UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

☒

For the quarterly period ended September 30, 2021

OR

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

☐

For the transition period from _____ to _____

Commission file number 001-40791

2seventy bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**86-3658454**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

2seventy bio, Inc.
60 Binney Street
Suite 200
Cambridge, MA 2142
(339) 499-9300
Registrant's telephone number, including area code

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

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

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

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

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

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

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

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

The registrant had outstanding 23,369,088 shares of common stock as of November 26, 2021.

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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:

- our business and operations 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 entered into with bluebird bio in connection with the separation and distribution; 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.

Summary of Risk Factors

Below is a summary of the material risks to our business, operations and the investment in our common stock. This summary does not address all of the risks that we face. Risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q in its entirety before making investment decisions regarding our common stock.

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.

PART I. FINANCIAL INFORMATION

Item 1. Financial Information

2seventy bio, Inc.

Condensed Combined Balance Sheets
(unaudited)
(in thousands)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Prepaid expenses	$ 8,460	$ 14,413
Receivables	16,135	10,691
Total current assets	24,595	25,104
Property, plant and equipment, net	33,752	144,025
Intangible assets, net	11,009	5,644
Goodwill	12,056	13,128
Operating lease right-of-use assets	105,310	116,456
Other non-current assets	6,237	8,263
Total assets	$ 192,959	$ 312,620
Liabilities and Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 6,197	$ 7,152
Accrued expenses and other current liabilities	76,273	43,347
Operating lease liability, current portion	14,480	15,313
Deferred revenue, current portion	—	820
Collaboration research advancement, current portion	9,130	9,236
Total current liabilities	106,080	75,868
Deferred revenue, net of current portion	25,762	25,762
Collaboration research advancement, net of current portion	16,767	21,581
Operating lease liability, net of current portion	99,819	112,290
Other non-current liabilities	2,938	2,490
Total liabilities	251,366	237,991
Commitments and contingencies (*Note 7)*		
Equity (deficit):		
Net parent investment	(58,407)	74,629
Total equity (deficit)	(58,407)	74,629
Total liabilities and equity (deficit)	$ 192,959	$ 312,620

See accompanying notes to unaudited condensed combined financial statements.

2seventy bio, Inc.

Condensed Combined Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Service revenue	$ 6,312	$ 12,513	$ 17,544	$ 106,733
Collaborative arrangement revenue	12,337	2,422	15,527	114,398
Royalty and other revenue	608	3,499	5,417	17,086
Total revenues	19,257	18,434	38,488	238,217
Operating expenses:				
Research and development	61,131	72,253	202,394	227,585
Selling, general and administrative	22,996	22,105	69,025	68,951
Share of collaboration loss	—	—	10,071	—
Cost of royalty and other revenue	320	1,318	2,111	3,897
Change in fair value of contingent consideration	48	(828)	464	(5,591)
Total operating expenses	84,495	94,848	284,065	294,842
Loss from operations	(65,238)	(76,414)	(245,577)	(56,625)
Other income, net	5,237	4,339	14,340	13,312
Loss before income taxes	(60,001)	(72,075)	(231,237)	(43,313)
Income tax (expense) benefit	—	—	—	—
Net loss and comprehensive loss	$ (60,001)	$ (72,075)	$ (231,237)	$ (43,313)

See accompanying notes to unaudited condensed combined financial statements.

2seventy bio, Inc.

Condensed Combined Statements of Equity (Deficit)
(unaudited)
(in thousands)

	Net parent investment
Balances at December 31, 2020	$ 74,629
Stock-based compensation	17,109
Transfers from bluebird bio	71,101
Net loss	(87,196)
Balances at March 31, 2021	75,643
Stock-based compensation	11,967
Transfers from bluebird bio	45,119
Net loss	(84,040)
Balances at June 30, 2021	48,689
Stock-based compensation	11,230
Transfers to bluebird bio	(58,325)
Net loss	(60,001)
Balances at September 30, 2021	$ (58,407)

	Net parent investment
Balances at December 31, 2019	$ 43,692
Stock-based compensation	14,359
Transfers from bluebird bio	88,018
Net loss	(74,424)
Balances at March 31, 2020	71,645
Stock-based compensation	18,944
Transfers to bluebird bio	(125,378)
Net income	103,186
Balances at June 30, 2020	68,397
Stock-based compensation	15,255
Transfers from bluebird bio	66,584
Net loss	(72,075)
Balances at September 30, 2020	$ 78,161

See accompanying notes to unaudited condensed combined financial statements.

2seventy bio, Inc.

Condensed Combined Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (231,237)	$ (43,313)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Change in fair value of contingent consideration	464	(5,591)
Depreciation and amortization	12,815	9,869
Stock-based compensation expense	40,306	48,558
Other non-cash items	247	76
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	3,036	(3,074)
Operating lease right-of-use assets	11,146	10,186
Accounts payable	607	(11,355)
Accrued expenses and other liabilities	32,066	(12,160)
Operating lease liabilities	(13,305)	(9,516)
Deferred revenue	(820)	8,558
Collaboration research advancement	(4,920)	(6,202)
Net cash used in operating activities	(149,595)	(13,964)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(10,600)	(15,260)
Purchase of intangible assets	(8,000)	—
Net cash used in investing activities	(18,600)	(15,260)
Cash flows from financing activities:		
Transfers from bluebird bio	168,195	29,224
Net cash provided by financing activities	168,195	29,224
Increase (decrease) in cash, cash equivalents and restricted cash	—	—
Cash, cash equivalents and restricted cash at beginning of period	—	—
Cash, cash equivalents and restricted cash at end of period	$ —	$ —
Supplemental cash flow disclosures:		
Purchases of property, plant and equipment included in accounts payable and accrued expenses	$ 321	$ 1,590
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 4,484
Non-cash return of bRT-related assets to bluebird bio	$ 110,300	$ —
Cash paid during the period for interest	$ —	$ —
Cash paid during the period for income taxes	$ —	$ —

See accompanying notes to unaudited condensed combined financial statements.

2seventy bio, Inc.

Notes to Condensed Combined Financial Statements
(unaudited)

1. Description of the business

2seventy bio, Inc. (the "Company" or "2seventy bio") was incorporated in Delaware on April 26, 2021 and is headquartered in Cambridge, Massachusetts. The Company is a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. It is led by a team with significant expertise and experience in this field, from discovery through clinical development to regulatory approval of idecabtagene vicleucel (ide-cel, marketed as ABECMA®), the first FDA-approved chimeric antigen receptor technology (CAR T) cell therapy for multiple myeloma. 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 innovative, targeted cellular therapies for patients with cancer. The Company is advancing multiple preclinical and clinical programs in oncology and, together with its partner Bristol-Myers Squibb (BMS), delivering ide-cel to multiple myeloma patients in the United States following approval by the FDA of ide-cel in March 2021 for the treatment of adults with multiple myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody. For further discussion of the Company's collaboration with BMS, please refer to Note 8, *Collaborative arrangements and strategic partnerships.*

The separation from bluebird bio, Inc.

In January 2021, bluebird bio, Inc. ("bluebird bio") announced its plans to separate its oncology portfolio and programs from its severe genetic disease portfolio and programs, and spin off its oncology portfolio and programs into a separate publicly traded company. In furtherance of this plan, on September 30, 2021, bluebird bio's board of directors approved the distribution of all of the issued and outstanding shares of 2seventy bio common stock on the basis of one share of 2seventy bio common stock for every three shares of bluebird bio common stock issued and outstanding on October 19, 2021, the record date for the distribution. As a result of the distribution, which occurred on November 4, 2021, 2seventy bio became an independent, publicly traded company.

On November 3, 2021, the Company also entered into a separation agreement with bluebird bio, which is referred to in this quarterly report as the separation agreement, as well as various other agreements with bluebird bio, including a tax matters agreement, an employee matters agreement, an intellectual property license agreement, a transition services agreement under which 2seventy bio temporarily receives certain services from bluebird bio, and a second transition services agreement under which 2seventy bio temporarily provides certain services to bluebird bio. These agreements also govern certain of 2seventy bio's relationships with bluebird bio after the separation. For additional information regarding the separation agreement and the other related agreements, see "Risk Factors—Risks Related to the Separation" and "Transactions with Related and Certain Other Parties."

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 condensed combined financial statements are issued. The Company has incurred losses and has experienced negative operating cash flows for all historical periods presented. During the nine months ended September 30, 2021, the Company incurred a loss of $231.2 million and used $149.6 million of cash in operations. The Company expects to continue to generate operating losses and negative operating cash flows for the next few years.

As further described in Note 13, *Subsequent events*, upon the Company's separation from bluebird bio on November 4, 2021, bluebird bio made a cash contribution to the Company of approximately $441.5 million, a portion of which is considered restricted, which alleviated the conditions that previously raised substantial doubt

about the Company's ability to continue as a going concern. Accordingly, as of the date of issuance of these condensed combined financial statements, the Company expects its cash, cash equivalents, and marketable securities will be sufficient to fund current planned operations for at least the next twelve months. The Company previously concluded that there was substantial doubt about its ability to continue as a going concern in prior periods due to the Company's need to obtain additional funding.

The Company intends to pursue additional cash resources through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. There can be no assurance that such financing will be available in sufficient amounts or on acceptable terms, if at all, and some could be dilutive to existing stockholders. 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.

2. Summary of significant accounting policies and basis of presentation

Basis of presentation

Because the previously described distribution occurred subsequent to September 30, 2021, the accompanying condensed 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 condensed combined financial statements reflect the historical results of 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"). Certain information and footnote disclosures included in the Company's annual financial statements have been condensed or omitted. These condensed combined financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended September 30, 2021 and 2020.

The historical results of operations, financial position and cash flows of 2seventy bio presented in these condensed 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.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These condensed combined financial statements should be read in conjunction with the audited combined financial statements as of and for the year ended December 31, 2020 and the notes thereto, which are included in Exhibit 99.1 to the Company's Form 10, which was most recently filed with the Securities and Exchange Commission on October 8, 2021.

As part of bluebird bio, the Company was dependent upon bluebird bio for all of its working capital and financing requirements, as bluebird bio used a centralized approach to cash management and financing its operations. There were no cash amounts specifically attributable to the Company for the historical periods presented; therefore, cash and cash equivalents have not been allocated to the Company in the condensed combined financial statements. Financing transactions related to bluebird bio are accounted for as a component of net parent investment in the condensed combined balance sheets and as a financing activity on the accompanying condensed combined statements of cash flows.

The Company's condensed 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 condensed 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 11, *Related-party transactions*, for a further description of the accounting for the separation from bluebird bio.

The condensed 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 condensed 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 condensed combined financial statements. Transactions with bluebird bio are reflected in the accompanying condensed combined statements of equity (deficit) as net transfers from (to) parent and in the accompanying condensed 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 and consolidation

The accompanying condensed 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 condensed 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 condensed 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.

Significant accounting policies

The significant accounting policies used in preparation of these condensed combined financial statements for the three and nine months ended September 30, 2021 and 2020 are consistent with those discussed in Note 2 to the combined financial statements for the year ended December 31, 2020 included in Exhibit 99.1 to the Company's Form 10, except as noted immediately below and as noted within the "*Recent accounting pronouncements - Recently adopted*" section.

Collaborative arrangement revenue

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("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 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.

In arrangements where the Company does not deem its collaborator to be its customer, payments to and from its collaborator are presented in the condensed combined statements of operations and comprehensive loss based on the nature of the payments, as summarized in the table and further described below.

Nature of Payment	Statement of Operations Presentation
The Company's share of profits in connection with commercialization of products	Collaborative arrangement revenue
The Company's share of losses in connection with commercialization of products	Share of collaboration loss
Net reimbursement of the Company's research and development expenses	Collaborative arrangement revenue
Net reimbursement of the collaborator's research and development expenses	Research and development expense

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

Recent accounting pronouncements

Recently 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 was effective beginning January 1, 2021. The adoption of ASU 2019-12 did not 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 early adopted the new standard, effective January 1, 2021. The adoption of ASU 2020-06 did not 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 was effective beginning January 1, 2021. The adoption of ASU 2020-08 did not 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 was effective beginning January 1, 2021. The adoption of ASU 2020-10 did not 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 September 30, 2021 and December 31, 2020 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2021				
Liabilities:				
Contingent consideration	$ 1,973	$ —	$ —	$ 1,973
Total liabilities	$ 1,973	$ —	$ —	$ 1,973
December 31, 2020				
Liabilities:				
Contingent consideration	$ 1,509	$ —	$ —	$ 1,509
Total liabilities	$ 1,509	$ —	$ —	$ 1,509

As of September 30, 2021 and December 31, 2020, 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 certain commercial 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 condensed 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 condensed 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):

	Nine Months Ended September 30,	
	2021	2020
Beginning balance	$ 1,509	$ 7,977
Additions	—	—
Changes in fair value	464	(5,591)
Payments	—	—
Ending balance	$ 1,973	$ 2,386

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 September 30, 2021	As of December 31, 2020
Land	$ —	$ 1,210
Building	—	15,745
Computer equipment and software	5,252	6,503
Office equipment	6,080	6,588
Laboratory equipment	30,818	24,080
Leasehold improvements	28,479	28,305
Construction-in-progress	799	91,631
Total property, plant and equipment	71,428	174,062
Less accumulated depreciation and amortization	(37,676)	(30,037)
Property, plant and equipment, net	$ 33,752	$ 144,025

Depreciation and amortization expense related to property, plant and equipment was $3.5 million and $2.4 million for the three months ended September 30, 2021 and 2020, respectively. Depreciation and amortization expense related to property, plant and equipment was $9.7 million and $7.0 million for the nine months ended September 30, 2021 and 2020, 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 was primarily dedicated to the Company's operations and, accordingly, prior to the sale of the facility as described below, was to be attributed to the Company in connection with the separation. Construction-in-progress as of December 31, 2020 includes $91.1 million related to the North Carolina manufacturing facility.

In July 2021, bluebird bio and National Resilience, Inc. ("Resilience") announced a strategic manufacturing collaboration aimed to accelerate the early research, development, and delivery of cell therapies. Agreements related to the collaboration were executed in September 2021. As part of the agreement, Resilience acquired bluebird bio's manufacturing facility in Durham and retained all staff employed at the site. As a result of the transaction, bluebird bio disposed of $111.2 million of net assets, primarily consisting of the building and laboratory equipment. In connection with the separation, the manufacturing facility was expected to be assigned to 2seventy bio and, accordingly, the manufacturing facility was included within the 2seventy bio carve-out financial statements in prior periods. The disposition of the net assets of the manufacturing facility previously assigned to 2seventy bio has been reflected as a transfer to bluebird bio via net parent investment as a result of bluebird bio’s sale of such facility. Please refer to Note 8, *Collaborative arrangements and strategic partnerships*, for further discussion.

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	As of September 30, 2021	As of December 31, 2020
Employee compensation	$ 28,465	$ 9,451
Collaboration research costs	27,553	19,605
Manufacturing costs	5,676	6,808
Clinical and contract research organization costs	2,497	2,854
Property, plant, and equipment	618	440
License and milestone fees	236	278
Other	11,228	3,911
Total accrued expenses and other current liabilities	$ 76,273	$ 43,347

6. Leases

The leases for certain office and laboratory space to which bluebird bio was a party were assigned to the Company in connection with the separation, and, therefore, are included in these condensed combined financial statements. Except as described below, there have been no material changes to the lease obligations from those disclosed in Note 6, *Leases*, to the annual combined financial statements included in Exhibit 99.1 to the Company's Form 10.

60 Binney Street lease

In October 2021, bluebird bio entered into a consent to assignment and amendment to its lease agreement for its 60 Binney Street lease, pursuant to which bluebird bio's interest in the lease was assigned to 2seventy bio. In November 2021, 2seventy bio executed a $25.0 million letter of credit related to this lease.

Seattle, Washington leases

In October 2021, bluebird bio entered into a consent to assignment and amendment to its lease agreement for office and laboratory space in Seattle, Washington and the related sublease that was executed in September 2020 for a portion of the space. The agreement reassigns bluebird bio's interest in the lease and the sublease to 2seventy bio. As part of the assignment, the sublease agreement associated with the expanded space was also assigned to 2seventy bio. In November 2021, 2seventy bio executed a $5.0 million letter of credit related to this lease.

7. Commitments and contingencies

Contingent consideration related to business combinations

On June 30, 2014, bluebird bio acquired Pregenen. All assets, liabilities and future obligations related to the Pregenen acquisition, including the resulting goodwill and contingent consideration, were assumed by the Company in connection with the separation. As of September 30, 2021, the Company may be required to make up to $99.9 million in contingent cash payments to the former equity holders of Pregenen upon the achievement of certain commercial milestones related to the Pregenen technology. In accordance with accounting guidance for business combinations, contingent consideration liabilities are required to be recognized on the condensed 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

Certain agreements that were assigned by bluebird bio to the Company in connection with the separation relate principally to licensed technology and may require future payments relating to milestones that may be met in subsequent periods or royalties on future sales of specified products. These agreements include the collaboration agreements entered into with BMS and Regeneron Pharmaceuticals, Inc. ("Regeneron") and the agreements entered into with Resilience, all of which were assigned to the Company in connection with the separation. Additionally, to the extent an agreement relating to licensed technology was not assigned to the Company, bluebird bio entered into a sublicense with the Company, which may require the Company to make future milestone and/or royalty payments. Please refer to Note 8, *Collaborative arrangements and strategic partnerships*, for further information on the BMS, Regeneron and Resilience agreements and to Note 9, *Royalty and other revenue*, for further information on license agreements.

Based on the Company's development plans as of September 30, 2021, 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 and strategic partnerships*, BMS assumed responsibility for amounts due to licensors as a result of any future ex-U.S. sales of ABECMA® and bb21217.

Concurrent with the sale of the manufacturing facility in Durham, North Carolina, bluebird bio also entered into a commercial supply agreement and a development manufacturing supply agreement with Resilience. Certain rights and obligations under the asset purchase agreement and certain of the ancillary agreements, including these two manufacturing agreements, among others, were assigned by bluebird bio to 2seventy bio on November 4, 2021 upon the separation of 2seventy bio from bluebird bio. The assignments under the asset purchase agreement and the development manufacturing supply agreement commit the Company to reimburse Resilience for an amount equal to 50% of the net operating losses of and relating to the manufacturing facility’s business incurred during the twelve-month period ending on the first anniversary of the closing of the transaction, as calculated in accordance with the asset purchase agreement, subject to a cap of $15.0 million. In exchange, under the terms of the development manufacturing supply agreement, the Company will receive up to eight batches of lentiviral vector during the twelve-month period ending on the first anniversary of the closing of the transaction. The Company has therefore committed to a minimum purchase of at least the Company's 50% share of the net operating losses during the twelve-month period ending on the first anniversary of the closing of the transaction. Please refer to Note 8, *Collaborative arrangements and strategic partnerships*, for further discussion.

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. There have been no material changes in future minimum purchase commitments from those disclosed in Note 7, *Commitments and Contingencies*, to the annual combined financial statements included in Exhibit 99.1 to the Company’s Form 10.

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 indemnifies, holds harmless, and agrees to reimburse bluebird bio for its indemnification obligations with respect to the Company’s business partners, relating to the Company’s business or

arising out of the Company's activities, in the past or to be conducted in the future. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments 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 such claims or indemnification agreements will have a material adverse effect on its results of operations, financial position, or liquidity. However, management cannot give any assurance regarding the ultimate outcome of any claims, and their resolution could be material to operating results for any particular period.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and by-laws and indemnification agreements entered into with each of its directors and officers. The term of the indemnification period will last as long as a director or officer may be subject to any proceeding arising out of acts or omissions of such director or officer in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company holds director and officer liability insurance.

8. Collaborative arrangements and strategic partnerships

To date, the Company's service and collaborative arrangement revenue has been primarily generated from collaboration arrangements with BMS and Regeneron, each as further described below. These agreements were assumed by the Company in connection with the separation.

Bristol-Myers Squibb

BMS Original Collaboration Agreement

In March 2013, bluebird bio entered into a collaboration agreement with BMS. The details of the collaboration agreements and the payments the Company has received, and is entitled to receive, are further described in Note 8, *Collaborative arrangements*, to the annual combined financial statements included in Exhibit 99.1 to the Company's Form 10. During the third quarter of 2021, there have been no changes to the terms of the collaboration agreement with BMS.

Ide-cel

Under the collaboration agreement with BMS, the Company shares equally in the profit and loss related to the development and commercialization of ide-cel in the United States. The Company has no remaining financial rights with respect to the development or commercialization of ide-cel outside of the United States. The Company accounts for its collaborative arrangement efforts with BMS in the United States within the scope of ASC 808 given that both parties are active participants in the activities and both parties are exposed to significant risks and rewards dependent on the commercial success of the activities. The calculation of collaborative activity to be recognized for joint ide-cel efforts in the United States is performed on a quarterly basis and is independent of previous quarterly activity. This may result in fluctuations between revenue and expense recognition period over period, depending on the varying extent of effort performed by each party during the period. The Company recognizes revenue related to the combined unit of accounting for the ex-U.S. license and lentiviral vector manufacturing services under Topic 606.

Ide-cel U.S. Share of Collaboration Profit or Loss

In March 2021, BMS received marketing approval from the U.S. Food and Drug Administration for ide-cel as a treatment for 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. BMS is primarily responsible for the commercialization of ide-cel and they are the principal for commercial activity.

On a quarterly basis, the Company determines its share of collaboration profit or loss for commercial activities. The Company's share of any collaboration profit for commercial activities is recognized as collaborative arrangement revenue and its share of any collaboration loss for commercial activity is recognized as an operating expense and classified as share of collaboration loss on the Company's condensed combined statement of operations and comprehensive loss.

The Company recognized the following on the condensed combined statements of operations and comprehensive loss related to its share of collaboration profit or loss associated with ide-cel commercial activities following approval (in thousands). These amounts represent the Company's share of BMS' ide-cel product revenue, cost of goods sold, and selling costs, offset by any reimbursement of commercial costs incurred by the Company, and exclude expenses related to ongoing development, which are separately reflected in the combined statements of operations and comprehensive loss as described below. Amounts incurred prior to commercial approval were not material.

	Three months ended			Nine months ended
	March 31, 2021	June 30, 2021	September 30, 2021	September 30, 2021
Collaborative arrangement revenue from ide-cel commercial activities [1]	$ —	$ —	$ 10,607	$ 10,607
Share of collaboration loss from ide-cel commercial activities [1]	$ —	$ (10,071)	$ —	$ (10,071)

(1) As noted above, the calculation 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.

The Company's year-to-date collaboration profit for commercial activities was $0.5 million.

The Company also is responsible for equally sharing in the ongoing ide-cel research and development activities being conducted by BMS in the United States. The net amount owed to BMS for research and development activities is classified as research and development expense on the condensed combined statement of operations and comprehensive loss. If BMS is obligated to reimburse the Company because the Company's research and development costs exceeds BMS' research and development costs, the net amount is recorded as collaborative arrangement revenue.

The following table summarizes the amounts associated with the research activities under the collaboration included in research and development expense or recognized as collaborative arrangement revenue for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
ASC 808 ide-cel research and development revenue - U.S. [1][2]	$ —	$ —	$ —	$ 108,196
ASC 808 ide-cel research and development expense - U.S. [1]	$ (5,660)	$ (16,084)	$ (31,678)	$ (21,164)

(1) As noted above, the calculation of collaborative arrangement activity to be recognized for joint ide-cel efforts in the United States is performed on a quarterly basis. The calculation is independent of previous activity, which may result in fluctuations between revenue and expense recognition period over period, depending on the varying extent of effort performed by each party during the period.

(2) In the second quarter of 2020, the Company recognized $169.2 million as a cumulative catch-up adjustment to revenue recorded in connection with the May 2020 First Amendment to the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement ("Amended Ide-cel CCPS"), a portion of which was recognized as ASC 808 research and development collaboration revenue.

Refer to Note 8, *Collaborative arrangements*, to the annual combined financial statements included in Exhibit 99.1 to the Company's Form 10 for further discussion on the Amended Ide-cel CCPS.

Ide-cel ex-U.S. Service Revenue

The following table summarizes the revenue recognized related to ide-cel ex-U.S. activities for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
ASC 606 ide-cel license and manufacturing revenue - ex-U.S. [1]	$ 5,314	$ 6,913	$ 14,698	$ 94,733

(1) In the second quarter of 2020, the Company recognized $169.2 million as a cumulative catch-up adjustment to revenue recorded in connection with the Amended Ide-cel CCPS, a portion of which was recognized as ASC 606 license and manufacturing revenue. Refer to Note 8, *Collaborative arrangements*, to the annual combined financial statements included in Exhibit 99.1 to the Company's Form 10 for further discussion on the Amended Ide-cel CCPS.

bb21217

In addition to the activities related to ide-cel, BMS previously exercised its option to obtain an exclusive worldwide license to develop and commercialize bb21217, the second product candidate under the collaboration arrangement with BMS which is further described in Note 8, *Collaborative arrangements*, to the annual combined financial statements included in Exhibit 99.1 to the Company's Form 10.

Under the collaboration arrangement with BMS, the Company has an option to co-develop and co-promote bb21217 within the United States. The Company is in the process of reviewing data from CRB-402, the on-going phase 1 clinical trial of bb21217, and its related decision to enter into an agreement to co-develop and co-promote bb21217 within the United States. The Company's election to co-develop and co-promote bb21217 within the United States must be made by the substantial completion of CRB-402. 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 have the right to participate in the development and promotion of bb21217 within the United States. Under this scenario, the U.S. milestones and royalties payable 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, 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.

All of the remaining development, regulatory, and commercial milestones related to U.S. development, regulatory and commercialization activities 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 transaction price associated with the collaboration arrangement consists of $31.0 million of upfront payments and option payments received from BMS and $1.8 million in variable consideration which represents reimbursement to be received from BMS for manufacturing vector and associated payloads through development.

The Company has identified two performance obligations with respect to the arrangement with BMS. The initial performance obligation was for research and development services that were substantially completed in September 2019, associated with the initial phase 1 clinical trial of bb21217. The Company allocated $5.4 million of consideration to the research and development services performance obligation and fully recognized the consideration through September 2019. The other performance obligation relates to a combined performance obligation for the bb21217 license and vector manufacturing services through development, and the remaining $27.3 million in consideration was allocated to this combined performance obligation. The Company will satisfy this combined performance obligation as the bb21217 manufacturing services are performed. As of September 30, 2021, the Company has not commenced manufacturing and the full amount of the allocated transaction price remains unsatisfied.

The Company re-evaluates the transaction price, including the 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.

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 nine months ended September 30, 2021 (in thousands):

	Balance at December 31, 2020	Additions	Deductions	Balance at September 30, 2021
Receivables	$ 400	$ 10,261	$ (400)	$ 10,261
Contract liabilities:				
Deferred revenue	$ 26,582	$ —	$ (820)	$ 25,762

The increase in the receivables balance for the nine months ended September 30, 2021 is driven by amounts owed to the Company from BMS in the period under the settlement terms of the collaboration agreement.

The decrease in deferred revenue during the nine months ended September 30, 2021 is driven by the release of the remaining $0.8 million of deferred revenue associated with the combined performance obligation consisting of the ide-cel license and manufacturing services.

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 was assumed by 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 collaborative arrangement 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 collaborative arrangement 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 September 30, 2021 and December 31, 2020, the Company has $25.9 million and $30.8 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 condensed combined balance sheets.

The Company recognized $1.7 million and $4.9 million of collaborative arrangement revenue from the Regeneron Collaboration Agreement during the three and nine months ended September 30, 2021, respectively. The Company recognized $2.4 million and $6.2 million of collaborative arrangement revenue from the Regeneron Collaboration Agreement during the three and nine months ended September 30, 2020, respectively.

Resilience

Background

In July 2021, bluebird bio and Resilience US, Inc. (formerly known as Resilience Boston, Inc.), an affiliate of Resilience, signed an Asset Purchase Agreement (the "Agreement"). As part of the Agreement, and upon the closing of the transaction which occurred in September 2021, Resilience acquired bluebird bio's lentiviral vector manufacturing facility located in Durham, North Carolina and retained staff employed at the site. In exchange, bluebird bio received $110.3 million for the facility and related fixed assets. Upon the completion of the separation in November 2021, 2seventy bio was assigned certain rights and obligations under the Agreement as well as certain Ancillary Agreements described below.

Upon closing, bluebird bio entered into certain ancillary agreements, including two manufacturing agreements and a license agreement (the "License Agreement"), among others (together referred to as the "Ancillary Agreements"). One manufacturing agreement will support the future manufacturing of lentiviral vector for the Company's commercial product in collaboration with BMS, ide-cel (the "Commercial Supply Agreement"), while the other will support ongoing manufacturing for lentiviral vector for the Company's development candidates (the "Development Manufacturing Supply Agreement"). The Company also agreed to reimburse Resilience for an amount equal to 50% of the net operating losses of and relating to the manufacturing facility's business incurred during the twelve-month period ending on the first anniversary of the closing of the transaction, as calculated in accordance with the Agreement, subject to a cap of $15.0 million. In exchange, under the terms of the Development Manufacturing Supply Agreement, the Company will receive up to eight batches of lentiviral vector during the twelve-month period ending on the first anniversary of the closing of the transaction. The License Agreement grants Resilience a worldwide, co-exclusive license to intellectual property controlled by the Company to perform Resilience's obligations and exercise Resilience's rights under the supply agreements, and a worldwide, nonexclusive right to offer certain manufacturing services to third-party customers under certain of the Company's intellectual property. Under the terms of the License Agreement, the Company may receive a high single-digit to

low double-digit percentage tiered royalty based on Resilience's gross margins for transactions entered into with parties other than the Company in which the Company's proprietary intellectual property is utilized as part of such transaction.

Under the Commercial Supply Agreement, the Company will pay fully burdened manufacturing cost plus a markup for production of vector. Under the Development Manufacturing Supply Agreement, services, manufacture, and delivery of batches of lentiviral vector during the first twelve months from the execution of this agreement will be free of cost, as the costs of these services are represented by the net operating loss sharing arrangement outlined within the Agreement. As such, the Company has committed to a minimum purchase of at least the Company's 50% share of the net operating losses during the first twelve months from the execution of such agreement. After the first twelve months, the Company will pay Resilience the fully burdened manufacturing cost plus a markup for production of vector.

Upon separation of 2seventy bio from bluebird bio, effective November 4, 2021, certain rights and obligations under the Agreement and certain Ancillary Agreements were assigned by bluebird bio to 2seventy bio with 2seventy bio assuming all rights and obligations these agreements convey.

Accounting analysis - Resilience

Since the January 2021 announcement by bluebird bio of its plans to separate and spin-off of 2seventy bio from its severe genetic disease portfolio and programs, the manufacturing facility was expected to be assigned to 2seventy bio and was therefore accounted for within the 2seventy bio carve-out financial statements. The disposition of the net assets of the manufacturing facility previously assigned to 2seventy bio has been reflected as a transfer to bluebird bio via net parent investment as a result of bluebird bio's sale of such facility. 2seventy bio is not a party to the sale of the manufacturing facility and, therefore, did not recognize any gain or loss arising from the transaction.

Future royalty payments under the License Agreement (which was assigned to the Company as previously described) are considered part of the consideration associated with the disposition of the manufacturing facility. In accordance with ASC 450, the Company will recognize future royalties received under the License Agreement in the period the contingencies are resolved as an adjustment to the consideration received as other income in the condensed combined statements of operations and comprehensive loss.

9. Royalty and other revenue

bluebird bio has out-licensed intellectual property to various third parties. Under the terms of these agreements, some of which were assumed by the Company in connection with the separation, bluebird bio and the Company may be entitled to royalties and milestone payments.

Novartis Pharma AG

In April 2017, bluebird bio entered into a worldwide license agreement with Novartis, which is further described in Note 9, *Royalty and other revenue*, to the annual combined financial statements included in Exhibit 99.1 to the Company's Form 10. Under the terms of the agreement, Novartis non-exclusively licensed certain patent rights related to lentiviral vector technology to develop and commercialize CAR T cell therapies for oncology, including Kymriah (formerly known as CTL19), Novartis's anti-CD19 CAR T therapy. The agreement was to be assumed by the Company in connection with the separation. Beginning in the fourth quarter of 2017, the Company began recognizing royalty revenue from sales of tisagenlecleucel under the agreement. This license agreement was terminated effective March 2021, at which point in time Novartis was no longer required to pay the Company royalty or other payments on net sales of tisagenlecleucel or any future products. The Company recognized $0.6 million and $3.5 million of royalty revenue in the three months ended September 30, 2021 and 2020, respectively, from sales of tisagenlecleucel. The Company recognized $2.9 million and $9.6 million of royalty revenue in the nine months ended September 30, 2021 and 2020, respectively, from sales of tisagenlecleucel. Such amounts are included within royalty and other revenue in the condensed combined statement of operations and comprehensive loss.

Juno Therapeutics

In May 2020, bluebird bio entered into a non-exclusive license agreement with Juno Therapeutics, Inc. (“Juno”), a wholly-owned subsidiary of BMS, related to lentiviral vector technology to develop and commercialize CD-19-directed CAR T cell therapies. The agreement was assumed by the Company in connection with the separation. Upon regulatory approval of lisocabtagene maraleucel during the first quarter of 2021, bluebird bio received a $2.5 million milestone payment from Juno, which is included within royalty and other revenue in the Company’s condensed combined financial statements. Royalty revenue recognized from sales of lisocabtagene maraleucel is also included within royalty and other revenue in the condensed combined statement of operations and comprehensive loss.

10. Stock-based compensation

During the first quarter of 2021, bluebird bio implemented a retention program designed to incentivize and retain employees through the separation of its severe genetic disease and oncology programs, which is intended to occur by the end of 2021. Under the retention program, employees are entitled to a one-time bonus payment, consisting of both a cash payment and unrestricted stock awards, with the condition that the employee remains employed at the end of 2021.

All awards granted under bluebird bio’s equity 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.

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 condensed combined statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 5,523	$ 7,916	$ 22,429	$ 24,765
Selling, general and administrative	5,707	7,339	17,877	23,793
	$ 11,230	$ 15,255	$ 40,306	$ 48,558

11. Related-party transactions

Historically, the Company was managed and operated in the normal course of business under bluebird bio. Accordingly, certain shared costs have been allocated to the Company and reflected as expenses in the Company's stand-alone condensed combined financial statements. The expenses reflected in the condensed combined financial statements may not be indicative of expenses that will be incurred by the Company in the future.

Corporate allocations

The condensed 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 $14.5 million and $18.9 million for the three months ended September 30, 2021 and 2020, respectively. Allocations for management costs and corporate support services provided to the Company totaled $49.9 million and $59.2 million for the nine months ended September 30, 2021 and 2020, respectively.

The financial information in these condensed 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 condensed 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 condensed combined financial statements as the underlying assets were assumed by 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 condensed 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 condensed 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 condensed combined financial statements and was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Imputed charge to bluebird bio for leases	$ 4,519	$ 4,085	$ 13,440	$ 12,410
Imputed charge from bluebird bio for leases	(209)	(261)	(836)	(714)
Imputed charge to bluebird bio for property, plant and equipment	507	571	1,714	1,695
Imputed charge from bluebird bio for property, plant and equipment	(13)	(57)	(1,125)	(174)
Imputed charge to bluebird bio for intangible assets	9	39	82	155
Other	—	61	(1)	86
	$ 4,813	$ 4,438	$ 13,274	$ 13,458

Other components of other income, net, that are not shown in the table above primarily include immaterial rental income and gains and losses on disposals of fixed assets.

Stock-based compensation

As discussed in Note 10, *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 condensed combined statements of operations and comprehensive loss.

Retirement plans

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 condensed combined statements of operations and comprehensive loss.

Transaction costs

As of September 30, 2021, bluebird bio had incurred costs related to the separation of the Company. To the extent separation costs are incurred that will directly benefit the Company as a stand-alone company, such costs 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 condensed combined financial statements, funding of 2seventy bio's expenditures is reflected in the condensed combined financial statements as a component of net parent investment.

12. Income taxes

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes.

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 Company did not operate as a stand-alone entity (or group of entities) prior to the separation and, accordingly, the amount and composition of its tax losses, credits, and other deferred tax assets included in the condensed 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.

13. Subsequent events

On November 4, 2021, bluebird bio completed the separation of its oncology portfolio and programs into 2seventy bio, retaining its severe genetic disease portfolio and programs. The separation was effected by means of a

distribution of all of the outstanding shares of common stock of 2seventy bio on the basis of one share of 2seventy bio common stock for every three shares of bluebird bio common stock issued and outstanding on October 19, 2021, the record date for the distribution. The distribution was effected at 12:01 a.m. on November 4, 2021. Immediately following the distribution, the Company had 23,369,088 shares of common stock and pre-funded warrants to purchase 757,575 shares of common stock outstanding.

In connection with the separation, on November 3, 2021, bluebird bio and 2seventy bio executed a separation agreement, a tax matters agreement, an employee matters agreement, an intellectual property license agreement, and transition services agreements, under which both companies will temporarily provide and receive certain services from each other. These agreements effectuated the separation and govern 2seventy bio's relationship with bluebird bio following the distribution.

In addition, in connection with the separation, bluebird bio made a cash contribution to the Company of approximately $441.5 million. As a result of the distribution and the separation, 2seventy bio is an independent, publicly traded company, effective as of November 4, 2021, and commenced regular way trading under the symbol “TSVT”’ on the Nasdaq Global Select Market on November 5, 2021.

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in Exhibit 99.1 to our Form 10, which was most recently filed with the Securities and Exchange Commission, or the SEC, on October 8, 2021.

Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as "may," "expect," "anticipate," "estimate," "intend," "plan," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

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 idecabtagene vicleucel (ide-cel, marketed as 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 ide-cel to multiple myeloma patients in the United States following approval by the FDA of ide-cel in March 2021 for the treatment of adults with multiple myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody.

We have never been profitable and have incurred net losses since inception. Our net loss was $60.0 million and $231.2 million for the three and nine months ended September 30, 2021. We expect to continue to incur significant expenses and operating losses for at least the next several years. We expect our expenses will increase in connection with our ongoing and planned activities, as we:

- add personnel to support our product development and any future commercialization efforts;
- seek regulatory approval for our product candidates;

- manufacture clinical study materials and establish the infrastructure necessary to support and develop manufacturing capabilities;
- conduct clinical studies for our clinical programs and advance our preclinical programs into clinical development;
- increase research and development-related activities for the discovery and development of product candidates and technologies in oncology; and
- incur costs related to the separation of us and bluebird bio into two separate, independent publicly traded companies.

In March 2021, bluebird bio placed a portion of the internal lentiviral vector manufacturing facility, which was expected to be assigned to us as part of the separation, into service, while still completing qualification of the remaining portion. In September 2021, bluebird bio completed the sale of this lentiviral vector manufacturing facility to National Resilience, Inc. Currently, all of our manufacturing activities are contracted out to third parties, including Resilience. Additionally, we currently utilize third-party contract research organizations, or CROs, to carry out our clinical development activities. As we seek to obtain regulatory approval for our product candidates and begin commercialization following marketing approval if obtained, we expect to incur significant commercialization expenses as we prepare for and begin product sales, marketing, commercial manufacturing, and distribution at such time. Accordingly, until we generate significant revenues from product sales at such time, we will continue to seek to fund our operations through public or private equity or debt financings, strategic collaborations, or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our products when and if approved in the United States, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Separation from bluebird bio, Inc.

On November 4, 2021, bluebird bio completed the separation and spin-off of its oncology portfolio and programs into 2seventy bio, retaining its severe genetic disease portfolio and programs. 2seventy bio is a Delaware corporation and was a wholly owned subsidiary of bluebird bio prior to the separation.

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 condensed combined financial statements for additional information on the preparation and basis of presentation of the financial statements. Our financial position, results of operations and cash flows historically operated as part of bluebird bio's financial position, results of operations and cash flows prior to and until the distribution of our common stock to bluebird bio's stockholders. The historical 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. Our historical financial statements do not yet reflect changes in our operating structure and our capitalization as a result of the separation from bluebird bio.

Business update

Beginning in late 2019, the outbreak of a novel strain of coronavirus (COVID-19) has evolved into a global pandemic. As a result, we continue to experience disruptions and increased risk in our operations and those of third parties upon whom we rely, which may materially and adversely affect our business. These include disruptions and risks related to the conduct of our clinical trials, manufacturing, and commercialization efforts, as policies at various clinical sites and federal, state, local and foreign laws, rules and regulations continue to evolve, including quarantines, travel restrictions, and direction of healthcare resources toward pandemic response efforts. The COVID-19 pandemic has impacted the timing of our ongoing clinical studies, with the result of slower patient enrollment and treatment in our clinical studies and delays in post-treatment follow up visits, the impact of which has varied by clinical study and by program. It has also affected our activities with and operations at our third-party manufacturers. It is unknown how long these disruptions could continue. The COVID-19 pandemic has also impacted the timing of our regulatory interactions for marketing approval across our programs. As a result of the demands upon healthcare regulatory authorities, review, inspection, and other activities related to review of regulatory submissions in drug development may be impacted and may result in delays for an unknown period of time.

We continue to evaluate the impact of the COVID-19 global pandemic on patients, healthcare providers and our employees, as well as our operations and the operations of our business partners and healthcare communities. However, 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.

Upon our separation from bluebird bio on November 4, 2021, bluebird bio contributed to us approximately $441.5 million of cash, cash equivalents, restricted cash and marketable securities. We expect that our cash, cash equivalents and marketable securities following the separation will be sufficient to fund current planned operations for at least the next twelve months from the date of issuance of these financial statements, although we intend to pursue additional cash resources through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties.

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

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* (“ASC 808”), which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a

vendor-customer relationship and therefore within the scope of ASC 606, *Revenue from Contracts with Customers* (“Topic 606” or "ASC 606"). For those elements of the arrangement that are accounted for pursuant to Topic 606, we apply the five-step model prescribed in Topic 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606. In arrangements where we do not deem our collaborator to be our customer, payments to and from our collaborator are presented in the combined statements of operations and comprehensive loss based on the nature of the payments, as summarized in the table and further described below.

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

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

Effective January 1, 2020, we adopted Accounting Standards Update ("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 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. We are in the process of reviewing CRB-402 data and our related decision to enter into an agreement to co-develop and co-commercialize bb21217 within the United States. 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
ide-cel	$ 10,879	$ 25,856	$ 56,451	$ 78,097
bb21217	1,125	7,080	5,737	20,106
Preclinical programs	15,232	12,478	39,399	39,331
Total direct research and development expense	27,236	45,414	101,587	137,534
Employee- and contractor-related expenses	11,174	5,232	28,871	16,985
Stock-based compensation expense	5,523	7,916	22,429	24,765
Laboratory and related expenses	2,509	450	7,313	1,640
License and other collaboration expenses	1,181	951	3,526	11,008
Facility expenses	13,014	11,915	37,629	34,675
Other expenses	494	375	1,039	978
Total other research and development expenses	33,895	26,839	100,807	90,051
Total research and development expense	$ 61,131	$ 72,253	$ 202,394	$ 227,585

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.

Share of Collaboration Loss

Share of collaboration loss represents our share of net loss arising from product sales less cost of goods sold and shared commercial costs and other expenses related to the commercialization of a product where the collaborator is the principal in the product sales.

Cost of Royalty and Other Revenue

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

Change in Fair Value of Contingent Consideration

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

As of September 30, 2021, there were $99.9 million in future contingent cash payments related to commercial milestones. We estimate future contingent cash payments have a fair value of $2.0 million as of September 30, 2021, which are classified within other non-current liabilities on our condensed combined balance sheet.

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 were assumed by 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 were not assumed by us. Other income, net also includes immaterial rental income and 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. 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. During the nine months ended September 30, 2021, there were no material changes to our significant accounting policies as reported in our annual combined financial statements included in Exhibit 99.1 to our Form 10, which was most recently filed with the SEC on October 8, 2021, except as otherwise described in Note 2, *Basis of presentation, principles of consolidation and significant accounting policies*, in the notes to the condensed combined financial statements.

Results of Operations

Historically, our operations were 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 condensed combined financial statements. We considered the allocation methodologies used to be a reasonable and appropriate reflection of the historical bluebird bio expenses attributable to us for purposes of the stand-alone financial statements. The expenses reflected in the condensed 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 condensed combined financial statements.

Comparison of the Three Months Ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Revenue:			
Service revenue	$ 6,312	$ 12,513	$ (6,201)
Collaborative arrangement revenue	12,337	2,422	9,915
Royalty and other revenue	608	3,499	(2,891)
Total revenues	19,257	18,434	823
Operating expenses:			
Research and development	61,131	72,253	(11,122)
Selling, general and administrative	22,996	22,105	891
Cost of royalty and other revenue	320	1,318	(998)
Change in fair value of contingent consideration	48	(828)	876
Total operating expenses	84,495	94,848	(10,353)
Loss from operations	(65,238)	(76,414)	11,176
Other income, net	5,237	4,339	898
Loss before income taxes	(60,001)	(72,075)	12,074
Income tax (expense) benefit	—	—	—
Net loss	$ (60,001)	$ (72,075)	$ 12,074

Revenue. Total revenue was $19.3 million for the three months ended September 30, 2021, compared to $18.4 million for the three months ended September 30, 2020. The increase of $0.8 million was primarily attributable to collaborative arrangement revenue recognized under our collaboration arrangement with BMS, driven by our share of ide-cel profits for the third quarter of 2021, offset by a decrease of revenue recognized in connection with treating additional patients in the bb21217 phase 1 trial under our agreement with BMS.

Research and Development Expenses. Research and development expenses were $61.1 million for the three months ended September 30, 2021, compared to $72.3 million for the three months ended September 30, 2020. The overall decrease of $11.1 million was primarily attributable to the following:

- $9.9 million of decreased collaboration research funding costs, which represents our share of research and development costs under our collaboration with BMS;

- $9.6 million of decreased manufacturing-related expenditures, primarily driven by an overall decrease in manufacturing activity;

- $2.4 million of decreased stock-based compensation expense due to attrition and an overall decrease in the value of awards; and
- $2.1 million of decreased clinical trial costs.

These decreased costs were partially offset by:

- $5.4 million of increased costs related to the non-equity component of employee compensation, benefit, and other headcount related expenses, primarily driven by our employee retention program which commenced during the first quarter of 2021;
- $5.1 million of increased license and milestone fees;
- $1.8 million of increased IT and other facility-related costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $23.0 million for the three months ended September 30, 2021, compared to $22.1 million for the three months ended September 30, 2020. The increase of $0.9 million was primarily due to the following:

- $1.6 million of increased costs related to the non-equity component of employee compensation, benefit, and other headcount related expenses, primarily driven by our employee retention program which commenced during the first quarter of 2021; and
- $1.1 million of increased IT and other facility-related costs.

The increased costs were partially offset by:

- $1.6 million of decreased stock-based compensation expense due to attrition and an overall decrease in the value of awards; and
- $0.6 million of decreased consulting and professional fees.

Cost of Royalty and Other Revenue. Cost of royalty and other revenue was $0.3 million for the three months ended September 30, 2021, compared to $1.3 million for the three months ended September 30, 2020. The decrease is attributable to decreased other 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 increase in other income, net was primarily related to an increase of $0.4 million in other income resulting from the allocation of facility-related and depreciation expense to bluebird bio for its proportional use of assets that were assumed by us and an increase of $0.4 million in rental income.

Comparison of the Nine Months Ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Revenue:			
Service revenue	$ 17,544	$ 106,733	$ (89,189)
Collaborative arrangement revenue	15,527	114,398	(98,871)
Royalty and other revenue	5,417	17,086	(11,669)
Total revenues	38,488	238,217	(199,729)
Operating expenses:			
Research and development	202,394	227,585	(25,191)
Selling, general and administrative	69,025	68,951	74
Share of collaboration loss	10,071	—	10,071
Cost of royalty and other revenue	2,111	3,897	(1,786)
Change in fair value of contingent consideration	464	(5,591)	6,055
Total operating expenses	284,065	294,842	(10,777)
Loss from operations	(245,577)	(56,625)	(188,952)
Other income, net	14,340	13,312	1,028
Loss before income taxes	(231,237)	(43,313)	(187,924)
Income tax (expense) benefit	—	—	—
Net loss	$ (231,237)	$ (43,313)	$ (187,924)

Revenue. Total revenue was $38.5 million for the nine months ended September 30, 2021, compared to $238.2 million for the nine months ended September 30, 2020. The decrease of $199.7 million was primarily attributable to a cumulative catch-up adjustment to revenue recorded in connection with the May 2020 BMS contract modification in the second quarter of 2020.

Research and Development Expenses. Research and development expenses were $202.4 million for the nine months ended September 30, 2021, compared to $227.6 million for the nine months ended September 30, 2020. The overall decrease of $25.2 million was primarily attributable to the following:

- $46.4 million of decreased manufacturing-related expenditures primarily attributable to decreased drug product and vector manufacturing costs driven mainly by the timing of manufacturing activities relating to ABECMA and the assignment of our manufacturing supply agreement in relation to the ABECMA program to BMS in May 2020;
- $4.3 million of decreased clinical trial costs and activities, primarily driven by completion of enrollment for the bb21217 phase 1 trial;
- $2.6 million of decreased platform-related costs, including laboratory expenditures and various license fees; and
- $2.3 million of decreased stock-based compensation expense due to attrition and an overall decrease in the value of awards.

These decreased costs were partially offset by:

- $15.6 million of increased collaboration research funding costs, which represents our share of research and development costs under our collaboration with BMS. The increase is also attributable to our recognition of collaborative arrangement revenue rather than collaboration expense associated with research and development activities in the second quarter of 2020 as a result of the May 2020 contract modification with BMS;

- $12.3 million of increased costs related to the non-equity component of employee compensation, benefit, and other headcount related expenses, primarily driven by our employee retention program which commenced during the first quarter of 2021; and

- $4.0 million of increased IT and other facility-related costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $69.0 million for the nine months ended September 30, 2021, compared to $69.0 million for the nine months ended September 30, 2020. The increase of $0.1 million was primarily due to the following:

- $3.8 million of increased costs related to the non-equity component of employee compensation, benefit, retention bonus and other headcount related expense;

- $2.4 million of increased IT and other facility-related costs; and

- $0.9 million of increased commercial readiness costs.

These increased costs were partially offset by:

- $5.9 million of decreased stock-based compensation expense due to attrition and an overall decrease in the value of awards; and

- $1.5 million of decreased consulting and professional fees.

Share of Collaboration Loss. Share of collaboration loss represents our share of net loss arising from the commercialization of ide-cel, under the BMS collaboration. BMS is the principal seller in the sales of ide-cel and they received marketing approval in the United States for the sale of ide-cel in March 2021.

Cost of Royalty and Other Revenue. Cost of royalty and other revenue was $2.1 million for the nine months ended September 30, 2021, compared to $3.9 million for the nine months ended September 30, 2020. The decrease is attributable to decreased other 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 increase in other income, net was primarily related to an increase of $1.1 million in rental income and an increase of $1.0 million in other income resulting from the allocation of facility-related and depreciation expense to bluebird bio for its proportional use of assets that were assumed by us, partially offset by an increase of $1.1 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 (deficit). Accordingly, we have not reported cash or cash equivalents for the periods presented in the combined balance sheets. bluebird bio continued to fund our cash needs through the date of the separation. Upon separation, bluebird bio funded us with approximately $441.5 million of cash, cash equivalents and marketable securities.

Going Concern

We have incurred losses and have experienced negative operating cash flows for all historical periods presented. During the nine months ended September 30, 2021, we incurred a loss of $231.2 million and used $149.6 million of cash in operations. We expect that our research and development and selling, general and administrative expenses will continue to increase and that we will continue to generate operating losses and negative operating cash flows for the next few years.

Upon separation from bluebird bio on November 4, 2021, bluebird bio made a contribution to us of approximately $441.5 million in cash, cash equivalents, restricted cash and marketable securities, which alleviated the conditions that previously raised substantial doubt about our ability to continue as a going concern. Accordingly, as of the date of issuance of the condensed combined financial statements for the three and nine months ended September 30, 2021 and 2020, we expect our cash, cash equivalents, and marketable securities will be sufficient to fund current planned operations for at least the next twelve months. We previously concluded that there was substantial doubt about our ability to continue as a going concern in prior periods due to our need to obtain additional funding.

We intend to pursue additional cash resources through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. There can be no assurance that such financing will be available in sufficient amounts or on acceptable terms, if at all, and some could be dilutive to existing stockholders. 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.

Sources of Liquidity

Cash Flows

The following table summarizes our cash flow activity:

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (149,595)	$ (13,964)
Net cash used in investing activities	(18,600)	(15,260)
Net cash provided by financing activities	168,195	29,224
Increase (decrease) in cash, cash equivalents and restricted cash	$ —	$ —

Cash Flows from Operating Activities. Net cash used in operating activities was $149.6 million for the nine months ended September 30, 2021 and primarily consisted of a net loss of $231.2 million adjusted for non-cash

items, including stock-based compensation of $40.3 million and depreciation and amortization of $12.8 million, as well as the change in our net working capital.

Net cash used in operating activities was $14.0 million for the nine months ended September 30, 2020 and primarily consisted of net loss of $43.3 million adjusted for non-cash items, including stock-based compensation of $48.6 million, depreciation and amortization of $9.9 million, and the change in fair value of the contingent consideration of $5.6 million, as well as the change in our net working capital.

Cash Flows from Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2021 was $18.6 million and was due to the purchase of property, plant and equipment of $10.6 million as well as the purchase of intangible assets of $8.0 million.

Net cash used in investing activities for the nine months ended September 30, 2020 was $15.3 million and was due to the purchase of property, plant and equipment.

Cash Flows from Financing Activities. As bluebird bio managed our cash and financing arrangements, all excess cash generated through earnings was deemed remitted to bluebird bio and all sources of cash were deemed funded by bluebird bio.

Net cash provided by financing activities for the nine months ended September 30, 2021 was $168.2 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 nine months ended September 30, 2020 was $29.2 million and was due to cash transferred to us from bluebird bio based on changes in our cash used for operating activities 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 for at least 12 months following the date of issuance of our condensed combined financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, 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

Except as discussed in Note 6, *Leases*, and Note 7, *Commitments and contingencies*, in the notes to condensed combined financial statements, there have been no material changes to our contractual obligations and commitments as included in our audited combined financial statements included in Exhibit 99.1 to our Registration Statement on Form 10, as filed on October 8, 2021.

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 have entered 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 two years. 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

On November 3, 2021, in connection with the separation and distribution, we entered into certain agreements with bluebird bio relating and giving effect to the separation, including a separation agreement, two transition services agreements, a tax matters agreement, an intellectual property license agreement and an employee matters agreement. The terms of these agreements, including information on the business purpose of such agreements, transaction prices, related ongoing contractual commitments and any related special risks or contingencies are discussed in greater detail in the section captioned "Certain Relationships and Related Persons Transactions," appearing in our Registration Statement on Form 10.

Off-Balance Sheet Arrangements

As of September 30, 2021, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the three months ending September 30, 2021, we participated in bluebird bio's centralized treasury management including centralized cash and securities management. We did not report cash, cash equivalents, or marketable securities on our condensed combined balance sheets due to our participation in bluebird bio's centralized treasury management. As such, our exposure to market risk related to changing interest rates was minimal.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, or the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reporting within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control

There were no changes during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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.

Item 1A. Risk Factors

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

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 ongoing 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 ongoing 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 to support the use of ABECMA in earlier lines of therapy. 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 ongoing 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 ongoing 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 ongoing COVID-19 pandemic 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 and those of third parties on which we rely 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, new variants, additional or modified government actions, including vaccine and testing mandates, 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, the availability and utilization of vaccines and treatments for COVID-19, 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 employees, 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 ongoing COVID-19 pandemic adversely affects our business and financial results and those of third parties on which we rely, 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 and separated from bluebird bio in November 2021. Although our business was conducted within bluebird bio prior to that time, we have no history as an independent company prior to the completion of the separation. We are developing an oncology pipeline of cell and gene therapies for cancer, the first of which, ABECMA (ide-cel), was approved by FDA in March 2021. FDA granted approval of ABECMA to BMS, our co-development partner, and although we are jointly commercializing this product with BMS 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, which we are co-developing with BMS.

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, and for the nine months ended September 30, 2021 was $231.2 million. 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 ABECMA 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 completion of the separation, we held cash and cash equivalents of $441.2 million, of which $33.0 million is restricted. Our management believes that our cash and cash equivalents are sufficient to fund our current operating plan for at least 12 months following the completion of the separation.

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

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

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, and we may experience delays in our clinical studies if we encounter difficulties in enrollment. The estimated incidence of our initial target indications, including non-Hodgkin's lymphoma and acute myeloid leukemia, the target indications for our product candidates, vary 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 recruitment and enrollment may also encounter difficulties for a variety of other reasons. The number of patients eligible for a clinical trial may be substantially limited by stringent eligibility criteria in a study protocol, such as the inclusion of biomarker-driven identification or other highly specific criteria related to stage of disease progression or to specific patient reported outcome measures. The number of patients required to power the statistical analysis of the study's endpoints may be very large leading to an extended enrollment period. Issues such as the proximity of subjects to a study site, the complexity of the study design, our ability to recruit investigators with appropriate skill and experience, competing clinical studies for similar therapies or targeting similar subjects, perceptions of the benefit-risk profile of the product candidate relative to other available therapies or product candidates, risk that patients enrolled in clinical trials drop out before clinical trial completion, and ability to obtain and maintain institutional review board, or IRB, approvals and patient consents all could have a substantial impact on the timing of clinical trial enrollment. In addition, our ability to recruit and enroll patients may be significantly delayed by the evolving COVID-19 pandemic, and we do not know the extent and scope of such delays at this point If we are unable to enroll sufficient subjects in clinical studies in a timely way, obtaining study results will be delayed, which may harm our business, prospects, financial condition, and results of operations.

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

We focus our research 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 ABECMA or any future approved products, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower or more difficult to identify than expected. Additionally, the potentially addressable patient population for ABECMA and any future approved products may be limited or may not be amenable to treatment with our products.

Even if we obtain significant market share for a product within an approved indication, because the potential target populations for our product and for the product candidates in our pipeline are small, we may never achieve profitability without obtaining marketing approval for additional indications. In the field of cancer, the FDA often approves new therapies initially only for use in patients with relapsed or refractory advanced disease. We expect to initially seek approval of our engineered cell therapy product candidates in cancer in this context. Subsequently, for those products that prove to be sufficiently beneficial, 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 ABECMA and any future approved 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 each of our product candidates, we must complete preclinical studies and then conduct extensive clinical studies to demonstrate the safety, purity and potency, and efficacy, of the product candidate in humans. Preclinical and clinical testing 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 encouraging results in preclinical studies or 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:

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

Furthermore, the timing of our clinical studies depends on the speed at which we can recruit eligible patients to participate in testing our product candidates, and we may experience delays if we encounter difficulties in recruitment or enrollment. The conditions for which we plan to evaluate our current product candidates in severe genetic diseases are rare disorders with limited patient pools from which to draw for clinical studies. The eligibility criteria of our clinical studies will further limit the pool of available study participants, and the process of finding and diagnosing patients may prove costly. Patients may be unwilling to participate in our studies because of negative publicity from adverse events in the biotechnology or gene therapy industries or for other reasons, including competitive clinical studies for similar patient populations, the proximity and availability of clinical study sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of

potential products may be delayed. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical studies in a timely manner or as required by the FDA or comparable foreign regulatory authorities. We have experienced delays in some of our clinical studies in the past, and we may experience similar delays in the future.

Even if our product candidates demonstrate 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, impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS, or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our 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 license application, or BLA, but in certain circumstances, will approve a BLA based on only one pivotal trial. Additionally, certain factors beyond our and our collaborators' control may impact the timeliness of the regulatory reviews of our submissions or any applications for approval.

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

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

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

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

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

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

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 adding a sufficient number of clinical trial sites and obtaining IRB or independent ethics committee approval at each site;
- challenges in recruiting suitable patients to participate in a trial;
- slower enrollment in clinical trials than anticipated or a larger number of patients required for a clinical trial than anticipated;
- the inability to enroll a sufficient number of patients in clinical trials to ensure adequate statistical power to detect statistically significant treatment effects;
- difficulties in having patients complete a trial or return for post-treatment follow-up;
- our CROs or clinical trial sites or other third parties failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a clinical trial;

- unforeseen safety issues, including occurrence of treatment emergent adverse events associated with the product candidate that are viewed to outweigh the product candidate's potential benefits;

- the need to suspend or terminate clinical trials for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;

- difficulties in adding new clinical trial sites;

- our preclinical studies or clinical trials failing to show safety or efficacy or otherwise producing ambiguous or negative interim results, leading us to decide, or regulators requiring us to conduct additional preclinical studies or clinical trials or abandon our research efforts for our other product candidates;

- lack of adequate funding to continue the clinical trial;

- greater costs than anticipated;

- difficulties in manufacturing sufficient quantities of acceptable product candidate for use in preclinical studies or clinical trials in a timely manner, or at all; or

- the ongoing 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 comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to recognize product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down 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.

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

Where possible, we may pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for our one or more of our therapeutic candidates from the FDA, EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and

Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a therapeutic candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the therapeutic candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval, we will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our therapeutic candidate would result in a longer time period to commercialization of such therapeutic candidate, could increase the cost of development of such therapeutic candidate and could harm our competitive position in the marketplace. Moreover, even if we are able to obtain accelerated approval for any of our therapeutic candidates, there is no guarantee that post-approval studies will be able to confirm the clinical benefit, which could cause FDA to withdraw our approval.

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

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

A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For therapeutic candidates that have been designated as breakthrough

therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Designation as a breakthrough therapy is within the discretion of the FDA, and drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval. Even if one or more of our therapeutic candidates qualify as breakthrough therapies pursuant to FDA standards, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek breakthrough therapy designation for one or more of our current or future therapeutic candidates, there can be no assurance that we will receive breakthrough therapy designation.

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

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

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, 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 for those indications 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 comparable foreign regulatory authorities may not authorize us or our investigators to commence planned clinical studies, or require that we suspend ongoing clinical studies through imposition of clinical holds;
- negative results from our ongoing studies or other industry studies involving engineered cell therapy product candidates;
- delays in reaching or failing to reach agreement on acceptable terms with prospective 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 ABECMA or any of our product candidates are revealed to have high and unacceptable severity and/or prevalence of side effects or unexpected characteristics, their 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 vasopressor support, and in several cases, resulted in death. Severe neurotoxicity is a condition that is currently defined clinically by cerebral edema, confusion, drowsiness, speech impairment, tremors, seizures, or other central nervous system side effects, when such side effects are serious enough to lead to intensive care. In some cases, severe neurotoxicity was thought to be associated with the use of certain lymphodepletion regimens used prior to the administration of the CAR T cell products. Cytokine release syndrome is a condition that is currently defined clinically by certain symptoms related to the release of cytokines, which can include fever, chills, low blood pressure, when such side effects are serious enough to lead to intensive care with mechanical ventilation or significant vasopressor support. The exact cause or causes of cytokine release syndrome and severe neurotoxicity in connection with treatment of CAR T cell products is not fully understood at this time. In addition, patients have experienced other adverse events in these studies, such as a reduction in the number of blood cells (in the form of neutropenia, thrombocytopenia, anemia or other cytopenias), febrile neutropenia, chemical laboratory abnormalities (including elevated liver enzymes), and renal failure.

Undesirable side effects caused by ABECMA 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.

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

- regulatory authorities may withdraw or limit their approval of ABECMA or our product candidates;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we and/or BMS may be required to change the way ABECMA or such product candidates are distributed or administered, conduct additional clinical trials or change the labeling for ABECMA or such product candidates;
- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we or BMS may decide to remove ABECMA or such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking ABECMA or our product candidates; and
- our reputation may suffer.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of 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 ABECMA or any future approved products, and a decrease in demand for any such product. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any approved products.

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

Changes in regulatory requirements, FDA guidance or unanticipated events during our preclinical studies and clinical studies may force us to amend preclinical studies and clinical study protocols. The FDA or comparable foreign regulatory authorities may also impose additional preclinical studies and clinical study requirements. Amendments or changes to our clinical study protocols would require resubmission to the FDA or comparable foreign regulatory authorities and IRBs for review and approval, which may increase the cost or delay the timing or successful completion of clinical studies. Similarly, amendments to our preclinical studies may increase the cost or delay the timing or successful completion of those preclinical studies. If we experience delays completing, or if we

terminate, any of our preclinical or clinical studies, or if we are required to conduct additional preclinical or clinical studies, the commercial prospects for our product candidates may be harmed and our ability to recognize product revenue will be delayed.

Obtaining and maintaining regulatory approval of our product candidates 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.

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

We rely on CROs and clinical study sites to ensure our studies are conducted properly and on time. While we have agreements governing their activities, we will have limited influence over their actual performance. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

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

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical studies may be extended, delayed or terminated, and we may not be able to obtain marketing approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to recognize revenues could be delayed.

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

We do not independently conduct all aspects of our lentiviral vector production, drug product manufacturing, and testing. We currently rely, and expect to continue to rely, on third parties with respect to these items, including manufacturing and testing in the 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. Our third-party manufacturers are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, or manufacture our lentiviral vectors and drug products in accordance with GMP, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise, we will not be able to complete, or may be delayed in completing, the preclinical and

clinical studies and manufacturing process validation activities required to support future IND, 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 or comparable foreign regulatory action, including injunction, recall, seizure or total or partial suspension of production. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We 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 comparable foreign 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 ABECMA 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 ABECMA 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 approved product or product candidates, we may not be able to compete effectively in our markets.

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

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

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

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent

information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, 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, derivation proceedings, oppositions, ex parte reexaminations, post-grant review, and inter partes review proceedings before the federal courts or the U.S. Patent and Trademark Office, or U.S. PTO, and corresponding foreign courts and patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we have an approved product or are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our approved product or product candidates may be subject to claims of infringement of the patent rights of third parties.

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

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

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

Presently we have rights to the intellectual property, through licenses from third parties 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 or approved product, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates, approved product, or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of

critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

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

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

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligible subject matter, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. Third parties 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 or derivation proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

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

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

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

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

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

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

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

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

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

Risks Related to the Commercialization of Our Product Candidates

We have limited experience as a commercial company and the marketing and sale of 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.

BMS is primarily responsible for the commercialization of ABECMA, and there can be no guarantee that BMS will be able to commercialize ABECMA successfully. Although we have recognized revenue from commercial sales of ABECMA, we cannot be certain that we will continue to generate such revenue. 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 and maintain a commercial sales force team for ABECMA;
- obtain and maintain third-party coverage or adequate reimbursement for ABECMA;
- achieve market acceptance of ABECMA, in the medical community and with third-party payors; and
- including placement in accepted clinical guidelines for the conditions for which ABECMA is intended to target.

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

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any future 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 ABECMA and any of our product candidates that may be approved by the FDA or other applicable regulatory authorities outside the United States, will depend upon the awareness and acceptance of ABECMA and our product candidates among the medical community, including patients, physicians, and healthcare payors. If ABECMA or any of our product candidates that may be approved do not achieve an adequate level of acceptance by patients, physicians, healthcare payors and others in the medical community, we may not recognize sufficient revenue to become, or remain, profitable. Market acceptance of ABECMA and any of our product candidates that may be 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;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved or licensed 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;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive products;
- our ability to generate cost effectiveness data that supports a profitable price;
- our ability to obtain sufficient reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of sufficient payor coverage;
- the timing of market introduction of our product candidates as well as competitive products;
- 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 ABECMA and any approved product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors and government authorities and may be affected by existing and future health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. 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. Novel and expensive cell therapies like CAR-T cell therapies have experienced and continue to experience coverage and reimbursement challenges. For example, Medicare only covers CAR-T cell therapies that meet specific criteria set forth in a national coverage decision. Other third party payors may impose coverage criteria more extensive than compliance with FDA labeling. We may have to negotiate coverage and reimbursement on a case-by case basis. Reimbursement, particularly if the cost of the therapy is reimbursed as part of a standard procedure, may not be adequate.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We or our partners may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our 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.

ABECMA and any product candidates for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements governing, among other things, the research, development, testing, manufacturing, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting of our products. These requirements include submissions of safety and other postmarketing information and reports, facility registration and drug listing requirements, as well as continued compliance with GMPs, GLPs, and GCPs, for any clinical trials that we conduct post-approval. Even if we, BMS or any other 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:

- impose restrictions on the marketing or manufacturing of our products, withdraw the product from the market, or impose a voluntary or mandatory product recall;
- impose limitations on approved uses or additional warnings, contraindications, or other safety information, or a REMS;
- require us and/or BMS to conduct additional post-market clinical trials to assess the product safety;

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical studies;
- refuse to approve a pending marketing application, such as a BLA or supplements to a BLA submitted by us;
- seize product;
- refuse to permit the import or export of product; or
- refuse to allow us to enter into supply contracts, including government contracts.

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

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting 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. Post-approval marketing and promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA or comparable foreign regulatory authorities, Department of Justice, Department of Health and Human Services, or HHS, Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue a regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we or our collaborators are not able to obtain FDA or comparable foreign regulatory authority approval for desired uses or indications for our products or 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;

- 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, as amended, which require 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; and

- 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.

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

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions In addition to HIPAA, as amended by HITECH, and their respective implementing regulations, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General was able to commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

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

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

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

The use of ABECMA and our product candidates in clinical studies and the sale of ABECMA or any other 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 ABECMA, our product candidates or any other 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. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

In addition, CMS published a final rule that would give states greater flexibility as of 2020 in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

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

- On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken.

- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.

- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining

FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

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.

At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations 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. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. 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 would have been 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. However, on August 6, 2021 CMS announced a proposed rule to rescind the Most Favored Nations rule. Additionally, on November 30, 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 court order, the removal and addition of the aforementioned safe harbors have been delayed until January 1, 2023. Further, implementation of these changes 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. 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, recruit 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.

We currently employ approximately 420 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.

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

We are subject to Section 404(a) of the Sarbanes-Oxley Act and, as of the expiration of our emerging growth company status, we will be broadly subject to enhanced reporting and other requirements under the Exchange Act and Sarbanes-Oxley Act. 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.

As a smaller and less diversified company than bluebird bio was prior to the separation, 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. As part of bluebird bio, we were 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 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 do 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.

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 historically operated as part of bluebird bio's corporate organization, and bluebird bio assisted us by providing various corporate and other business functions. Following the separation, bluebird bio no longer has an 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, we need to develop internal capabilities to perform these services, or obtain from other third parties services we used to 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 received 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 limited history of operating as an independent company and we expect to incur increased administrative and other costs following the separation by virtue of our status as an independent public company. Our historical financial information is not necessarily representative of the results that we would have achieved as a separate, publicly traded company and should not be relied upon as an indicator of our future results.

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

- 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 report. As a result of the separation, it may be difficult for investors to compare our future results to historical results or to evaluate our relative performance or trends in our business.

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 created 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 separation for a limited period of time, pursuant to the transition services agreements and certain other agreements we entered 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.

We need to continue to attract, recruit 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 our business following 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.

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

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

In connection with the distribution, we and bluebird bio entered into a tax matters agreement pursuant to which we are responsible for certain liabilities and obligations following the distribution. In general, under the terms of the tax matters agreement, if the distribution, together with certain related transactions, were to fail to qualify as a transaction that is generally tax-free, for U.S. federal income tax purposes, under Sections 355 and 368(a)(1)(D) of the Code, and if and to the extent that such failure results from a prohibited change of control in bluebird bio under Section 355(e) of the Code or an acquisition of bluebird bio stock or assets or certain actions, omissions or failures to act, by bluebird bio, then bluebird bio will bear any resulting taxes, interest, penalties and other costs. If and to the extent that such failure results from a prohibited change of control in 2seventy bio under Section 355(e) of the Code or an acquisition of our stock or assets or certain actions by us, then we will indemnify bluebird bio for any resulting taxes, interest, penalties and other costs, including any reductions in bluebird bio's net operating loss carryforwards or other tax assets. If such failure does not result from a prohibited change of control in bluebird bio or 2seventy bio

under Section 355(e) of the Code and both we and bluebird bio are responsible for such failure, liability will be shared according to relative fault. If neither we nor bluebird bio is responsible for such failure, bluebird bio will bear any resulting taxes, interest, penalties and other costs. For a discussion of the tax matters agreement, see “Certain Relationships and Related Person Transactions—Agreements with bluebird bio —Tax Matters Agreement.” Our indemnification obligations to bluebird bio under the tax matters agreement are not expected to be limited in amount or subject to any cap. If we are required to pay any taxes or indemnify bluebird bio and its subsidiaries and their respective officers and directors under the circumstances set forth in the tax matters agreement, we may be subject to substantial liabilities.

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

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

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

Pursuant to the separation agreement and certain other agreements we entered into with bluebird bio, we assumed and agreed to indemnify bluebird bio for certain liabilities for uncapped amounts, which may include, among other items, associated defense costs, settlement amounts and judgments, as discussed further in "Certain Relationships and Related Person Transactions—Agreements with bluebird bio" and "Index to Financial Statements—Audited 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 has agreed to indemnify us for liabilities of the bluebird bio business, but such indemnity from bluebird bio may not be sufficient to protect us against the full amount of such liabilities, and bluebird bio may not fully satisfy its indemnification obligations. Moreover, even if we ultimately succeed in recovering from bluebird bio any amounts for which we are held liable, we may be temporarily required to bear these losses ourselves. Each of these risks could harm our business, prospects, financial condition and results of operations

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

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

bluebird bio may compete with us.

bluebird bio is not 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, serves as a director of bluebird bio. 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 trading price of our common stock may not reflect the full value of our business and assets.

The trading price of our common stock may not reflect the full value of our business and assets, due to market inefficiencies or variations in investor views regarding our business and prospects, among other market forces. The aggregate market value our common stock may fluctuate.

Risks Related to Ownership of Our Common Stock

An active trading market for our shares may not be sustained and the market price of these shares may fluctuate widely.

Prior to the first trading day following the distribution, there had been no public market for our shares of common stock. Although our common stock is listed on the Nasdaq Global Select Market, there can be no assurance that an active trading market for our shares of common stock will be sustained.

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:

- results and timing of preclinical studies and clinical studies of ABECMA or our product candidates;
- the commercial performance of ABECMA or any of our products that may be approved, as well as the costs associated with such activities;
- BMS' disclosure of revenue from ABECMA in its earning releases or otherwise;
- results 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.

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, we are authorized under our amended and restated certificate of incorporation to issue, without the approval of our stockholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our common stock with respect to dividends and distributions, as our board of directors may determine. The terms of one or more classes or series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, we could grant the holders of preferred stock the right to elect some number of directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of the common stock. See "Description of 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 contain, and Delaware law contains, provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and by-laws include provisions that:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, our chief executive officer or our president;
- prohibit stockholder action by written consent;

- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

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

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

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

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

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

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing the claims identified above, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the Delaware Forum Provision and the Federal Forum Provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be

brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable in an action, we may incur additional costs associated with resolving such an action. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Chancery Court or the federal district courts of the United States of America may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

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

Item 2. Unregistered Sale of Equity Securities and Use of Proceeds

Unregistered Sales of Equity 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.

On November 3, 2021, we issued 23,368,988 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.

On November 4, 2021, we issued to certain institutional investors (who previously purchased pre-funded warrants to purchase shares of bluebird bio common stock) pre-funded warrants to purchase the number of shares of our common stock that such institutional investors would have been entitled to receive in connection with the distribution had the unexercised portion of the bluebird bio pre-funded warrant at the effective time of the distribution been fully exercised at the effective time of the distribution. We did not register the issuance of such warrants 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 and Rule 506(b) of Regulation D as promulgated by the SEC under the Securities Act. Each institutional investor is either (i) an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act or (ii) a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act and acquired the securities for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof. The securities were not issued through any general solicitation or advertisement.

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

None

Item 5. Other Information

None

Item 6. Exhibit Index

Exhibit Number	Description	Provided Herein	Incorporated by Reference			
			Form	File Number	Exhibit	Filing Date
2.1	Separation Agreement, dated as of November 3, 2021, by and between bluebird bio, Inc. and 2seventy bio, Inc.		8-K	001-40791	2.1	November 4, 2021
3.1	Amended and Restated Certificate of Incorporation of 2seventy bio, Inc.		8-K	001-40791	3.1	November 4, 2021
3.2	Amended and Restated By-Laws of 2seventy bio, Inc.		8-K	001-40791	3.2	November 4, 2021
10.1	Tax Matters Agreement, dated as of November 3, 2021, by and between bluebird bio, Inc. and 2seventy bio, Inc.		8-K	001-40791	10.1	November 4, 2021
10.2*	Employee Matters Agreement, dated as of November 3, 2021, by and between bluebird bio, Inc. and 2seventy bio, Inc.		8-K	001-40791	10.2	November 4, 2021
10.3*	Intellectual Property License Agreement, dated as of November 3, 2021, by and between bluebird bio, Inc. and 2seventy bio, Inc.		8-K	001-40791	10.3	November 4, 2021
10.4*	Transition Services Agreement, dated as of November 3, 2021, by and between bluebird bio, Inc. and 2seventy bio, Inc.		8-K	001-40791	10.4	November 4, 2021
10.5*	Transition Services Agreement, dated as of November 3, 2021, by and between 2seventy bio, Inc. and bluebird bio, Inc.		8-K	001-40791	10.5	November 4, 2021
10.6*#	Assumption Agreement, dated as of November 3, 2021, by and between 2seventy bio, Inc. and bluebird bio, Inc. with respect to Securities Purchase Agreement, dated September 7, 2021, by and among bluebird bio, Inc. and the institutional investors named therein, and Registration Rights Agreement, dated September 7, 2021, by and among bluebird bio, Inc. and the persons listed on the attached Schedule A thereto.		8-K	001-40791	10.6	November 4, 2021
10.7	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to Registration Statement on Form 10 filed on October 8, 2021 (File No. 001-40791)).		8-K	001-40791	10.7	November 4, 2021
10.8+	Executive Employment Agreement, effective as of November 4, 2021, by and between 2seventy bio, Inc. and Nick Leschly		8-K	001-40791	10.8	November 4, 2021

10.9+	Executive Employment Agreement, effective as of November 4, 2021, by and between 2seventy bio, Inc. and William Baird	8-K	001-40791	10.9	November 4, 2021
10.10+	Executive Employment Agreement, effective as of November 4, 2021, by and between 2seventy bio, Inc. and Philip Gregory	8-K	001-40791	10.1	November 4, 2021
10.11#	Amended and Restated Master Collaboration Agreement by and between bluebird bio, Inc. and Celgene Corporation, dated June 3, 2015	10-12B	001-40791	10.9	September 9, 2021
10.12	Amendment No. 1 to Amended and Restated Master Collaboration Agreement by and between bluebird bio, Inc. and Celgene Corporation, dated February 17, 2016	10-12B	001-40791	10.10	September 9, 2021
10.13	Amendment No. 2 to Amended and Restated Master Collaboration Agreement by and between bluebird bio, Inc. and Celgene Corporation, dated September 28, 2017	10-12B	001-40791	10.11	September 9, 2021
10.14#	Amended and Restated License Agreement by and between bluebird bio, Inc. and Celgene Corporation, dated February 16, 2016	10-12B	001-40791	10.12	September 9, 2021
10.15#	Second Amended and Restated License Agreement by and between bluebird bio, Inc. and Celgene Corporation and Celgene European Investment Company LLC, dated May 8, 2020	10-12B	001-40791	10.13	September 9, 2021
10.16#	Amended and Restated Co-Development, Co-Promote and Profit Share Agreement by and between bluebird bio, Inc. and Celgene Corporation and Celgene European Investment Company LLC, dated March 26, 2018	10-12B	001-40791	10.14	September 9, 2021
10.17#	First Amendment to Amended and Restated Co-Development, Co-Promote and Profit Share Agreement by and between bluebird bio, Inc. and Celgene Corporation and Celgene European Investment Company LLC, dated May 8, 2020	10-12B	001-40791	10.15	September 9, 2021
10.18#	Lease, dated September 21, 2015, by and between bluebird bio, Inc. and ARE-MA Region No. 40 LLC	10-12B/A	001-40791	10.22	October 8, 2021
10.19	First Amendment to Lease, dated June 21, 2016, by and between bluebird bio, Inc. and ARE-MA Region No. 40 LLC	10-12B/A	001-40791	10.23	October 8, 2021
10.20	Second Amendment to Lease, dated November 14, 2016, by and between bluebird bio, Inc. and ARE-MA Region No. 40 LLC	10-12B/A	001-40791	10.24	October 8, 2021
10.21	2021 Stock Option and Incentive Plan, and forms of agreements thereunder.	S-8	333-260669	99.1	November 1, 2021

10.22	2021 Employee Stock Purchase Plan.		S-8	333-260669	99.2	November 1, 2021
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	x				
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	x				
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	x				

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*Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. 2seventy bio hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the U.S. Securities and Exchange Commission.

+ Management contract or compensatory plan or arrangement.

Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the SEC.

** The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements 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.

Date: December 1, 2021

By: /s/ Nick Leschly

Nick Leschly

President and Chief Executive Officer (Principal Executive Officer and Duly Authorized Officer)

Date: December 1, 2021

By: /s/ Chip Baird

Chip Baird

Chief Financial Officer (Principal Financial Officer, Principal Accounting Officer and Duly Authorized Officer)

Exhibit 31.1

CERTIFICATION
PURSUANT TO RULE 13a-14(a) AND RULE 15d-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Nick Leschly, certify that:

I have reviewed this Quarterly Report on Form 10-Q of 2seventy bio, Inc.;

Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942);

Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: December 1, 2021 /s/ Nick Leschly

Nick Leschly
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION
PURSUANT TO RULE 13a-14(a) AND RULE 15d-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED
RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Chip Baird, certify that:

I have reviewed this Quarterly Report on Form 10-Q of 2seventy bio, Inc.;

Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942);

Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: December 1, 2021 /s/ Chip Baird

Chip Baird
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of 2seventy bio, Inc. (the "Company") for the quarter ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to his knowledge, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: December 1, 2021 /s/ Nick Leschly

Nick Leschly
President and Chief Executive Officer
(Principal Executive Officer)

Dated: December 1, 2021 /s/ Chip Baird

Chip Baird
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)