —	$ —	$ —

Operating Activities. Net cash used in operating activities was $67.8 million for the year ended December 31, 2020 and primarily consisted of a net loss of $120.1 million adjusted for non-cash items, including stock-based compensation of $61.0 million, depreciation and amortization of $13.2 million, and the change in fair value of the contingent consideration of $6.5 million, as well as the change in our net working capital.

Net cash used in operating activities was $208.0 million for the year ended December 31, 2019 and primarily consisted of a net loss of $320.6 million adjusted for non-cash items, including stock-based compensation of $62.0

million, depreciation and amortization of $12.6 million, and the change in fair value of the contingent consideration of $2.7 million, as well as the change in our net working capital.

Net cash used in operating activities was $146.2 million for the year ended December 31, 2018 and primarily consisted of a net loss of $199.7 million adjusted for non-cash items, including stock-based compensation of $40.8 million, depreciation and amortization of $13.3 million, and the change in fair value of the contingent consideration of $3.0 million, as well as the change in our net working capital.

Investing Activities. Net cash used in investing activities for the year ended December 31, 2020 was $22.3 million and was due to the purchase of property, plant and equipment.

Net cash used in investing activities for the year ended December 31, 2019 was $59.8 million and was due to the purchase of property, plant and equipment.

Net cash used in investing activities for the year ended December 31, 2018 was $50.8 million and was due to the purchase of property, plant and equipment.

Financing Activities. As bluebird bio manages our cash and financing arrangements, all excess cash generated through earnings is deemed remitted to bluebird bio and all sources of cash are deemed funded by bluebird bio.

Net cash provided by financing activities for the year ended December 31, 2020 was $90.1 million and was due to cash transferred to us from bluebird bio based on changes in our cash used for operating and investing activities.

Net cash provided by financing activities for the year ended December 31, 2019 was $267.7 million and was due to cash transferred to us from bluebird bio based on changes in our cash used for operating and investing activities.

Net cash provided by financing activities for the year ended December 31, 2018 was $197.0 million and was primarily due to cash transferred to us from bluebird bio based on changes in our cash used for operating and investing activities.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, following the distribution, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase as we:

- leverage our programs to continue advancing our product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and our operations as a public company; and
- maintain, expand and protect our intellectual property portfolio.

We believe that our initial cash capitalization following the completion of the separation will enable us to fund our operating expenses and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. The scope of our future funding requirements will depend on, and could increase significantly as a result of, many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including medical affairs, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;
- the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in increased fixed payment obligations.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Lease Commitments

60 Binney Street Lease

In September 2015, bluebird bio entered into a lease agreement, which will be attributed to us in connection with the separation, for office and laboratory space located at 60 Binney Street, Cambridge, Massachusetts. Under

the terms of the lease, starting on October 1, 2016, we leased approximately 253,108 square feet of office and laboratory space at $72.50 per square foot per year, or $18.4 million per year in base rent, which is subject to scheduled annual rent increases of 1.75% plus certain operating expenses and taxes. bluebird bio currently maintains a $13.8 million collateralized letter of credit and, subject to the terms of the lease and certain reduction requirements specified therein, including market capitalization requirements, this amount may decrease to $9.2 million over time. The lease will continue until March 31, 2027. Pursuant to a work letter entered into in connection with the lease, the landlord contributed an aggregate of $42.4 million toward the cost of construction and tenant improvements for the building.

Seattle, Washington Leases

In July 2018, bluebird bio entered into a lease agreement for office and laboratory space located in a portion of a building in Seattle, Washington. This lease will be attributed to us in connection with the separation. The lease was amended in October 2018 to increase the total rentable space to approximately 36,126 square feet at $54.00 per square foot in base rent per year, which is subject to scheduled annual rent increases of 2.5% plus certain operating expenses and taxes. The lease commenced on January 1, 2019 and the lease term will continue through January 31, 2027. We moved into the facility in June 2019. The lease allowed for a tenant improvement allowance of up to $215.00 per square foot, or approximately $8.0 million. We utilized the $8.0 million tenant improvement allowance and it has been fully reimbursed by the landlord as of December 31, 2020.

In September 2019, we entered into a second amendment to the lease (the “Second Amendment”). The Second Amendment added approximately 22,188 square feet to the existing space and extended the lease term of the entire premises by 16 months, or until April 2028. Fixed monthly rent for the expanded space will be incurred at a rate of $62.80 per square foot per year beginning in January 2021, subject to annual increases of 2.5%. The Second Amendment includes a five-year option to extend the term. In September 2020, bluebird bio entered into a sublease agreement for the 22,188 square feet added under the Second Amendment at a fixed monthly rent of $62.80 per square foot per year beginning in January 2021, subject to annual increases of 2.5%. The sublease term will continue through April 2028.

Contingent Consideration Related to Business Combinations

In connection with the Pregenen acquisition, bluebird bio agreed to make contingent cash payments to the former equityholders of Pregenen. All assets and liabilities related to the Pregenen acquisition, including the resulting goodwill and contingent consideration, will be attributed to us in connection with the separation. In accordance with accounting guidance for business combinations, these contingent cash payments are recorded as a component of other non-current liabilities on our combined balance sheets at fair value. During the second quarter of 2017, a $5.0 million preclinical milestone was achieved, which resulted in a $5.0 million payment to the former equityholders of Pregenen during the third quarter of 2017. The aggregate remaining undiscounted amount of contingent consideration potentially payable is $120.0 million. As of December 31, 2020, and 2019, $1.5 million and $8.0 million, respectively, is reflected as a non-current liability in the combined balance sheets, which represents the fair value of our contingent consideration obligations as of that date.

Contingent Milestone and Royalty Payments

We also have obligations to make future payments to third parties that become due and payable on the achievement of certain development, regulatory and commercial milestones (such as the start of a clinical trial, filing of a BLA, approval by the FDA or product launch). We do not recognize these commitments in our financial statements until they become payable or have been paid.

Based on our development plans as of December 31, 2020, we may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products associated with our collaboration and license agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. Because the achievement of these milestones or sales had not occurred as of December 31, 2020, such contingencies have not been recorded in our financial statements.

Amounts related to contingent milestone payments and sales-based royalties are not yet considered contractual obligations as they are contingent upon success.

- Under a license agreement with Biogen Inc., which will be attributed to us in the separation, pursuant to which we license certain patents and patent applications related to our ide-cel and bb21217 product candidates, we will be required to make certain payments related to certain development milestone obligations and must report on our progress in achieving these milestones on a periodic basis. We may be obligated to pay up to $23.0 million in the aggregate for each licensed product upon the achievement of remaining milestones. Upon commercialization of our products covered by the in-licensed intellectual property, we will be obligated to pay a percentage of net sales as a royalty in the low single digits.

- Under a license agreement with the National Institutes of Health, or NIH, which will be attributed to us in the separation, pursuant to which we license certain patent applications related to our ide-cel and bb21217 product candidates, we have agreed to certain development and regulatory milestone obligations and must report on our progress in achieving these milestones on a periodic basis. We may be obligated to pay up to $9.7 million in the aggregate for a licensed product upon the achievement of these milestones. Upon commercialization of our products covered by the in-licensed intellectual property, we will be obligated to pay NIH a percentage of net sales as a royalty in the low single digits. The royalties payable under this license agreement are subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. During the year ended December 31, 2020, we paid NIH $1.0 million upon milestones reached for a product covered by in-licensed intellectual property.

- Under a license and collaboration agreement with Gritstone Oncology Inc., or Gritstone, which will be attributed to us in the separation, we may utilize Gritstone's proprietary technology platform to identify and validate tumor-specific targets, among other activities under our research plan. We may be obligated to pay up to $129.0 million in the aggregate per therapy product and $27.5 million in the aggregate per target product for development, regulatory, and commercial milestones as well as low single-digit tiered royalty payments based on annual net sales.

- Under a license and collaboration agreement with Inhibrx, Inc., or Inhibrx, which will be attributed to us in the separation, we will research, develop and commercialize chimeric antigen receptor (CAR) T cell therapies using Inhibrx's proprietary single domain antibody (sdAb) platform to multiple cancer targets. We may be obligated to pay up to $51.5 million in the aggregate per target for development, regulatory, and commercial milestones as well as mid single-digit tiered royalty payments based on annual net sales.

Transition From bluebird bio and Costs to Operate as an Independent Company

The combined financial statements reflect our operating results and financial position as it was operated by bluebird bio, rather than as an independent company. We will incur additional ongoing operating expenses to operate as an independent company. These costs will include the cost of various corporate headquarters functions, incremental information technology-related costs and incremental costs to operate stand-alone accounting, legal and other administrative functions. We will also incur non-recurring expenses and non-recurring capital expenditures.

As an independent company, our information technology operating costs may be higher than the costs allocated in the historical combined financial statements. In addition, we will incur non-recurring expenses and capital expenditures to establish independent information technology systems.

We are currently building our accounting and other administrative infrastructure. We expect to enter into a transition services agreement with bluebird bio that will provide us with certain services and resources related to corporate functions for an initial term of years (as applicable). This transition services agreement will allow us to operate our business independently prior to establishing stand-alone infrastructure. During the transition from bluebird bio, we will incur non-recurring expenses to expand our infrastructure.

It is not practicable to estimate the costs that would have been incurred in each of the periods presented in the historical financial statements for the functions described above. Actual costs that would have been incurred if we operated as a stand-alone company during these periods would have depended on various factors, including organizational design, outsourcing and other strategic decisions related to corporate functions, information technology and back office infrastructure.

Transactions with Related and Certain Other Parties

Prior to or concurrently with the distribution, we expect to enter into certain agreements with bluebird bio resulting from and relating to the separation, including a separation agreement, transition services agreement, a tax matters agreement, an intellectual property license agreement and an employee matters agreement. The terms of these agreements, including information on the business purpose of such agreements, transaction prices, related ongoing contractual commitments and any related special risks or contingencies are discussed in greater detail in the section captioned "Certain Relationships and Related Party Transactions", appearing elsewhere in this information statement.

Off-Balance Sheet Arrangements

As of December 31, 2020, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

BUSINESS

Overview

2seventy bio is a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. We are led by an accomplished team with significant expertise and experience in this field, from discovery through clinical development to regulatory approval of Abecma (idecabtagene vicleucel, or ide-cel), the first FDA-approved CAR T cell therapy for multiple myeloma. Our approach combines our expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. We are advancing multiple preclinical and clinical programs in oncology and, together with our partner Bristol-Myers Squibb (BMS), delivering Abecma to multiple myeloma patients in the United States.

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

While medicines such as Abecma have highlighted the power of first-generation CAR T cell therapy by achieving previously unobtainable levels of efficacy in the late line setting, we believe that to be broadly successful in the treatment of cancer, a combination therapy approach is necessary, and that our multiplex approach to next-generation autologous cellular therapy, which allows multiple encoded mechanisms of action to be delivered within a single drug product, represents an attractive solution. Based on our experience in the research and development of Abecma, we believe we can develop next-generation, engineered cell therapies to bring new options to patients suffering from a broad range of different tumor types.

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

Our Approach

Our approach is to create multiplex engineered cell therapies by combining: (1) CAR and T cell receptor technology, which programs T cells to recognize and kill cancer cells based on the cell surface expression or presentation of intracellular protein targets, respectively; (2) dual-targeting CAR architecture for multi-target tumor cell recognition; (3) our core lentiviral gene transfer technology which delivers these genetic cargos (and more) to program a patient's own T cells to the kill the cancer cells; (4) our megaTAL-based gene editing technology which allows us to perform site specific gene addition or deletion from the genome to improve the properties of the T cell; and (5) genetically encoded technologies for engineering T cells to enhance the cytotoxic activity and reprogram the tumor microenvironment for more effective anti-tumor responses. This approach is differentiated by (1) careful analysis of clinical and correlative data with the goal of precisely defining the key attributes of a cellular therapy necessary for anti-tumor effect; (2) the ability to design and then engineer a cell with these key attributes; combined with (3) a technology suite capable of delivering multiple innovations within a single drug product.

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

Our past experience in the clinical setting also provides us with a unique advantage, given the relative nascency of the CAR T cell field and the consequent paucity of large data sets of autologous cellular therapies in cancer. We, and through our collaborators at BMS, have treated hundreds of patients with multiple myeloma in the clinical setting, and the clinical and correlative data sets from the studies of Abecma and the bb21217 product candidate provides us with a deep, data-based understanding of the biology of the tumor itself, its interplay with immune cells and which cell therapy attributes are key to patient response. We believe that understanding is critical to identifying the key barriers in the treatment of the cancer. Specifically, we believe that understanding the heterogeneity of target expression combined with any tumor-specific mechanisms of immune evasion at play can help define the components of a cellular therapy with the potential for maximal anti-tumor activity. This understanding will be key to our product candidate design and selection, manufacturing process design and execution, and clinical trial design and development strategy.

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

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

Our lead preclinical programs in B cell non-Hodgkin's lymphoma and acute myeloid leukemia are illustrations of our multiplex approach applied to address the specific challenges of treating those cancers.

We are developing our bbT369 product candidate as a treatment for patients with B-NHL. The advent of the first generation of anti-CD19 CAR T products represents a significant advancement in the field of B-NHL and has established a new standard for the treatment of patients with relapsed and refractory B-NHL. However, more than half of patients treated with an anti-CD19 CAR T do not achieve durable remission. Prognosis remains poor for these patients, with median overall survival after axi-cel of approximately 6 months for patients initially responding and less than 2 months for patients without initial response. The main limitations of the first-generation CAR T therapies are the lack of complete response in some patients and the potential for late relapse, indicating a need for deeper and more durable treatment responses. We take a differentiated approach from the approved anti-CD19 CAR T therapies: we have designed a dual-targeting CAR to target antigens that are co-expressed in many B-NHL tumors to limit antigen escape (as has been seen with CD19-targeted therapies). We provide split co-stimulation to drive

maximal activation of the T cell in response to antigens. We include a gene edit designed to drive increased expansion, resist anergy, and maintain potency in sub-optimal conditions for T cell activation. Together, we believe these technologies will enable bbT369 to drive rapid tumor clearance, a hallmark of the CD19 CAR T cell patients who proceed to achieve complete responses. We plan to file an Investigational New Drug Application (IND) for the Phase 1 clinical study for bbT369 in the fourth quarter of 2021.

Although CAR T therapy has shown transformative potential and durable efficacy in other hematologic tumors, the use of CAR T therapy in the treatment of acute myeloid leukemia (AML) has been complicated by the expression of key targets such as CD33 across healthy myeloid cells in addition to leukemic blasts and stem cells. In other words, a highly potent CAR T cell directed towards one of these targets carries the significant risk of "on-target, off-tumor" toxicity because of broad myeloid aplasia. In our program for AML, we seek to address the challenge of balancing potency and safety risk by combining advanced CAR T receptor technology with our DARIC technology, a pharmacologically controlled "on-off" switch to reversibly regulate the activity of the CAR T cell. We have designed the CAR to target both full-length and alternatively spliced CD33 variants to address heterogeneity in the disease, and to reduce the risk of antigen escape and disease relapse. We believe that the DARIC switch will give treating physicians the ability to turn off highly potent CAR T cell activity to allow for myeloid recovery, while being able to re-activate CAR T cell activity on demand. We expect an investigator-initiated proof-of-concept clinical trial of our DARIC33 product candidate in pediatric relapsed and refractory AML patients will begin in the first half of 2022.

Our Strengths

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

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

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

- ***Manufacturing experience:*** Our team has accumulated significant experience in the manufacturing, analytical testing, and quality aspects from both lentiviral vectors and autologous lentiviral vector-transduced cellular drug products, from shepherding Abecma through clinical development, regulatory approval, and to commercialization in the United States, as well as from bluebird bio's betibeglogene autotemcel in Europe. Moreover, we have successfully scaled-up our suspension-based manufacturing process for lentiviral vector (sLVV), which is being utilized in ongoing clinical trials for ide-cel. We believe our experience spanning first-in-human to commercial manufacturing, quality control and quality assurance represents know-how critical to the efficient translation and development of our multiplex product candidates.

- ***Collaboration and connectivity:*** We have a strategic network of collaborations across industry, academic scientists, and medical experts to access technologies and expertise that supplement our proprietary

technologies. We believe these collaborations and partnerships provide us with a rich suite of technologies permitting the design of impactful multiplex product candidates.

Who We Are

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

2seventy bio's incoming chief executive officer, Nick Leschly, launched bluebird bio in 2010 and has led the growth of the pioneering gene and cell therapy company, leveraging his deep business strategy and entrepreneurial skills built over the last two decades. William "Chip" Baird, chief financial officer of bluebird bio since 2019 and future chief financial officer of 2seventy bio, is leading the separation of the companies and launch of the new company. Mr. Baird has more than 20 years of financial and strategic planning experience in the biopharmaceutical sector. Philip Gregory, D. Phil, has held the reigns as chief scientific offer at bluebird bio since 2015 and will transition to chief scientific officer of 2seventy bio. Dr. Gregory has led the scientific development of products for a range of diseases with our three gene therapy technology platforms: gene addition with lentiviral gene delivery, cell therapy and megaTAL-enabled gene editing.

In addition to our executive leadership team, we have structured the company to include more than individuals with deep experience and expertise in building high growth, disruptive companies, including key scientists and researchers who have made important discoveries and progress across our technologies.

Our Strategy

Our strategy is to apply our broad range of technologies to design multiplex product candidates that address the key treatment challenges in cancer. Unlike other oncology-focused companies in our space, we believe our breadth of technology enables us to develop tailored products focused on the specific areas of cancer biology we have identified. We selectively combine the relevant features and components from our range of tools and technologies to address the defined attributes of a cellular therapy necessary for anti-tumor effect.

To execute on our strategy, we plan to:

- Commercialize Abecma and develop bb21217 through our collaboration with BMS, the learnings from which allow us to leverage our clinical experience and product revenue stream to further invest in our next-generation proprietary programs.
- Leverage our leadership position in autologous CAR T therapies to advance into the clinic our next-generation programs in B cell non-Hodgkin's lymphoma, acute myeloid leukemia, and multiple myeloma.
- Apply our multiplex approach to the discovery and design of transformative cell and gene therapy products for the treatment of solid tumors.
- Seek to extend our approach to other cell types beyond T cells and to include allogeneic approaches, as we gain additional experience in our autologous T cell programs.
- Build upon our existing internal lentiviral vector manufacturing know-how and experience through selective investments in manufacturing collaborations and expanding our internal capabilities over time, with the objectives of enabling rapid iteration on clinical learnings into research and development, increasing the efficiency of manufacturing processes, and improving the overall patient and healthcare professional experience.

Background

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

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

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

- **Selecting an appropriate target tumor antigen**. If a potential cancer target antigen is also expressed or presented on normal tissues, the risk of on-target, off-tumor toxicity is increased. If an engineered T cell is designed to target a singular antigen, the risk of tumor escape mechanisms increase, if the expression of the antigen is reduced or lost due to selective pressure or due to cellular internalization. If any of these occur, the safety and/or efficacy of the engineered cell therapy would be compromised.

- **Engineering an optimal receptor**. The properties of the receptor and receptor construct are critical for the overall success of the therapy. These properties include the affinity and flexibility of the antigen-binding domains (which are important for tumor-specific recognition), and the co-stimulatory domains for CAR T cell activation (which are important for the metabolism, function and persistence of T cells).

- **Complex manufacturing**. The manufacture of individualized cell and gene therapies may be lengthy and complex. Patients typically wait approximately approximately three weeks to two months to be treated with autologous engineered cells, and in the meantime such patients may experience complications or progressions from underlying disease without bridging therapies, which may introduce additional risk and toxicities for the patients, rendering them ineligible for treatment. In addition, the "process is the product" in the case of engineered cell therapies because of the complex nature of their manufacture compared to other common biologically derived modalities such as recombinant proteins and antibodies. Such therapies are inherently more complex to characterize and control in part due to the variability of collected cells from the individual patients, and the process and analytical sciences to enable scale-up for commercial manufacturing are still significantly less advanced than that of proteins and antibodies, which limits access to patients.

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

Our Technologies

Our oncology programs use a lentiviral vector to deliver the genetic cargo necessary to program a patient's own T cells to recognize specific proteins or protein fragments on the surface of cancer cells to kill the cancer cells. Our current programs are based on CAR technology to program T cells to recognize cancer cells based on expression of specific cell surface antigens, and T cell receptor technology to program T cells to recognize cancer cells based on protein fragments derived from either intracellular or extracellular proteins displayed on the tumor cell surface. The genetically engineered T cells are designed to supplement a patient's immune system and may be further engineered to overcome immune evasion mechanisms employed by cancer cells. Our approach is to create multiplex engineered cell therapies by combining our foundational lentiviral vector and CAR/TCR technology with next-generation tools to address the challenges in existing cancer treatments.

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

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

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

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

- **Gene editing.** megaTALs are highly specific, compact nucleases that efficiently catalyze the formation and mutagenic resolution of double-stranded breaks at pre-specified genetic target sequences. Using our megaTAL gene editing platform, we have demonstrated that disrupting genes that intersect with T cell signaling and response pathways can promote more potent immune responses. In addition, we have

developed a full suite of on-target editing assays, functional bioassays, and off-target discovery and verification analytics to deeply characterize gene editing events and their functional consequences in target cells enabling the potential application of this technology in the clinical setting.

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

- **Cellular chassis**. Beyond genetic modifications, we are also developing approaches aimed at selecting for or enriching distinct cell types for tumor targeting that may be broadly applicable to both autologous and allogeneic settings. For instance, our bb21217 program utilizes a PI3K-inhibiting small molecule to enrich for memory-like T cells with the goal of extending the durability of action of our CAR T cells for multiple myeloma. In addition, we have developed approaches for the selection, transduction and expansion of gamma delta T cells. We believe gamma delta T cells may be useful in the allogeneic setting due to the absence of alloreactivity or graft versus host disease while demonstrating potent anti-tumor activity.

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

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

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

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

- **Manufacturing process innovations**. Our analytical development, clinical bioassays, correlative research, and data sciences teams have unique access to clinical trial data using CAR T therapies. We are continuously interrogating these data sets to isolate key manufacturing variables and correlates of clinical signals that enable hypothesis testing. These activities derive insights that inform process research

directions for optimizing T cell manufacturing through reagents, processes, and culture timing, and for the discovery of underlying biological relationships between clinical and correlative data.

Our Programs

B-Cell Non-Hodgkin's Lymphoma

We are developing our bbT369 product candidate as a treatment for patients with B-cell non-Hodgkin's Lymphoma (B-NHL), a heterogeneous group of neoplasms that can result in enlarged nodes across the body, neck, and abdomen, often coinciding with "B-symptoms" that are significant to the prognosis and staging of the disease, such as fever, drenching night sweats, and rapid and extreme weight loss. B-cell NHLs represent more than 85% of all NHL cases worldwide, and we plan to develop bbT369 to treat several subtypes of B-cell NHLs, specifically Diffuse Large B-Cell Lymphoma (DLBCL), High-Grade B-Cell Lymphoma (HGBCL), Primary Mediastinal Large B-Cell Lymphoma (PMBCL), Follicular Lymphoma (FL), or Transformed Follicular Lymphoma (TFL). DLBCL is the most common form of NHL, accounting for a third of all NHL cases, with annual incidence in the United States estimated at approximately 25,000 in 2020. DLBCL is a particularly aggressive form of NHL that requires immediate therapy upon diagnosis (with a median overall survival of approximately one year in untreated patients).

CAR T cells targeting CD19 represent a significant advancement in the field of B-NHL establishing a new standard of treatment for relapsed and refractory patients and the potential for curative therapy. Specifically, anti-CD19 CAR T products axicabtagene ciloleucel, tisagenlecleucel, and lisocabtagene maraleucel have been approved for the treatment of adult patients with relapsed and refractory large B Cell lymphoma (including DLBCL, HGBCL and TFL) after two or more lines of systemic therapy. However, survival for certain high-risk subtypes (e.g., non-GCB, DHL) and relapsed and refractory patients is poor. More than half of patients treated with CD19 CAR T do not achieve durable remission, and prognosis is poor with a median overall survival of approximately five months. The main limitations of the currently available CAR T treatments are the lack of complete response in some patients, and the potential for late relapse, indicating a need for deeper and more durable treatment options.

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

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

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

Our planned first-in-human clinical trial is expected to be an open label, multi-site Phase 1/2 clinical trial, that will enroll patients who are either naïve to CD19 CAR T or who have relapsed after CD19 CAR T. We anticipate that the phase 1 portion will be a dose-escalation study, with the phase 2 stage allowing continued investigation of these two different patient populations at the recommended dose. We are planning to file the IND for this Phase 1/2 clinical trial in late 2021.

Acute Myeloid Leukemia

We are developing our DARIC33 product candidate for the treatment of patients with acute myeloid leukemia (AML). Systemic therapy (including chemotherapy, hypomethylating agents, and targeted biologics) alongside hematopoietic stem cell transplant (HSCT) are the mainstays of AML treatment today. Of note, many adult patients are unfit for such intensive therapy, which in turn leads to less favorable clinical outcomes. Though HSCT provides meaningful clinical benefit to those who are eligible, the unmet need in this heterogenous and aggressive disease remains high. Prognosis is typically poor for adult patients, with a 5-year survival rate of 24% across all subtypes. In children and adolescents, the 5-year survival rate is 50 to 70%, with variation by subtype and other risk factors as seen in adults. Of note, median overall survival in adults with relapsed and refractory AML is less than 12 months, indicating a particularly high unmet need for these patients.

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

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

In collaboration with Seattle Children’s Therapeutics (a non-profit enterprise associated with Seattle Children’s Research Institute), we are planning an investigator-initiated proof-of-concept clinical trial of DARIC33 in pediatric relapsed and refractory AML patients, which we expect to begin in early 2022. This dose-finding trial is aimed at establishing safety, manufacturability, and early efficacy signals for DARIC33 and we expect to conduct correlative analyses to confirm rapamycin-driven regulation in humans. In parallel, we are also advancing next-generation, preclinical product concepts for pediatric and adult AML in partnership with Seattle Children’s Research Institute. These concepts include multiplex targeting and additional enhancement technologies to address the heterogeneity of disease and prevent relapse.

Multiple Myeloma

Multiple myeloma is a blood cancer caused by malignant plasma cells and typically originates in the bone marrow. In the United States, more than 34,000 new cases of multiple myeloma are estimated to be diagnosed in 2021. Despite advances in treatment, multiple myeloma remains an aggressive and incurable disease characterized by periods of remission and relapse. Most patients experience relapse following initial therapies, and depth and duration of response as well as survival outcomes decrease with each successive treatment. No standard of care has been established for patients who have disease progression despite receiving the three main classes of myeloma therapy (immunomodulatory drugs, proteasome inhibitors, and anti-CD38 antibodies), and outcomes are poor, with very low response rates (20% to 30%), a median progression-free survival of three to four months, and a median overall survival of eight to nine months. Through our collaboration with BMS, Abecma and bb21217 are our lead programs in multiple myeloma. The terms of our arrangements with BMS are described more fully below under “Strategic collaborations in oncology—Our strategic alliance with BMS.” We are also conducting next-generation discovery programs in multiple myeloma on our own.

Abecma. In March 2021, Abecma (idecabtagene vicleucel; ide-cel) was approved by the FDA in the United States for the treatment of adults with multiple myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Abecma is the first-in-class B cell maturation antigen (BCMA) CAR T therapy for the treatment of multiple myeloma, and represents our first oncology product candidate that has progressed from our internal research programs, through clinical development to approval and commercialization, together with our collaboration partner, BMS. BCMA is a cell surface protein that is nearly universally expressed on cancer cells in multiple myeloma, and on normal plasma cells and mature B cells, but not other cells. As the first CAR T cell therapy approved for multiple myeloma, Abecma is a potentially transformative, single-infusion, individualized treatment that offers patients who have limited effective treatment options the potential for long-term disease control. The approval of Abecma in the United States was based on positive results from the pivotal KarMMa study. In the KarMMa study, the overall response rate was 73%, and 33% of patients achieved a complete response. Onset of response was rapid with a median time to response of one month. Median duration of response was 10.7 months and 19 months for those who achieved a complete response. Abecma has a well-established and predictable safety profile with mostly low-grade cytokine release syndrome (Grade ≥3: 6%) and neurologic toxicities (Grade ≥3: 3.1%) with early onset and resolution. Results from the KarMMa study were published in the February 24, 2021 issue of the New England Journal of Medicine. The FDA and EMA have granted Orphan Drug status to ide-cel for the treatment of patients with relapsed and refractory multiple myeloma. The EMA has granted PRIME eligibility to ide-cel for relapsed and refractory multiple myeloma. BMS is conducting studies to support the use of Abecma in earlier lines of therapy.

bb21217. The bb21217 product candidate is an investigational BCMA-targeted CAR T cell therapy that uses the same CAR molecule as ide-cel, but is cultured with a PI3K inhibitor to enrich for T cells displaying a memory-like phenotype with the intention of increasing the in vivo persistence and function of CAR T cells. We believe that the persistence of functional CAR T cells after infusion may be one determinant of duration of response. The clinical development program for bb21217 includes an ongoing Phase 1 CRB-402 study, a first-in-human study of bb21217 in patients with relapsed and refractory multiple myeloma, designed to assess safety, pharmacokinetics, efficacy, and duration of effect. Data from CRB-402 were presented, together with our collaboration partners at BMS, at the annual meeting of the American Society of Hematology in December 2020. As of the September 1, 2020 cutoff date, 69 patients were treated with bb21217. The study has completed enrollment and follow-up is ongoing as data continue to mature. The safety profile of bb21217 in this Phase 1 study was consistent with known toxicities of BCMA CAR T-cell therapies, with low rates of cytokine release syndrome (Grade ≥3) and neurotoxicity. Clinical endpoints including overall response rate, complete response, and MRD negativity rates were promising across the study and at the recommended Phase 2 dose. Consistent with our hypothesis that enriching drug product for memory-like T cells may translate to improved durability of response, the estimated median duration of response was promising at 17.0 months across doses. Long-term CAR T cell persistence was observed in six of eleven evaluable patients at Month 12 and three of six evaluable patients at Month 18.

Next-generation approaches. CAR T therapies have transformed the treatment landscape in multiple myeloma and created the possibility for outcomes that were not possible with traditional therapies. Despite the significant advances that the current generation of CAR T therapies brought to patients, there are still significant challenges such as the need to improve duration of response and reduce manufacturing turnaround time. Our next-generation multiple myeloma program strategy is focused on leveraging our clinical experience from Abecma and bb21217, translational and correlative data, and technology platforms to solve definable and meaningful problems in the field. Leveraging our leadership in autologous CAR T therapy, our next-generation autologous multiple myeloma program utilizes multiple technologies including process improvements and dual targeting, with the goal of achieving best-in-class efficacy through deeper and more durable responses than the current generation of autologous CAR T products. We are also pursuing an allogeneic program that leverages our expertise with BCMA targeting and an innovative gamma-delta T-cell chassis to develop an off-the-shelf CAR T cell therapy that avoids the risk of toxicities such as graft versus host disease, while potentially offering additional advantages such as increasing manufacturing robustness, decreasing manufacturing turnaround time, and lowering cost of goods.

Solid Tumors

Solid tumors represent the next frontier for cell and gene therapies. Survival expectations in patients with solid tumor who have relapsed after existing therapies are often less than one year. While cell and gene therapies have demonstrated durable remission in hematologic malignancies, none have yet been approved for treating solid tumors. Key challenges to the discovery and development of cell and gene therapies in solid tumors includes the lack of strongly and selectively expressed targets as well as a hostile tumor microenvironment that serves as a barrier for T cells accessing the tumor and suppresses immune-mediated responses. We believe that our exclusive set of technologies, partnerships and cell and gene therapy experience enables the engineering of multiplex products to uniquely address the key challenges of solid tumors. Our research-stage programs in solid tumors include tumors expressing the MAGE-A4 antigen. Over ten types of solid tumors express the MAGE-A4 antigen, making it a promising target for cell therapy, including lung, head and neck, gynecologic and gastric cancers. Our MAGE-A4 program addresses the challenges of solid tumors in a three-pronged way: (1) we have identified a potent T cell receptor targeting a prevalent intracellular peptide antigen from MAGE-A4, (2) engineered this receptor for a strong anti-tumor response, and(3) incorporated an innovative switch receptor (CTBR12) that converts the highly suppressive TGFβ signal in the hostile tumor microenvironment into a potent T cell intrinsic activation signal. The TGFβ signaling pathway has been broadly implicated as a key suppressive factor in the TME of multiple MAGEA4+ indications, including non-small cell lung, bladder, ovarian, and head and neck carcinomas.

Manufacturing

We have internal lentiviral vector manufacturing capability at our facility in Durham, North Carolina. We manufacture vector supply for our pipeline programs at this facility, and we intend to support commercial manufacturing of vector supply for Abecma at this facility, pending regulatory approvals. Our internal lentiviral vector manufacturing capability is a core pillar of our strategy to rapidly iterate on clinical learnings in the clinical development of our pipeline programs, and to increase the efficiency of manufacturing processes for cell and gene therapies to reduce the cost of supply and enable patient access. In addition, we have entered into agreements with external manufacturing partners in the United States and Europe to support our various preclinical and clinical programs in oncology.

Strategic Collaborations

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

BMS. We began our collaboration with BMS under a broad-ranging research collaboration agreement between bluebird bio and Celgene Corporation in 2013. Currently, our collaboration focuses on the co-development and co-promotion of Abecma in multiple myeloma, as well as the development of bb21217, also in multiple myeloma.

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

Medigene. Through our collaboration, we have access to Medigene's proprietary platform for the generation and design of T cell receptors that we may leverage in our product candidates.

Inhibrx. Through our collaboration, we have access to Inhibrx's proprietary single-domain antibody platform to multiple cancer targets that we may leverage in our product candidates.

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

We also have significant academic collaborations for the discovery, preclinical development, and initial clinical proof-of-concept of our product concepts, such as our collaboration with Seattle Children's Therapeutics and the University of North Carolina. In addition, we have a collaboration with Novo Nordisk for the in vivo application of our megaTAL gene editing technology to genetic diseases, including hemophilia.

Competition

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

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

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

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

These efforts include the following:

Multiple Myeloma. The current standard of care for relapsed and refractory multiple myeloma includes IMIDs (e.g., thalidomide, lenalidomide, pomalidomide), proteasome inhibitors (e.g., bortezomib, carfilzomib, ixazomib), monoclonal antibodies (e.g., daratumamab, isatuximab, elotuzumab), cytotoxic agents, and HSCT. There are several companies developing autologous T cell therapies for relapsed and refractory multiple myeloma that use a similar autologous ex vivo approach, but a different target antigen, BCMA single-chain variable fragment or, we believe, cell processing techniques. These programs include: an anti-BCMA CAR T cell therapy that has been submitted to the FDA in 1Q2021 based on a phase 1b/2 study in the United States (Nanjing Legend in collaboration with Janssen); an anti-BCMA CAR T cell therapy that is in phase 1 study (Poseida Therapeutics, Inc.); an anti-BCMA CAR T cell therapy in clinical development (phase 1) sponsored by BMS following the completion of its acquisition of Juno Therapeutics, Inc and several other anti-BCMA CAR T cell therapies in phase I study, including and not limited to Novartis, Gracell Biotechnologies and Innovent Biologics Inc. In addition to these autologous T cell-based approaches, Allogene Therapeutics, Inc., Poseida, and CRISPR Therapeutics have disclosed preclinical and clinical programs for allogeneic BCMA targeted CAR T cell therapies. There are also therapies using other modalities being developed by several groups, including multiple bispecific T cell engagers, including programs currently in clinical studies supported by Amgen, Regeneron, Janssen, AbbVie, and BMS, as well as a specific antibody therapy currently in a phase 1 study supported by Pfizer, Inc., and a commercially approved antibody drug conjugate therapy supported by GSK.

B Cell Non-Hodgkin's Lymphoma. The current standard of care for majority of non-Hodgkin's lymphoma, or NHL, is focused around CD20 immunotherapy, mainly rituximab, combined with chemotherapy agents such as bendamustine or the four-drug cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) regimen as the first-line option; patients with certain mutations may receive a different chemotherapy cocktail called EPOCH. As patients fail these therapies and reach the relapsed/refractory setting, patients who are eligible for stem cell transplant typically receive CD20 antibodies and high-dose chemotherapy followed by autologous stem cell transplantation. The immunomodulatory drug lenalidomide may be used in combination with rituximab for such patients who are not eligible for high-dose chemotherapy. CD19 chimeric antigen receptor (CAR T) cell therapies tisagenlecleucel and axicabtagene ciloleucel were both approved in 2017 and lisocabtagene maraleucel was approved and launched in 2021 as therapies for NHL in relapsed/refractory patients. As many as 60 development programs for NHL therapies are in phase 1 through phase 3 trials in the US, including over 15 CAR T cell therapies, most of which target CD19. Among these programs are two dual targeting assets: Miltenyi's CD19/20 targeting CAR T in a Phase 1/2 trial and Autolus Therapeutics' AUTO3, a CD19/22 dual targeting CAR T for relapsed/refractory NHL in an ongoing phase 1/2 trial in the US with promising early data. Most cell therapies, marketed or in the clinic, are exploring patient populations across the treatment paradigm with expectations of replacing current standard of care and procuring expanded labels. In addition to autologous therapies, efforts are ongoing for allogeneic platforms that offer "off-the-shelf" advantage with the option of potentially treating greater number of patients over currently marketed CARs. Allo-501 has shown promising preliminary data in R/R NHL including patients failed on or refractory to prior CARs. Beyond cell therapies, Roche's anti-body drug conjugate, polatuzumab received approval in relapsed/refractory NHL in the US in 2019 and a broader EMA approval in patients not eligible for stem cell transplant. Morphosys' tafasitamab, a CD-19 targeted antibody, was approved and launched in 2020 in the US in combination with lenalidomide for patients with relapsed or refractory disease. Bispecific antibody therapies including Regeneron's REGN1979 (CD20 X CD3) are also attracting interest with recent promising data not only in relapsed/refractory patients but also in patients previously treated with a CAR T, in a phase 1 trial.

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

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

Intellectual Property

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

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

We have developed or in-licensed numerous patents and patent applications and possess substantial know-how and trade secrets relating to the development and commercialization of gene therapy products. Our proprietary intellectual property, including patent and non-patent intellectual property, is generally directed to, for example, certain genes, transgenes, methods of transferring genetic material into cells, genetically modified cells, processes to manufacture our lentivirus-based product candidates and other proprietary technologies and processes related to our product development candidates. As of April 13, 2021, our patent portfolio includes the following:

- approximately 74 patents or patent applications that we own or have exclusively in-licensed from third parties related to lentiviral vectors and vector manufacturing or production;

- approximately 157 patents or patent applications that we own or have exclusively or co-exclusively in-licensed from third parties related to therapeutic cellular product candidates;

- approximately 466 patents or patent applications that we own or have exclusively in-licensed or optioned from third parties related to oncology product candidates, including CAR T cell vector systems and manufacturing, T cell manufacturing, and therapeutic T cells;

- approximately 165 patents or patent applications that we own or have exclusively or co-exclusively in-licensed from third parties related to gene editing compositions and methods; and

- approximately 2 patent applications that we have non-exclusively in-licensed from third parties related to gene editing compositions and methods.

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

Ide-cel, bb21217, and Independent Multiple Myeloma Program

The multiple myeloma programs include the patent portfolios described below. These rights will be assigned or sublicensed to us pursuant to the intellectual property license agreement and other agreements that we intend to enter into with bluebird bio in connection with the separation.

- **Pasteur Institute**. The in-licensed Pasteur patent portfolio contains patents and patent applications directed to FLAP/cPPT elements and lentiviral vectors used to produce ide-cel and bb21217 for multiple myeloma. As of April 13, 2021, we had an exclusive license in the field of oncology (from bluebird bio) to two issued U.S. patents. We expect the issued composition of matter patents to expire in 2022 and 2023 in the United States (excluding possible patent term extensions).

- **RDF.** The in-licensed Research Development Foundation, or RDF, patent portfolio contains the patents and patent applications directed towards aspects of our lentiviral vectors used to produce ide-cel and bb21217 for multiple myeloma. As of April 13, 2021, we had an exclusive license in the field of oncology (bluebird bio) to 10 issued U.S. patents and two pending U.S. patent applications related to our lentiviral vector platform. Corresponding foreign patents related to our lentiviral vector platform include issued patents in Canada, Europe, and Israel. We expect the issued composition of matter patents to expire from 2021-2027 in the United States, and in 2022 in the rest of the world (excluding possible patent term extensions). Further, we expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2021-2022 (excluding possible patent term extensions).

- **Biogen**. The in-licensed Biogen Inc. (formerly Biogen Idec MA Inc.; referred to herein as “Biogen”) patent portfolio, contains patents and patent applications directed toward aspects of T cell-based products that target BCMA. As of April 13, 2021, we had a co-exclusive license to five issued U.S. patents, one pending U.S. patent application, 49 issued corresponding foreign patents, and one pending corresponding foreign application related to T cell-based products that target BCMA. We expect the issued composition of matter patents to expire from 2024-2032 (excluding possible patent term extensions). Further, we expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2024-2030 (worldwide, excluding possible patent term extensions).

- **NIH**. The in-licensed patent portfolio from National Institutes of Health, or NIH, contains patents and patent applications directed towards aspects of chimeric antigen receptor-based immunotherapies that target BCMA. As of April 13, 2021, we had an exclusive license to 13 issued U.S. patents, 3 pending U.S. patent applications, 20 issued corresponding foreign patents and 19 corresponding foreign patent applications related to chimeric antigen receptor-based immunotherapies that target BCMA and methods of use. We expect the issued composition of matter and methods patents to expire from 2033-2034 (excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2033 (worldwide, excluding possible patent term extensions).

- **2seventy IP**. The owned patent portfolio contains patents and patent applications directed to certain specific compositions of matter for generating CAR T cells. As of April 13, 2021, we owned seven issued U.S. patents, 11 pending U.S. patent applications, 185 corresponding foreign patents, 108 corresponding foreign patent applications, and one pending PCT application. We expect the issued composition of matter and methods patents to expire in 2035 (worldwide, excluding possible patent term extensions). We expect any other patents, if issued from the pending patent applications or a corresponding national stage application, if applicable, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2035-2040 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire from 2035-2040 (worldwide, excluding possible patent term extensions).

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

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

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

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

- **SIRION.** The in-licensed patent portfolio from SIRION Biotech GmbH, or SIRION, contains patents and patent applications directed to methods of manufacturing ex vivo gene therapy products with a lentiviral vector. As of April 13, 2021, we had a nonexclusive license in the field of oncology (from bluebird bio) to two issued U.S. patents, one pending U.S. patent application, 23 issued corresponding foreign patents, and two corresponding foreign patent applications. We expect the issued method patents to expire in 2033 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2033 (worldwide, excluding possible patent term extensions).

- **2seventy IP.** Another component of the owned patent portfolio includes the vector manufacturing platform and is potentially applicable to our oncology programs. This portion of the portfolio contains patent applications directed to improved methods for transfection and transduction of therapeutic cells. As of April 13, 2021, we owned one pending U.S. patent application and one corresponding foreign patent application. We expect composition of matter and method patents, if issued from the pending patent applications and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2038 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in 2038 (worldwide, excluding possible patent term extensions).

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

Our T cell-based oncology platform and oncology research program, which is applicable to our multiple myeloma programs and other potential programs in cancer, includes the following patent portfolios described below. These rights will be assigned or sublicensed to us pursuant to the intellectual property license agreement and other agreements that we intend to enter into with bluebird bio in connection with the separation.

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

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

- **2seventy IP.** One aspect of the owned patent portfolio contains patent applications directed to certain specific compositions of matter for generating CAR T cells directed against various cancers and improved CAR T cell compositions. As of April 13, 2021, we owned 25 patent families that include three issued U.S. patents, 13 pending U.S. patent applications, three corresponding foreign patents, and 77 corresponding foreign patent applications; four families of pending U.S. provisional applications; and 10 pending PCT applications. We expect the issued composition of matter patent to expire in 2034 (worldwide, excluding possible patent term extensions). We expect any other patents, if issued from a corresponding nonprovisional patent application, the pending patent applications or a corresponding national stage application, if applicable, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2034-2041 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other

governmental fees are paid, to expire from 2034-2041 (worldwide, excluding possible patent term extensions).

- **T Cell Manufacturing Methods License**. We are in the process of in-licensing patents and patent applications that are directed to certain specific methods for generating CAR T cells. As of April 13, 2021, we had a nonexclusive license to two issued U.S. patents, one pending U.S. patent application, and 30 corresponding issued foreign patents. We expect the issued method patents to expire in 2026 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2026 (excluding possible patent term extensions).

- **T Cell Immunotherapy Product Candidate Licenses.** We are in the process of in-licensing or obtaining assignments to patents and patent applications that are directed to certain specific compositions of matter for generating CAR T cells directed against various cancers and related methods of treatment. As of April 13, 2021, we had an exclusive license to one issued U.S. patent and ten corresponding foreign patents and co-own a pending US application and seven corresponding foreign patent applications to a particular target antigen. We expect the issued composition of matter patent to expire in 2025 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2036 (worldwide, excluding possible patent term extensions). In addition, as of April 13, 2021, we had an exclusive license to three families of U.S. non-provisional applications and corresponding PCT applications directed to compositions and methods for treating cancers that express particular target antigens. We expect any composition of matter or methods patents, if issued from the pending patent applications or a corresponding national stage application, if applicable, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2040 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in 2040 (worldwide, excluding possible patent term extensions). Also as of April 13, 2021, we co-owned (with Medigene AG) a PCT application directed to compositions and methods for treating cancers that express a particular antigen. We expect any composition of matter or methods patents, if issued from a corresponding national stage application, if applicable, and if the appropriate, renewal, annuity or other governmental fees are paid, to expire in 2040 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in 2040 (worldwide, excluding possible patent term extensions). Also as of April 13, 2021, we co-owned (with Inhibrx, Inc.) three families of PCT applications directed to compositions and methods for treating cancers that express a particular antigen. We expect any composition of matter or methods patents, if issued from a corresponding national stage application, if applicable, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2040 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire from 2040 (worldwide, excluding possible patent term extensions). Also as of April 13, 2021, we had an option to exclusively license two U.S. patent applications and 7 corresponding foreign patent applications that are directed to compositions and methods for treating cancers that express a particular antigen. We expect any composition of matter or methods patents, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2037-2039 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire from 2037-2039 (worldwide, excluding possible patent term extensions).

Gene Editing Platform (e.g., homing endonucleases, chimeric endonucleases, megaTALs, genetically modified cells)

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

- **Gene Editing License.** We are in the process of in-licensing patent portfolios that contain patents and patent applications directed to aspects of our gene editing platform to produce genome modifying enzymes and genetically modified cells that are potentially applicable to oncology programs. As of April 13, 2021, we had an exclusive/co-exclusive license to seven issued U.S. patents, one pending U.S. patent application, 26 corresponding foreign patents, and three corresponding patent applications related to our gene editing platform. We expect the issued composition of matter patents to expire in 2030 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued from the pending patent applications and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2030 (worldwide, excluding possible patent term extensions). In addition, as of April 13, 2021, we had an exclusive license to two issued U.S. patents and six corresponding foreign patents related to our gene editing platform. We expect the issued composition of matter patent to expire from 2027-2031 in the United States (excluding possible patent term extensions) and in 2027 in the rest of the world.

- **Academic Gene Editing License**s. We in-licensed patent portfolios from multiple academic medical centers, each portfolio containing patents and patent applications directed to aspects of our gene editing platform to produce genome modifying enzymes and genetically modified cells that are potentially applicable to our oncology programs. As of April 13, 2021, we had an exclusive license to five issued U.S. patents, four pending U.S. patent applications, 15 corresponding foreign patents, and two corresponding patent applications related to our gene editing platform. We expect the issued patent to expire in 2027-2032 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2027-2032 (worldwide, excluding possible patent term extensions). As of April 13, 2021, we also had a non-exclusive license to one issued U.S. patent and one pending U.S. patent application related to our gene editing platform. We expect the issued composition of matter patent to expire in 2035 (excluding possible patent term extensions). We expect any other patents in this portfolio, if issued and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2035 (worldwide, excluding possible patent term extensions).

- **2seventy IP.** One aspect of the owned patent portfolio contains patent applications that are potentially applicable to certain aspects of our gene editing platform to produce genome modifying enzymes and genetically modified cells that are potentially applicable to our oncology and other programs. As of April 13, 2021, we owned 10 patent families that include two issued U.S. patents, 12 pending U.S. patent applications, and 53 corresponding foreign patent applications related to our gene editing platform. We expect the issued composition of matter patent to expire in 2038 (excluding possible patent term extensions). We expect any composition of matter or methods patents, if issued from the pending patent applications, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2037-2038 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire from 2037-2038 (worldwide, excluding possible patent term extensions). As of April 13, 2021, we owned two PCT applications related to our gene editing platform. We expect any composition of matter or methods patents, if issued from a corresponding national stage application, if applicable, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2039 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire from 2039 (worldwide, excluding possible patent term extensions). As of April 13, 2021, we also owned one provisional application related to our gene editing platform. We expect any composition of matter or methods patents, if issued from a corresponding nonprovisional patent

application, if applicable, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2041 (worldwide, excluding possible patent term extensions). We expect any other patents in this portfolio, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in 2041 (worldwide, excluding possible patent term extensions). As of April 13, 2021, we co-owned (with Cellectis SA) two issued U.S. patents, 17 corresponding foreign patents, and two corresponding foreign patent applications related to our gene editing platform. We expect the issued composition of matter patent to expire in 2034 (worldwide, excluding possible patent term extensions).We expect any other patents in this portfolio, if issued from the pending patent applications and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2034 (worldwide, excluding possible patent term extensions).

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent.

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

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

License Agreements

We intend to enter into an intellectual property license agreement with bluebird bio prior to the distribution pursuant to which each party will grant a license to certain intellectual property and technology. bluebird bio will grant 2seventy bio a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to certain intellectual property to allow 2seventy bio to use such intellectual property in connection with 2seventy bio's ongoing and future research and development activities and product candidates. 2seventy bio will grant bluebird bio a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to certain intellectual property for use in bluebird bio's existing products and product candidates. Such licenses between the parties generally will allow current or future uses of the intellectual property in connection with each party's respective fields.

Government Regulation

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

Within the FDA, the Center for Biologics Evaluation and Research, or CBER, regulates cell and gene therapy products. CBER works closely with the NIH. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols. The FDA also has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing subjects involved in gene therapy studies for delayed adverse events, potency testing, and chemistry, manufacturing and control information in gene therapy INDs.

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

U.S. Biological Products Development Process

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

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical studies may begin;
- performance of adequate and well-controlled human clinical studies according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical studies;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with GMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;

- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

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

The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. A clinical hold may either be a full clinical hold or a partial clinical hold that would limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical studies due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such studies.

In addition to the IND submission process, sponsors of certain clinical studies of cells containing recombinant or synthetic nucleic acid molecules, including human gene transfer studies, must comply with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or the NIH Guidelines. In the past, where a gene therapy study was conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research, prior to the submission of an IND to the FDA, a protocol and related documentation was submitted to and the study was registered with the NIH Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines. Pursuant to the current NIH Guidelines, research involving recombinant or synthetic nucleic acid molecules, including cells containing such molecules, must be approved by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA, however many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Such trials remain subject to FDA and other clinical trial regulations, and only after FDA, IBC, and other relevant approvals are in place can these protocols proceed.

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

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

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients who have the disease or condition the product candidate is intended to treat.

- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3. Clinical studies are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical studies, sometimes referred to as phase 4 clinical studies, may be conducted after initial marketing approval. These clinical studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire, of study subjects.

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

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

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

U.S. Review and Approval Processes

After the completion of clinical studies of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, as amended, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

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

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. For a cell or gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical studies were conducted in compliance with IND study requirements and GCP requirements. To assure GMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

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

condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application, or request a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical studies, sometimes referred to as phase 4 clinical studies, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

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

Orphan Drug Designation

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

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

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of

the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Under the Breakthrough Therapy program, products intended to treat a serious or life-threatening disease or condition may be eligible for the benefits of the Fast Track program when preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies. Additionally, FDA will seek to ensure the sponsor of a breakthrough therapy product receives timely advice and interactive communications to help the sponsor design and conduct a development program as efficiently as possible. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Regenerative Medicine Advanced Therapies Designation

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

Post-Approval Requirements

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

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

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

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

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term

restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant BLA.

A biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The Patient Protection and Affordable Care Act, or Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

Healthcare and Privacy Laws

In addition to restrictions on marketing of pharmaceutical products, several other types of state/ federal laws and trade association membership codes of conduct have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include Anti-Kickback and false claims statutes. The U.S. federal healthcare program Anti-Kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging healthcare professionals or patients as speakers or consultants, may be subject to scrutiny if they do not fit squarely within the

exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient assistance programs.

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

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

The U.S. federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics and medical supplies to engage in extensive tracking of payments and other transfers of value to prescribers and teaching hospitals, including physician ownership and investment interests, and public reporting of such data. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. Pharmaceutical and biological manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program are required to track such payments, and must submit a report on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year. A number of other countries, states and municipalities have also implemented additional payment tracking and reporting requirements, which if not done correctly may result in additional penalties.

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

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

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In California the California Consumer Protection Act ("CCPA"), which went into effect on January 1, 2020, establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While clinical trial data and information governed by HIPAA are currently exempt from the current version of the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope.

The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. In addition, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers, marketing expenditures, and drug pricing information. Certain state and local laws require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Government Regulation Outside of the United States

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

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical studies. In the European Union, for example, a CTA must be submitted for each clinical trial to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, the corresponding clinical study may proceed.

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

To obtain regulatory approval of an investigational product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, region-specific document requirements. The EMA has established the Adaptive Pathways pilot program intended to expedite or facilitate either an initial approval of a medicinal product in a well-defined patient subgroup with a high medical need and subsequent iterative expansion of the indication to a larger patient population, or an early regulatory approval (e.g., conditional approval), which is prospectively planned, and where uncertainty is reduced through the collection of post-approval data on a medicinal product's use in patients. The approach builds in regulatory processes already in place within the existing EU legal framework.

The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic or biosimilar application during such eight-year period starting from the date of grant of the innovative medicinal product's marketing authorization. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity (and the grant of the relevant generic or biosimilar marketing authorization). However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be an innovative medicinal product, and products may not qualify for data exclusivity. Products receiving orphan designation in the European Union and being granted a marketing authorization for an orphan medicinal product can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the European Union where the application for a marketing authorization includes the results of all studies conducted in accordance with an agreed pediatric investigation plan for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of

diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation itself does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

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

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

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

Failure to comply with the EU member state laws implementing the Community Code on medicinal products, and EU rules governing the promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, with the EU member state laws that apply to the promotion of medicinal products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements can result in enforcement action by the EU member state authorities (or in addition, in some member states, enforcement action from industry bodies or legal action from competitors), which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

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

For other countries outside of the EU, such as countries in Eastern Europe, Central and South America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. This act could have implications for our interactions with physicians in and outside the UK. In

all cases, again, the clinical trials are conducted in accordance with GCP, applicable regulatory requirements, and ethical principles that have their origin in the Declaration of Helsinki.

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

Pricing, Coverage and Reimbursement

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

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payers tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the drug product. Third-party payers may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payers may provide coverage, but place stringent limitations on such coverage, such as requiring alternative treatments to be tried first. These third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety, efficacy, and overall value. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to incurring the costs required to obtain FDA approvals. Our product candidates may not be considered medically reasonable or necessary or cost-effective. Factors payors consider in determining reimbursement are based on whether the product is:

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

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

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

Healthcare Reform

Payers, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court. Additionally, the former Trump Administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business, especially given the new administration.

Federal, state and local governments in the United States and foreign governments continue to consider other legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Future legislation could limit payments for pharmaceuticals such as the drug candidates that we are developing.

The former Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the former Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the former Trump administration also previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

In 2020, former President Trump announced several executive orders related to prescription drug pricing that sought to implement several of the former administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price

reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Facilities

Following the separation, our corporate offices will be located in , where we will occupy approximately rentable square feet of office and laboratory space under a lease that expires in . We believe our facility is sufficient to meet our current needs until the expiration of our lease and that suitable space will be available as and when needed.

Employees

Following the separation, we expect to have approximately employees, of whom hold M.D. or Ph.D. degrees. Approximately employees are expected to be in discovery research, in our drug development organization, in our strategy and corporate development organizations and in general and administrative functions. None of our employees are expected to be subject to a collective bargaining agreement or represented by a trade or labor union. We consider our employee relations to be good.

Compensation and benefits programs

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

Employee development and training

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

Diversity

We are committed to taking action to help address racial injustice and inequality. Our senior leadership team and board of directors have committed to help improve representation and culture of inclusion in the future.

Legal Proceedings

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims, which may have a material adverse effect on our financial position or results of operations.

MANAGEMENT

Directors and Executive Officers

The following table sets forth the names and ages, as of , 2021, and titles of the individuals we currently expect to serve as our executive officers and members of our board of directors at the time of the separation. Certain biographical information with respect to those executive officers and directors follows the table.

Name	Age	Position
Nick Leschly		President, Chief Executive Officer and Director
William D. Baird, III		Chief Financial Officer
Philip Gregory, D. Phil.		Chief Scientific Officer
		Director
		Director
		Director
		Director
		Director

Executive Officers

Nick Leschly will serve as our chief executive officer upon completion of this separation. Mr. Leschly has served as bluebird bio's chief executive officer, since September 2010. Prior to joining bluebird bio, Mr. Leschly served as a partner of Third Rock Ventures, L.P. since its founding in 2007, Mr. Leschly played an integral role in the overall formation, development and business strategy of several of Third Rock's portfolio companies, including Agios Pharmaceuticals, Inc. and Edimer Pharmaceuticals, Inc. Prior to joining Third Rock, he worked at Millennium Pharmaceuticals, Inc. (now a subsidiary of Takeda), leading several early-stage drug development programs and served as the product and alliance leader for VELCADE. Mr. Leschly also founded and served as chief executive officer of MedXtend Corporation. He received his B.S. in molecular biology from Princeton University and his M.B.A. from The Wharton School of the University of Pennsylvania.

William D. Baird, III will serve as our chief financial officer upon completion of this separation. Mr. Baird has served as bluebird bio's chief financial officer since February 2019, bluebird bio's Principal Financial Officer since March 2019 and bluebird bio's Principal Accounting Officer since February 2021. Mr. Baird served as chief financial officer of Amicus Therapeutics, Inc. from April 2012 until December 2018. From April 2005 until April 2012, Mr. Baird served as chief financial officer of PTC Therapeutics, Inc. ("PTC"). Before that, Mr. Baird held various positions of increasing responsibility with PTC from 2002 to 2005. Mr. Baird previously worked in the life science practice at L.E.K. Consulting, a strategy consulting firm, from 1999 to 2002, and at First Union National Bank as a corporate underwriter from 1994 to 1997. Since June 2018, Mr. Baird has served on the Board of Directors of Axcella Health, a biotechnology company. Mr. Baird received a B.S. from Georgetown University's Edmund A. Walsh School of Foreign Service, and an M.B.A. from The Wharton School of the University of Pennsylvania.

Philip Gregory, D. Phil. will serve as our chief scientific officer upon completion of this separation. Dr. Gregory has served as bluebird bio's chief scientific officer since June 2015. Prior to joining bluebird bio, Dr. Gregory was formerly with Sangamo BioSciences, where he held multiple leadership positions over a nearly 15-year tenure, most recently serving as chief scientific officer and senior vice president, Research. In this role, he was responsible for the scientific direction and strategic research planning for the company. Dr. Gregory played an integral role in Sangamo's partnerships and drove early discovery and development for several product candidates in multiple therapeutic areas. Prior to joining Sangamo, he was a postdoctoral fellow at Ludwig-Maximilians-Universität in Munich, Germany. Dr. Gregory holds a D. Phil in biochemistry from Oxford University, Keble College and a B.Sc. in microbiology from Sheffield University.

Non-Management Directors

We expect to appoint non-management directors to serve on our board of directors upon completion of the separation. We will identify these individuals in a subsequent amendment to the registration statement on Form 10 of which this information statement is a part.

Board Composition and Independence

Our business and affairs are managed under the direction of our board of directors. Upon completion of the separation, our board of directors consists of members. Our directors hold office until their successors have been elected and qualified or until their earlier death, resignation or removal. There are no family relationships among any of our directors or executive officers. It is anticipated that a majority of our board of directors will satisfy the independence standard established by the listing standards of Nasdaq Global Market as well as the corporate governance principles to be adopted by our board of directors.

Board Committees

Upon the completion of the separation, our board of directors will have three standing committees: an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our board of directors.

Audit Committee

The responsibilities of the Audit Committee will be more fully described in our Audit Committee Charter and are expected to include, among other duties:

- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements, earnings releases and related disclosures;
- reviewing and discussing with management and our independent registered public accounting firm our internal controls and internal auditing procedures, including any material weaknesses in either;
- discussing our accounting policies and all material correcting adjustments with our management and our independent registered public accounting firm;
- discussing with our management and our independent registered public accounting firm any significant risks facing the company and the related mitigation plans, as well as monitoring our internal control over financial reporting and disclosure controls and procedures; appointing, overseeing, and approving the compensation for and, when necessary, terminating our independent registered public accounting firm;
- approving all audit services and all permitted non-audit, tax and other services to be performed by our independent registered public accounting firm, in each case, in accordance with the audit committee's pre-approval policy;
- discussing with the independent registered public accounting firm its independence and ensuring that it receives the written disclosures regarding these communications required by the Public Company Accounting Oversight Board;
- reviewing and approving all transactions or series of similar transactions to which we were or are a party in which the amount involved exceeded or exceeds $120,000 and in which any of our directors, executive officers, holders of more than 5% of any class of our voting securities, or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest, other than compensation arrangements with directors and executive officers;

- recommending whether the audited financial statements should be included in our annual report and preparing the audit committee report required by SEC rules;

- reviewing all material communications between our management and our independent registered public accounting firm;

- reviewing, updating and recommending to our board approval of our code of business conduct and ethics; and establishing procedures for the receipt, retention, investigation and treatment of accounting related complaints and concerns.

Upon completion of the distribution, the Audit Committee will consist entirely of independent directors, and we intend that each will meet independence requirements set forth in the listing standards of the Nasdaq Global Market and Rule 10A under the Exchange Act. Each member of the Audit Committee will be financially literate and have accounting or related financial management expertise as such terms are interpreted by our board of directors in its business judgment. Additionally, upon completion of the distribution, at least one member of the Audit Committee will be an "audit committee financial expert" under SEC rules and the Nasdaq Global Market listing standards applicable to audit committees. The initial members of the Audit Committee will be determined prior to the completion of the distribution.

Compensation Committee

The responsibilities of the Compensation Committee will be more fully described in our Compensation Committee Charter and are expected to include, among other duties:

- reviewing and approving corporate goals and objectives relevant to executive officer compensation and evaluating the performance of executive officers in light of those goals and objectives;

- reviewing and approving executive officer compensation, including salary, bonus and incentive compensation, deferred compensation, perquisites, equity compensation, benefits provided upon retirement, severance or other termination of employment, and any other forms of executive compensation;

- reviewing and approving our chief executive officer's compensation based on its evaluation of our chief executive officer's performance;

- overseeing and administering our incentive compensation plans and equity based plans and recommending the adoption of new incentive compensation plans and equity based plans to our board of directors;

- making recommendations to our board of directors with respect to director compensation; and

- making recommendations to our board of directors with respect to management succession planning, including planning with respect to our chief executive officer.

Upon completion of the distribution, the Compensation Committee will consist entirely of independent directors, and we intend that each will meet the independence requirements set forth in the listing standards of the Nasdaq Global Market. We also intend the members of the Compensation Committee will qualify as "non-employee directors" (within the meaning of Rule 16b-3 of the Exchange Act). The initial members of the Compensation Committee will be determined prior to the completion of the distribution.

Nominating and Corporate Governance Committee

The responsibilities of the Nominating and Corporate Governance Committee will be more fully described in our Nominating and Corporate Governance Committee Charter and are expected to include, among other duties:

- identifying individuals qualified to become members of our board of directors;

- recommending to our board of directors the persons to be nominated for election as directors;
- assisting our board of directors in recruiting such nominees;
- recommending to our board of directors qualified individuals to serve as committee members;
- performing an annual evaluation of our board of directors;
- evaluating the need and, if necessary, creating a plan for the continuing education of our directors;
- assessing and reviewing our corporate governance guidelines and recommending any changes to our board of directors; and
- evaluating and approving any requests from our executives to serve on the board of directors of another for-profit company.

The Nominating & Corporate Governance Committee will consist entirely of independent directors, and we intend that each will meet the independence requirements set forth in the listing standards of the Nasdaq Global Market. The initial members of the Nominating & Corporate Governance Committee will be determined prior to the completion of the distribution.

Our board of directors may establish other committees from time to time.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2020, 2seventy bio did not exist and did not have a compensation committee or any other committee serving a similar function. Prior to the separation, decisions as to the compensation of those who are expected to serve as our executive officers were made by the bluebird bio Compensation Committee.

Code of Business Conduct and Ethics

In connection with the separation and the distribution, our board of directors is expected to adopt corporate governance principles that set forth the responsibilities of the board of directors and the qualifications and independence of its members and the members of its standing committees. In addition, in connection with the separation and distribution, our board of directors is expected to adopt, among other codes and policies, a code of conduct setting forth standards applicable to all of our companies and our directors, officers and employees. The corporate governance principles and code of conduct will be available on 2seventy bio's website at . We expect that any amendment to the code, or any waivers of its requirements, will be disclosed on our website.

EXECUTIVE COMPENSATION

Executive Compensation

Overview

The following tables and discussion relate to the compensation paid to or earned by our executive officers who were serving as executive officers of bluebird bio as of December 31, 2020. Nick Leschly currently serves as chief executive officer of bluebird bio and will serve as our chief executive officer, William D. Baird currently serves as chief financial officer of bluebird bio and will serve as our chief financial officer, and Philip Gregory, D. Phil. currently serves as chief scientific officer of bluebird bio and will serve as our chief scientific officer. Mr. Leschly, Mr. Baird, and Dr. Gregory are referred to collectively in this information statement as our "named executive officers."

We are currently part of bluebird bio and not an independent company and our Compensation Committee has not yet been formed. The historical compensation shown below was determined by bluebird bio and the bluebird bio Compensation Committee. Prior to the completion of this separation, we will continue to be a part of bluebird bio, and therefore, compensation of our executives will continue to be determined based on the design and objectives of the bluebird bio executive compensation programs. Future compensation arrangements for our executive officers will be determined based on the compensation policies, programs and procedures to be established by the Compensation Committee that our board of directors will form in connection with this separation. Accordingly, the amounts and forms of compensation reported below are not necessarily indicative of the compensation that our named executive officers will receive following the separation, which could be higher or lower than the amounts shown below.

Summary Compensation Table

The following table sets forth the total compensation awarded to, earned by and paid to our named executive officers under bluebird bio's compensation and benefit plans and programs during the fiscal years ended December 31, 2020 and December 31, 2019:

Name and principal position	Year	Salary ($)	Bonus ($)	Option awards ($)	Stock Awards ($)[1]	Nonequity incentive plan compensation ($)	All other compensation ($)	Total ($)
Nick Leschly	2020	830,554 [2]	—	2,999,893	2,399,800	—	11,400 [3]	6,241,647
President, Chief Executive Officer	2019	660,000	—	8,698,341	3,365,750	418,275 [4]	11,200	13,153,566
William D. Baird, III	2020	474,600	—	923,044	738,400	121,800 [5]	122,206 [7]	2,380,050
Chief Financial Officer	2019	398,077 [7]	—	6,093,675	2,349,900	178,200 [6]	180,072	9,199,924
Philip Gregory, D. Phil.	2020	493,510 [2]	—	923,044	738,400	123,000 [5]	11,400 [3]	2,289,354
Chief Scientific Officer	2019	455,000	—	2,348,552	908,753	194,600 [4]	11,200	3,918,105

(1) The amounts reported in the "Option awards" and "Stock awards" columns above represent the aggregate grant date fair value of the bluebird bio stock options and restricted stock units granted to the named executive officers during 2019 and 2020 as computed in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718, not including any estimates of forfeitures related to service-based vesting conditions. See note 14 of "Notes to Consolidated Financial Statements" in bluebird bio's Annual Report on Form 10-K filed with the SEC on February 23, 2021 for a discussion of assumptions made by bluebird bio in determining the aggregate grant date fair value of bluebird bio stock option and restricted stock unit awards. Note that the amounts reported in these columns reflect the accounting cost for these stock options and restricted stock units, and do not correspond to the actual economic value that may be received by the named executive officers from the stock options and restricted stock units.

(2) For participating named executive officers, salary amounts reported in 2020 reflect a voluntary salary reduction and include the grant date fair value of restricted stock unit awards granted in 2020 equal to 80% of the voluntary salary reduction amount.

(3) Amounts represent the employer matching contribution to the executive's 401(k) plan contributions.

(4) Amounts represent cash payment under bluebird bio's annual cash incentive program earned in 2019, and paid during 2020, based on achievement of performance goals.

(5) Amounts represent incentive payments under bluebird bio's annual incentive program earned in 2020, and paid during 2021, based on achievement of performance goals, 50% of which was paid in cash, and 50% of which was paid in fully vested bluebird bio common stock.

(6) Mr. Baird's employment with bluebird bio commenced on February 11, 2019. His annual base salary for 2019 was $450,000. The amounts reported in the “Salary” column and the “Non-equity incentive plan compensation” column for 2019 are prorated to reflect his start date.
(7) Amount represents the employer matching contributions to Mr. Baird's 401(k) plan contribution during the year as well as $50,581 of lodging and travel expenses and a related tax gross-up of $60,074 paid pursuant to the terms of his employment agreement with bluebird bio.

Overview

bluebird bio’s Compensation Committee reviews compensation annually for executive officers and is primarily responsible for determining the compensation for the named executive officers. The bluebird bio Compensation Committee typically reviews and discusses the compensation of other executive officers with the chief executive officer. bluebird bio’s Compensation Committee has the authority to engage the services of a consulting firm or other outside advisor to assist it in designing our executive compensation programs and in making compensation decisions. For 2020, the bluebird bio Compensation Committee engaged Radford, which is part of the Rewards Solutions practice at Aon plc, as its independent compensation consultant to advise on executive and board of directors compensation matters including: overall compensation program design, peer group development and updates, and collection of market data to inform our compensation programs for our executives and members of our board of directors. bluebird bio develops its compensation programs after reviewing publicly available compensation data and it also subscribes to Radford’s various global annual and specialized life sciences and general industry surveys on an ongoing basis. Radford advised the bluebird bio Compensation Committee on all of the principal aspects of executive compensation, including executive new hire compensation arrangements. Radford consultants attend meetings of the bluebird bio Compensation Committee when requested to do so. Radford reports directly to the bluebird bio Compensation Committee and not to management, although it meets with management for purposes of gathering information for its analyses and recommendations. The bluebird bio Compensation Committee has assessed the independence of Radford consistent with SEC regulations and Nasdaq listing standards and has concluded that the engagement of Radford does not raise any conflict of interest.

Base Salaries

bluebird bio provides base salaries to its executive officers to compensate them with a fair and competitive base level of compensation for services rendered during the year. bluebird bio’s Compensation Committee typically determines the base salary for each executive based on the executive’s responsibilities, experience and, if applicable, the base salary level of the executive prior to joining bluebird bio. In addition, bluebird bio’s Compensation Committee reviews and considers the level of base salary paid by companies in bluebird bio’s peer group for similar positions.

At the beginning of 2020, bluebird bio’s Compensation Committee reviewed the compensation for each of the named executive officers and approved merit increases in base salary for each of the named executive officers. With respect to Mr. Leschly, the determination to increase his base salary was based on his critical role, bluebird bio’s performance throughout 2019 and the critical upcoming execution and risk inflection points throughout 2020 and into 2021, as well as a consideration of market conditions and a comparison of his base salary to the base salary of chief executive officers in bluebird bio’s 2020 peer group. The base salary increases for the other named executive officers were based on bluebird bio’s performance against its 2019 goals, as well as each such named executive officer’s achievement of individual goals in 2019. The table below sets forth the 2020 base salaries for each of the named executive officers:

Name	2020 Base Salary ($)
Nick Leschly	725,000
William D. Baird, III	474,600
Philip Gregory, D. Phil.	479,500

However, 2020 was an extraordinary year globally due to the COVID-19 pandemic, and bluebird bio’s operations and ability to execute on its strategy were impacted as a result. As part of bluebird bio’s comprehensive

business review in the second quarter of 2020, and with the goal of ensuring bluebird bio's ability to execute on its strategy in light of the COVID-19 pandemic, certain senior executives of bluebird bio voluntarily elected to reduce their base salaries for a 12-month period beginning May 2020. Mr. Leschly reduced his base salary by approximately 100% during this 12-month period, and each other participating senior executive reduced his or her base salary by 20%. Each participant received a grant of restricted stock units equal to 80% of the amount of his or her salary reduction, determined using $50.77, the closing market price on the Nasdaq Global Select Market of bluebird bio's common stock on May 1, 2020, rounded down to the nearest whole share. The named executive officers participating in this program, their original 2020 base salaries, their base salaries as reduced through participation in this program, and the number of restricted stock units granted are set forth in the table below.

Name	2020 Base Salary ($)	Reduction of Base Salary ($)	Reduced 2020 Base Salary (effective May 2020) ($)	Number of Restricted Stock Units (#)
Nick Leschly	$ 725,000	$ 722,513	$ 2,487	11,384
Philip Gregory, D. Phil.	$ 479,500	$ 95,900	$ 383,600	1,511

At the beginning of 2021, the bluebird bio Compensation Committee reviewed the base salaries of the named executive officers and approved a 3.5% increase in each of named executive officer's base salary in recognition of bluebird bio's performance in 2020 amid the challenging context of the COVID-19 pandemic, and the need to provide a competitive base level of salary balanced against financial discipline. The 2021 base salaries for the named executive officers are set forth in the table below.

Name	2021 Base Salary ($)
Nick Leschly	$ 750,500
William D. Baird, III	$ 491,300
Philip Gregory, D. Phil.	$ 496,300

Bonuses

At the beginning of 2020, bluebird bio's Compensation Committee approved bluebird bio's annual incentive program for 2020. At the time of such approval, consistent with past practice, the 2020 annual incentive program consisted of the opportunity for eligible participants to earn cash incentive awards calculated as a percentage of pre-established bonus targets. Under bluebird bio's annual incentive plan, the chief executive officer's incentive award is based entirely on bluebird bio's performance relative to pre-established company goals, and the incentive award for each of the other named executive officers is based 80% on bluebird bio's performance relative to the pre-established company goals, and 20% on individual performance. bluebird bio's Compensation Committee however, reserves the discretion to adjust upward or downward any cash incentive award as it deems appropriate, provided that neither company performance nor individual performance may exceed 150% and, accordingly, bonuses are capped at 150% of target amounts.

After careful consideration, bluebird bio's Compensation Committee determined not to adjust the pre-established 2020 company goals. Given the exceptional circumstances of 2020 however, and the impacts of the COVID-19 pandemic across bluebird bio's industry and bluebird bio's business, bluebird bio's Compensation Committee reviewed its 2020 annual incentive plan in the second quarter of 2020 and determined that incentive awards for the named executive officers would be paid in an equal mix of cash and fully-vested stock rather than entirely in cash.

In the fourth quarter of 2020, bluebird bio's Compensation Committee assessed company performance relative to the pre-established 2020 company goals, taking into account the impact the COVID-19 pandemic had on bluebird bio's business, operations, and industry, including: the transition to a work-from-home policy applicable to the majority of bluebird bio's people, increased restrictions on the number of people and activities in research and

development laboratories and manufacturing facilities, disruption of clinical trial enrollment and other development activities, impacts to available healthcare resources within health systems to provide services and support activities unrelated to pandemic response, decreased patient demand in the commercial context, interruptions in activities in bluebird bio's supply chain due to staffing shortages at our third-party manufacturing sites, and effects on bluebird bio's ongoing interactions with health regulatory agencies and pricing and reimbursement agencies due to shifting priorities. Ultimately, the Compensation Committee determined that overall, bluebird bio achieved an 85% performance level against the pre-established 2020 company goals, taking into consideration these external factors due to the COVID-19 pandemic and unplanned accomplishments. However, the Compensation Committee also recognized that bluebird bio as a whole missed critical goals based on a failure to execute leading to meaningful impacts on its business, and that the efforts of bluebird bio at large did not translate into demonstrable results. As a consequence and consistent with its pay for performance philosophy, the bluebird bio Compensation Committee held senior executives accountable and used its discretion to adjust downward the company performance level applicable to the chief executive officer to 0%, and the company performance level applicable to the other named executive officers to 50%. In addition, bluebird bio's Compensation Committee assessed individual performance of the named executive officers other than the chief executive officer and determined that the individual performance of each such named executive officer was achieved at 85% of target level.

The table below shows each named executive officer's target incentive award under the bluebird bio 2020 annual incentive program as a percentage of the named executive officer's annual base salary in 2020, the target incentive award opportunity in dollars for 2020 and the actual incentive awards to our named executive officers for 2020 performance, which were paid in February 2021, as well as the actual 2020 incentive award payment as a percentage of the 2020 target incentive award opportunity.

Name	2020 Target Incentive Award (% of 2020 Base Salary)	2020 Target Incentive Award Opportunity ($)	Actual Total 2020 Incentive Award Amount ($) [1]	Cash Portion of 2020 Incentive Award Amount ($)	Equity Portion of 2020 Incentive Award Amount (# of shares) [2]	2020 Actual Incentive Award Amount (% of 2020 Target Incentive Award Opportunity)
Nick Leschly	65 %	471,250	—	—	—	— %
William D. Baird, III	45 %	213,570	121,800	60,900	2,141	57 %
Philip Gregory, D. Phil.	45 %	215,775	123,000	61,500	2,162	57 %

(1) Represents the total 2020 incentive award amount, which was paid 50% in cash, and 50% in the form of a grant of fully-vested bluebird bio stock.
(2) Represents the number of shares of bluebird bio stock granted, determined by dividing 50% of the total 2020 incentive award amount by $28.44, the closing price of bluebird bio's common stock on the date of the grant.

In the first quarter of 2021, the bluebird bio Compensation Committee approved the bluebird bio annual incentive program for 2021. The terms of the 2021 annual incentive program are substantially the same as the 2020 annual incentive program. In light of the separation, bluebird bio's Compensation Committee determined that 2021 performance for bluebird bio and 2seventy bio will be pro-rated for each business, to be defined by timing for completion of the separation. The annual incentive award target for each named executive officer for 2021 is set forth below.

Name	2021 Base Salary ($)	2021 Target Award (% of Base Salary)	2021 Target Award ($)
Nick Leschly	750,500	65 %	487,825
William D. Baird, III	491,300	45 %	221,085
Philip Gregory, D. Phil.	496,300	45 %	223,335

Equity-Based Compensation

bluebird bio's long-term incentive equity awards have generally been in the form of stock options and restricted stock units. The size of equity awards has varied among executive officers based on their positions and annual performance assessments. All stock options granted by bluebird bio have exercise prices equal to the fair market value of bluebird bio's common stock on the date of grant, so that the recipient will not realize any value from the option unless bluebird bio's share price increases above the stock price on the date of grant. Typically, annual stock options granted executive officers have a ten-year term and vest as to 25% of the shares on the first anniversary of the grant date and then the remaining shares vest in equal monthly installments thereafter until the fourth anniversary of such date. Annual restricted stock units granted to our executives generally vest in equal annual installments beginning on or about the first anniversary of the first business day of the year of grant, until the fourth anniversary of such date.

As part of the ongoing review of bluebird bio's compensation strategy and practices, bluebird bio's Compensation Committee determines the appropriate mix of the type of equity awards, based in part on recommendations from Radford, its independent compensation consultant. Because of the volatility of bluebird bio's stock price in relation to when equity grants are made, bluebird bio's equity compensation guidelines set forth aggregate grant targets reflecting stock options plus restricted stock units based on number of shares (rather than value of the equity grants), and these guidelines are developed based on and in reference to our equity grant data for our peer companies. In 2020, the target mix for long-term incentive equity grants to the named executive officers was generally split approximately one-half in stock options and one-half in restricted stock units based on value. The bluebird bio Compensation Committee believes that this deliberate mix of equity ensures that wealth creation remains tied to stock performance and promotes retention.

In connection with bluebird bio's annual review of named executive officers' performance during 2019 and consistent with bluebird bio's compensation philosophy, in January 2020, bluebird bio's Compensation Committee approved the annual long-term equity incentive awards to the named executive officers as set forth in the table below:

	2020 Option Award		2020 RSU Award	
Name	**Shares (#)**	**Grant date fair value ($)**	**Shares (#)**	**Grant date fair value ($)**
Nick Leschly	65,000	2,999,893	32,500	2,399,800
William D. Baird, III	20,000	923,044	10,000	738,400
Philip Gregory, D.Phil.	20,000	923,044	10,000	738,400

The equity awards granted to the named executive officers during 2020, and the grant date fair values of those awards determined in accordance with FASB ASC Topic 718, are shown in the Summary Compensation Table above.

In connection with the annual review of the named executive officers' performance during 2020 and consistent with bluebird bio's compensation philosophy, in January 2021, bluebird bio's Compensation Committee approved the annual long-term equity incentive awards to the named executive officers as set forth in the table below:

	2021 Option Award		2021 RSU Award Time-Based Vesting		2021 RSU Award Performance-Based Vesting (based on relative total stockholder return)	
Name	**Shares (#)**	**Grant date fair value ($)**	**Shares (#)**	**Grant date fair value ($)**	**Target Shares (#)**	**Grant date fair value ($)**
Nick Leschly	90,000	1,494,095	18,000	511,920	27,000	1,708,560
William D. Baird, III	25,000	415,026	12,500	355,500	—	—
Philip Gregory, D.Phil.	25,000	415,026	12,500	355,500	—	—

In 2021, bluebird bio introduced a new type of performance-based restricted stock unit award to further align the chief executive officer's compensation with stockholder experience, and in response to investor feedback. This performance-based award is earned based on total stockholder return over the three-year period of 2021 through 2023 compared to a peer group of companies in the Standard & Poor Biotechnology Select Industry Index having a market value of between $750 million and $4.5 billion, which reflects a weighted average of bluebird bio and the projected size of 2seventy bio following the separation. The multiplier used to determine the number of earned restricted stock units could range between 50% and 200%, with a threshold achievement level at -25th percentile (as compared to the peer median) required to earn any restricted stock units, and a ceiling achievement level at the +50th percentile (as compared to the peer median). The total stockholder return performance-based restricted stock units, to the extent earned, vest in full on the third anniversary of the grant date, subject to Mr. Leschly's continued service. For 2021, this award made up approximately 20% of the chief executive officer's total target equity compensation.

Employee Benefits

Other compensation to the named executive officers at bluebird bio consists primarily of the broad-based benefits bluebird bio provides to all full-time employees in the United States, including medical, dental and vision insurance, group life and disability insurance, an employee stock purchase plan and a 401(k) plan. Pursuant to bluebird bio's employee stock purchase plan, bluebird bio employees, including the named executive officers, have an opportunity to purchase bluebird bio common stock at a discount on a tax-qualified basis through payroll deductions. The employee stock purchase plan is designed to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code of 1986, as amended. The purpose of the employee stock purchase plan is to encourage employees, including the named executive officers, to become bluebird bio stockholders and better align their interests with those of our other stockholders. Pursuant to bluebird bio's 401(k) plan, bluebird bio employees, including the named executive officers, may elect to defer a portion of their current compensation up to the statutorily prescribed annual limit (which was $19,500 in 2020), with additional salary deferrals not to exceed $26,000 available to those employees 50 years of age or older, and to have the amount of this deferral contributed to bluebird bio's 401(k) plan. bluebird bio makes discretionary matching contributions and other employer contributions on behalf of eligible employees under its 401(k) plan. For fiscal year 2020, bluebird bio matched a portion of eligible employee contributions equal to 100% of the first 4% of eligible contributions pursuant to the 401(k) plan's matching formula.

Currently, bluebird bio does not view perquisites or other personal benefits as a significant component of its executive compensation program. Accordingly, bluebird bio does not provide perquisites to the named executive officers, except in situations where bluebird bio believes it is appropriate to assist an individual in the performance of his or her duties, to make him or her more efficient and effective, and for recruitment and retention purposes.

Agreements with our Named Executive Officers

In connection with the separation, we intend to enter into new employment agreements with our named executive officers to be effective upon the completion of the separation. Below are descriptions of the employment agreements between our named executive officers and bluebird bio.

Nick Leschly. bluebird bio has entered into an amended and restated employment agreement, effective as of the closing of bluebird bio's initial public offering on June 24, 2013, with Mr. Leschly for the position of president and chief executive officer. Mr. Leschly currently receives an annual base salary from bluebird bio of $750,500, which is subject to adjustment at the discretion of the bluebird bio Compensation Committee. Mr. Leschly is also eligible for an annual cash incentive award targeted at 65% of his annual base salary. Mr. Leschly is currently eligible to participate in bluebird bio's employee benefit plans, subject to the terms of those plans.

William D. Baird, III. bluebird bio has entered into an employment agreement, effective as of December 18, 2018, with Mr. Baird for the position of chief financial officer. Mr. Baird currently receives an annual base salary of $491,300, which is subject to adjustment at the discretion of the bluebird bio Compensation Committee. Mr. Baird is also eligible for an annual cash incentive award targeted at 45% of his annual base salary, payable at the discretion

of the bluebird bio Compensation Committee. Mr. Baird is currently eligible to participate in bluebird bio's employee benefit plans, subject to the terms of those plans. In addition, pursuant to the terms of the employment agreement, prior to Mr. Baird's permanent relocation to the Cambridge, Massachusetts area for up to a period of three years, bluebird bio has agreed to reimburse Mr. Baird for the cost of temporary living arrangements reasonably acceptable to bluebird bio, grossed up for Mr. Baird's anticipated income tax liability.

Philip Gregory, D. Phil. bluebird bio has entered into an employment agreement with Dr. Gregory, effective as of May 30, 2015, and amended on November 3, 2016. Dr. Gregory currently serves as bluebird bio's chief scientific officer and receives an annual base salary of $496,800, which is subject to adjustment at the discretion of the bluebird bio Compensation Committee. Dr. Gregory is also eligible for an annual cash incentive award targeted at 45% of his annual base salary, payable at the discretion of the Compensation Committee. Dr. Gregory is currently eligible to participate in bluebird bio's employee benefit plans, subject to the terms of those plans.

These employment agreements also contain provisions that provide for certain payments and benefits in the event of an involuntary termination of employment. In addition, the named executive officers may be entitled to accelerated vesting of their outstanding and unvested awards in certain circumstances. The information below describes certain compensation that may become due as a result of certain events. Outstanding bluebird bio equity awards held by the named executive officers as of December 31, 2020 are set forth under "Outstanding Equity Awards at Fiscal Year-End" below.

Involuntary Termination of Employment

Pursuant to their employment agreements, each named executive officer is eligible to receive certain payments and benefits in the event his employment is terminated by bluebird bio without "cause" (as defined in the employment agreements) or in the event he terminates his employment with "good reason" (as defined in the employment agreements). Upon the timely execution of a severance agreement, including a general release of claims, each named executive officer is eligible to receive the following payments and benefits:

- 12 months of base salary continuation; and
- if he elects to continue his group healthcare benefits, to the extent authorized by and consistent with COBRA, bluebird bio will pay the named executive officer a monthly cash payment equal to the monthly employer contribution bluebird bio would have made to provide him health insurance if he had remained employed by bluebird bio until the earlier of (1) 12 months following the date of termination, or (2) the end of the named executive officer's COBRA health continuation period.

Sale Event

In addition, in the event that any of the named executive officers terminates his employment with bluebird bio for good reason or his employment with bluebird bio is terminated by bluebird bio without cause, in either case within 12 months following a "sale event" (as defined in the bluebird bio 2013 Stock Option and Incentive Plan, or the 2013 Plan), he will be entitled to receive the following payments and benefits (in lieu of the payments and benefits described above) upon the timely execution of a severance agreement, including a general release of claims:

- a lump sum cash payment equal to one times (or one and a half times in the case of Mr. Leschly) the sum of (1) the named executive officer's then-current base salary (or base salary in effect immediately prior to the sale event, if higher) and (2) the named executive officer's target annual cash incentive compensation; and
- if he elects to continue his group healthcare benefits, to the extent authorized by and consistent with COBRA, bluebird bio will pay the named executive officer a monthly cash payment equal to the monthly employer contribution bluebird bio would have made to provide him health insurance if he had remained employed by bluebird bio until the earlier of (1) 12 months (or 18 months in the case of Mr. Leschly) following the date of termination or (2) the end of the named executive officer's COBRA health continuation period; and

- all stock options and other stock-based awards granted to the named executive officer after the date of his employment agreement will become fully exercisable and non-forfeitable as of the date of the named executive officer's termination.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information regarding bluebird bio equity awards held by our named executive officers as of December 31, 2020.

	Option Awards [1]				Stock Awards [1]	
Name	Number of Securities Underlying Unexercised Options ((#) Exercisable)	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)/share	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Nick Leschly	15,999	—	5.50	1/16/2023	—	
	33,649	—	5.50	1/16/2023	—	
	73,006	—	5.50	1/16/2023	—	
	70,504	—	5.50	1/16/2023	—	
	10,197	—	5.50	1/16/2023	—	
	165,000	—	24.47	3/3/2024	—	
	165,000	—	97.40	3/2/2025	—	
	90,000	—	50.51	3/1/2026	—	
	107,685	2,315 [2]	75.60	2/1/2027	—	
	87,500	32,500 [3]	205.25	2/1/2028	—	
	47,913	52,087 [4]	134.63	2/1/2029	—	
	—	65,000 [5]	73.84	3/2/2030	—	
	—	—	—	—	6,875 [6]	297,481
	—	—	—	—	15,000 [7]	649,050
	—	—	—	—	19 [8]	811
	—	—	—	—	32,500 [9]	1,406,275
	—	—	—	—	4,743 [12]	205,230
William D. Baird, III	27,500	32,500 [10]	156.66	3/1/2029	—	—
	—	20,000 [5]	73.84	3/2/2030	—	—
	—	—	—	—	11,250 [11]	486,788
	—	—	—	—	10,000 [9]	432,700
Philip Gregory	50,000	—	163.07	7/1/2025	—	—
	6,200	—	50.51	3/1/2026	—	—
	24,275	725 [2]	75.60	2/1/2027	—	—
	24,784	9,216 [3]	205.25	2/1/2028	—	—
	12,932	14,068 [4]	134.63	2/1/2029	—	—
	—	20,000 [5]	73.84	3/2/2030	—	—
	—	—	—	—	2,125 [6]	91,949
	—	—	—	—	4,250 [7]	183,898
	—	—	—	—	5,063 [8]	219,076
	—	—	—	—	10,000 [9]	432,700
	—	—	—	—	630 [12]	27,260

(1) All unvested stock options and restricted stock unit awards were granted under bluebird bio's 2013 Plan. The market value of the restricted stock unit award is based on the closing price of $43.27 per share for bluebird bio's common stock on December 31, 2020, as reported on the Nasdaq Global Select Market.

(2) Represents options to purchase shares of bluebird bio's common stock granted on February 1, 2017. The shares underlying these options vest as follows: 25% vested on January 4, 2018, with the remainder of the shares vesting in equal monthly installments over the following three years through January 4, 2021, subject to continued service through each applicable vesting date.
(3) Represents options to purchase shares of bluebird bio's common stock granted on February 1, 2018. The shares underlying these options vest as follows: 25% vested on January 4, 2019, with the remainder of the shares vesting in equal monthly installments over the following three years through January 4, 2022, subject to continued service through each applicable vesting date.
(4) Represents options to purchase shares of bluebird bio's common stock granted on February 1, 2019. The shares underlying these options vest as follows: 25% vested on January 4, 2020, with the remainder of the shares vesting in equal monthly installments over the following three years through January 4, 2023, subject to continued service through each applicable vesting date.
(5) Represents options to purchase shares of bluebird bio's common stock granted on March 2, 2020. The shares underlying these options vest as follows: 25% vested on January 4, 2021, with the remainder of the shares vesting in equal monthly installments over the following three years through January 4, 2024, subject to continued service through each applicable vesting date.
(6) Restricted stock unit award vests in four equal annual installments through January 4, 2021.
(7) Restricted stock unit award vests in four equal annual installments through January 4, 2022, subject to continued service through each applicable vesting date.
(8) Restricted stock unit award vests in four equal annual installments through January 4, 2023, subject to continued service through each applicable vesting date.
(9) Restricted stock unit award vests in four equal annual installments through January 4, 2024, subject to continued service through each applicable vesting date.
(10) Represents an option to purchase shares of bluebird bio's common stock granted on March 1, 2019. The shares underlying this options vest as follows: 25% vested on February 11, 2020, with the remainder of the shares vesting in equal monthly installments over the following three years through February 11, 2023, subject to continued service through each applicable vesting date.
(11) Restricted stock unit award vests in four equal annual installments through February 11, 2023, subject to continued service through each applicable vesting date.
(12) Restricted stock unit award vests in 12 equal monthly installments through May 1, 2021.

Director Compensation

We have not yet identified the members of our board of directors. Once identified, we will disclose the compensation earned by our directors during fiscal year 2020 for their service on the board of directors of bluebird bio, if any.

Limitations on Liability and Indemnification Matters

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation, which will become effective upon the separation, and amended and restated bylaws, which will become effective upon the separation, limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director's liability under other laws, such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation will also authorize us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws will provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws will also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we plan to enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which will be filed as an exhibit to the registration statement of which this information statement is a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Relationship with bluebird bio

Prior to the completion of this separation, all of our outstanding shares of common stock are owned by bluebird bio. Following the completion of this separation, bluebird bio will no longer own any shares of our common stock. See “Risk Factors—Risks Related to the Separation” and “The Separation and Distribution”.

Following the distribution, 2seventy bio and bluebird bio will operate separately, each as an independent public company. In connection with this separation, we and bluebird bio have entered or will enter into certain agreements that will effect the separation of our business from bluebird bio and govern our relationship with bluebird bio after this separation. The following is a summary of the terms of the material agreements that we intend to enter into with bluebird bio prior to the completion of this separation, which will be filed as exhibits to the registration statement of which this information statement is a part. These summaries set forth the terms of the agreements that we believe are material and are qualified in their entirety by reference to the full text of such agreements.

The forms of material agreements described below will be filed as exhibits in a subsequent amendment to the registration statement on Form 10 of which this information statement is a part. The terms of the agreements described below that will be in effect following the distribution have not yet been finalized. Changes to these agreements, some of which may be material, may be made prior to the distribution.

Agreements with bluebird bio

Separation Agreement

We intend to enter into a separation agreement with bluebird bio prior to the distribution of our common stock to bluebird bio stockholders. The separation agreement will set forth our agreements with bluebird bio regarding the principal actions to be taken in connection with the separation, including the distribution. The separation agreement will identify assets to be transferred, liabilities to be assumed and contracts to be assigned to each of 2seventy bio and bluebird bio as part of the separation, and it will provide for when and how these transfers, assumptions and assignments will occur.

Transfer of Assets and Assumption of Liabilities. The separation agreement will identify assets to be transferred, liabilities to be assumed and contracts to be assigned to each of bluebird bio and us as part of an internal reorganization, and will describe when and how these transfers, assumptions and assignments will occur, though many of the transfers, assumptions and assignments will have already occurred prior to the parties' entering into the separation agreement. The separation agreement will provide for those transfers of assets and assumptions of liabilities that are necessary in connection with the separation so that we and bluebird bio retain the assets necessary to operate our respective businesses and retain or assume the liabilities allocated in accordance with the separation. The separation agreement will also provide for the settlement or extinguishment of certain liabilities and other obligations between us and bluebird bio.

Except as otherwise set forth in the separation agreement or any ancillary agreement, each party to the separation agreement will assume the liability for, and control of, all pending, threatened and future legal matters related to its own business or its assumed or retained liabilities. The allocation of liabilities with respect to taxes, except for payroll taxes and reporting and other tax matters expressly covered by the employee matters agreement, are solely covered by the tax matters agreement.

The Distribution. The separation agreement will govern the rights and obligations of the parties with respect to the distribution and certain actions that must occur prior to the distribution. bluebird bio will cause its agent to distribute to holders of shares of bluebird bio’s common stock as of the record date for the distribution all of the issued and outstanding shares of our common stock. bluebird bio will have the sole and absolute discretion to determine (and change) the terms of, and whether to proceed with, the distribution and, to the extent it determines to so proceed, to determine the date of the distribution.

Conditions. The separation agreement will provide that the distribution is subject to several conditions that must be satisfied (or waived by bluebird bio, in its sole discretion). bluebird bio may, in its sole discretion, determine the record date, the distribution date and the terms of the distribution and may at any time prior to the completion of the distribution decide to abandon or modify the distribution. For further information regarding these conditions, see "The Separation and Distribution—Conditions to the Distribution."

Indemnification. The separation agreement will provide for cross-indemnities that, except as otherwise provided in the separation agreement, are principally designed to place financial responsibility for the obligations and liabilities allocated to us under the separation agreement with us and financial responsibility for the obligations and liabilities allocated to bluebird bio under the separation agreement with bluebird bio. The separation agreement will also specify procedures with respect to claims subject to indemnification and related matters. Indemnification with respect to taxes will be governed by the tax matters agreement described below.

Term/Termination. Prior to the distribution, bluebird bio will have the unilateral right to terminate or modify the terms of the separation agreement. After the effective time of the distribution, the term of the separation agreement is indefinite and it may only be terminated with the prior written consent of both bluebird bio and 2seventy bio.

Transitional Services Agreements

bluebird bio Transitional Services. Historically, bluebird bio has provided us significant corporate and shared services and resources related to corporate functions such as finance, human resources, internal audit, research and development, financial reporting, and information technology, which we refer to collectively as the " bluebird bio Services." This transitional services agreement will become operative as of the completion of this separation and each of the bluebird bio Services will continue for an initial term of between to years (as applicable), unless earlier terminated or extended according to the terms of the transitional services agreement. We will pay bluebird bio fees for the bluebird bio Services, to be mutually agreed upon by us and bluebird bio as provided under this transitional services agreement, which fees will be based on bluebird bio's cost of providing the bluebird bio Services.

2seventy bio Transitional Services. We also intend to enter into a second transitional services agreement whereby we will provide certain services to bluebird bio, which we refer to herein collectively as the "2seventy bio Services." This second transitional services agreement will be effective as of the completion of this separation and each of the 2seventy bio Services will continue for an initial term of between to years (as applicable), unless earlier terminated or extended according to the terms of such transitional services agreement. bluebird bio will pay us fees for the 2seventy bio Services, to be mutually agreed upon by us and bluebird bio as provided under this transitional services agreement, which fees will be based on our cost of providing the 2seventy bio Services.

Intellectual Property License Agreement

We intend to enter into an intellectual property license agreement with bluebird bio prior to the distribution pursuant to which each party will grant a license to certain intellectual property and technology. bluebird bio will grant 2seventy bio a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to certain intellectual property to allow 2seventy bio to use such intellectual property in connection with 2seventy bio's ongoing and future research and development activities and product candidates. 2seventy bio will grant bluebird bio a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to certain intellectual property for use in bluebird bio's existing products and product candidates. Such licenses between the parties generally will allow current or future uses of the intellectual property in connection with each party's respective fields.

Tax Matters Agreement

We intend to enter into a tax matters agreement with bluebird bio prior to or concurrently with the completion of the separation that will govern bluebird bio's and 2seventy bio's respective rights, responsibilities and obligations with respect to taxes (including taxes arising in the ordinary course of business and taxes, if any, incurred as a result of any failure of the distribution and certain related transactions to qualify as tax-free for U.S. federal income tax

purposes), tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings, and assistance and cooperation in respect of tax matters.

In addition, the tax matters agreement will impose certain restrictions on us and our subsidiaries (including restrictions on share issuances, business combinations, sales of assets and similar transactions) that will be designed to preserve the tax-free status of the distribution and certain related transactions. The tax matters agreement will provide special rules that allocate tax liabilities in the event the distribution, together with certain related transactions, is not tax-free. 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.

Employee Matters Agreement

We intend to enter into an employee matters agreement with bluebird bio prior to or concurrently with the completion of this separation. The employee matters agreement will govern bluebird bio's, our and the parties' respective subsidiaries' and affiliates' rights, responsibilities and obligations after this separation with respect to the following matters:

- employment, benefits and compensation matters relating to employees and former employees (and their respective dependents and beneficiaries) who are or were associated with bluebird bio, including those who will become employees of 2seventy bio following the separation;
- the allocation of assets and liabilities generally relating to employees, employment or service-related matters and employee benefit plans; and
- other human resources, employment and employee benefits matters.

Related Party Transactions Policy

In connection with this separation, we plan to adopt a related party transactions policy that will govern the review and approval of related party transactions following this separation. Pursuant to this policy, if we want to enter into a transaction with a related party or an affiliate of a related party, our audit committee will review the proposed transaction to determine, based on applicable rules of Nasdaq and the SEC, whether such transaction requires pre-approval by our audit committee or our board of directors. If pre-approval is required, the proposed transaction will be reviewed at the next regular or special meeting of our audit committee or our board of directors, as applicable. We may not enter into a related party transaction unless our audit committee has specifically confirmed in writing that either no further reviews are necessary or that all requisite corporate reviews have been obtained.

Each of the agreements between us and bluebird bio and its subsidiaries that have been entered into prior to the completion of this separation, and any transactions contemplated thereby, will be deemed to be approved and not subject to the terms of such policy.

SECURITY OWNERSHIP BY CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Prior to the distribution, all of the outstanding shares of our common stock will be owned beneficially and of record by bluebird bio. The following tables set forth information with respect to the expected beneficial ownership of our common stock immediately following the distribution: (i) each person who we believe will be a beneficial owner of more than five percent of our common stock, (ii) each of our expected directors and named executive officers and (iii) all of our expected directors and executive officers as a group. Except as noted below, we based the share amounts on each person's beneficial ownership of bluebird bio common stock as of , 2021, after giving effect to a distribution ratio of one share of 2seventy bio common stock for every shares of bluebird bio common stock. Immediately following the distribution, we estimate that shares of our common stock will be issued and outstanding based on the number of shares of bluebird bio common stock outstanding as of , 2021. The actual number of our outstanding shares of our common stock issued in the distribution will be determined on , 2021, the record date. Unless otherwise indicated, the address of each beneficial owner is in care of bluebird bio, Inc., 60 Binney Street, Cambridge, MA 02142.

Security Ownership of Certain Beneficial Owners

Based solely on the information publicly available reporting beneficial ownership of bluebird bio common stock, we anticipate the following stockholders will beneficially own more than five percent of our common stock following the distribution.

Name of Beneficial Owner	Number of Shares of Our Common Stock	Percent of Shares Outstanding

Security Ownership of Directors and Executive Officers

The following table provides information regarding beneficial ownership of our named executive officers, our expected directors and all of our expected directors and executive officers as a group as of , 2021.

Name of Beneficial Owner	Number of Shares of Our Common Stock[1]	Percent of Shares Outstanding
Nick Leschly		
William D. Baird, III		
Philip Gregory, D. Phil.		
Directors and Officers as a Group (persons)		

* Less than one percent

(1) Does not include shares of 2seventy bio common stock that may be issued upon exercise or settlement of 2seventy bio equity awards that will be converted from bluebird bio equity awards in connection with the distribution, as the conversion ratio is not currently calculable and such shares will not affect the beneficial ownership of our directors and named executive officers at the time of the distribution unless the equity awards are exercised or settled prior to the record date of the distribution.

THE SEPARATION AND DISTRIBUTION

Overview

In January 2021, bluebird bio announced its plans to separate its oncology portfolio and programs from its severe genetic disease portfolio and programs through a pro rata distribution of 2seventy bio common stock to stockholders of bluebird bio. The distribution is intended to be generally tax-free for U.S. federal income tax purposes.

In furtherance of this plan, on , 2021, bluebird bio's board of directors approved the distribution of all of the issued and outstanding shares of 2seventy bio common stock on the basis of shares of 2seventy bio common stock for every shares of bluebird bio common stock issued and outstanding as of the close of business on , 2021, the record date for the distribution. As a result of the distribution, 2seventy bio and bluebird bio will become two independent, publicly traded companies.

On , 2021, the distribution date, each bluebird bio stockholder will receive shares of 2seventy bio common stock for every shares of bluebird bio common stock held of record at the close of business on the record date, as described below. Registered stockholders will receive cash in lieu of any fractional shares of 2seventy bio common stock that they would have received as a result of the application of the distribution ratio. Stockholders will not be required to make any payment, surrender or exchange their bluebird bio common stock or take any other action to receive shares of 2seventy bio common stock in the distribution.

The distribution of 2seventy bio common stock as described in this information statement is subject to the satisfaction or waiver of certain conditions. For a more detailed description of these conditions, see this section under "—Conditions to the Distribution."

Reasons for the Separation

bluebird bio's board of directors determined that separating its oncology portfolio and programs from its severe genetic disease business would be in the best interests of bluebird bio and its stockholders and approved the plan of separation. A wide variety of factors were considered by bluebird bio's board of directors in evaluating the separation. Among other things, bluebird bio's board of directors considered the following potential benefits of the separation:

- the separation will allow each business to pursue its own operational and strategic priorities and more quickly respond to trends, developments and opportunities in its respective markets;
- the separation will create two separate and distinct management teams focused on each business's unique strategic priorities, target markets and corporate development opportunities;
- the separation will give each business opportunity and flexibility by pursuing its own investment, capital allocation and growth strategies consistent with its long-term objectives;
- the separation will enable the boards and management teams of each business to better align corporate performance goals with the specific vision, strategy, and objectives of each business; and
- the separation will allow investors to separately value each business based on the unique merits, performance and future prospects of each business, providing investors with two distinct investment opportunities.

bluebird bio's board of directors also considered a number of potentially negative factors in evaluating the separation, including the following factors impacting 2seventy bio:

- bluebird bio and 2seventy bio may not achieve the anticipated benefits of the separation for a variety of reasons, including: (i) the separation will require significant amounts of management's time and effort, which may divert management's attention from operating and growing the bluebird bio and 2seventy bio businesses and (ii) following the separation, each business will be less diversified than bluebird bio's business prior to the separation;

- costs and liabilities that were less significant to bluebird bio as a whole will be more significant for 2seventy bio as a stand-alone company, and after the distribution, as a separate, independent entity, 2seventy bio may be unable to obtain goods, services, and technologies at prices or on terms as favorable as those bluebird bio obtained prior to the distribution;

- 2seventy bio will incur costs in connection with the transition to being a stand-alone public company that will include establishment of accounting, tax, auditing, legal and other professional services costs, recruiting and relocation costs associated with hiring personnel new to 2seventy bio and costs to separate information systems;

- under the terms of the tax matters agreement that 2seventy bio intends to enter into with bluebird bio, for a period of years following the distribution, 2seventy bio will be restricted from taking certain actions that could cause the distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes, which may limit 2seventy bio's ability to pursue certain strategic transactions and equity issuances or engage in other transactions that might increase the value of its business; and

- the trading prices of 2seventy bio and bluebird bio common stock following the separation, and whether the combined market value of shares of 2seventy bio common stock and shares of bluebird bio common stock will be less than, equal to, or greater than the market value of shares of bluebird bio common stock prior to the separation, cannot be predicted with certainty.

bluebird bio's board of directors concluded that the potential benefits of the separation outweighed these factors. However, neither bluebird bio nor 2seventy bio can assure you that, following the separation, any of the benefits described above or otherwise will be realized to the extent anticipated or at all. For more information on the risks involved in the separation process, see "Risk Factors—Risks Related to the Separation."

Formation of a Holding Company Prior to the Distribution

In connection with and prior to the distribution, 2seventy bio was incorporated by bluebird bio in the State of Delaware on April 26, 2021, for the purpose of holding bluebird bio's oncology portfolio and programs in connection with the separation described herein. As part of the plan to create two independent public companies, bluebird bio plans to transfer the assets and liabilities of the oncology portfolio and programs to 2seventy bio and its subsidiaries prior to the distribution through an internal reorganization.

When and How You Will Receive the Distribution

With the assistance of the distribution agent, bluebird bio expects to distribute 2seventy bio common stock on , 2021, the distribution date, to all holders of outstanding bluebird bio common stock as of the close of business on , 2021, the record date. will serve as the distribution agent in connection with the distribution.

If you own bluebird bio common stock as of the close of business on the record date, 2seventy bio common stock that you are entitled to receive in the distribution will be issued electronically, as of the distribution date, to you in direct registration form or to your bank or brokerage firm on your behalf. If you are a registered holder, the

distribution agent or the transfer agent will then mail you a direct registration account statement that reflects your shares of 2seventy bio common stock. “Direct registration form” refers to a method of recording share ownership when no physical share certificates are issued to stockholders, as is the case in this distribution.

Commencing on or shortly after the distribution date, if you hold physical share certificates that represent your bluebird bio common stock and you are the registered holder of the shares represented by those certificates, the distribution agent will mail to you an account statement that indicates the number of shares of 2seventy bio common stock that have been registered in book-entry form in your name, and the distribution agent will mail you a check for any cash in lieu of fractional shares you are entitled to receive. If you sell bluebird bio common stock in the “regular way” market up to and including the distribution date, you will be selling your right to receive shares of 2seventy bio common stock in the distribution.

Most bluebird bio stockholders hold their common stock through a bank or brokerage firm. In such cases, the bank or brokerage firm would be said to hold the shares in “street name” and ownership would be recorded on the bank or brokerage firm's books. If you hold your bluebird bio common stock through a bank or brokerage firm, your bank or brokerage firm will credit your account for the 2seventy bio common stock that you are entitled to receive in the distribution. If you have any questions concerning the mechanics of having shares held in “street name,” please contact your bank or brokerage firm.

Results of the Distribution

After its separation from bluebird bio, 2seventy bio will be an independent, publicly traded company. The actual number of shares to be distributed will be determined on , 2021, the record date for the distribution, and will reflect any exercise of bluebird bio options between the date the bluebird bio board of directors declares the distribution and the record date for the distribution. The distribution will not affect the number of outstanding shares of bluebird bio common stock or any rights of bluebird bio’s stockholders. bluebird bio will not distribute any fractional shares of 2seventy bio common stock.

Prior to the distribution, 2seventy bio intends to enter into a separation agreement and other agreements with bluebird bio to effect the separation and govern 2seventy bio's relationship with bluebird bio after the separation. These agreements will provide for the allocation between bluebird bio and 2seventy bio of bluebird bio’s assets, liabilities and obligations (including employee benefits, intellectual property, and tax-related assets and liabilities) attributable to periods prior to and after 2seventy bio's separation from bluebird bio and will govern certain relationships between bluebird bio and 2seventy bio after the separation. For a more detailed description of these agreements, see “Certain Relationships and Related Person Transactions—Agreements with bluebird bio.”

The Number of Shares of 2seventy bio Common Stock You Will Receive

For every shares of bluebird bio common stock that you own at the close of business on , 2021, the record date, you will receive shares of 2seventy bio common stock on the distribution date. bluebird bio will not distribute any fractional shares of 2seventy bio common stock to its stockholders. Instead, the distribution agent will aggregate fractional shares into whole shares, sell the whole shares in the open market at prevailing market prices and distribute the aggregate cash proceeds (net of discounts and commissions) of the sales pro rata (based on the fractional share such holder would otherwise have been entitled to receive) to each holder who otherwise would have been entitled to receive a fractional share in the distribution. The distribution agent, in its sole discretion, without any influence by bluebird bio or 2seventy bio, will determine when, how, through which broker-dealer and at what price to sell the whole shares. is not an affiliate of either bluebird bio or 2seventy bio. Any broker-dealer used by the transfer agent will not be an affiliate of either bluebird bio or 2seventy bio. Neither 2seventy bio nor bluebird bio will be able to guarantee any minimum sale price in connection with the sale of these shares. Recipients of cash in lieu of fractional shares will not be entitled to any interest on the amounts of payment made in lieu of fractional shares.

The aggregate net cash proceeds distributed to bluebird bio stockholders in lieu of fractional shares will be taxable for U.S. federal income tax purposes. See “Material U.S. Federal Income Tax Consequences” for an

explanation of the material U.S. federal income tax consequences of the distribution. If you hold physical certificates for bluebird bio common stock and are the record holder, you will receive a check from the distribution agent in an amount equal to your pro rata share of the aggregate net cash proceeds of the sales. 2seventy bio estimates that it will take approximately from the distribution date for the distribution agent to complete the distributions of the aggregate net cash proceeds. If you hold your bluebird bio common stock through a bank or brokerage firm, your bank or brokerage firm will receive, on your behalf, your pro rata share of the aggregate net cash proceeds of the sales and will distribute to your account your share of such proceeds.

Transferability of Shares You Receive

Shares of 2seventy bio common stock distributed to holders through the distribution will be transferable without registration under the Securities Act, except for shares received by persons who may be deemed to be 2seventy bio affiliates. Persons who may be deemed to be 2seventy bio's affiliates after the distribution generally include individuals or entities that control, are controlled by or are under common control with 2seventy bio, which may include certain of 2seventy bio executive officers, directors or principal stockholders. Securities held by 2seventy bio affiliates will be subject to resale restrictions under the Securities Act. 2seventy bio affiliates will be permitted to sell shares of 2seventy bio common stock only pursuant to an effective registration statement or an exemption from the registration requirements of the Securities Act, such as the exemption afforded by Rule 144 promulgated under the Securities Act.

Market for 2seventy bio Common Stock

There is currently no public trading market for 2seventy bio common stock. 2seventy bio intends to apply to have its common stock authorized for listing on the Nasdaq Global Market under the symbol “TSVT”. 2seventy bio has not and will not set the initial price of its common stock. The initial price will be established by the public markets.

2seventy bio cannot predict the price at which its common stock will trade after the distribution. In fact, the combined trading prices, after the distribution, of the shares of 2seventy bio common stock that each bluebird bio stockholder will receive in the distribution and bluebird bio common stock held at the record date may not equal the “regular way” trading price of a share of bluebird bio common stock immediately prior to the distribution. The price at which 2seventy bio common stock trades may fluctuate significantly, particularly until an orderly public market develops. Trading prices for 2seventy bio common stock will be determined in the public markets and may be influenced by many factors. See “Risk Factors—Risks Related to Ownership of Our Common Stock.”

Trading Between the Record Date and Distribution Date

Beginning on or shortly before the record date and continuing up to and including through the distribution date, we expect that there will be two markets in bluebird bio common stock: a “regular way” market and an “ex-distribution” market. Shares of bluebird bio common stock that trade on the “regular way” market will trade with an entitlement to 2seventy bio common stock distributed pursuant to the separation. Shares of bluebird bio common stock that trade on the “ex-distribution” market will trade without an entitlement to 2seventy bio common stock distributed pursuant to the distribution. Therefore, if you sell bluebird bio common stock in the “regular way” market up to and including through the distribution date, you will be selling your right to receive 2seventy bio common stock in the distribution. If you own bluebird bio common stock at the close of business on the record date and sell those shares on the “ex-distribution” market up to and including through the distribution date, you will receive the shares of 2seventy bio common stock that you are entitled to receive pursuant to your ownership as of the record date of bluebird bio common stock.

Furthermore, we anticipate that trading in our common stock will begin on a “when issued” basis on or shortly before the record date for the distribution and will continue up to and including the distribution date. “When issued” trading in the context of a separation refers to a sale or purchase made conditionally on or before the distribution date because the securities of the separated entity have not yet been distributed. The “when issued” trading market will be a market for 2seventy bio common stock that will be distributed to holders of bluebird bio common stock on

the distribution date. If you owned bluebird bio common stock at the close of business on the record date, you would be entitled to 2seventy bio common stock distributed pursuant to the distribution. You may trade this entitlement to shares of 2seventy bio common stock, without bluebird bio common stock you own, on the "when issued" market. On the first trading day following the distribution date, "when issued" trading with respect to 2seventy bio common stock will end, and "regular way" trading will begin.

Conditions to the Distribution

2seventy bio expects that the distribution will be effective at 12:01 a.m., Eastern Time, on , 2021, the distribution date, provided that certain conditions shall have been satisfied or waived by bluebird bio in its sole discretion, including that bluebird bio will have received a private letter ruling from the IRS and an opinion from Goodwin Procter LLP, both satisfactory to bluebird bio's board of directors, together confirming that the distribution, together with certain related transactions generally is tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code.

Neither bluebird bio, 2seventy bio nor Goodwin Procter LLP can assure you that any or all of these conditions will be met and, to the extent permissible under applicable law, bluebird bio in its sole discretion may waive any of the conditions to the distribution. In addition, bluebird bio will have the sole and absolute discretion to determine (and change) the terms of, and whether to proceed with, the distribution and, to the extent it determines to so proceed, to determine the record date for the distribution and the distribution date and the distribution ratio. bluebird bio does not intend to notify its stockholders of any modifications to the terms of the separation that, in the judgment of its board of directors, are not material. For example, the bluebird bio board of directors might consider material such matters as significant changes to the distribution ratio, the assets to be contributed or the liabilities to be assumed in the separation. To the extent that the bluebird bio board of directors determines that any modifications by bluebird bio materially change the material terms of the distribution or to abandon the distribution, bluebird bio will notify bluebird bio stockholders in a manner reasonably calculated to inform them about the modification as may be required by law, by, for example, publishing a press release, filing a Current Report on Form 8-K, or circulating a supplement to this information statement.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following is a discussion of material U.S. federal income tax consequences of the distribution of 2seventy bio common stock to "U.S. holders" (as defined below) of bluebird bio common stock. This summary is based on the Code, U.S. Treasury Regulations promulgated thereunder, rulings and other administrative pronouncements issued by the IRS, and judicial decisions, all as in effect on the date of this information statement, and all of which are subject to differing interpretation and change at any time, possibly with retroactive effect. This discussion applies only to U.S. holders of shares of bluebird bio common stock who hold such shares as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion is based upon the assumption that the distribution, together with certain related transactions, will be consummated in accordance with the separation agreement and the other separation-related agreements and as described in this information statement. This summary is for general information only and is not tax advice. It does not discuss all aspects of U.S. federal income taxation that may be relevant to particular holders in light of their particular circumstances or to holders subject to special rules under the Code (including, but not limited to, insurance companies, tax-exempt organizations, financial institutions, broker-dealers, partners in partnerships (or entities or arrangements treated as partnerships for U.S. federal income tax purposes) that hold bluebird bio common stock, pass-through entities (or investors therein), traders in securities who elect to apply a mark-to-market method of accounting, stockholders who hold bluebird bio common stock as part of a "hedge," "straddle," "conversion," "synthetic security," "integrated investment" or "constructive sale transaction," individuals who receive bluebird bio or 2seventy bio common stock upon the exercise of employee stock options or otherwise as compensation, holders who are liable for the alternative minimum tax or any holders who actually or constructively own 5% or more of bluebird bio's common stock). This discussion also does not address any tax consequences arising under the unearned Medicare contribution tax pursuant to Section 1411 of the Code, nor does it address any tax considerations under state, local or foreign laws or U.S. federal laws other than those pertaining to the U.S. federal income tax. The distribution may be taxable under such other tax laws and all holders should consult their own tax advisors with respect to the applicability and effect of any such tax laws.

If a partnership, including for this purpose any entity or arrangement that is treated as a partnership for U.S. federal income tax purposes, holds bluebird bio common stock, the tax treatment of a partner in such partnership will generally depend upon the status of the partner and the activities of the partnership. Holders of bluebird bio common stock that are partnerships and partners in such partnerships should consult their own tax advisors about the U.S. federal income tax consequences of the distribution.

For purposes of this discussion, a "U.S. holder" is any beneficial owner of bluebird bio common stock that is, for U.S. federal income tax purposes:

- an individual who is a citizen or a resident of the United States;
- a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, (i) if a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (ii) that has a valid election in place under applicable Treasury Regulations to be treated as a United States person.

THE FOLLOWING DISCUSSION IS A SUMMARY OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE DISTRIBUTION UNDER CURRENT LAW AND IS FOR GENERAL INFORMATION ONLY. ALL HOLDERS SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES OF THE DISTRIBUTION TO THEM, INCLUDING THE APPLICATION AND EFFECT OF U.S. FEDERAL, STATE, LOCAL AND FOREIGN TAX LAWS.

It is a condition to the distribution that bluebird bio receive a private letter ruling from the IRS and an opinion from Goodwin Procter LLP, both satisfactory to bluebird bio's board of directors, together confirming that the distribution, together with certain related transactions, generally is tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code. Any opinion of Goodwin Procter LLP and any IRS private letter ruling will be based, among other things, on various facts and assumptions, as well as certain representations, statements and undertakings of bluebird bio and 2seventy bio (including those relating to the past and future conduct of bluebird bio and 2seventy bio). If any of these facts, assumptions, representations, statements or undertakings is, or becomes, inaccurate or incomplete, or if bluebird bio or 2seventy bio breach any of their respective covenants relating to the separation, any IRS private letter ruling and any tax opinion may be invalid. Accordingly, notwithstanding receipt of an IRS private letter ruling and an opinion of Goodwin Procter LLP, 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 any such IRS private letter ruling or on which any such opinion was based are false or have been violated. In addition, an opinion of Goodwin Procter LLP represents the judgment of Goodwin Procter LLP, which is not binding on the IRS or any court, and any IRS private letter ruling will not address all of the issues that are relevant to determining whether the distribution, together with certain related transactions, qualifies as a transaction that is generally tax-free for U.S. federal income tax purposes. Accordingly, notwithstanding receipt by bluebird bio of the tax opinion referred to above and an IRS private letter ruling, the IRS could assert that the distribution and certain related transactions do not qualify for tax-free treatment for U.S. federal income tax purposes. If the IRS were successful in taking this position, bluebird bio, 2seventy bio and bluebird bio stockholders could be subject to significant U.S. federal income tax liability. See "—Material U.S. Federal Income Tax Consequences if the Distribution is Taxable" below.

Material U.S. Federal Income Tax Consequences if the Distribution, Together with Certain Related Transactions, Qualifies as a Transaction that is Generally Tax-Free Under Sections 355 and 368(a)(1)(D) of the Code

Assuming the distribution, together with certain related transactions, qualifies 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, the U.S. federal income tax consequences of the distribution generally are as follows:

- no gain or loss will be recognized by, and no amount will be includible in the income of bluebird bio as a result of the distribution;
- no gain or loss will be recognized by (and no amount will be included in the income of) U.S. holders of bluebird bio common stock, upon the receipt of 2seventy bio common stock in the distribution, except with respect to any cash received in lieu of fractional shares of 2seventy bio common stock (as described below);
- the aggregate tax basis of the bluebird bio common stock and the 2seventy bio common stock received in the distribution (including any fractional share interest in 2seventy bio common stock for which cash is received) in the hands of each U.S. holder of bluebird bio common stock immediately after the distribution will equal the aggregate basis of bluebird bio common stock held by the U.S. holder immediately before the distribution, allocated between the bluebird bio common stock and the 2seventy bio common stock (including any fractional share interest in 2seventy bio common stock for which cash is received) in proportion to the relative fair market value of each on the date of the distribution; and
- the holding period of the 2seventy bio common stock received by each U.S. holder of bluebird bio common stock in the distribution (including any fractional share interest in 2seventy bio common stock for which

cash is received) will generally include the holding period at the time of the distribution for the bluebird bio common stock with respect to which the distribution is made.

A U.S. holder who receives cash in lieu of a fractional share of 2seventy bio common stock in the distribution will be treated as having sold such fractional share for cash, and will recognize capital gain or loss in an amount equal to the difference between the amount of cash received and such U.S. holder's adjusted tax basis in such fractional share. Such gain or loss will be long-term capital gain or loss if the U.S. holder's holding period for its bluebird bio common stock exceeds one year at the time of distribution.

If a U.S. holder of bluebird bio common stock holds different blocks of bluebird bio common stock (generally shares of bluebird bio common stock acquired on different dates or at different prices), such holder should consult its tax advisor regarding the determination of the basis and holding period of shares of 2seventy bio common stock received in the distribution in respect of particular blocks of bluebird bio common stock.

Material U.S. Federal Income Tax Consequences if the Distribution is Taxable

As discussed above, notwithstanding receipt by bluebird bio of a private letter ruling from the IRS and an opinion of Goodwin Procter LLP, the IRS could assert that the distribution does not qualify for tax-free treatment for U.S. federal income tax purposes. If the IRS were successful in taking this position, the consequences described above would not apply and bluebird bio, 2seventy bio and bluebird bio stockholders could be subject to significant U.S. federal income tax liability. In addition, certain events that may or may not be within the control of bluebird bio or 2seventy bio could cause the distribution and certain related transactions to not qualify for tax-free treatment for U.S. federal income tax purposes. Depending on the circumstances, 2seventy bio may be required to indemnify bluebird bio for taxes (and certain related losses) resulting from the distribution and certain related transactions not qualifying as tax-free for U.S. federal income tax purposes.

If the distribution were to fail to qualify as a tax-free transaction for U.S. federal income tax purposes, in general, bluebird bio would recognize taxable gain as if it had sold the 2seventy bio common stock that was distributed by bluebird bio in the distribution in a taxable sale for its fair market value (unless bluebird bio and 2seventy bio jointly make an election under Section 336(e) of the Code with respect to the distribution, in which case, in general, (i) the bluebird bio group would recognize taxable gain as if 2seventy bio had sold all of its assets in a taxable sale in exchange for an amount equal to the fair market value of 100% of the 2seventy bio common stock and the assumption of all 2seventy bio's liabilities and (ii) 2seventy bio would obtain a related step up in the basis of its assets), such gain may be partially offset by bluebird bio's net operating loss carryforward and bluebird bio stockholders who receive shares of 2seventy bio 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.

Even if the distribution were otherwise to qualify as tax-free, for U.S. federal income tax purposes, under Sections 355 and 368(a)(1)(D) of the Code, it may result in taxable gain to bluebird bio under Section 355(e) of the Code if the distribution were later deemed to be part of a plan (or series of related transactions) pursuant to which one or more persons acquire, directly or indirectly, shares representing a 50% or greater interest (by vote or value) in bluebird bio or 2seventy bio. For this purpose, any acquisitions of bluebird bio or 2seventy bio shares within the period beginning two years before the distribution and ending two years after the distribution are presumed to be part of such a plan, although bluebird bio or 2seventy bio may be able to rebut that presumption.

In connection with the distribution, 2seventy bio and bluebird bio will enter into a tax matters agreement pursuant to which 2seventy bio will be 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 2seventy bio stock or assets or certain actions by 2seventy

bio, then 2seventy bio 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 2seventy bio and bluebird bio are responsible for such failure, liability will be shared according to relative fault. If neither 2seventy bio nor bluebird bio is responsible for such failure, bluebird bio will bear any resulting taxes, interest, penalties and other costs. For a discussion of the tax matters agreement, see "Certain Relationships and Related Person Transactions—Agreements with bluebird bio—Tax Matters Agreement." The indemnification obligations of 2seventy bio to bluebird bio under the tax matters agreement are not expected to be limited in amount or subject to any cap. If 2seventy bio is 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, 2seventy bio may be subject to substantial liabilities.

Backup Withholding and Information Reporting

Payments of cash to U.S. holders of bluebird bio common stock in lieu of fractional shares of 2seventy bio common stock may be subject to information reporting and backup withholding (currently, at a rate of 24%), unless such U.S. holder delivers a properly completed IRS Form W-9 certifying such U.S. holder's correct taxpayer identification number and certain other information, or otherwise establishes an exemption from backup withholding. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be refunded or credited against a U.S. holder's U.S. federal income tax liability provided that the required information is timely furnished to the IRS.

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DESCRIPTION OF 2SEVENTY BIO'S CAPITAL STOCK

The following description of our capital stock is intended as a summary only and is qualified in its entirety by reference to our charter and by-laws that will be in effect at the closing of this separation, which will be filed as exhibits to the Form 10 of which this information statement is a part, and to the applicable provisions of the DGCL. The description of our capital stock reflects changes to our capital structure that will occur upon the closing of this separation.

General

Upon completion of this separation, our authorized capital stock will consist of shares of common stock, par value $0.0001 per share, and shares of preferred stock, par value $0.0001 per share, all of which shares of preferred stock will be undesignated.

As of , 2021, shares of our common stock were outstanding and held by one stockholder of record.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Preferred Stock

Upon the consummation of the separation, our board of directors will have the authority, without further action by our stockholders, to issue up to shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our Company or other corporate action. Upon consummation of this separation, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Anti-Takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that

directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our certificate of incorporation provides for authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to

obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum

Our amended and restated bylaws will 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 will 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 will 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.

Section 203 of the Delaware General Corporation Law

Upon completion of the separation, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or

- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Nasdaq Global Market Listing

We intend to apply to list our common stock on the Nasdaq Global Market under the trading symbol “TSVT.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be .

Limitations of Liability and Indemnification Matters

For a discussion of liability and indemnification, see “Executive Compensation.”

Sale of Unregistered Securities

On April 26, 2021, in connection with the formation of 2seventy bio, Inc., we issued 100 shares of our common stock to bluebird bio . We did not register the issuance of such shares under the Securities Act because the issuance did not constitute a public offering and was made pursuant to Section 4(a)(2) of the Securities Act.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form 10 with the SEC with respect to the shares of our common stock being distributed as contemplated by this information statement. This information statement is a part of, and does not contain all of the information set forth in, the registration statement and the exhibits and schedules to the registration statement. For further information with respect to us and our common stock, please refer to the registration statement, including its exhibits and schedules. Statements made in this information statement relating to any contract or other document are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract or document. You may review a copy of the registration statement, including its exhibits and schedules, on the Internet website maintained by the SEC at www.sec.gov.

As a result of the distribution, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with the Exchange Act, we will file periodic reports, proxy statements and other information with the SEC, which will be available at www.sec.gov.

We intend to furnish holders of our common stock with annual reports containing consolidated financial statements prepared in accordance with GAAP and audited and reported on, with an opinion expressed, by an independent registered public accounting firm.

You should rely only on the information contained in this information statement or to which we have referred you. We have not authorized any person to provide you with different information or to make any representation not contained in this information statement.

2seventy bio, Inc.

Index to Combined Financial Statements

	Pages
Report of Independent Registered Public Accounting Firm	F-2
Combined Balance Sheets	F-3
Combined Statements of Operations and Comprehensive Loss	F-4
Combined Statements of Equity	F-5
Combined Statements of Cash Flows	F-6
Notes to Combined Financial Statements	F-7

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of 2seventy bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying combined balance sheets of 2seventy bio, Inc. (the Company) as of December 31, 2020 and 2019, the related combined statements of operations and comprehensive loss, equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "combined financial statements"). In our opinion, the combined financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying combined financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the combined financial statements, the Company has recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The combined financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the combined financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842), and the related amendments.

Basis for Opinion

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.
Boston, Massachusetts
May 11, 2021

2seventy bio, Inc.

Combined Balance Sheets
(in thousands)

	As of December 31,	
	2020	2019
Assets		
Current assets:		
Prepaid expenses	$ 14,413	$ 13,416
Receivables	10,691	7,426
Total current assets	25,104	20,842
Property, plant and equipment, net	144,025	132,290
Intangible assets, net	5,644	9,406
Goodwill	13,128	13,128
Operating lease right-of-use assets	116,456	125,231
Other non-current assets	8,263	14,052
Total assets	$ 312,620	$ 314,949
Liabilities and Equity		
Current liabilities:		
Accounts payable	$ 7,152	$ 20,389
Accrued expenses and other current liabilities	43,347	52,837
Operating lease liability, current portion	15,313	11,317
Deferred revenue, current portion	820	8,474
Collaboration research advancement, current portion	9,236	10,380
Total current liabilities	75,868	103,397
Deferred revenue, net of current portion	25,762	9,791
Collaboration research advancement, net of current portion	21,581	27,834
Operating lease liability, net of current portion	112,290	122,258
Other non-current liabilities	2,490	7,977
Total liabilities	237,991	271,257
Commitments and contingencies *Note 7*		
Equity:		
Net parent investment	74,629	43,692
Total equity	74,629	43,692
Total liabilities and equity	$ 312,620	$ 314,949

See accompanying notes to combined financial statements.

2seventy bio, Inc.

Combined Statements of Operations and Comprehensive Loss
(in thousands)

	Year ended December 31,		
	2020	**2019**	**2018**
Revenue:			
Service revenue	$ 111,452	$ 30,351	$ 44,533
Collaborative arrangement revenue	115,594	5,740	7,820
Royalty and other revenue	21,076	8,205	2,226
Total revenues	248,122	44,296	54,579
Operating expenses:			
Research and development	296,467	297,645	200,490
Selling, general and administrative	90,897	81,646	53,631
Cost of royalty and other revenue	5,396	2,978	885
Change in fair value of contingent consideration	(6,468)	2,747	2,999
Total operating expenses	386,292	385,016	258,005
Loss from operations	(138,170)	(340,720)	(203,426)
Interest expense	—	—	(15,486)
Other income, net	18,056	20,126	19,163
Loss before income taxes	(120,114)	(320,594)	(199,749)
Income tax (expense) benefit	—	—	—
Net loss and comprehensive loss	$ (120,114)	$ (320,594)	$ (199,749)

See accompanying notes to combined financial statements.

2seventy bio, Inc.

Combined Statements of Equity
(in thousands)

	Net parent investment
Balances at December 31, 2017	$ 21,313
Adjustment to beginning net parent investment from adoption of ASU 2014-09	(29,375)
Stock-based compensation	40,801
Transfers from bluebird bio	194,961
Net loss	(199,749)
Balances at December 31, 2018	27,951
Adjustment to beginning net parent investment from adoption of ASU 2016-02	6,564
Stock-based compensation	62,049
Transfers from bluebird bio	267,722
Net loss	(320,594)
Balances at December 31, 2019	43,692
Stock-based compensation	60,997
Transfers from bluebird bio	90,054
Net loss	(120,114)
Balances at December 31, 2020	$ 74,629

See accompanying notes to combined financial statements.

2seventy bio, Inc.

Combined Statements of Cash Flows
(in thousands)

	Year ended December 31,		
	2020	**2019**	**2018**
Cash flows from operating activities:			
Net loss	$ (120,114)	$ (320,594)	$ (199,749)
Adjustments to reconcile net loss to net cash used in operating activities:			
Change in fair value of contingent consideration	(6,468)	2,747	2,999
Depreciation and amortization	13,188	12,587	13,345
Stock-based compensation expense	60,997	62,049	40,801
Other non-cash items	73	110	207
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	1,526	6,700	(18,938)
Operating lease right-of-use assets	13,764	12,214	—
Accounts payable	(13,240)	14,611	2,230
Accrued expenses and other liabilities	(7,479)	26,341	10,808
Operating lease liabilities	(10,960)	(2,309)	—
Deferred revenue	8,317	(16,674)	(41,872)
Collaboration research advancement	(7,397)	(5,739)	43,954
Net cash used in operating activities	(67,793)	(207,957)	(146,215)
Cash flows from investing activities:			
Purchase of property, plant and equipment	(22,261)	(59,765)	(50,827)
Net cash used in investing activities	(22,261)	(59,765)	(50,827)
Cash flows from financing activities:			
Transfers from bluebird bio	90,054	267,722	194,961
Reimbursement of tenant improvements for financing lease obligation	—	—	3,098
Payments on financing lease obligation	—	—	(1,017)
Net cash provided by financing activities	90,054	267,722	197,042
Increase (decrease) in cash, cash equivalents and restricted cash	—	—	—
Cash, cash equivalents and restricted cash at beginning of year	—	—	—
Cash, cash equivalents and restricted cash at end of year	$ —	$ —	$ —
Supplemental cash flow disclosures:			
Purchases of property, plant and equipment included in accounts payable and accrued expenses	$ 2,039	$ 3,064	$ 6,842
Right-of-use assets obtained in exchange for operating lease liabilities	$ 4,989	$ 9,745	$ —
Cash paid during the period for interest	$ —	$ —	$ 15,486
Cash paid during the period for income taxes	$ —	$ —	$ —

See accompanying notes to combined financial statements.

2seventy bio, Inc.

Notes to Combined Financial Statements
For the Years Ended December 31, 2020, 2019 and 2018

1. Description of the business

2seventy bio, Inc. (the “Company” or “2seventy bio”) is a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. The Company’s approach combines its expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. The Company is advancing multiple preclinical and clinical programs in oncology and, together with Bristol-Myers Squibb (“BMS”), delivering the first FDA-approved CAR T therapy in multiple myeloma, Abecma (idecabtagene vicleucel, or ide-cel), to patients in the United States. Please refer to Note 8, *Collaborative arrangements*, for further discussion of the collaboration with BMS.

The separation

In January 2021, bluebird bio, Inc. ("bluebird bio") announced its plans to separate its oncology portfolio and programs from its severe genetic disease, or SGD, portfolio and programs through a pro rata distribution of 2seventy bio's common stock to stockholders of bluebird bio. As a part of the separation, bluebird bio intends to transfer the assets, liabilities and operations of its oncology portfolio and programs to 2seventy bio, pursuant to the terms of a separation agreement, to be entered into between 2seventy bio and bluebird bio. On the distribution date, each bluebird bio stockholder will receive a pro rata share of 2seventy bio's common stock for every share of bluebird bio common stock held of record at the close of business on the record date for the distribution. Registered stockholders will receive cash in lieu of any fractional shares of 2seventy bio's common stock that they would have received as a result of the application of the distribution ratio. Following the distribution, 2seventy bio will operate as a separate, independent, publicly traded company. The distribution of 2seventy bio's common stock is subject to the satisfaction or waiver by bluebird bio of certain conditions.

Going concern

In accordance with Accounting Standards Codification (“ASC”) 205-40, *Going Concern*, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the combined financial statements are issued. The Company has incurred losses and has experienced negative operating cash flows for all historical periods presented. During the year ended December 31, 2020, the Company incurred a loss of $120.1 million and used $67.8 million of cash in operations. The Company expects to continue to generate operating losses and negative operating cash flows for the next few years. The Company's continued operations are dependent on its ability to raise additional funding. The Company expects to finance its cash needs through a cash contribution from bluebird bio in connection with separation as well as through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. However, there can be no assurance that such financing will be available in sufficient amounts or on acceptable terms, if at all. If the Company is unable to obtain additional funding on a timely basis, it may be forced to significantly curtail, delay, or discontinue one or more of its planned research or development programs or be unable to expand its operations. Based on its recurring losses from operations, expectation of continuing operating losses for the next few years, and the need to raise additional funding to finance its future operations, as of May 11, 2021, the issuance date of the combined financial statements for the year ended December 31, 2020, the Company has concluded that there is substantial doubt about its ability to continue as a going concern for a period of one year from the date that these combined financial statements are issued. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of significant accounting policies and basis of presentation

Basis of presentation

The accompanying combined financial statements have been prepared on a carve-out basis and are derived from bluebird bio's consolidated financial statements and accounting records. The accompanying combined financial statements reflect the historical results of the operations, financial position and cash flows of the Company and have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States GAAP as included in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB").

The historical results of operations, financial position and cash flows of 2seventy bio presented in these combined financial statements may not be indicative of what they would have been had 2seventy bio been an independent stand-alone entity, nor are they necessarily indicative of 2seventy bio's future results of operations, financial position and cash flows.

As part of bluebird bio, the Company was dependent upon bluebird bio for all of its working capital and financing requirements, as bluebird bio uses a centralized approach to cash management and financing its operations. There were no cash amounts specifically attributable to the Company for the historical periods presented; therefore, cash and cash equivalents have not been allocated to the Company in the combined financial statements. Financing transactions related to bluebird bio are accounted for as a component of net parent investment in the combined balance sheets and as a financing activity on the accompanying combined statements of cash flows.

The Company's combined financial statements include an allocation of expenses related to certain bluebird bio corporate functions, including senior management, legal, human resources, finance and information technology. In addition, the Company's combined financial statements include an allocation of certain research and development costs not directly attributable to individual programs. These expenses have been allocated to the Company based on direct usage or benefit where specifically identifiable, with the remainder allocated based on employee time spent on projects, square footage or other measures that management believes are consistent and reasonable. These allocations may not be indicative of the actual expense that would have been incurred had the Company operated as an independent, publicly traded company for the periods presented. See Note 12, *Related-party transactions*, for a further description of the accounting for the separation from bluebird bio.

The combined balance sheets of the Company include assets and liabilities that were allocated principally on a specific identification basis. As 2seventy bio's operations were not historically held by a single legal entity or separate legal entities, net parent investment is shown in lieu of stockholder's equity in the combined financial statements. Net parent investment represents the cumulative investment by bluebird bio in the Company through the dates presented, inclusive of operating results. Balances between the Company and bluebird bio that were not historically settled in cash are included in net parent investment. All significant transactions between the Company and bluebird bio have been included in the accompanying combined financial statements. Transactions with bluebird bio are reflected in the accompanying combined statements of equity as net transfers from parent and in the accompanying combined balance sheets within net parent investment.

Amounts reported are computed based on thousands, except percentages or as otherwise noted. As a result, certain totals may not sum due to rounding.

Principles of combination

The accompanying combined financial statements include the attribution of certain assets and liabilities that have historically been held by bluebird bio but which are specifically identifiable or attributable to the Company. All intercompany balances and transactions with bluebird bio are deemed to be effectively settled in the combined financial statements at the time the transaction is recorded. Expenses related to corporate allocations from bluebird

bio to the Company are considered to be effectively settled for cash in the combined financial statements at the time the transaction is recorded.

The Company continually assesses whether it is the primary beneficiary of a variable interest entity as changes to existing relationships or future transactions may result in consolidation or deconsolidation of one or more collaborators or partners. In determining whether it is the primary beneficiary of an entity in which the Company has a variable interest, management applies a qualitative approach that determines whether the Company has both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements.

Estimates and judgments are used in the following areas, among others: allocations of revenue, expenses, assets and liabilities from bluebird bio's historical consolidated financial statements to the Company, future undiscounted cash flows and subsequent fair value estimates used to assess potential and measure any impairment of long-lived assets, including goodwill and intangible assets, the measurement of right-of-use assets and lease liabilities, contingent consideration, stock-based compensation expense, accrued expenses, income taxes, and the assessment of the Company's ability to fund its operations for at least the next twelve months from the date of issuance of these financial statements. In addition, estimates and judgments are used in the Company’s accounting for its revenue-generating arrangements, in particular as it relates to determining the stand-alone selling price of performance obligations, evaluating whether an option to acquire additional goods and services represents a material right, estimating the total transaction price, including estimating variable consideration and the probability of achieving future potential development and regulatory milestones, assessing the period of performance over which revenue may be recognized, and accounting for modifications to revenue-generating arrangements.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original final maturities of 90 days or less from the date of purchase to be cash equivalents. Cash equivalents may consist of marketable securities with maturities of less than 90 days when purchased. Cash equivalents are reported at fair value. There were no cash or cash equivalents specifically attributable to 2seventy bio for the historical periods presented; therefore, there are no cash or cash equivalents reflected in the combined financial statements.

Segment information

The Company operates in a single segment, focusing on researching, developing and commercializing potentially transformative treatments for cancer. Consistent with its operational structure, its chief operating decision maker manages and allocates resources for the Company at a combined level. Therefore, results of the Company's operations are reported on a combined basis for purposes of segment reporting. All material long-lived assets of the Company reside in the United States.

Fair value of financial instruments

The Company has certain financial liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements:

Level 1—Fair values are determined utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Fair values are determined utilizing quoted prices for identical or similar assets or liabilities in active markets or other market observable inputs such as interest rates, yield curves and foreign currency spot rates.

Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Items measured at fair value on a recurring basis relate to contingent consideration liabilities (see Note 3, *Fair value measurements*). The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term nature.

Business combinations

Business combinations are accounted for using the acquisition method of accounting. Using this method, the tangible and intangible assets acquired and the liabilities assumed are recorded as of the acquisition date at their respective fair values. The Company evaluates a business as an integrated set of activities and assets that is capable of being managed for the purpose of providing a return in the form of dividends, lower costs or other economic benefits and consists of inputs and processes that provide or have the ability to provide outputs. In an acquisition of a business, the excess of the fair value of the consideration transferred over the fair value of the net assets acquired is recorded as goodwill. In an acquisition of net assets that does not constitute a business, no goodwill is recognized.

The combined financial statements include the results of operations of an acquired business after the completion of the acquisition.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting. Goodwill is not amortized; rather, it is evaluated for impairment within the Company's single reporting unit on an annual basis, during the fourth quarter, or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the Company's reporting unit below its carrying amount. The Company adopted ASC 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* ("ASU 2017-04"), for purposes of performing its annual goodwill impairment test for 2019 during the fourth quarter of 2019. ASU 2017-04 removes the second step of the goodwill impairment test. Under this ASU, the Company performs a one-step quantitative test and records the amount of goodwill impairment, if any, as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The Company has not recognized any impairment charges related to goodwill to date.

Intangible assets, net

Intangible assets, net consist of acquired core technology, net of accumulated amortization. The Company amortizes its intangible assets using the straight-line method over their estimated economic lives and periodically reviews for impairment. The Company has not recognized any impairment charges related to intangible assets to date.

Contingent consideration

Each reporting period, the Company remeasures the contingent consideration obligations associated with business combinations to their fair value and records within operating expenses increases or decreases in their fair value as change in fair value of contingent consideration within the combined statements of operations and comprehensive loss. Changes in contingent consideration result from changes in the assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones may be achieved, and the discount rate used to estimate the fair value of the liability. Contingent consideration may change significantly as development of the Company's programs in certain indications progress and additional data is obtained, impacting the Company's assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value. See Note 3, *Fair value measurements*, for additional information.

Property, plant and equipment

Property, plant and equipment is stated at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Depreciation and amortization is calculated using the straight-line method over the estimated useful lives of the assets, which are as follows:

Asset	Estimated useful life
Building	40 years
Computer equipment and software	3 years
Furniture and fixtures	2-5 years
Laboratory equipment	2-5 years
Leasehold improvements	Shorter of the useful life or remaining lease term

Prior to the adoption of ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02" or "ASC 842"), on January 1, 2019 (discussed further below), the Company recorded certain construction costs incurred by a landlord on behalf of the Company related to a lease arrangement as a building asset and corresponding financing obligation on the consolidated balance sheets. See Note 6, *Leases*, for additional information.

Impairment of long-lived assets

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets.

Leases

Effective January 1, 2019, the Company adopted ASC 842 using the required modified retrospective approach and utilizing the effective date as its date of initial application. As a result, amounts for the year ended December 31, 2018 are presented in accordance with the previous guidance in ASC 840, *Leases* ("ASC 840").

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the relevant facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable. The Company does not have material financing leases.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. To estimate its incremental borrowing rate, a credit rating applicable to the Company is estimated using a synthetic credit rating analysis since the Company does not currently have a rating agency-based credit rating.

The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless it is reasonably certain that the Company will exercise its renewal option.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the stand-alone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

ASC 842 transition practical expedients and application of transition provisions to leases at the transition date

The Company elected the following practical expedients, which must be elected as a package and applied consistently to all of its leases at the transition date (including those for which the entity is a lessee or a lessor): (i) the Company did not reassess whether any expired or existing contracts are or contain leases; (ii) the Company did not reassess the lease classification for any expired or existing leases (that is, all existing leases that were classified as operating leases in accordance with ASC 840 are classified as operating leases, and all existing leases that were classified as capital leases in accordance with ASC 840 are classified as finance leases); and (iii) the Company did not reassess initial direct costs for any existing leases.

For leases that existed prior to the date of initial application of ASC 842 (which were previously classified as operating leases), a lessee may elect to use either the total lease term measured at lease inception under ASC 840 or the remaining lease term as of the date of initial application of ASC 842 in determining the period for which to measure its incremental borrowing rate. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

Application of ASC 842 policy elections to leases post adoption

The Company has made certain policy elections to apply to its leases executed post adoption, or subsequent to January 1, 2019, as further described below.

In accordance with ASC 842, components of a lease should be separated into lease components and non-lease components. The fixed and in-substance fixed contract consideration must be allocated based on the relative stand-alone prices to the lease components and non-lease components.

Entities may elect not to separate lease and non-lease components. Rather, entities would account for each lease component and related non-lease component together as a single lease component. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only.

ASC 842 allows for the use of judgment in determining whether the lease term is for a major part of the remaining economic life of the underlying asset and whether the present value of lease payments represents substantially all of the fair value of the underlying asset. The Company applies the bright line thresholds referenced in ASC 842-10-55-2 to assist in evaluating leases for appropriate classification. The aforementioned bright lines are applied consistently to the Company's entire portfolio of leases.

Revenue recognition

Under ASC Topic 606, *Revenue from Contracts with Customers* ("Topic 606"), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying good or service relative to the option exercise price. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

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

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most

likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

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

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

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

The Company recognizes revenue within the following financial statement captions:

Service revenue

To date, the Company's service revenue has primarily been generated from the elements of its collaboration arrangement with BMS that are accounted for pursuant to Topic 606, using the five-step model described above. As discussed further below, the Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") or Topic 606. For the elements of a collaboration arrangement which are more reflective of a vendor-customer relationship and therefore within the scope of Topic 606, the Company records the related revenue as service revenue on the combined statement of operations and comprehensive loss. Refer below for additional discussion around the Company's policy for recognizing collaborative arrangement revenue and the determination of whether elements of a collaboration arrangement are within the scope of ASC 808 or Topic 606.

Collaborative arrangement revenue

To date, the Company's collaborative arrangement revenue has been generated from its collaboration arrangements with BMS and Regeneron Pharmaceuticals, Inc. ("Regeneron"), as further described in Note 8, *Collaborative arrangements.*

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the

commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of Topic 606 (refer above for further discussion of the Company's policy for recognizing service revenue). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606. Amounts that are owed to collaboration partners are recognized as an offset to collaborative arrangement revenues as such amounts are incurred by the collaboration partner. Where amounts owed to a collaboration partner exceed the Company's collaborative arrangement revenues in each quarterly period, such amounts are classified as research and development expense.

As the Company recognizes revenue under its collaborative arrangements both within and outside the scope of Topic 606, the Company presents revenue on its combined statements of operations and comprehensive loss as follows: service revenue includes revenue from collaborative partners recognized within the scope of Topic 606 and collaborative arrangement revenue includes revenue from collaborative partners recognized outside the scope of Topic 606.

Royalty and other revenue

The Company enters into out-licensing agreements that are within the scope of Topic 606. The Company does not have any material license arrangements that contain more than one performance obligation. The terms of such out-license agreements include the license of functional intellectual property, given the functionality of the intellectual property is not expected to change substantially as a result of the licensor's ongoing activities, and typically include payment of one or more of the following: non-refundable up-front license fees; development and regulatory milestone payments and milestone payments based on the level of sales; and royalties on net sales of licensed products. Nonrefundable up-front license fees are recognized as revenue at a point in time when the licensed intellectual property is made available for the customer's use and benefit, which is generally at the inception of the arrangement. Development and regulatory milestone fees, which are a type of variable consideration, are recognized as revenue to the extent that it is probable that a significant reversal will not occur. The Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

For a complete discussion of accounting for collaboration and other revenue-generating arrangements, see Note 8, *Collaborative arrangements*, and Note 9, *Royalty and other revenue.*

Research and development expenses

Research and development costs are charged to expense as costs are incurred in performing research and development activities, including salaries and benefits, facilities costs, overhead costs, clinical study and related clinical manufacturing costs, license and milestone fees, contract services, manufacturing costs for pre-launch inventory that did not qualify for capitalization, and other related costs. Up-front fees and milestones paid to third parties in connection with technologies that have not reached technological feasibility and do not have an alternative future use are expensed as research and development expense as incurred. In circumstances where amounts have been paid in excess of costs incurred, the Company records a prepaid expense. The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations, clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Where amounts owed to a collaboration partner exceed the Company's collaborative arrangement revenues in each quarterly period, such amounts are classified as research and development expense.

Cost of royalty and other revenue

Cost of royalty and other revenue represents expense associated with amounts owed to third parties as a result of revenue recognized under the Company's out-license arrangements.

Interest expense

Interest expense was $0.0 million, $0.0 million, and $15.5 million for the years ended December 31, 2020, 2019, and 2018, respectively. Please refer to Note 6, *Leases*, for further discussion of interest expense incurred on the 60 Binney Street lease.

Other income, net

Other income, net consists primarily of income resulting from the allocation of facility-related, depreciation and amortization expense to bluebird bio for its proportional use of assets that will be attributed to the Company as well as expense resulting from the allocation of facility-related, depreciation and amortization expense to the Company for its proportional use of bluebird bio assets that will not be attributed to the Company. Other income, net also includes immaterial gains and losses on disposal of assets.

Income taxes

Income taxes as presented in the combined financial statements of 2seventy bio attribute current and deferred income taxes of bluebird bio to 2seventy bio's stand-alone financial statements in a manner that is systematic, rational and consistent with the asset and liability method prescribed by FASB ASC Topic 740: *Income Taxes* ("ASC 740"). Accordingly, 2seventy bio's income tax provision was prepared following the separate return method. The separate return method applies ASC 740 to the stand-alone financial statements of each member of the consolidated group as if each group member was a separate taxpayer and a stand-alone enterprise. The calculation of the Company's income taxes on a separate return basis requires a considerable amount of judgment and use of both estimates and allocations. As a result, actual transactions included in the consolidated financial statements of bluebird bio may not be included in the separate combined financial statements of 2seventy bio. Similarly, the tax treatment of certain items reflected in the combined financial statements of 2seventy bio may not be reflected in the consolidated financial statements and tax returns of bluebird bio. Therefore, items such as net operating losses, credit carryforwards and valuation allowances may exist in the Company's stand-alone financial statements that may or may not exist in bluebird bio's consolidated financial statements. As such, the income taxes of 2seventy bio as presented in the combined financial statements may not be indicative of the income taxes that 2seventy bio will generate in the future.

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense.

In general, the taxable income (loss) of bluebird bio entities was included in bluebird bio's consolidated tax returns. As such, separate income tax returns were not prepared for the entities included within the combined financial statements. Consequently, income taxes currently payable by 2seventy bio are deemed to have been

remitted to bluebird bio, in cash, in the period in which the liability arose, and income taxes currently receivable by 2seventy bio are deemed to have been received from bluebird bio in the period in which the receivable arose.

Comprehensive loss

Comprehensive loss is composed of net loss and other comprehensive income (loss). There was no difference between net loss and comprehensive loss for each of the periods presented in the combined financial statements.

Recent accounting pronouncements

ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements, ASU No. 2019-5 Financial Instruments – Credit Losses (Topic 326): Targeted Transition Relief, ASU No. 2019-11, Codification Improvements to Topic 326, Financial Instruments - Credit Losses

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements*. The new standard, as amended, requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The targeted transition relief standard allows filers an option to irrevocably elect the fair value option of ASC 825-10, *Financial Instruments-Overall*, applied on an instrument-by-instrument basis for eligible instruments. The Company adopted this standard on January 1, 2020 on a prospective basis and the adoption did not have a material impact on its financial position and results of operations.

ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*. The new standard removes certain disclosures, modifies certain disclosures, and adds additional disclosures related to fair value measurement. The Company adopted this standard as of January 1, 2020, and it did not have a material impact on its financial position and results of operations upon adoption.

ASU No. 2018-15, Intangibles-Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* The amendments in this update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this update. The Company adopted this standard on a prospective basis as of January 1, 2020, and it did not have a material impact on its financial position and results of operations upon adoption.

ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, ("ASU 2018-18"). The amendments in this update clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, *Revenue from Contracts with Customers* ("Topic 606" or "ASC 606") when the counter party is a customer in the

context of a separate unit of account for the arrangement. ASU 2018-18 also precludes companies from presenting transactions with collaborative partners that are outside the scope of Topic 606 together with revenue within the scope of Topic 606. The Company adopted this standard on a retrospective basis on January 1, 2020. As a result, revenue for prior periods is presented in accordance with the new standard.

As the Company recognizes revenue under its collaborative arrangements both within and outside the scope of Topic 606, the Company presents revenue on its combined statements of operations and comprehensive loss as follows: service revenue includes revenue from collaborative partners recognized within the scope of Topic 606 and collaborative arrangement revenue includes revenue from collaborative partners recognized outside the scope of Topic 606.

ASU No. 2019-4, Codification Improvements to Topic 326, Financial Instruments – Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments

In April 2019, the FASB issued ASU 2019-4, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments.* This update provides clarifications for three topics related to financial instruments accounting, some of which apply to the Company. The Company adopted this standard as of January 1, 2020 on a prospective basis, and it did not have a material impact on its financial position and results of operations upon adoption.

Not yet adopted

ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective beginning January 1, 2021. The adoption of ASU 2019-12 is not expected to have a material impact on the Company's financial position or results of operations upon adoption.

ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). ASU 2020-06 simplifies the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. More specifically, the amendments focus on the guidance for convertible instruments and derivative scope exception for contracts in an entity's own equity. The Company will early adopt the new standard, effective January 1, 2021. The adoption of ASU 2020-06 is not expected to have an impact on the Company's financial position or results of operations upon adoption.

ASU No. 2020-08, Codification Improvements to Subtopic 310-20, Receivables - Nonrefundable Fees and Other Costs

In October 2020, the FASB issued ASU 2020-08, *Codification Improvements to Subtopic 310-20, Receivables - Nonrefundable Fees and Other Costs* ("ASU 2020-08") to provide further clarification and update the previously issued guidance in ASU 2017-08, *Receivables - Nonrefundable Fees and Other Costs (Subtopic 310-20: Premium Amortization on Purchased Callable Debt Securities)* ("ASU 2017-08"). ASU 2017-08 shortened the amortization period for certain callable debt securities purchased at a premium by requiring that the premium be amortized to the earliest call date. ASU 2020-08 requires that at each reporting period, to the extent that the amortized cost of an individual callable debt security exceeds the amount repayable by the issuer at the next call date, the excess premium

shall be amortized to the next call date. The new standard will be effective beginning January 1, 2021. The adoption of ASU 2020-08 is not expected to have a material impact on the Company's financial position or results of operations upon adoption.

ASU No. 2020-10, Codification Improvements

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements* ("ASU 2020-10"). The amendments in this ASU represent changes to clarify the ASC, correct unintended application of the guidance, or make minor improvements to the ASC that are not expected to have a significant effect on current accounting practice or create a significant administrative cost to most entities. This new standard will be effective beginning January 1, 2021. The adoption of ASU 2020-10 is not expected to have a material impact on the Company's financial position or results of operations upon adoption.

3. Fair value measurements

The following table sets forth the Company’s assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2020 and 2019 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2020				
Liabilities:				
Contingent consideration	$ 1,509	$ —	$ —	$ 1,509
Total liabilities	$ 1,509	$ —	$ —	$ 1,509
December 31, 2019				
Liabilities:				
Contingent consideration	$ 7,977	$ —	$ —	$ 7,977
Total liabilities	$ 7,977	$ —	$ —	$ 7,977

As of December 31, 2020 and 2019, the Company did not have any assets that are measured at fair value on a recurring basis.

Contingent consideration

In connection with bluebird bio's prior acquisition of Precision Genome Engineering, Inc. (“Pregenen”), the Company may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. Contingent consideration is measured at fair value and is based on significant unobservable inputs, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. Future changes in the fair value of contingent consideration related to updated assumptions and estimates are recognized within the combined statements of operations and comprehensive loss. In the absence of new information related to the probability of milestone achievement, changes in fair value will reflect changing discount rates and the passage of time. Contingent consideration is included in other non-current liabilities on the combined balance sheets.

The table below provides a roll-forward of fair value of the Company's contingent consideration obligations that include Level 3 inputs (in thousands):

	Year ended December 31,	
	2020	2019
Beginning balance	$ 7,977	$ 5,230
Additions	—	—
Changes in fair value	(6,468)	2,747
Payments	—	—
Ending balance	$ 1,509	$ 7,977

Please refer to Note 7, *Commitments and contingencies*, for further information.

4. Property, plant and equipment, net

Property, plant and equipment, net, consists of the following (in thousands):

	As of December 31,	
	2020	2019
Land	$ 1,210	$ 1,210
Building	15,745	15,664
Computer equipment and software	6,503	6,485
Office equipment	6,588	6,570
Laboratory equipment	24,080	19,381
Leasehold improvements	28,305	28,153
Construction-in-progress	91,631	75,543
Total property, plant and equipment	174,062	153,006
Less accumulated depreciation and amortization	(30,037)	(20,716)
Property, plant and equipment, net	$ 144,025	$ 132,290

Depreciation and amortization expense related to property, plant and equipment was $9.4 million, $8.8 million, and $9.6 million for the years ended December 31, 2020, 2019, and 2018, respectively.

North Carolina manufacturing facility

In November 2017, bluebird bio acquired a manufacturing facility in Durham, North Carolina for the future manufacture of lentiviral vectors for the Company's gene therapies. This manufacturing facility is fully dedicated to the Company's operations and, accordingly, will be attributed to the Company in connection with the separation. As of December 31, 2020, a portion of the facility has been placed into service and the remainder of the facility is still in process of construction and qualification, which is required for the facility to be ready for its intended use. Construction-in-progress as of December 31, 2020 and 2019, includes $91.1 million and $74.2 million, respectively, related to the North Carolina manufacturing facility. The Company expects the majority of the facility to be placed into service in 2021.

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	As of December 31,	
	2020	2019
Employee compensation	$ 9,451	$ 4,903
Manufacturing costs	6,808	15,981
Clinical and contract research organization costs	2,854	1,141
Collaboration research costs	19,605	25,538
Property, plant, and equipment	440	1,470
License and milestone fees	278	275
Other	3,911	3,529
Total accrued expenses and other current liabilities	$ 43,347	$ 52,837

6. Leases

bluebird bio leases certain office and laboratory space that will be attributed to the Company in connection with the separation.

60 Binney Street lease

In September, 2015, bluebird bio entered into a lease agreement, which will be attributed to the Company and is the Company's corporate headquarters, for office and laboratory space located in a building (the "Building") at 60 Binney Street, Cambridge, Massachusetts (the "60 Binney Street Lease"). Under the terms of the 60 Binney Street Lease, starting on October 1, 2016, the Company leases approximately 253,108 square feet of office and laboratory space at $72.50 per square foot per year, or $18.4 million per year in base rent, which is subject to scheduled annual rent increases of 1.75% plus certain operating expenses and taxes. bluebird bio currently maintains a $13.8 million collateralized letter of credit and, subject to the terms of the lease and certain reduction requirements specified therein, including market capitalization requirements, this amount may decrease to $9.2 million over time. As the Company did not have legal ownership over any bank accounts, there were no cash and cash equivalents balances specifically attributable to the Company for the historical periods presented and, accordingly, no restricted cash is reflected in the combined financial statements related to the letter of credit. Pursuant to a work letter entered into in connection with the 60 Binney Street Lease, the landlord contributed an aggregate of $42.4 million toward the cost of construction and tenant improvements for the Building.

The 60 Binney Street Lease term will continue until March 31, 2027. The Company has the option to extend the 60 Binney Street Lease for two successive five-year terms.

Beginning in 2015 through construction completion in 2017, the Company recorded certain construction costs incurred and reported to it by the landlord for the 60 Binney Street Lease as an asset and corresponding construction financing lease obligation because bluebird bio was deemed to be the owner of the building during the construction period for accounting purposes. The Company evaluated the 60 Binney Street Lease upon occupancy on March 27, 2017 and determined that the 60 Binney Street Lease did not meet the criteria for "sale-leaseback" treatment under ASC 840. This determination was based on, among other things, bluebird bio's continuing involvement with the property in the form of non-recourse financing to the lessor. Accordingly, upon occupancy, the Company commenced depreciating the portion of the building in service over a useful life of 40 years and incurred interest expense related to the financing obligation.

In applying the ASC 842 transition guidance, the Company classified this lease as an operating lease and recorded a right-of-use asset and lease liability on the effective date. The Company is recognizing rent expense on a straight-line basis throughout the remaining term of the lease.

Seattle, Washington leases

In July 2018, bluebird bio entered into a lease agreement for office and laboratory space located in a portion of a building in Seattle, Washington, and moved into the facility in June 2019. This lease will be attributed to the Company in connection with the separation. The lease was amended in October 2018 to increase the total rentable space to approximately 36,126 square feet at $54.00 per square foot in base rent per year, which is subject to scheduled annual rent increases of 2.5% plus certain operating expenses and taxes. The lease commenced on January 1, 2019 and the lease term will continue through January 31, 2027. The Company determined the classification of this lease to be an operating lease and recorded a right-of-use asset and lease liability at lease commencement.

In September 2019, bluebird bio entered into a second amendment to the lease (the "Second Amendment"). The Second Amendment added approximately 22,188 square feet to the existing space and extended the lease term of the entire premises by 16 months, or until April 2028. Fixed monthly rent for the expanded space will be incurred at a rate of $62.80 per square foot per year beginning in January 2021, subject to annual increases of 2.5%. The Second Amendment includes a five-year option to extend the term.

Upon the execution of the Second Amendment, which was deemed to be a lease modification, the Company re-evaluated the assumptions made at the original lease commencement date. The Company determined the Second Amendment consists of two separate contracts under ASC 842. One contract is related to a new right-of-use for the expanded 22,188 square feet of space, which is to be accounted for as a new lease, and the other is related to the modification of term for the original 36,126 square feet of space. The Company recorded an additional right-of-use asset and lease liability upon lease commencement of the expanded space. In September 2020, bluebird bio entered into a sublease agreement for the 22,188 square feet added under the Second Amendment at a fixed monthly rent of $62.80 per square foot per year beginning in January 2021, subject to annual increases of 2.5%. The sublease term will continue through April 2028. The Company is recognizing rent expense on a straight-line basis through the remaining extended term of the respective leases. The head lease and the sublease will be accounted for as two separate contracts with the income from the sublease presented separately from the lease expense on the head lease.

Summary of all lease costs recognized under ASC 842

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases for the years ended December 31, 2020 and 2019 (in thousands):

	For the year ended December 31,	
	2020	**2019**
Lease cost [(1)]		
Operating lease cost	$ 22,454	$ 21,406
Total lease cost	$ 22,454	$ 21,406
Other information		
Operating cash flows used for operating leases	$ 19,632	$ 19,521
Weighted average remaining lease term	6.4 years	7.4 years
Weighted average discount rate	6.72 %	6.73 %

(1) Short-term lease costs and variable lease costs incurred by the Company for the twelve months ended December 31, 2020 and 2019 were immaterial.

Rent expense is calculated on a straight-line basis over the term of the lease. Rent expense recognized under all leases, including additional charges for utilities, parking, maintenance, and real estate taxes that are not included within lease costs in the table above, was $32.5 million, $30.6 million, and $9.2 million for the years ended December 31, 2020, 2019 and 2018, respectively. Note that the Company adopted ASC 842 effective January 1, 2019 using the required modified retrospective approach and utilizing the effective date as its date of initial

application. Therefore, amounts pertaining to the year ended December 31, 2018 are presented under previous accounting guidance and are therefore not comparable to the amounts recorded during the years ended December 31, 2020 and 2019 under ASC 842.

As of December 31, 2020, future minimum commitments under ASC 842 under the Company's operating leases were as follows (in thousands):

Maturity of lease liabilities	As of December 31, 2020
2021	$ 23,293
2022	23,712
2023	24,149
2024	24,595
2025	25,039
2026 and thereafter	36,640
Total lease payments	157,428
Less: imputed interest	(29,825)
Total operating lease liabilities	$ 127,603

7. Commitments and contingencies

Lease commitments

bluebird bio leases certain office and laboratory space. Refer to Note 6, *Leases*, for further information on the terms of these lease agreements.

Contingent consideration related to business combinations

On June 30, 2014, bluebird bio acquired Pregenen. All assets and liabilities related to the Pregenen acquisition, including the resulting goodwill and contingent consideration, will be attributed to the Company in connection with the separation. The Company may be required to make up to an additional $120.0 million in remaining future contingent cash payments to the former equityholders of Pregenen upon the achievement of certain clinical and commercial milestones related to the Pregenen technology, of which $20.1 million relates to clinical milestones and $99.9 million relates to commercial milestones. In accordance with accounting guidance for business combinations, contingent consideration liabilities are required to be recognized on the combined balance sheets at fair value. Estimating the fair value of contingent consideration requires the use of significant assumptions primarily relating to probabilities of successful achievement of certain clinical and commercial milestones, the expected timing in which these milestones will be achieved and discount rates. The use of different assumptions could result in materially different estimates of fair value.

Other funding commitments

bluebird bio is party to various agreements, principally relating to licensed technology, certain of which will be attributed to the Company in connection with the separation, that require future payments relating to milestones that may be met in subsequent periods or royalties on future sales of specified products. Additionally, to the extent an agreement relating to licensed technology is not attributed to the Company, bluebird bio may enter into a sublicense with the Company, which may require future milestone and/or royalty payments. These agreements include the collaboration agreements entered into with BMS and Regeneron. Please refer to Note 8, *Collaborative arrangements*, for further information on the BMS and Regeneron agreements.

Based on the Company's development plans as of December 31, 2020, the Company may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. When the achievement of these milestones or sales has not occurred, such contingencies are not recorded in the Company's financial statements. As further discussed in Note 8, *Collaborative arrangements*, BMS assumed responsibility for amounts due to licensors as a result of any future ex-U.S. sales of Abecma and bb21217.

Additionally, bluebird bio is party to various contracts with contract research organizations and contract manufacturers that generally provide for termination on notice, with the exact amounts in the event of termination to be based on the timing of the termination and the terms of the agreement.

bluebird bio has various manufacturing development agreements that will be attributed to the Company to support clinical and commercial product needs. The following table presents non-cancelable contractual obligations arising from these arrangements:

Years ended December 31,	Purchase commitment
2021	$ 5,198
Total purchase commitments	$ 5,198

Litigation

From time to time, bluebird bio has been and the Company expects to be party to various claims and complaints arising in the ordinary course of business, including securities class action litigation. bluebird bio has entered into, and the Company expects to enter into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, bluebird bio indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally bluebird bio's business partners. Pursuant to the separation agreement, the Company expects to indemnify, hold harmless, and agree to reimburse bluebird bio for its indemnification obligations with respect to the Company's business partners, relating to the Company's business or arising out of the Company's activities, in the past or to be conducted in the future. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments bluebird bio or the Company could be required to make under these indemnification agreements is unlimited. Management does not believe that any ultimate liability resulting from any of these claims will have a material adverse effect on its results of operations, financial position, or liquidity. However, management cannot give any assurance regarding the ultimate outcome of any claims, and their resolution could be material to operating results for any particular period.

Following the separation, the Company will indemnify each of its directors and officers for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and by-laws. The term of the indemnification period will last as long as a director or officer may be subject to any proceeding arising out of acts or omissions of such director or officer in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company expects to hold director and officer liability insurance following the separation.

8. Collaborative arrangements

To date, the Company's service and collaborative arrangement revenue has been primarily generated from collaboration arrangements with BMS, formerly Celgene Corporation ("Celgene") prior to its acquisition by BMS in November 2019, and Regeneron, each as further described below. These agreements will be attributed to the Company in connection with the separation.

Bristol-Myers Squibb

BMS Original Collaboration Agreement

In March 2013, bluebird bio entered into a Master Collaboration Agreement (the "BMS Collaboration Agreement") with Celgene (now BMS following its acquisition of Celgene in November 2019) to discover, develop and commercialize potentially disease-altering gene therapies in oncology. The collaboration is focused on applying gene therapy technology to genetically modify a patient's own T cells, known as chimeric antigen receptor, or CAR T cells, to target and destroy cancer cells. Additionally, in March 2013, bluebird bio entered into a Platform Technology Sublicense Agreement (the "Sublicense Agreement") with BMS pursuant to which bluebird bio obtained a sublicense to certain intellectual property from BMS, originating under BMS's license from Baylor College of Medicine, for use in the collaboration.

Under the terms of the BMS Collaboration Agreement, the Company received an up-front, non-refundable, non-creditable payment of $75.0 million. The Company was responsible for conducting discovery, research and development activities through completion of phase 1 clinical studies, if any, during the initial term of the BMS Collaboration Agreement, or three years.

BMS Amended Collaboration Agreement

In June 2015, bluebird bio and BMS amended and restated the BMS Collaboration Agreement (the "Amended BMS Collaboration Agreement"). Under the Amended BMS Collaboration Agreement, the parties narrowed the focus of the collaboration to exclusively work on anti-B-cell maturation antigen ("BCMA") product candidates for a new three-year term. In connection with the Amended BMS Collaboration Agreement, the Company received an up-front, one-time, non-refundable, non-creditable payment of $25.0 million to fund research and development under the collaboration. Under the terms of the Amended BMS Collaboration Agreement, for up to two product candidates selected for development under the collaboration, the Company was responsible for conducting and funding all research and development activities performed up through completion of the initial phase 1 clinical study of such product candidates.

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

BMS Ide-cel License Agreement

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

BMS Ide-cel Co-Development, Co-Promote and Profit Share Agreement

In March 2018, the Company elected to co-develop and co-promote ide-cel within the United States pursuant to the execution of the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement (“Ide-cel CCPS”), which replaced the Ide-cel License Agreement. As a result of executing the Ide-cel CCPS, the responsibilities of the parties remain unchanged from those under the Ide-cel License Agreement, however, the Company will share equally in all profits and losses relating to developing, commercializing and manufacturing ide-cel within the United States and has the right to participate in the development and promotion of ide-cel in the United States. BMS is responsible for the costs incurred to manufacture vector and associated payload for use outside of the United States, plus a markup. As a result of electing to co-develop and co-promote ide-cel within the United States, the milestones and royalties payable under the Ide-cel License Agreement were adjusted. Under the Ide-cel CCPS, the Company was eligible to receive a $10.0 million milestone related to the development of ide-cel in the United States and, for the first indication to be addressed by ide-cel, ex-U.S. regulatory and commercial milestones of up to $60.0 million. Under the Ide-cel CCPS, the $10.0 million development milestone was achieved in the second quarter of 2019 and subsequently paid by BMS.

In May 2020, the First Amendment to the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement (as amended, the "Amended Ide-cel CCPS") was executed, which amended the Ide-cel CCPS. Under the Amended Ide-cel CCPS, the parties will continue to share equally in all profits and losses related to developing, commercializing and manufacturing ide-cel within the United States. Under the Amended Ide-cel CCPS and the Amended bb21217 License Agreement, described further below, BMS was relieved of its obligations to pay the Company for future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217 in exchange for an up-front, non-refundable, non-creditable payment of $200.0 million, which represents the aggregate of the probability-weighted, net present value of the future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217. In connection with these amendments, BMS assumed the contract manufacturing agreements related to ide-cel adherent lentiviral vector. Over time, BMS is assuming responsibility for manufacturing ide-cel suspension lentiviral vector outside of the United States, with the Company responsible for manufacturing ide-cel suspension lentiviral vector in the United States. In addition, under the Amended Ide-cel CCPS and the Amended bb21217 License Agreement, described further below, the parties are released from future exclusivity related to BCMA-directed T cell therapies. There are no remaining milestones or royalties under the Amended Ide-cel CCPS.

Ide-cel is marketed as Abecma in the United States following its approval by the FDA in March 2021 for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Under the Amended Ide-cel CCPS, BMS is primarily responsible for the commercialization of Abecma and the Company has concluded BMS is the principal under ASC 808.

BMS bb21217 License Agreement

In September 2017, BMS exercised its option to obtain an exclusive worldwide license to develop and commercialize bb21217, the second product candidate under the Amended BMS Collaboration Agreement, pursuant to an executed license agreement (“bb21217 License Agreement”) entered into by the parties in September 2017 and paid the Company an option fee of $15.0 million. Pursuant to the bb21217 License Agreement, BMS is responsible for development and related funding of bb21217 after the substantial completion of the ongoing phase 1 clinical trial. In 2019, the parties amended the protocol for the ongoing phase 1 clinical trial to enroll additional patients for which the Company will be reimbursed based upon an agreed-upon amount per patient. Under the bb21217 License Agreement, the Company is eligible to receive U.S. milestones of up to $85.0 million for the first indication to be addressed by bb21217 and royalties for U.S. sales of bb21217. Additionally, the Company was eligible to receive ex-U.S. milestones of up to $55.0 million and royalties for ex-U.S. sales of bb21217.

In May 2020, the Second Amended and Restated License Agreement ("Amended bb21217 License Agreement") was executed, which replaced the bb21217 License Agreement. Under the Amended bb21217 License Agreement, over time, BMS is assuming responsibility for manufacturing suspension lentiviral vector outside of the

United States, with the Company responsible for manufacturing suspension lentiviral vector in the United States. Under the Amended bb21217 License Agreement, expenses incurred by the Company associated with these activities are fully reimbursable by BMS at cost plus a mark-up. Throughout both development and commercialization, BMS is responsible for the manufacture of drug product. There are no remaining milestones and royalties related to the ex-U.S. development or commercialization of bb21217 following execution of the Amended bb21217 License Agreement.

The Company currently expects it will exercise its option to co-develop and co-promote bb21217 within the United States. The Company's election to co-develop and co-promote bb21217 must be made by the substantial completion of the on-going phase 1 clinical trial of bb21217. If elected, the Company expects the responsibilities of the parties to remain largely unchanged, however, the Company expects it will share equally in all profits and losses relating to developing, commercializing and manufacturing bb21217 within the United States and to have the right to participate in the development and promotion of bb21217 in the United States. Under this scenario, the U.S. milestones and royalties payable under the Amended bb21217 License Agreement would be adjusted and the Company would be eligible to receive a $10.0 million development milestone payment related to the development of bb21217 within the United States. The Company would not be eligible for royalties on U.S. sales of bb21217 under this scenario.

In the event the Company does not exercise its option to co-develop and co-promote bb21217, the Company will receive an additional fee in the amount of $10.0 million. Under this scenario, there would be no change to the U.S. milestones and royalties for U.S. sales of bb21217, as previously described above, for which the Company would be eligible to receive.

Accounting Analysis – Amended Ide-cel CCPS and Amended bb21217 License Agreement

In accordance with the Company's accounting policies related to variable consideration, as further described in Note 2, *Summary of Significant Accounting Policies and Basis of Presentation*, if an arrangement includes variable consideration, including milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price of an arrangement. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

Prior to the May 2020 amendments, the Company had constrained all variable consideration related to the remaining ex-U.S. milestones and royalties for ex-U.S. sales under the Ide-cel CCPS and bb21217 License Agreement. As a result of the May 2020 amendments, the uncertainty associated with the previously constrained variable consideration for future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217 was resolved in exchange for an up-front, non-refundable, non-creditable payment of $200.0 million.

While the Ide-cel CCPS and bb21217 License Agreement were historically accounted for as separate contracts, the May 2020 amendments to each agreement were negotiated as a package with a single commercial objective and, as such, the Amended Ide-cel CCPS and Amended bb21217 License Agreement were combined for accounting purposes and treated as a single arrangement.

At the time of the May 2020 amendments, there was one remaining performance obligation under each of the Ide-cel CCPS and bb21217 License Agreement, neither of which were fully satisfied: a combined performance obligation of the ide-cel license and ide-cel vector manufacturing through development; and a combined performance obligation of the bb21217 license and bb21217 vector manufacturing through development. Subsequent to the May 2020 amendments, the Company concluded the two performance obligations are distinct from each other as BMS can benefit from each license and associated manufacturing services separately and the respective licenses and manufacturing services do not modify one another and are not interdependent. Accordingly, the Company will continue to account for each performance obligation separately.

The Company allocated the $200.0 million up-front payment received in connection with the May 2020 amendments to the remaining performance obligations described above based on the general allocation principles of Topic 606. In applying these principles, the Company considered the $200.0 million up-front payment is representative of previously constrained variable consideration that has been changed and the related uncertainties resolved by the May 2020 amendments. Moreover, the Company considered that a portion of the $200.0 million was specifically attributable to each remaining performance obligation as the amount represents the aggregate of the probability-weighted, net present value of the future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217 and that each respective portion therefore (i) relates specifically to the Company's satisfaction of each of its remaining performance obligations and (ii) is representative of the amount of consideration the Company expects to be entitled to in exchange for satisfying the respective performance obligations. As such, the Company concluded that the portion of the $200.0 million up-front payment specifically attributable to each of ide-cel and bb21217 should be allocated to each respective performance obligation pursuant to the variable consideration allocation exception.

The Amended Ide-cel CCPS and Amended bb21217 License Agreement represent a contract modification to an existing contract under Topic 606 given the May 2020 amendments resulted in a reduction in scope of the Company's responsibilities under each performance obligation described above. Specifically, the May 2020 amendments reduced the scope of the Company's obligation to provide ex-U.S. vector manufacturing services through development for both ide-cel and bb21217 as those activities will transition to BMS over time. In addition, the May 2020 amendments resulted in a change in the overall transaction price under the arrangement. The May 2020 amendments did not include any additional promised goods and services.

The remaining goods and services to be provided in order to fully satisfy each performance obligation described above are not distinct from those previously provided with respect to each performance obligation. Therefore, for each performance obligation, the remaining goods and services are part of a single performance obligation that is partially satisfied at the date of the contract modification. Accordingly, the effect that the contract modification had on the transaction price and the measure of progress toward complete satisfaction of each respective performance obligation has been recognized on a cumulative catch-up basis. The accounting for any previously satisfied performance obligations as of the contract modification date are not affected by the modification.

Ide-cel transaction price

The following tables summarize the total transaction price, the allocation of the total transaction price to the identified performance obligations under the arrangement (including those performance obligations that were completed as of the May 2020 contract modification date), and the amount of the transaction price unsatisfied as of December 31, 2020 (in thousands):

	Ide-cel transaction price as of December 31, 2020
Upfront non-refundable payments received prior to May 2020 contract modification [1]	$ 120,000
Allocated portion of the upfront non-refundable payment received in connection with the Amended Ide-cel CCPS and bb21217 License Agreement [2]	184,029
Estimated variable consideration [3]	83,900
	$ 387,929

(1) Composed of all up-front payments and option fee and milestone payments received under the BMS Collaboration Agreement, Amended BMS Collaboration Agreement, Ide-cel License Agreement, and Ide-cel CCPS. This consideration was allocated to the performance obligations under the Ide-cel CCPS based on a relative stand-alone selling price (“SSP”) basis. The Company estimated the SSP of the ide-cel license after considering potential future cash flows under the license. The Company then discounted these probability-weighted cash flows to their present value. The Company estimated the SSP of each of the ide-cel research and development services and ide-cel manufacturing services to be provided based on the Company’s estimated cost of providing the services plus an applicable profit margin commensurate with observable market data for similar services.

(2) This represents the portion of the $200.0 million up-front payment received under the Amended Ide-cel CCPS and Amended bb21217 License Agreement which was allocated to ide-cel.
(3) Estimated variable consideration represents the estimated reimbursement from BMS for the manufacture of vectors and associated payload through development.

	Allocation of transaction price to performance obligations	Transaction price unsatisfied as of December 31, 2020
Ide-cel research and development services	$ 40,912	$ —
Ide-cel license and manufacturing services	347,017	1,082
	$ 387,929	$ 1,082

Ide-cel research and development services

The Company allocated $40.9 million of the transaction price to the research and development services. The Company satisfied this performance obligation as the research and development services were performed. The Company determined that the period of performance of the research and development services was through projected initial phase 1 clinical study substantial completion, or through May 2018. The research and development performance obligation was satisfied prior to the May 2020 amendments and, as a result, the accounting for this previously satisfied performance obligation was not affected by the modification. The Company recognized no revenue related to ide-cel research and development services for the year ended December 31, 2020. The Company recognized $2.3 million and $5.8 million related to ide-cel research and development services for the year ended December 31, 2019 and 2018, respectively.

Ide-cel license and manufacturing services

The Company allocated $347.0 million of the transaction price to the combined unit of accounting which consists of the license and manufacture of vectors and associated payload for incorporation into ide-cel.

The Company accounts for its vector manufacturing services for development in theUnited States and BMS's U.S. development efforts within the scope of ASC 808 given that both parties are active participants in the activities and both parties are exposed to significant risks and rewards dependent on the commercial success of the activities. The Company recognizes collaboration revenue for its U.S. manufacturing services by analogy to Topic 606. The portion of BMS's U.S. development costs that the Company is responsible for are recognized as a reduction to its collaboration revenues, or, if in excess of such revenues in a given quarter, the excess is recorded as research and development expense.

The Company recognizes revenue associated with the combined performance obligation using the proportional performance method, as the Company will satisfy this performance obligation as the manufacturing services are performed through development. In using this method, the Company estimated its development plan for ide-cel, including expected demand from BMS, and the costs associated with the manufacture of vectors and associated payload for incorporation into ide-cel. On a quarterly basis, the Company determines the proportion of effort incurred as a percentage of total effort it expects to expend. This ratio is applied to the transaction price, which includes variable consideration, allocated to the combined performance obligation consisting of the ide-cel license and manufacturing services. Management has applied significant judgment in the process of developing its budget estimates and any changes to these estimates will be recognized in the period in which they change as a cumulative catch-up.

The following table summarizes the net collaboration revenue recognized or expense incurred for the joint ide-cel development efforts in the United States under ASC 808, including revenue or expense related to the combined

performance obligation for the license and vector manufacturing of ide-cel in the United States for the years ended December 31, 2020, 2019, and 2018 (in thousands):

	For the years ended December 31,		
	2020	2019	2018
ASC 808 ide-cel license and manufacturing revenue - U.S. [1]	$ 108,196	$ —	$ 6,255
ASC 808 ide-cel research and development expense - U.S. [1]	$ 41,599	$ 32,415	$ 8,689

(1) As noted above, the calculation of collaboration revenue or research and development expense to be recognized for joint ide-cel development efforts in the United States is performed on a quarterly basis. The calculation is independent of previous activity, which may result in fluctuations between revenue and expense recognition period over period, depending on the varying extent of effort performed by each party during the period.

Revenue related to the combined unit of accounting for the non-US license and vector manufacturing services is accounted for in accordance with Topic 606. The following table summarizes the revenue recognized related to the combined unit of accounting for the ide-cel ex-U.S. license and vector manufacturing services for the years ended December 31, 2020, 2019, and 2018 (in thousands):

	For the years ended December 31		
	2020	2019	2018
ASC 606 ide-cel license and manufacturing revenue - ex-U.S.	$ 99,053	$ 25,522	$ 35,900

As of December 31, 2020, the aggregate amount of the transaction price allocated to the combined performance obligation, which consists of the ide-cel license and manufacturing services, that is unsatisfied, or partially unsatisfied, is $1.1 million, which the Company expects to recognize as revenue as manufacturing services are provided through the remaining development period. As of December 31, 2020 and 2019, the Company had $0.8 million and $8.5 million, respectively, of deferred revenue associated with the combined performance obligation consisting of the ide-cel license and manufacturing services.

bb21217 transaction price

The following tables summarize the total transaction price, the allocation of the total transaction price to the identified performance obligations under the arrangement (including those performance obligations that were completed as of the May 2020 contract modification date), and the amount of the transaction price unsatisfied as of December 31, 2020 (in thousands):

(in thousands)	bb21217 transaction price as of December 31, 2020
Upfront non-refundable payments received prior to May 2020 contract modification [1]	$ 15,000
Allocated portion of the up-front non-refundable payment received in connection with the Amended Ide-cel CCPS and bb21217 License Agreement [2]	15,971
Estimated variable consideration [3]	1,803
	$ 32,774

(1) Composed of the up-front non-refundable payment received under the bb21217 License Agreement. This consideration was allocated to the performance obligations under the bb21217 License Agreement based on a relative SSP basis. The Company estimated the SSP of the bb21217 license after considering potential future cash flows under the license. The Company then discounted these probability-weighted cash flows to their present value. The Company estimated the SSP of each of the bb21217 research and development services and bb21217 manufacturing services to be provided based on the Company's estimated cost of providing the services plus an applicable profit margin commensurate with observable market data for similar services.

(2) This represents the portion of the $200.0 million up-front payment received under the Amended Ide-cel CCPS and Amended bb21217 License Agreement which was allocated to bb21217.

(3) Estimated variable consideration represents the estimated reimbursement from BMS for the manufacture of vectors and associated payload through development.

	Allocation of transaction price to performance obligations	Transaction price unsatisfied as of December 31, 2020
bb21217 research and development services	$ 5,444	$ —
bb21217 license and manufacturing services	27,330	27,330
	$ 32,774	$ 27,330

All of the remaining development, regulatory, and commercial milestones under the Amended bb21217 License Agreement are related to U.S. development, regulatory and commercialization activities and are fully constrained and are therefore excluded from the transaction price. As part of its evaluation of the constraint, the Company considered numerous factors, including the fact that achievement of the milestones is outside the control of the Company and contingent upon the future success of its clinical trials, the licensee's efforts, or the receipt of regulatory approval. Any consideration related to U.S. sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to BMS and therefore are recognized at the later of when the performance obligation is satisfied, or the related sales occur.

The Company re-evaluates the transaction price, including its estimated variable consideration included in the transaction price and all constrained amounts, each reporting period and as uncertain events are resolved or other changes in circumstances occur.

bb21217 research and development services

The Company satisfied this performance obligation as the research and development services were performed. The Company determined that the period of performance of the research and development services was two years through projected substantial completion of the initial phase 1 clinical study, or through September 2019. The research and development performance obligation was satisfied prior to the May 2020 amendments, and as a result, the accounting for this previously satisfied performance obligation was not affected by the modification. As part of performing its initial obligation to complete a phase 1 trial as originally contemplated, the Company recognized no revenue for the year ended December 31, 2020 and revenue of $2.2 million and $2.9 million for the years ended December 31, 2019 and 2018, respectively.

The agreement to expand the bb21217 phase 1 trial that occurred in 2019 was previously treated as a separate contract for accounting purposes, because the trial expansion was for the addition of a promised good or service that is distinct and the associated consideration reflected the stand-alone selling price of the additional promised good or service. This contract was not affected by the May 2020 amendments and, accordingly, the accounting for this agreement was not impacted by the May 2020 amendments. The transaction price associated with these additional patients consists of variable consideration and is based upon an agreed-upon amount per patient which will be recognized as revenue as the patients are treated. The Company began fulfilling the performance obligation in the fourth quarter of 2019 and it was satisfied in the fourth quarter of 2020. In connection with treating additional patients in the phase 1 trial, the Company recognized revenue of $12.4 million, $0.4 million, and $0.0 million for the years ended December 31, 2020, 2019, and 2018, respectively.

bb21217 license and manufacturing services

The Company will satisfy its performance obligation related to the manufacture of vectors and associated payload for incorporation into bb21217 through development as the bb21217 manufacturing services are performed. As of December 31, 2020, the manufacturing services for bb21217 had not yet commenced. Therefore, no amounts have been recognized for the combined performance obligation in the combined statements of operations and comprehensive loss for the years ended December 31, 2020, 2019, and 2018.

The aggregate amount of the transaction price allocated to the combined performance obligation, which consists of the bb21217 license and manufacturing services, is $27.3 million. The Company does not expect that recognition will begin in the next twelve months and has therefore classified deferred revenue associated with the combined performance obligation as deferred revenue, net of current portion on its combined balance sheet. The Company had $25.8 million and $9.8 million of remaining deferred revenue as of December 31, 2020 and 2019, respectively, associated with the combined performance obligation consisting of the bb21217 license and manufacturing services.

Contract assets and liabilities – ide-cel and bb21217

The Company receives payments from its collaborative partners based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until such time as the Company satisfies its performance obligations under these arrangements. A contract asset is a conditional right to consideration in exchange for goods or services that the Company has transferred to a customer. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

The following table presents changes in the balances of the Company's BMS receivables and contract liabilities during the twelve months ended December 31, 2020 (in thousands):

	Balance at December 31, 2019	Additions	Deductions	Balance at December 31, 2020
Receivables	$ 400	$ 12,400	$ (12,400)	$ 400
Contract liabilities:				
Deferred revenue	$ 18,265	$ 200,000	$ (191,683)	$ 26,582

The change in the receivables balance for the year ended December 31, 2020 is primarily driven by amounts owed to the Company for bb21217 research and development services provided during the period (expanded phase 1 clinical trial), offset by amounts collected from BMS in the period.

The increase in deferred revenue during the year ended December 31, 2020 is primarily driven by the $200.0 million consideration received in connection with the May 2020 amendments, offset by revenue recognized in the year-to-date period related to the combined unit of accounting for ide-cel license and vector manufacturing services. A total of $191.7 million was released from deferred revenue during the year-to-date period, of which $169.2 million is related to a cumulative catch-up adjustment to revenue recorded in connection with the May 2020 contract modification described further above. As of December 31, 2019, the Company had $8.5 million of deferred revenue associated with the combined performance obligation consisting of the ide-cel license and manufacturing services, of which $8.2 million was released during the year ended December 31, 2020.

Regeneron

Regeneron Collaboration Agreement

In August 2018, bluebird bio entered into a Collaboration Agreement (the "Regeneron Collaboration Agreement") with Regeneron pursuant to which the parties will apply their respective technology platforms to the discovery, development, and commercialization of novel immune cell therapies for cancer. In August 2018, following the completion of required regulatory reviews, the Regeneron Collaboration Agreement became effective. As noted above, the agreement will be attributed to the Company in connection with the separation. Under the terms of the agreement, the parties will leverage Regeneron's proprietary platform technologies for the discovery and characterization of fully human antibodies, as well as T cell receptors directed against tumor-specific proteins and peptides and the Company will contribute its field-leading expertise in gene therapy.

In accordance with the Regeneron Collaboration Agreement, the parties jointly selected six initial targets and intend to equally share the costs of research up to the point of submitting an IND application for a potential gene

therapy product directed to a particular target. Additional targets may be selected to add to or replace any of the initial targets during the five-year research collaboration term as agreed to by the parties.

Regeneron will accrue a certain number of option rights exercisable against targets as the parties reach certain milestones under the terms of the agreement. Upon the acceptance of an IND for the first product candidate directed to a target, Regeneron will have the right to exercise an option for co-development/co-commercialization of product candidates directed to such target on a worldwide or applicable opt-in territory basis, with certain exceptions. Where Regeneron chooses to opt-in, the parties will share equally in the costs of development and commercialization, and will share equally in any profits or losses therefrom in applicable opt-in territories. Outside of the applicable opt-in territories, the target becomes a licensed target and Regeneron would be eligible to receive, with respect to any resulting product, milestone payments of up to $130.0 million per product and royalties on net sales outside of the applicable opt-in territories at a rate ranging from the mid-single digits to low-double digits. A target would also become a licensed target in the event Regeneron does not have an option to such target, or Regeneron does not exercise its option with respect to such target.

Either party may terminate a given research program directed to a particular target for convenience, and the other party may elect to continue such research program at its expense, receiving applicable cross-licenses. The terminating party will receive licensed product royalties and milestone payments on the potential applicable gene therapy products. Where the Company terminates a given research program for convenience, and Regeneron elects to continue such research program, the parties will enter into a transitional services agreement. Under certain conditions, following its opt-in, Regeneron may terminate a given collaboration program and the Company may elect to continue the development and commercialization of the applicable potential gene therapy products as licensed products.

Regeneron Share Purchase Agreement

A Share Purchase Agreement (“SPA”) was entered into by bluebird bio and Regeneron in August 2018. In August 2018, on the closing date of the transaction, bluebird bio issued Regeneron 0.4 million shares of bluebird bio’s common stock, subject to certain restrictions, for $238.10 per share, or $100.0 million in the aggregate. The purchase price represents $63.0 million worth of common stock plus a $37.0 million premium, which represents a collaboration research advancement, or credit to be applied to Regeneron’s initial 50 percent funding obligation for collaboration research, after which the collaborators will continue to fund ongoing research equally. The collaboration research advancement only applies to pre-IND research activities and is not refundable or creditable against post-IND research activities for any programs where Regeneron exercises its opt-in rights.

Accounting analysis – Regeneron

At the commencement of the arrangement, two units of accounting were identified, which are the issuance of 0.4 million shares of bluebird bio’s common stock and joint research activities during the five year research collaboration term. The Company determined the total transaction price to be $100.0 million, which comprises $54.5 million attributed to the bluebird bio equity sold to Regeneron and $45.5 million attributed to the joint research activities. In determining the fair value of the bluebird bio common stock at closing, the Company considered the closing price of the bluebird bio common stock on the closing date of the transaction and included a lack of marketability discount because Regeneron received shares subject to certain restrictions.

The Company analyzed the joint research activities to assess whether they fall within the scope of ASC 808, and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the arrangement as outlined above, for the collaboration research performed prior to submission of an IND application for a potential gene therapy product, both parties are deemed to be active participants in the collaboration. Both parties are performing research and development activities and will share equally in these costs through IND. Additionally, Regeneron and the Company are exposed to significant risks and rewards dependent on the commercial success of any product candidates that may result from the collaboration. As such, the collaboration arrangement is deemed to be within the scope of ASC 808.

The $45.5 million attributed to the joint research activities includes the $37.0 million creditable against amounts owed to the Company by Regeneron. The collaboration research advancement will be reduced over time for amounts due to the Company by Regeneron as a result of the parties agreeing to share in the costs of collaboration research equally. The remainder of the amount attributed to the joint research activities will be recognized over the five-year research collaboration term.

Consistent with its collaboration accounting policy, the Company will recognize collaboration revenue or research and development expense related to the joint research activities in future periods depending on the amounts incurred by each party in a given reporting period. That is, if the Company's research costs incurred exceed those research costs incurred by Regeneron in a given quarter, the Company will record collaboration revenue and reduce the original $37.0 million advance by the amount due from Regeneron until such advancement is fully utilized, after which the Company would record an amount due from Regeneron. If Regeneron's research costs incurred exceed those research costs incurred by the Company in a given quarter, the Company will record research and development expense and record a liability for the amount due to Regeneron. As of December 31, 2020 and 2019, the Company has $30.8 million and $38.2 million, respectively, of the amount attributed to the joint research activities remaining to be recognized which is classified as collaboration research advancement, current portion and collaboration research advancement, net of current portion on the combined balance sheet.

The Company recognized $7.4 million and $5.7 million of collaboration revenue from the Regeneron Collaboration Agreement during the years ended December 31, 2020 and 2019, respectively.

9. Royalty and other revenue

Novartis Pharma AG

In April 2017, bluebird bio entered into a worldwide license agreement with Novartis. Under the terms of the agreement, Novartis non-exclusively licensed certain patent rights related to lentiviral vector technology to develop and commercialize CAR T cell therapies for oncology, including Kymriah (formerly known as CTL19), Novartis's anti-CD19 CAR T therapy. The agreement will be attributed to the Company in connection with the separation. At contract inception, financial terms of the agreement included a $7.5 million payment upon execution, $7.5 million of potential future milestone payments associated with regulatory approvals, and $1.1 million of payments for each subsequently licensed product, as well as low single digit royalty payments on net sales of covered products. In August 2017, Novartis received FDA approval for Kymriah and paid the Company $2.5 million as a result of the achievement of a related milestone.

Under Topic 606, the Company identified only one performance obligation, consisting of the license, which was satisfied at contract inception. Accordingly, the nonrefundable license fee of $7.5 million was recognized as revenue upon contract execution in the second quarter of 2017 and a $2.5 million regulatory milestone was recognized as revenue upon milestone achievement, also in the second quarter of 2017, given there were no other unsatisfied performance obligations in the arrangement. Regulatory approvals are not within the Company's control or the licensee's control and are generally not considered probable of being achieved until those approvals are received. As such, these milestones are constrained until such time as regulatory approvals are received. Because the single performance obligation was previously satisfied, all regulatory milestones will be recognized as revenue in full in the period in which the associated milestone is achieved.

The Company began recognizing royalty revenue from sales of Kymriah in the fourth quarter of 2017. As the license was deemed to be the predominant item to which the royalties relate, the Company recognizes royalties from the sales of Kymriah when the related sales occur. For the years ended December 31, 2020, 2019, and 2018, the Company recognized royalty and other revenue of $21.1 million, $8.2 million, and $2.2 million, respectively. For the years ended December 31, 2020, 2019, and 2018, the Company recognized cost of royalty and other revenue of $5.4 million, $3.0 million, and $0.9 million, respectively.

In December 2020, the Company received notice of termination from Novartis for the license agreement described above. This termination is effective in March 2021 and Novartis will no longer be required to pay the Company royalty or other payments on net sales of Kymriah or any future products.

Juno Therapeutics

In May 2020, bluebird bio entered into a non-exclusive license agreement with Juno Therapeutics, Inc. (“Juno”), a wholly-owned subsidiary of BMS, related to lentiviral vector technology to develop and commercialize CD-19-directed CAR T cell therapies. The agreement will be attributed to the Company in connection with the separation. Under the terms of this agreement, the Company may receive regulatory milestones for the first licensed product and a low single-digit royalty based on aggregate net sales.

10. Intangible assets

Intangible assets, net of accumulated amortization, are summarized as follows (in thousands):

	As of December 31, 2020			As of December 31, 2019		
	Cost	Accumulated amortization	Net	Cost	Accumulated amortization	Net
Developed technology	$ 30,100	$ (24,456)	$ 5,644	$ 30,100	$ (20,694)	$ 9,406
Total	$ 30,100	$ (24,456)	$ 5,644	$ 30,100	$ (20,694)	$ 9,406

Amortization expense for intangible assets was $3.8 million for each of the years ended December 31, 2020, 2019 and 2018.

Developed technology

The Company's developed technology was obtained through the acquisition of Pregenen, a privately-held biotechnology company in 2014. The Company obtained gene editing and cell signaling technology with a broad range of potential therapeutic applications. The Company considered the intangible asset acquired to be developed technology, as at the date of the acquisition it could be used the way it was intended to be used in certain ongoing research and development activities. The gene editing platform intangible asset is being amortized on a straight-line basis over its expected useful life of approximately eight years from the date of the acquisition.

The following table summarizes the estimated future amortization for intangible assets for the next five years and thereafter (in thousands):

	As of December 31, 2020
2021	$ 3,763
2022	1,881
Total	$ 5,644

11. Stock-based compensation

In June 2013, bluebird bio’s board of directors adopted its 2013 Stock Option and Incentive Plan (“2013 Plan”), which was subsequently approved by its stockholders and became effective upon the closing of bluebird bio’s IPO. The 2013 Plan replaces the 2010 Stock Option and Grant Plan (“2010 Plan”).

The 2013 Plan allows for the granting of incentive stock options, non-qualified stock options, restricted stock units and restricted stock awards to bluebird bio’s employees, members of the board of directors, and consultants of bluebird bio, including those of bluebird bio who will become employees of the Company in connection with the

separation. All awards granted under bluebird bio's plans consist of shares of bluebird bio's common stock. Accordingly, the amounts presented are not necessarily indicative of future stock-based compensation and do not necessarily reflect the amounts that the Company would have recorded as an independent, publicly traded company for the periods presented.

In June 2013, bluebird bio's board of directors adopted its 2013 Employee Stock Purchase Plan ("2013 ESPP"), which was subsequently approved by its stockholders and became effective upon the closing of bluebird bio's IPO. The 2013 ESPP authorizes the initial issuance of a specified number of shares of bluebird bio's common stock to participating employees.

Stock-based compensation expense

Stock-based compensation expense was allocated to the Company using a combination of specific identification and time spent on projects at various levels of the organization, which management believes are consistent and reasonable.

Stock-based compensation expense under bluebird bio's stock option and incentive plans allocated to the Company by classification included within the combined statements of operations and comprehensive loss was as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 30,935	$ 33,853	$ 21,846
Selling, general and administrative	30,062	28,196	18,955
	$ 60,997	$ 62,049	$ 40,801

12. Related-party transactions

Historically, the Company has been managed and operated in the normal course of business under bluebird bio. Accordingly, certain shared costs have been allocated to the Company and reflected as expenses in the Company's stand-alone combined financial statements. The expenses reflected in the combined financial statements may not be indicative of expenses that will be incurred by the Company in the future.

Corporate allocations

The combined financial statements reflect allocations of certain expenses from bluebird bio, including, but not limited to, general corporate expenses, such as senior management, legal, human resources, accounting, other financial services (such as treasury, audit and purchasing), tax, information technology, and corporate employee benefits, incentives and stock-based compensation included within selling, general and administrative expense.

These expenses have been allocated to the Company based on direct usage or benefit where specifically identifiable, with the remainder allocated based on employee time spent on projects, square footage or other measures that management believes are consistent and reasonable. Allocations for management costs and corporate support services provided to the Company totaled $76.6 million, $67.8 million and $44.0 million for the years ended December 31, 2020, 2019 and 2018, respectively.

The financial information in these combined financial statements does not necessarily include all the expenses that would have been incurred by the Company had it been a separate, stand-alone entity. Actual costs that may have been incurred if the Company had been a stand-alone company would depend on a number of factors, including the chosen organization structure and functions outsourced or performed by employees. See Note 2, *Summary of significant accounting policies and basis of presentation*, for additional information on the preparation and basis of presentation of these combined financial statements, including the treatment of certain research and development costs not directly attributable to individual programs.

Usage of the Company's assets by bluebird bio and of bluebird bio's assets by the Company

Certain assets have been reflected in these combined financial statements as the underlying assets will be attributed to the Company; however, bluebird bio has historically utilized a portion of the underlying asset as part of its operations. Accordingly, the expense related to the underlying asset has been reflected in the combined financial statements. The Company has also recorded an imputed charge to bluebird bio to reflect the cost of bluebird bio's proportional usage. In addition, the Company has recorded as an expense an imputed charge to reflect the cost of the Company's proportional usage of certain underlying assets not reflected in the combined financial statements but for which the Company has historically utilized a portion of the underlying asset as part of its operations. The income and expense recognized by the Company resulting from these imputed charges is recorded as other income, net in the combined financial statements and was as follows:

	Year ended December 31,		
	2020	2019	2018
Imputed charge to bluebird bio for leases	$ 16,562	$ 17,694	$ 15,139
Imputed charge from bluebird bio for leases	(1,072)	(696)	—
Imputed charge to bluebird bio for property, plant and equipment	2,225	3,385	4,274
Imputed charge from bluebird bio for property, plant and equipment	(229)	(99)	(59)
Imputed charge to bluebird bio for intangible assets	199	65	204
Other	155	(116)	(228)
	$ 17,840	$ 20,233	$ 19,330

Other components of other income, net, that are not shown in the table above include immaterial gains and losses on disposals of fixed assets.

Stock-based compensation

As discussed in Note 11, *Stock-based compensation*, 2seventy bio’s employees participate in bluebird bio's stock-based compensation plans, the costs of which have been allocated to 2seventy bio and recorded in research and development and selling, general and administrative expenses in the combined statements of operations and comprehensive loss.

Retirement plans

As discussed in Note 13, *401(k) Savings plan*, 2seventy bio’s employees participate in bluebird bio's 401(k) Savings plan, the costs of which have been allocated to 2seventy bio and recorded in research and development and selling, general and administrative expenses in the combined statements of operations and comprehensive loss.

Transaction costs

As of December 31, 2020, bluebird bio had incurred an immaterial amount of costs related to the separation of the Company. To the extent separation costs are incurred that will directly benefit the Company as a stand-alone company, such costs will be allocated to the Company.

Centralized cash management

No separate cash accounts for 2seventy bio were historically maintained and, therefore, bluebird bio is presumed to have funded 2seventy bio’s operating, investing and financing activities as necessary. As cash is disbursed and received by bluebird bio, for purposes of the combined financial statements, funding of 2seventy bio’s expenditures is reflected in the combined financial statements as a component of net parent investment.

13. 401(k) Savings plan

In 1997, bluebird bio established a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code ("the 401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements, including those who will become employees of the Company, and allows participants to defer a portion of their annual compensation on a pretax basis. Expense related to the 401(k) Plan allocated to the Company totaled $2.2 million, $2.0 million, $0.9 million for the years ended December 31, 2020, 2019, and 2018, respectively.

14. Income taxes

The components of loss before income taxes were as follows (in thousands):

	Year ended December 31,		
	2020	2019	2018
U.S.	(120,114)	(320,594)	(199,749)
Foreign	—	—	—
Total	$ (120,114)	$ (320,594)	$ (199,749)

For the years ended December 31, 2020, 2019 and 2018, the Company did not recognize any income tax expense (benefit) as the Company was subject to a full valuation allowance. A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to the Company's effective income tax rate as reflected in the financial statements is as follows:

	Year ended December 31,		
	2020	2019	2018
Federal income tax expense at statutory rate	21.0 %	21.0 %	21.0 %
State income tax, net of federal benefit	3.8 %	5.5 %	6.5 %
Permanent differences	0.3 %	(0.1)%	(0.2)%
Stock-based compensation	(4.1)%	(0.5)%	2.1 %
Research and development credit	13.8 %	5.6 %	9.6 %
Officer compensation limitation	(1.6)%	(0.7)%	(0.2)%
Uncertain tax positions	(1.1)%	(0.4)%	(0.8)%
Other	— %	(0.2)%	— %
Change in valuation allowance	(32.1)%	(30.2)%	(38.0)%
Effective income tax rate (expense) benefit	— %	— %	— %

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities are composed of the following (in thousands):

	Year ended December 31,	
	2020	2019
Deferred tax assets:		
U.S. net operating loss carryforwards (federal and state)	$ 149,570	$ 122,303
Tax credit carryforwards (federal and state)	49,379	34,152
Capitalized license fees and research and development expenses	13,091	14,744
Deferred revenue	15,348	15,233
Stock-based compensation	21,400	18,786
Lease liabilities	34,119	36,499
Accruals and other	2,715	6,112
Total deferred tax assets	285,622	247,829
Intangible assets	(1,509)	(2,537)
Right-of-use assets	(31,139)	(33,776)
Fixed assets	(5,477)	(2,598)
Less: valuation allowance	(247,497)	(208,918)
Net deferred taxes	$ —	$ —

A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets. The valuation allowance increased on a net basis by approximately $38.6 million during the year ended December 31, 2020 due primarily to net operating losses, tax credit carryforwards, and stock-based compensation. Effective January 1, 2019, the Company adopted ASU 2016-02, which resulted in the de-recognition of the 60 Binney Street lease and related fixed assets and the recognition of lease liabilities and right-of-use assets. The Company adjusted its deferred tax balances as a result of the adoption.

As of December 31, 2020, 2019 and 2018, the Company had U.S. federal net operating loss carryforwards of approximately $559.6 million, $453.9 million, and $171.1 million, respectively, which may be available to offset future income tax liabilities and which will carryforward indefinitely. As of December 31, 2020, 2019 and 2018, the Company also had U.S. state net operating loss carryforwards of approximately $507.2 million, $427.1 million, and $161.4 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2040.

As of December 31, 2020, 2019 and 2018, the Company had federal research and development and orphan drug tax credit carryforwards of approximately $43.6 million, $29.8 million, and $15.0 million, respectively, available to reduce future tax liabilities which expire at various dates through 2040. As of December 31, 2020, 2019 and 2018, the Company had state research and development credit carryforwards of approximately $6.7 million, $5.0 million, and $3.1 million, respectively, available to reduce future tax liabilities which expire at various dates through 2035. The Company also has Massachusetts investment tax credit carryforwards of approximately $0.6 million, $0.5 million and $0.3 million available to reduce future tax liabilities which expire at various dates through 2023. An analysis of the U.S. research and development and orphan drug credits has not yet been completed for 2018, 2019, or 2020.

Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), and corresponding provisions of state law, due to ownership changes that have occurred

previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percent over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company did not operate as a stand-alone entity (or group of entities) in the past and, accordingly, the amount and composition of its tax losses, credits, and other deferred tax assets included in the combined financial statements may change as the result of the Company's separation from bluebird bio.

In March 2020, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was enacted. This law temporarily suspends and adjusts certain law changes enacted in the Tax Cuts and Jobs Act in 2017. In December 2020, the Consolidated Appropriations Act was enacted. This law modified the employee retention credit under the CARES Act and created credit extenders for certain credits. The Company has concluded that the provisions in the CARES Act and Consolidated Appropriations Act have an immaterial impact on the Company's income tax expense due to its cumulative losses and full valuation allowance position.

bluebird bio files Federal and state income tax returns in the United States, which includes the Company's operations. The Federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2017 through December 31, 2019. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, or state or foreign tax authorities to the extent utilized in a future period.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Unrecognized tax benefits
Balance as of December 31, 2018	$ 1,624
Increases (decreases) for tax positions related to current period	1,446
Increases (decreases) for tax positions related to prior periods	—
Balance as of December 31, 2019	3,070
Increases (decreases) for tax positions related to current period	1,333
Increases (decreases) for tax positions related to prior periods	—
Balance as of December 31, 2020	$ 4,403

The unrecognized tax benefits at December 31, 2020, if recognized, would not affect the Company's effective tax rate due to its full valuation allowance position. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. The Company has elected to include interest and penalties related to uncertain tax positions as a component of its provision for income taxes. For the years ended December 31, 2020, 2019 and 2018, the Company's accrued interest and penalties related to uncertain tax positions were not material.

15. Subsequent events

The Company has assessed subsequent events through May 11, 2021, the date the financial statements were available to be issued. No material events subsequent to December 31, 2020 were noted for disclosure.