

**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 March 31, 2022  
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

*(State or other jurisdiction of incorporation or organization)*

86-3658454

*(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:**

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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):

Large accelerated filer   
Non-accelerated filer

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 37,622,368 shares of common stock as of May 5, 2022.

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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;
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- 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.

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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Information**

**2seventy bio, Inc.**  
**Condensed Consolidated Balance Sheets**  
**(unaudited)**  
**(in thousands, except par value amounts)**

	As of March 31, 2022	As of December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 270,893	\$ 130,414
Marketable securities	106,973	134,643
Prepaid expenses	18,002	9,512
Receivables and other current assets	16,931	16,995
Total current assets	412,799	291,564
Property, plant and equipment, net	35,038	34,913
Marketable securities	74,683	97,124
Intangible assets, net	8,774	9,892
Goodwill	12,056	12,056
Operating lease right-of-use assets	270,825	275,534
Restricted cash and other non-current assets	37,746	38,592
Total assets	\$ 851,921	\$ 759,675
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 13,647	\$ 6,024
Accrued expenses and other current liabilities	58,475	55,410
Operating lease liability, current portion	10,066	9,769
Deferred revenue, current portion	5,000	5,000
Collaboration research advancement, current portion	19,125	22,185
Total current liabilities	106,313	98,388
Deferred revenue, net of current portion	25,762	25,762
Collaboration research advancement, net of current portion	710	1,135
Operating lease liability, net of current portion	269,289	272,446
Other non-current liabilities	2,431	2,122
Total liabilities	404,505	399,853
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized, 0 shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, \$0.0001 par value; 200,000 shares authorized, 37,616 and 23,585 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	4	2
Additional paid-in capital	575,421	400,026
Accumulated other comprehensive loss	(2,804)	(712)
Accumulated deficit	(125,205)	(39,494)
Total stockholders' equity	447,416	359,822
Total liabilities and stockholders' equity	\$ 851,921	\$ 759,675

*See accompanying notes to unaudited condensed consolidated and combined financial statements.*

2seventy bio, Inc.

Condensed Consolidated and Combined Statements of Operations and Comprehensive Loss  
(unaudited)  
(in thousands, except per share data)

	For the three months ended March 31,	
	2022	2021
Revenue:		
Service revenue	\$ 4,055	\$ 5,918
Collaborative arrangement revenue	3,487	1,519
Royalty and other revenue	887	4,464
Total revenues	8,429	11,901
Operating expenses:		
Research and development	69,245	77,571
Selling, general and administrative	23,861	24,627
Share of collaboration loss	5,352	—
Cost of royalty and other revenue	511	1,704
Change in fair value of contingent consideration	48	369
Total operating expenses	99,017	104,271
Loss from operations	(90,588)	(92,370)
Interest income, net	115	—
Other income, net	4,762	5,174
Loss before income taxes	(85,711)	(87,196)
Income tax (expense) benefit	—	—
Net loss and comprehensive loss	\$ (85,711)	\$ (87,196)
Net loss per share - basic and diluted	\$ (3.20)	\$ (3.73)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	26,751	23,369
Other comprehensive loss:		
Other comprehensive loss, net of tax benefit (expense) of \$0.0 million and \$0.0 million for the three months ended March 31, 2022 and 2021, respectively.	\$ (2,092)	\$ —
Total other comprehensive loss	\$ (2,092)	\$ —
Comprehensive loss	\$ (87,803)	\$ (87,196)

See accompanying notes to unaudited condensed consolidated and combined financial statements.

2seventy bio, Inc.

Condensed Consolidated and Combined Statements of Stockholders' Equity  
(unaudited)  
(in thousands)

	Common stock		Net parent investment	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount					
<b>Balances at December 31, 2021</b>	23,585	\$ 2	\$ —	\$ 400,026	\$ (712)	\$ (39,494)	\$ 359,822
Vesting of restricted stock units	97	—	—	—	—	—	—
Exercise of stock options	—	—	—	1	—	—	1
Issuance of common stock in private placement, net of issuance costs	13,934	2	—	165,655	—	—	165,657
Stock-based compensation	—	—	—	9,739	—	—	9,739
Other comprehensive loss	—	—	—	—	(2,092)	—	(2,092)
Net loss	—	—	—	—	—	(85,711)	(85,711)
<b>Balances at March 31, 2022</b>	<u>37,616</u>	<u>\$ 4</u>	<u>\$ —</u>	<u>\$ 575,421</u>	<u>\$ (2,804)</u>	<u>\$ (125,205)</u>	<u>\$ 447,416</u>

	Common stock		Net parent investment	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount					
<b>Balances at December 31, 2020</b>	—	\$ —	\$ 74,629	\$ —	\$ —	\$ —	\$ 74,629
Stock-based compensation - bluebird bio allocation	—	—	17,109	—	—	—	17,109
Transfers from bluebird bio	—	—	71,101	—	—	—	71,101
Net loss	—	—	(87,196)	—	—	—	(87,196)
<b>Balances at March 31, 2021</b>	<u>—</u>	<u>\$ —</u>	<u>\$ 75,643</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 75,643</u>

See accompanying notes to unaudited condensed consolidated and combined financial statements.

2seventy bio, Inc.

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

	For the three months ended March 31,	
	2022	2021
<b>Cash flows from operating activities:</b>		
Net loss	\$ (85,711)	\$ (87,196)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Change in fair value of contingent consideration	48	369
Depreciation and amortization	3,530	3,676
Stock-based compensation expense	9,739	17,109
Other non-cash items	1,227	69
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(7,768)	2,262
Operating lease right-of-use assets	4,710	3,652
Accounts payable	6,228	4,535
Accrued expenses and other liabilities	280	(1,248)
Operating lease liabilities	(2,860)	(5,639)
Deferred revenue	—	(820)
Collaboration research advancement	(3,487)	(1,519)
Net cash used in operating activities	(74,064)	(64,750)
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(3,585)	(6,351)
Purchases of marketable securities	(22,450)	—
Proceeds from maturities of marketable securities	70,784	—
Net cash provided by (used in) investing activities	44,749	(6,351)
<b>Cash flows from financing activities:</b>		
Transfers from bluebird bio	—	71,101
Proceeds from issuance of common stock in private placement	170,000	—
Proceeds from exercise of stock options and ESPP contributions	99	—
Net cash provided by financing activities	170,099	71,101
Increase (decrease) in cash, cash equivalents and restricted cash	140,784	—
Cash, cash equivalents and restricted cash at beginning of period	163,266	—
Cash, cash equivalents and restricted cash at end of period	\$ 304,050	\$ —
<b>Reconciliation of cash, cash equivalents, and restricted cash</b>		
Cash and cash equivalents	\$ 270,893	\$ —
Restricted cash included in restricted cash and other non-current assets	33,157	—
Total cash, cash equivalents, and restricted cash	\$ 304,050	\$ —
<b>Supplemental cash flow disclosures:</b>		
Purchases of property, plant and equipment included in accounts payable and accrued expenses	\$ 2,925	\$ 1,954
Private placement issuance costs included in accounts payable and accrued expenses	\$ 4,343	\$ —

See accompanying notes to unaudited condensed consolidated and combined financial statements.



**2seventy bio, Inc.**

**Notes to Condensed Consolidated and 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 a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. The Company’s approach combines its expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. The Company is advancing multiple preclinical and clinical programs in oncology and, together with Bristol Myers Squibb (“BMS”), delivering the first FDA-approved CAR T therapy in multiple myeloma, ABECMA (idecabtagene vicleucel, or ide-cel), to patients in the United States. Please refer to Note 9, *Collaborative arrangements and strategic partnerships* for further discussion of the collaboration with BMS.

2seventy bio Securities Corporation is a wholly-owned subsidiary of the Company which was incorporated in Massachusetts on December 13, 2021 and was granted securities corporation status in Massachusetts for the 2021 tax year. 2seventy bio Securities Corporation has no employees.

***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, refer to Note 13, *Related-party transactions* and the section captioned “Transactions with Related and Certain Other Parties” in this Quarterly Report on Form 10-Q.

***Going concern***

In accordance with Accounting Standards Codification 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 consolidated and combined financial statements are issued. The Company has incurred losses and has experienced negative operating cash flows for all historical periods presented. During the three months ended March 31, 2022, the Company incurred a net loss of \$85.7 million and used \$74.1 million of cash in operations. The Company expects to continue to generate operating losses and negative operating cash flows for the next few years. The Company’s continued operations are dependent on its ability to raise additional funding.

As of March 31, 2022, the Company had cash, cash equivalents, and marketable securities of \$452.5 million. The Company expects that its cash, cash equivalents, and marketable securities will be sufficient to fund current planned operations for at least the next twelve months from the date of issuance of these financial statements. 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**

### ***Significant accounting policies***

The significant accounting policies used in preparation of these condensed consolidated and combined financial statements for the three months ended March 31, 2022 and 2021 are consistent with those discussed in Note 2 to the consolidated and combined financial statements for the year ended December 31, 2021 included in the Company's 2021 Annual Report on Form 10-K.

### ***Basis of presentation***

The Company did not operate as a separate, stand-alone entity prior to its separation from bluebird bio. Accordingly, the Company's consolidated and combined statements of operations and comprehensive loss, stockholders' equity and cash flows for the three months ended March 31, 2021, have been prepared on a carve out basis, derived from bluebird bio's consolidated financial statements and accounting records.

The accompanying condensed consolidated and combined financial statements reflect the historical results of the operations, financial position and cash flows of the Company and have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as included in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB").

The historical results of operations and cash flows of 2seventy bio presented in these condensed consolidated and combined financial statements for periods prior to the separation may not be indicative of what they would have been had 2seventy bio operated as an independent, stand-alone entity for those periods. The historical results of operations, financial position and cash flows of 2seventy bio presented in these condensed consolidated and combined financial statements for periods subsequent to the separation are not necessarily indicative of 2seventy bio's future results of operations, financial position and cash flows.

In the opinion of management, the unaudited interim condensed consolidated and combined financial statements reflect all normal recurring adjustments considered necessary for a fair presentation of the Company's financial position and the results of its operations for the interim periods presented.

### ***Use of estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This

process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements.

Estimates and judgments are used in the following areas, among others: allocations of revenue, expenses, assets and liabilities from bluebird bio's historical consolidated financial statements to the Company for periods prior to the separation, future undiscounted cash flows and subsequent fair value estimates used to assess potential and measure any impairment of long-lived assets, including goodwill and intangible assets, the measurement of right-of-use assets and lease liabilities, contingent consideration, stock-based compensation expense, accrued expenses, income taxes, and the assessment of the Company's ability to fund its operations for at least the next twelve months from the date of issuance of these financial statements. In addition, estimates and judgments are used in the Company's accounting for its revenue-generating arrangements, in particular as it relates to determining the stand-alone selling price of performance obligations, evaluating whether an option to acquire additional goods and services represents a material right, estimating the total transaction price, including estimating variable consideration and the probability of achieving future potential development and regulatory milestones, assessing the period of performance over which revenue may be recognized, and accounting for modifications to revenue-generating arrangements.

### 3. Marketable securities

The following table summarizes the marketable securities held at March 31, 2022 and December 31, 2021 (in thousands):

	Amortized cost/ cost	Unrealized gains	Unrealized losses	Fair Value
<b>March 31, 2022</b>				
U.S. government agency securities and treasuries	\$ 140,192	\$ 3	\$ (2,028)	\$ 138,167
Corporate bonds	33,803	—	(136)	33,667
Commercial paper	9,822	—	—	9,822
Total	<u>\$ 183,817</u>	<u>\$ 3</u>	<u>\$ (2,164)</u>	<u>\$ 181,656</u>
<b>December 31, 2021</b>				
U.S. government agency securities and treasuries	\$ 128,899	\$ —	\$ (507)	\$ 128,392
Corporate bonds	49,368	—	(58)	49,310
Commercial paper	54,065	—	—	54,065
Total	<u>\$ 232,332</u>	<u>\$ —</u>	<u>\$ (565)</u>	<u>\$ 231,767</u>

No available-for-sale debt securities held as of March 31, 2022 or December 31, 2021 had remaining maturities greater than five years.

#### 4. Fair value measurements

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2022 and December 31, 2021 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>March 31, 2022</b>				
Assets:				
Cash and cash equivalents	\$ 270,893	\$ 270,893	\$ —	\$ —
Marketable securities:				
U.S. government agency securities and treasuries	138,167	—	138,167	—
Corporate bonds	33,667	—	33,667	—
Commercial paper	9,822	—	9,822	—
Total assets	<u>\$ 452,549</u>	<u>\$ 270,893</u>	<u>\$ 181,656</u>	<u>\$ —</u>
Liabilities:				
Contingent consideration	\$ 1,996	\$ —	\$ —	\$ 1,996
Total liabilities	<u>\$ 1,996</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,996</u>
<b>December 31, 2021</b>				
Assets:				
Cash and cash equivalents	\$ 130,414	\$ 130,414	\$ —	\$ —
Marketable securities:				
U.S. government agency securities and treasuries	128,392	—	128,392	—
Corporate bonds	49,310	—	49,310	—
Commercial paper	54,065	—	54,065	—
Total assets	<u>\$ 362,181</u>	<u>\$ 130,414</u>	<u>\$ 231,767</u>	<u>\$ —</u>
Liabilities:				
Contingent consideration	\$ 1,948	\$ —	\$ —	\$ 1,948
Total liabilities	<u>\$ 1,948</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,948</u>

Accrued interest receivable on the Company's available-for-sale debt securities totaled \$0.3 million as of March 31, 2022. No accrued interest receivable was written off during the three months ended March 31, 2022.

The Company determined that there was no material change in the credit risk of the above investments during the three months ended March 31, 2022. As such, an allowance for credit losses was not recognized. As of March 31, 2022, the Company does not intend to sell such securities and it is not more likely than not that the Company will be required to sell the securities before recovery of their amortized cost bases.

#### *Contingent consideration*

In connection with bluebird bio's prior acquisition of Precision Genome Engineering, Inc. ("Pregen"), 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 consolidated and combined statements of operations and comprehensive loss. In the absence of new information related to the probability of milestone achievement, changes in fair value will reflect changing discount rates and the passage of time. Contingent consideration is included in other non-current liabilities on the condensed consolidated balance sheets.

The table below provides a roll-forward of fair value of the Company's contingent consideration obligations that include Level 3 inputs (in thousands):

	<b>For the three months ended March 31, 2022</b>
Beginning balance	\$ 1,948
Additions	—
Changes in fair value	48
Payments	—
Ending balance	<u>\$ 1,996</u>

Please refer to Note 8, Commitments and contingencies, for further information.

## 5. Property, plant and equipment, net

Property, plant and equipment, net, consists of the following (in thousands):

	<b>As of March 31, 2022</b>	<b>As of December 31, 2021</b>
Laboratory equipment	\$ 33,065	\$ 31,710
Leasehold improvements	26,709	28,479
Office equipment	6,080	6,080
Construction-in-progress	5,515	3,462
Computer equipment and software	5,260	5,260
Total property, plant and equipment	<u>76,629</u>	<u>74,991</u>
Less accumulated depreciation and amortization	<u>(41,591)</u>	<u>(40,078)</u>
Property, plant and equipment, net	<u>\$ 35,038</u>	<u>\$ 34,913</u>

### *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 North Carolina manufacturing facility and retained all staff employed at the site. As a result, bluebird bio disposed of \$111.2 million of net assets, primarily consisting of the building and laboratory equipment. Prior to its disposal by bluebird bio, the North Carolina manufacturing facility was expected to be attributed to the Company as part of the separation and, accordingly, the manufacturing facility was included within the Company's financial statements prior to its disposal. The disposition of the net assets of the North Carolina manufacturing facility was 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 9, *Collaborative arrangements and strategic partnerships*, for further discussion regarding the strategic manufacturing collaboration with Resilience.

## 6. Accrued expenses and other current liabilities

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

	As of March 31, 2022	As of December 31, 2021
Employee compensation	\$ 14,796	\$ 24,655
Collaboration research costs	14,082	2,576
Manufacturing costs	11,097	5,459
Royalties	4,146	6,768
Professional fees	1,942	1,688
Clinical and contract research organization costs	1,938	3,229
Property, plant, and equipment	1,311	2,241
Separation related costs	818	762
Other	8,345	8,032
Total accrued expenses and other current liabilities	<u>\$ 58,475</u>	<u>\$ 55,410</u>

## 7. Leases

The Company leases certain office and laboratory space, primarily located in Cambridge, Massachusetts and Seattle, Washington, that was attributed to it in connection with the separation. There have been no material changes to the lease obligations from those disclosed in Note 7, *Leases*, to the consolidated and combined financial statements included in the Company's 2021 Annual Report on Form 10-K.

## 8. 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 March 31, 2022, 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 consolidated balance sheets at fair value. Estimating the fair value of contingent consideration requires the use of significant assumptions primarily relating to probabilities of successful achievement of certain clinical and commercial milestones, the expected timing in which these milestones will be achieved and discount rates. The use of different assumptions could result in materially different estimates of fair value.

### *Other funding commitments*

Certain agreements that were assigned by bluebird bio to the Company in connection with the separation relate principally to licensed technology and may require future payments relating to milestones that may be met in subsequent periods or royalties on future sales of specified products. These agreements include the collaboration

agreements entered into with BMS 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 9, *Collaborative arrangements and strategic partnerships*, for further information on the BMS, Regeneron and Resilience agreements and to Note 10, *Royalty and other revenue*, for further information on license agreements.

Based on the Company's development plans as of March 31, 2022, 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 9, *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®.

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 the commercial supply agreement and the development manufacturing supply agreement, 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. As of March 31, 2022, the Company has accrued \$8.0 million related to the net operating losses of Resilience. 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 9, *Collaborative arrangements and strategic partnerships*, for further discussion.

Additionally, 2seventy 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 8, *Commitments and Contingencies*, to the consolidated and combined financial statements included in the Company's 2021 Annual Report on Form 10-K.

### ***Litigation***

From time to time, the Company expects to be party to various claims and complaints arising in the ordinary course of business. However, the Company is not currently a party to any litigation or legal proceedings that, in the opinion of its management, are probable of having a material adverse effect on its business. The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners. In addition, pursuant to the separation agreement, the Company indemnifies, holds harmless, and agrees to reimburse bluebird bio for its indemnification obligations with respect to the Company's business partners, relating to the Company's business or arising out of the Company's activities, in the past or to be conducted in the future. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Management does not believe that any ultimate liability resulting from any of these claims will have a material adverse effect on its results

of operations, financial position, or liquidity. However, management cannot give any assurance regarding the ultimate outcome of any claims, and their resolution could be material to operating results for any particular period.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and by-laws 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.

## **9. 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 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 10, *Collaborative arrangements and strategic partnerships*, to the consolidated and combined financial statements included in the Company's 2021 Annual Report on Form 10-K. During the first quarter of 2022, there have been no changes to the terms of the collaboration agreement with BMS.

#### ***ABECMA***

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**

The U.S. commercial and development activities under the Amended Ide-Cel CCPS are within the scope of ASC 808. On a quarterly basis, the Company determines its share of collaboration profit or loss for commercial activities (i.e., commercial sales of ABECMA by BMS). The Company's share of any collaboration profit for commercial activities is recognized as collaborative arrangement revenue and its share of any collaboration loss for commercial activity is recognized as an operating expense and classified as share of collaboration loss on the Company's condensed consolidated and combined statement of operations and comprehensive loss.

The Company's share of collaboration loss from commercial activities was \$5.4 million and \$0.0 million for the three months ended March 31, 2022 and March 31, 2021, respectively. ABECMA was approved for commercial sale in the U.S. in March 2021 and commercial sales did not begin until April 2021. Accordingly, there is no



collaboration profit or loss on commercial activities for the three months ended March 31, 2021. The amounts reported for the three months ended March 31, 2022 represent the Company's share of BMS' ABECMA product revenue, cost of goods sold, and selling costs, along with reimbursement by BMS of commercial costs incurred by the Company, and exclude expenses related to ongoing development, which are separately reflected in the condensed consolidated and combined statements of operations and comprehensive loss as described below.

The Company is also responsible for equally sharing in the ongoing ide-cel research and development activities being conducted by BMS in the United States as BMS continues conducting ongoing clinical studies to support the use of ABECMA in earlier lines of therapy. The net amount owed to BMS for research and development activities determined on a quarterly basis is classified as research and development expense on the condensed consolidated and 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 in a particular quarterly period, 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 months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net expense	\$ (6,893)	\$ (16,825)

#### Ide-cel ex-U.S. Service Revenue

The Company accounts for any ex-U.S. activities under the Amended Ide-cel CCPS pursuant to ASC 606. The following table summarizes the revenue recognized related to ide-cel ex-U.S. activities for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
ASC 606 ide-cel license and manufacturing revenue - ex-U.S.	\$ 2,790	\$ 5,104

#### *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 10, *Collaborative arrangements and strategic partnerships*, to the consolidated and combined financial statements included in the Company's 2021 Annual Report on Form 10-K.

Under the collaboration arrangement with BMS, the Company has an option to co-develop and co-promote bb21217 within the United States. However, following completion of the CRB-402 clinical trial, and based in part on the strength of ABECMA clinical data and commercial sales to date, in January 2022 the Company, along with BMS, evaluated its plans with respect to bb21217 and does not expect to co-develop and co-promote bb21217. Because the Company does not intend to exercise this option, it expects to receive an additional fee in the amount of \$10.0 million from BMS pursuant to the terms of the collaboration arrangement. Under this scenario, there would be no change to the U.S. milestones and royalties for U.S. sales of bb21217, for which the Company would be eligible to receive.

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. 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 which has not yet been received. 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 \$27.4 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 March 31, 2022, the Company has not commenced manufacturing and the full amount of the allocated transaction price remains unsatisfied. The Company had \$25.8 million of deferred revenue as of March 31, 2022 and December 31, 2021 associated with the combined performance obligation consisting of the bb21217 license and manufacturing services.

*Contract assets and liabilities – ide-cel and bb21217*

The Company receives payments from its collaborative partners based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until such time as the Company satisfies its performance obligations under these arrangements. A contract asset is a conditional right to consideration in exchange for goods or services that the Company has transferred to a customer. Amounts are recorded as accounts receivable when the Company’s right to consideration is unconditional.

The following table presents changes in the balances of the Company’s BMS receivables and contract liabilities during the three months ended March 31, 2022 (in thousands):

	Balance at December 31, 2021		Additions		Deductions		Balance at March 31, 2022
Receivables	\$ 652	\$	—	\$	(652)	\$	—
Contract liabilities:							
Deferred revenue	\$ 25,762	\$	—	\$	—	\$	25,762

The decrease in the receivables balance for the three months ended March 31, 2022 is driven by amounts paid to the Company from BMS in the period under the settlement terms of the collaboration agreement.

**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 collaboration revenue or research and development expense related to the joint research activities in future periods depending on the amounts incurred by each party in a given reporting period. That is, if the Company's research costs incurred exceed those research costs incurred by Regeneron in a given quarter, the Company will record collaboration revenue and reduce the original \$37.0 million advance by the amount due from Regeneron until such advancement is fully utilized, after which the Company would record an amount due from Regeneron. If Regeneron's research costs incurred exceed those research costs incurred by the Company in a given quarter, the Company will record research and development expense and record a liability for the amount due to Regeneron. As of March 31, 2022 and December 31, 2021, the Company has \$19.8 million and \$23.3 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 consolidated balance sheets.

The Company recognized \$3.5 million and \$1.5 million of collaborative arrangement revenue from the Regeneron Collaboration Agreement during the three months ended March 31, 2022, and 2021, 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, 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.

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.

#### ***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 consolidated and combined statements of operations and comprehensive loss.

#### **Novo Nordisk**

##### ***Novo Collaboration and License Agreement***

On December 23, 2021, the Company entered into a Collaboration and License Agreement (the "Novo Collaboration Agreement") with Novo Nordisk A/S ("Novo") for the discovery, development, and commercialization of a potential new gene therapy in hemophilia A. The Company and Novo have agreed to develop an initial research program with the goal of researching and developing a lead candidate directed to hemophilia A. The Company will provide Novo with research licenses to support the companies' activities during the initial research program and an option to enable Novo to obtain an exclusive license to commercialize the product derived from or containing compounds developed during the initial research program.

Under the terms of the Novo Collaboration Agreement, Novo agreed to pay the Company:

- a non-refundable, non-creditable upfront payment of \$5.0 million;
- \$15.0 million upon achievement of certain scientific milestones during the initial research program, or \$9.0 million should Novo decide to continue the initial research program without achieving the scientific milestones;
- up to \$26.0 million of exclusive license fees for the development, manufacture, and commercialization of the product should Novo exercise its option; and,
- up to \$72.0 million in development and commercialization milestones.

Novo also agreed to reimburse the Company for research costs incurred in connection with the initial research program up to a mutually agreed upon amount, initially budgeted at \$6.7 million. If Novo exercises its option to obtain a license to commercialize the product developed during the initial research program, the Company is also eligible to receive mid-single digit royalties on product sales on a country-by-country and product-by-product basis, subject to certain royalty step-down provisions set forth in the agreement.

##### ***Accounting Analysis - Novo***

The Company concluded that Novo is a customer, and as such, the arrangement falls within the scope of Topic 606. The Company identified two performance obligations consisting of (i) the research license and research and development services to be provided during the initial research program and (ii) a material right related to Novo's option to obtain an exclusive license for the development, manufacture, and commercialization of the product developed during the initial research program. The Company determined that the research license and research and development services promises were not separately identifiable and were not distinct or distinct within the context of the contract due to the specialized nature of the services to be provided by 2seventy, specifically with respect to the Company's expertise related to gene therapy and the interdependent relationship between the promises. The material right is considered a separate performance obligation pursuant to the provisions of Topic 606.

At contract inception, the Company determined the unconstrained transaction price was \$11.7 million, consisting of the \$5.0 million in up-front consideration and the \$6.7 million in reimbursement for the research and development services. Variable consideration associated with the scientific milestones was fully constrained due to the uncertainty associated with the outcome of the research efforts under the initial research program. The Company allocated \$6.7 million of the transaction price to the research services and \$5.0 million to the material right using a relative selling price methodology. Management will re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur and adjust the transaction price as necessary.

Revenue associated with the research and development performance obligation will be recognized as services are provided and costs are incurred. The portion of the transaction price attributed to the material right will be deferred and recognized as revenue upon Novo exercising its option to license the product. For the three months ended March 31, 2022, \$1.3 million of revenue was recognized under this agreement.

## 10. Royalty and other revenue

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

The Company recognized \$0.9 million and \$4.5 million of royalty and other revenue in the three months ended March 31, 2022 and 2021, respectively.

### *Novartis Pharma AG*

In April 2017, bluebird bio entered into a worldwide license agreement with Novartis. Under the terms of the agreement, Novartis non-exclusively licensed certain patent rights related to lentiviral vector technology to develop and commercialize CAR T cell therapies for oncology, including Kymriah (formerly known as CTL19), Novartis's anti-CD19 CAR T therapy. The agreement was assumed by the Company in connection with the separation. Beginning in the fourth quarter of 2017, bluebird bio began receiving royalties from sales of tisagenlecleucel under the agreement. This license agreement was terminated effective March 2021, at which point in time Novartis was no longer required to make royalty or other payments on net sales of tisagenlecleucel or any future products. Royalty revenue recognized from sales of tisagenlecleucel is included within royalty and other revenue in the condensed consolidated and combined statement of operations and comprehensive loss.

### *Juno Therapeutics*

In May 2020, bluebird bio entered into a non-exclusive license agreement with Juno Therapeutics, Inc. ("Juno"), a wholly-owned subsidiary of BMS, related to lentiviral vector technology to develop and commercialize CD-19-directed CAR T cell therapies. The agreement was assumed by the Company in connection with the separation. Upon regulatory approval of lisocabtagene maraleucel 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 consolidated and combined financial statements. Royalty revenue recognized from sales of

lisocabtagene maraleucel is also included within royalty and other revenue in the condensed consolidated and combined statement of operations and comprehensive loss.

## 11. Equity

In March 2022, the Company entered into stock purchase agreements with certain investors, pursuant to which the Company agreed to sell and issue, in a private placement, an aggregate of 13,934,427 shares of the Company's common stock at a purchase price per share of \$12.20. This resulted in aggregate net proceeds to the Company of approximately \$165.7 million, after deducting placement agent fees and other offering expenses payable by the Company.

## 12. Stock-based compensation

In connection with 2seventy's separation from bluebird bio on November 4, 2021, under the provisions of the existing plans, the outstanding bluebird bio equity awards were adjusted in accordance with the terms of the employee matters agreement (equitable adjustment) to preserve the intrinsic value of the awards immediately before and after distribution. Refer to Note 13, *Stock-based compensation*, to the consolidated and combined financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021 for details on the conversion methodology of the equity awards.

In October 2021, the Company's board of directors adopted the 2021 Stock Option and Incentive Plan ("2021 Plan") which allows for the granting of incentive stock options, non-qualified stock options, restricted stock units ("RSUs"), performance-based restricted stock units ("PRSUs"), and restricted stock awards to 2seventy bio's employees, members of the board of directors, and consultants of 2seventy bio, including those who became employees of the Company in connection with the separation. Shares of the Company's common stock underlie all awards granted under the 2021 Plan.

### *Stock-based compensation expense*

For periods prior to the separation, stock-based compensation expense was allocated to the Company using a combination of specific identification and time spent on projects at various levels of the organization, which management believes are consistent and reasonable. Post separation, stock-based compensation expense includes compensation cost related to 2seventy equity awards held by its employees as well as bluebird bio equity awards issued upon separation to its employees.

Stock-based compensation expense recognized by award type was as follows (in thousands):

	For the three months ended March 31,	
	2022	2021
Stock options	\$ 4,404	\$ 7,586
Restricted stock units	5,314	7,205
Employee stock purchase plan and other	21	2,318
	<u>\$ 9,739</u>	<u>\$ 17,109</u>

Stock-based compensation expense by classification included within the condensed consolidated and combined statements of operations and comprehensive loss was as follows (in thousands):

	For the three months ended March 31,	
	2022	2021
Research and development	\$ 4,218	\$ 9,431
Selling, general and administrative	5,521	7,678
	<u>\$ 9,739</u>	<u>\$ 17,109</u>

#### ***Employee Stock Purchase Plan***

During the three months ended March 31, 2022, no shares of common stock were issued under the Company's 2021 Employee Stock Purchase Plan.

### **13. Related-party transactions**

#### ***Relationship with bluebird bio***

Following the separation, bluebird bio is considered a related party.

In connection with the separation, the Company entered into a separation agreement (the "Separation Agreement") with bluebird bio, dated as of November 3, 2021, that, among other things, set forth bluebird bio's agreements with 2seventy bio regarding the principal actions to be taken in connection with the separation, including the distribution. The effective time of the distribution was 12:01 a.m. on November 4, 2021. The Separation Agreement identifies assets transferred to, liabilities assumed by and contracts assigned to 2seventy bio as part of the separation, and it provides for when and how these transfers, assumptions and assignments occur. The purpose of the Separation Agreement is to provide 2seventy bio and bluebird bio with assets to operate their respective businesses and retain or assume liabilities related to those assets. Each of 2seventy bio and bluebird bio agreed to releases, with respect to pre-separation claims, and cross indemnities with respect to post-separation claims, that are principally designed to place financial responsibility for the obligations and liabilities allocated to 2seventy bio under the Separation Agreement with 2seventy bio and financial responsibility for the obligations and liabilities allocated to bluebird bio under the Separation Agreement. bluebird bio and 2seventy bio are also each subject to mutual 12-month employee non-solicit and non-hire restrictions, subject to certain customary exceptions. In accordance with the Separation Agreement with bluebird bio, there were certain other transactions and adjustments post-Separation between the Company and bluebird bio. For the three months ended March 31, 2022, the Company recorded a net receivable to operating income of \$2.9 million related to the Separation Agreement.

The Company and bluebird bio also entered into a tax matters agreement, dated as of November 3, 2021, governing bluebird bio's and 2seventy bio's respective rights, responsibilities and obligations with respect to taxes (including taxes arising in the ordinary course of business and taxes, if any, incurred as a result of any failure of the distribution and certain related transactions to qualify as tax-free for U.S. federal income tax purposes, tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings, and assistance and cooperation in respect of tax matters).

In connection with the separation, the Company also entered into an employee matters agreement with bluebird bio, dated as of November 3, 2021. The employee matters agreement allocates assets, liabilities and responsibilities relating to the employment, compensation and employee benefits of bluebird bio and 2seventy bio employees, and other related matters, in connection with the separation, including the treatment of outstanding bluebird bio incentive equity awards and certain retirement and welfare benefit obligations. The employee matters agreement generally



provides that, unless otherwise specified, 2seventy bio is responsible for liabilities associated with employees who transfer to 2seventy bio and employees whose employment terminated prior to the distribution but who primarily supported the 2seventy bio business, and bluebird bio is responsible for liabilities associated with other employees, including employees retained by bluebird bio. Included in the agreement are also specific clauses relating to liabilities assumed by bluebird bio for the costs incurred prior to the separation. For the three months ended March 31, 2022, the Company recorded a net charge to operating expense of \$0.2 million for costs stipulated by the employee matters agreement.

The Company and bluebird bio also entered into an intellectual property license agreement on November 3, 2021, pursuant to which each party granted a license to certain intellectual property and technology to the other. bluebird bio granted 2seventy bio a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to certain intellectual property to allow 2seventy bio to use such intellectual property in connection with 2seventy bio's ongoing and future research and development activities and product candidates. 2seventy bio granted bluebird bio a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to certain intellectual property for use in bluebird bio's existing products and product candidates. Such licenses between the parties generally allow current or future uses of the intellectual property in connection with each party's respective fields. Charges associated to the intellectual property license agreement commenced in 2022. For the three months ended March 31, 2022, the Company recorded immaterial costs associated with this agreement.

The Company and bluebird bio entered into two transition services agreements on November 3, 2021, pursuant to which bluebird bio will provide 2seventy bio with corporate and shared services and resources related to corporate functions such as finance, human resources, internal audit, research and development, financial reporting, and information technology, and to which 2seventy bio will provide certain services to bluebird bio, each for an initial term of two years, unless earlier terminated or extended according to the terms of the transition services agreement. For the three months ended March 31, 2022, the Company recorded \$3.6 million in other income reflecting services provided to bluebird bio and \$0.6 million of operating expenses reflecting services received from bluebird bio, for activities related to the transition services.

Additionally, under the transition services agreements, 2seventy bio is subleasing 30% of its headquarters at 60 Binney Street in Cambridge, Massachusetts to bluebird bio through the first quarter of 2022. Beginning in the second quarter of 2022, this percentage will decrease to 23% for the remainder of the year. The Company recorded \$1.2 million in other income related to sublease income from bluebird under this arrangement during the three months ended March 31, 2022.

As of March 31, 2022, amounts due to bluebird bio under the above agreements were \$0.4 million and are included in accrued expenses. As of March 31, 2022, amounts due from bluebird bio under the above agreements were \$6.5 million and are included in receivables and other current assets.

#### ***Corporate allocations***

Prior to the separation, the Company did not operate as a separate, stand-alone entity, but rather was managed and operated in the normal course of business under bluebird bio. Accordingly, certain shared costs have been allocated to the Company and reflected as expenses in the Company's stand-alone condensed consolidated and combined financial statements for periods prior to the separation as described. The expenses reflected in the consolidated and combined financial statements may not be indicative of expenses that will be incurred by the Company in the future.

For periods prior to the separation, the condensed consolidated and combined financial statements reflect allocations of certain expenses from bluebird bio, including, but not limited to, general corporate expenses, such as senior management, legal, human resources, accounting, other financial services (such as treasury, audit and

purchasing), tax, information technology, and corporate employee benefits, incentives and stock-based compensation included within selling, general and administrative expense.

These expenses have been allocated to the Company based on direct usage or benefit where specifically identifiable, with the remainder allocated based on employee time spent on projects, square footage or other measures that management believes are consistent and reasonable. Allocations for management costs and corporate support services provided to the Company totaled \$19.9 million for the three months ended March 31, 2021.

The financial information in these condensed consolidated and combined financial statements for periods prior to the separation does not necessarily include all the expenses that would have been incurred by the Company had it been a separate, stand-alone entity. Actual costs that may have been incurred if the Company had been a stand-alone company would depend on a number of factors, including the chosen organization structure and functions outsourced or performed by employees. See Note 2, *Summary of significant accounting policies and basis of presentation*, to the consolidated and combined financial statements included in the Company's 2021 Annual Report on 10-K for additional information on the preparation and basis of presentation of these condensed consolidated and combined financial statements, including the treatment of certain research and development costs not directly attributable to individual programs.

***Usage of the Company's assets by bluebird bio and of bluebird bio's assets by the Company prior to separation***

Certain assets have been reflected in these condensed consolidated and 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 2021 condensed consolidated and 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 consolidated and combined financial statements but for which the Company has historically utilized a portion of the underlying asset as part of its operations. The income and expense recognized by the Company resulting from these imputed charges is recorded as other income, net in the 2021 condensed consolidated and combined financial statements and was as follows (in thousands):

	<b>For the three months ended March 31, 2021</b>
Imputed charge to bluebird bio for leases	\$ 4,465
Imputed charge from bluebird bio for leases	(259)
Imputed charge to bluebird bio for property, plant and equipment	528
Imputed charge from bluebird bio for property, plant and equipment	(51)
Imputed charge to bluebird bio for intangible assets	36
Other	(1)
	<u>\$ 4,718</u>

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. There are no such imputed charges in 2022 as the Company recognized all post separation income and costs related pursuant to the terms of the various transition agreements between the Company and bluebird bio, as discussed in previous section.

### **Stock-based compensation**

As discussed in Note 12, *Stock-based compensation*, 2seventy bio's employees participated in bluebird bio's stock-based compensation plans, the costs of which have been allocated to 2seventy bio and recorded in research and development and selling, general and administrative expenses in the condensed consolidated and combined statements of operations and comprehensive loss.

### **Retirement plans**

2seventy bio's employees participated in bluebird bio's 401(k) Savings plan, the costs of which have been allocated to 2seventy bio and recorded in research and development and selling, general and administrative expenses in the condensed consolidated and combined statements of operations and comprehensive loss.

### **Transaction costs**

Prior to the separation, bluebird bio had incurred costs related to the separation of the Company. To the extent separation costs were incurred that directly benefited the Company as a stand-alone company, such costs were allocated to the Company.

### **Centralized cash management**

Prior to separation, no separate cash accounts for 2seventy bio were maintained and, therefore, bluebird bio was presumed to have funded 2seventy bio's operating, investing and financing activities as necessary. As cash was disbursed and received by bluebird bio, for purposes of the condensed consolidated and combined financial statements, funding of 2seventy bio's expenditures was reflected in the condensed consolidated and combined financial statements as a component of net parent investment.

## **14. 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.

## **15. Net Loss Per Share**

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect (in thousands):

	For the three months ended March 31,	
	2022	2021
Outstanding stock options <sup>(1)</sup>	2,780	—
Restricted stock units <sup>(1)</sup>	1,655	—
ESPP shares and other	35	—
	<u>4,470</u>	<u>—</u>

(1) Outstanding stock options and restricted stock units include awards outstanding to employees of bluebird bio.

As described further in Note 9, *Stockholders' equity*, to the consolidated and combined financial statements included in the Company's 2021 Annual Report on Form 10-K, in November 2021, the Company issued to certain

institutional investors (who previously purchased pre-funded warrants to purchase shares of bluebird bio common stock) pre-funded warrants to purchase 757,575 shares of the Company's common stock at an exercise price of \$0.0001 per share. The pre-funded warrants can be exercised at any time or times on or after November 4, 2021, until exercised in full. Based on the terms of the pre-funded warrants, management concluded that they should be considered outstanding shares in the computation of basic and diluted net loss per share.

## 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 the Company's 2021 Annual Report on Form 10-K, which was most recently filed with the Securities and Exchange Commission, or the SEC, on March 22, 2022.*

*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

We are 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<sup>®</sup>). 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 \$85.7 million and \$87.2 million for the three months ended March 31, 2022 and 2021, respectively. We expect to continue to incur operating losses for at least the next several years as we:

- advance our next-generation programs in B-NHL, AML, and multiple myeloma through the clinic;
- manufacture clinical study drug product and materials and establish the infrastructure necessary to support and develop manufacturing capabilities;

- seek regulatory approval for our product candidates 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 our separation from bluebird bio into an independent, publicly traded company.

We are in the process of building a facility at our existing headquarters in Cambridge, Massachusetts to manufacture drug product for our future Phase 1 clinical trials, but 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, 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.

As of March 31, 2022, we had cash, cash equivalents and marketable securities of \$452.5 million. Based on our current operating plans, including with respect to the ongoing commercialization of ABECMA, we expect that our cash, cash equivalents and marketable securities will be sufficient to fund current planned operations for at least the next twelve months, 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.

### **Separation from bluebird bio, Inc.**

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

On November 4, 2021, bluebird bio completed the separation and spin-off of its oncology portfolio and programs into 2seventy bio, retaining its severe genetic disease portfolio and programs. In connection with the separation, certain assets and liabilities, including certain accounts receivables and accounts payables, included on the condensed consolidated and combined balance sheets prior to the separation have been retained by bluebird bio post-separation and, therefore, were adjusted through net parent investment in our consolidated and combined financial statements. In addition, in connection with the separation, certain equity awards were converted in accordance with the employee matters agreement, as further described in Note 12, *Stock-based compensation*. As a result of the separation, our net parent investment balance was reclassified to additional paid-in capital.

## Financial Operations Overview

### Revenue

Our revenues have been derived from collaboration arrangements and out-licensing arrangements, primarily related to our collaboration arrangement with BMS as part of which we are jointly commercializing ABECMA in the United States. To date, we have not recognized any revenue from the sale of products.

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 consolidated and combined statements of operations and comprehensive loss based on the nature of the payments, as summarized in the table and further described below.

Nature of Payment	Statement of Operations Presentation
Our share of net profits in connection with commercialization of products	Collaborative arrangement revenue
Our share of net losses in connection with commercialization of products	Share of collaboration loss
Net reimbursement 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, along with reimbursement by BMS of commercial costs incurred by the Company, 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 consolidated and combined statements of operations and comprehensive loss as follows: service revenue

includes revenue from collaborative partners recognized within the scope of Topic 606 and collaborative arrangement revenue includes only revenue from collaborative partners recognized outside the scope of Topic 606.

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

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

### ***Research and Development Expenses***

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

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

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

- CRB-401 study – an open label, single-arm, multi-center, phase 1 study 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 are winding down the study in 2022 following our election to discontinue development of bb21217.
- CRC-403 study – an open-label, multi-site Phase 1/2 dose-escalation study to examine the safety and efficacy of bbT369 in relapsed and/or refractory B Cell Non-Hodgkin's Lymphoma (NHL).
- PLAT-08 study – an open-label Phase 1 study to examine the safety and efficacy of SC-DARIC33 in pediatric and young adult relapsed or refractory acute myeloid leukemia (AML).

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

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

We expect our ongoing research and development expenses to be driven mainly by our advancement of the SC-DARIC33 and bbT369 clinical programs through phase 1 studies, funding our share of the costs of development of ABECMA, including clinical expansion to earlier lines of therapy, through our collaboration with BMS and manufacture clinical study materials in support of our clinical 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 benefits, personnel-related discretionary bonus, and stock-based compensation costs directly related to specific programs. We do not allocate certain general research and platform personnel costs, certain laboratory and related expenses, rent expense,

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

	Three Months Ended March 31,	
	2022	2021
ide-cel	\$ 13,848	\$ 34,840
bb21217	2,000	3,799
bbT369	6,459	5,822
SC-DARIC33	2,162	1,562
Preclinical programs	13,433	6,858
Total direct research and development expense	37,902	52,881
General research and platform personnel costs	7,644	8,195
Unallocated laboratory and manufacturing expenses	6,071	3,462
Facility and other support costs	17,628	13,033
Total other research and development expenses	31,343	24,690
Total research and development expense	\$ 69,245	\$ 77,571

The costs associated with our bbT369 and SC-DARIC33 programs were included in pre-clinical programs in the table shown above through December 31, 2021. The costs associated with our bbT369 and SC-DARIC33 programs are presented separately in the table above beginning in the first quarter of 2022 as we initiated the clinical studies for bbT369 and SC-DARIC33 in the first quarter of 2022.

#### ***Selling, General and Administrative Expenses***

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

#### ***Share of Collaboration Loss***

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

#### ***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 Pregonen. All assets, liabilities and future obligations related to the Pregonen 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 Pregonen technology.

As of March 31, 2022, 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 March 31, 2022, which are classified within other non-current liabilities on our condensed consolidated 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 three months ended March 31, 2022, there were no material changes to our significant accounting policies as reported in our annual consolidated and combined financial statements included in our 2021 Annual Report on Form 10-K, except as otherwise described in Note 2, *Basis of presentation, principles of consolidation and significant accounting policies*, in the notes to the condensed consolidated and combined financial statements.

#### **Results of Operations**

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

**Comparison of the Three Months Ended March 31, 2022 and 2021:**

	Three Months Ended March 31,		Change
	2022	2021	
	(in thousands)		
Revenue:			
Service revenue	\$ 4,055	\$ 5,918	\$ (1,863)
Collaborative arrangement revenue	3,487	1,519	1,968
Royalty and other revenue	887	4,464	(3,577)
Total revenues	8,429	11,901	(3,472)
Operating expenses:			
Research and development	69,245	77,571	(8,326)
Selling, general and administrative	23,861	24,627	(766)
Share of collaboration loss	5,352	—	5,352
Cost of royalty and other revenue	511	1,704	(1,193)
Change in fair value of contingent consideration	48	369	(321)
Total operating expenses	99,017	104,271	(5,254)
Loss from operations	(90,588)	(92,370)	1,782
Interest income, net	115	—	115
Other income, net	4,762	5,174	(412)
Loss before income taxes	(85,711)	(87,196)	1,485
Income tax (expense) benefit	—	—	—
Net loss	\$ (85,711)	\$ (87,196)	\$ 1,485

*Revenue.* Total revenue was \$8.4 million for the three months ended March 31, 2022, compared to \$11.9 million for the three months ended March 31, 2021. The decrease of \$3.5 million was primarily attributable to a decrease in royalty and other revenue as a result of the termination of our license agreement with Novartis in March 2021.

*Research and Development Expenses.* Research and development expenses were \$69.2 million for the three months ended March 31, 2022, compared to \$77.6 million for the three months ended March 31, 2021. The overall decrease of \$8.3 million was primarily attributable to the following:

- \$9.9 million of decreased collaboration research funding costs, which is primarily driven by a decrease in our share of research and development costs under our collaboration with BMS;
- \$1.3 million of decreased lab expenses and other platform costs; and
- \$1.3 million of decreased employee compensation expenses, primarily due to decreased stock-based compensation expense resulting from the completion of our employee retention plan at the end of 2021 and an overall decrease in the value of stock-based compensation awards.

These decreased costs were partially offset by \$3.7 million of increased IT and other facility-related costs, mainly driven by higher rent charges under the assigned and amended 60 Binney Street lease.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$23.9 million for the three months ended March 31, 2022, compared to \$24.6 million for the three months ended March 31, 2021. The decrease of \$0.8 million was primarily due to the following:

- \$2.4 million of decreased employee compensation expenses, primarily due to decreased stock-based compensation expense resulting from the completion of our employee retention plan at the end of 2021 and an overall decrease in the value of stock-based compensation awards; and
- \$1.7 million of decreased IT and other facility-related costs.

The decreased costs were partially offset by \$3.4 million of increased legal fees related to patent applications and maintenance and increased consulting costs as we began incurring costs to operate as standalone company during the first quarter of 2022.

*Share of Collaboration Loss.* Share of collaboration loss for the three months ended March 31, 2022 represents our share of net loss arising from the commercialization of ABECMA under the BMS collaboration during the first quarter of 2022. During the period, we incurred significant costs related to vector and drug product manufacturing as we increase manufacturing capacity to support the commercial launch. ABECMA was approved in the U.S. at the end of March 2021 and sales did not begin until April 2021.

*Cost of Royalty and Other Revenue.* Cost of royalty and other revenue was \$0.5 million for the three months ended March 31, 2022, compared to \$1.7 million for the three months ended March 31, 2021. The decrease is attributable to decreased royalty and 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.* For the three months ended March 31, 2022, other income, net primarily consisted of income recognized under our transition services agreements with bluebird bio. For the three months ended March 31, 2021, other income, net primarily consisted of 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.

#### **Note on the COVID-19 Pandemic**

Beginning in late 2019, the outbreak of a novel strain of coronavirus (COVID-19) was reported and has since 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. Despite progress with distribution and administration of vaccines, the COVID-19 pandemic and its effects continue to evolve and the extent to which the pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence. We continue to evaluate the impact of the COVID-19 pandemic on patients, healthcare providers and our employees, as well as our operations and the operations of our business partners and healthcare communities.

## Liquidity and Capital Resources

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

As of March 31, 2022, we had cash, cash equivalents, and marketable securities of approximately \$452.5 million. Based on our current operating plans, including with respect to the ongoing commercialization of ABECMA, we expect our cash, cash equivalents and marketable securities will be sufficient to fund current planned operations for at least the next twelve months from the date of filing these financial statements. We 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.

We have incurred losses and have experienced negative operating cash flows for all periods presented. During the three months ended March 31, 2022, we incurred a loss of \$85.7 million and used \$74.1 million of cash in operations. We will continue to incur research and development and selling, general and administrative expenses and we expect to continue to generate operating losses and negative operating cash flows for the next few years.

### Sources of Liquidity

#### Cash Flows

The following table summarizes our cash flow activity:

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	\$ (74,064)	\$ (64,750)
Net cash provided by (used in) investing activities	44,749	(6,351)
Net cash provided by financing activities	170,099	71,101
Increase (decrease) in cash, cash equivalents and restricted cash	\$ 140,784	\$ —

*Cash Flows from Operating Activities.* Net cash used in operating activities was \$74.1 million for the three months ended March 31, 2022 and primarily consisted of a net loss of \$85.7 million adjusted for non-cash items, including stock-based compensation of \$9.7 million and depreciation and amortization of \$3.5 million, as well as the change in our net working capital.

Net cash used in operating activities was \$64.8 million for the three months ended March 31, 2021 and primarily consisted of net loss of \$87.2 million adjusted for non-cash items, including stock-based compensation of \$17.1 million, depreciation and amortization of \$3.7 million, and the change in fair value of the contingent consideration of \$0.4 million, as well as the change in our net working capital.

*Cash Flows from Investing Activities.* Net cash provided by investing activities for the three months ended March 31, 2022 was \$44.7 million and was due to proceeds from maturities of marketable securities of \$70.8

million, offset by the purchase of marketable securities of \$22.5 million and the purchase of property, plant and equipment of \$3.6 million.

Net cash used in investing activities for the three months ended March 31, 2021 was \$6.4 million and was due to the purchase of property, plant and equipment.

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

Net cash provided by financing activities for the three months ended March 31, 2022 was \$170.1 million and was primarily due to gross proceeds received of \$170.0 million from the issuance of common stock in a private placement in March 2022.

Net cash provided by financing activities for the three months ended March 31, 2021 was \$71.1 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 intend to incur costs in support of the following activities:

- development of SC-DARIC33 and bbT369, including conduct of PLAT-08, the Phase 1 study of SC-DARIC33 in pediatric and young adult relapsed or refractory AML and CRC-403, the Phase 1/2 Study of bbT369 in relapsed and/or refractory B Cell Non-Hodgkin's Lymphoma (NHL);
- advancement of the KarMMA trials for ABECMA in additional indications, pursuant to our cost sharing arrangements with BMS;
- development of our pipeline of early research programs;
- the planned build-out of our drug product manufacturing capabilities at our Cambridge, Massachusetts headquarters, which will enable rapid translational research in our clinical trials and the manufacture of drug product for preclinical and Phase 1 clinical development activities; and
- additional research discovery efforts, other capital expenditures, working capital requirements, and other general corporate activities.

We also expect to incur additional costs associated with operating as a public company.

Based on our current operating plans, including with respect to the ongoing commercialization of ABECMA, we expect that our cash, cash equivalents and marketable securities will be sufficient to fund current planned operations for at least the next twelve months from the date of filing these financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, 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, this could result in dilution and could adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in increased fixed payment obligations.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or 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 7, *Leases*, and Note 8, *Commitments and contingencies*, in the notes to condensed consolidated and combined financial statements, there have been no material changes to our contractual obligations and commitments as included in our audited consolidated and combined financial statements included in the Company's 2021 Annual Report on Form 10-K.

### **Transactions with Related and Certain Other Parties**

#### **Agreements with bluebird bio**

On November 3, 2021, in connection with the separation and distribution, we entered into certain agreements with bluebird bio relating and giving effect to the separation, including a separation agreement, two transition services agreements, a tax matters agreement, an intellectual property license agreement and an employee matters agreement. The terms of these agreements, including information on the business purpose of such agreements,



transaction prices, related ongoing contractual commitments and any related special risks or contingencies are discussed in greater detail in Item 13. “Certain Relationships and Related Transactions, and Director Independence,” included in our Annual Report on Form 10-K, which was filed with the SEC on March 22, 2022.

### Participation in our 2022 Private Placement

On March 17, 2022, we issued and sold an aggregate of 13,934,427 shares of Common Stock (the “Shares”) pursuant to share purchase agreements between us and the purchasers of the Shares, for a purchase price of \$12.20 per share, for aggregate gross proceeds to us of approximately \$170 million, before deducting offering commissions and estimated offering expenses payable by us (the “Private Placement”). Certain affiliates of 2seventy bio purchased Shares on the same terms and conditions of the other investors in the Private Placement. The following table sets forth the number of shares of our common stock purchased by directors, executive officers and 5% stockholders and their affiliates and the aggregate purchase price paid for such shares.

Name	Shares of Common Stock Purchased	Aggregate Cash Purchase Price
Entities affiliated with EcoR1 Capital, LLC (1)	2,049,180	\$ 24,999,996
Baker Bros Advisors LP (2)	1,229,508	\$ 14,999,998
Nick Leschly (3)	368,857	\$ 4,500,055
Total:	<u>3,647,545</u>	<u>\$ 44,500,049</u>

(1) EcoR1 Capital LLC is a holder of greater than five percent of our common stock.

(2) Consists of 1,135,960 shares of common stock purchased and received by Baker Brothers Life Sciences, L.P., (“BBLs”) and 93,548 shares of common stock purchased and received by 667, L.P. (“667” and together with BBLs, the “BBA Funds”). Baker Bros. Advisors LP, or BBA, is the investment adviser to the BBA Funds and has sole voting and investment power with respect to the securities held by the BBA Funds and thus may be deemed to beneficially own such securities. Baker Bros. Advisors (GP) LLC, or BBA-GP, is the sole general partner of BBA and thus may be deemed to beneficially own the securities held by the BBA Funds. The BBA Funds are holders of greater than five percent of our common stock.

(3) Nick Leschly is our chief executive officer and a member of our Board. Mr. Leschly’s acquisition of shares in the Private Placement was approved by our Board of Directors and is exempted from the “short-swing” liability provisions of Section 16(b) of the Exchange Act pursuant to Rule 16b-3 promulgated thereunder.

### 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

#### *Interest rate fluctuation risk*

We are exposed to market risk related to changes in interest rates. As of March 31, 2022 we had cash, cash equivalents and marketable securities of \$452.5 million, primarily invested in U.S. government agency securities and treasuries, corporate bonds and commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points, or one percentage point, from levels at March 31, 2022, the net fair value of our interest-sensitive marketable securities would have resulted in a hypothetical decline of \$1.4 million.

#### *Foreign currency fluctuation risk*

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. While we have not engaged in the hedging of our foreign currency transactions to date, we are evaluating the costs and benefits of initiating such a program and may in the future hedge selected significant transactions denominated in currencies other than the U.S. dollar as we expand our international operations and our risk grows.

#### *Inflation fluctuation risk*

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2022.

## 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 reported 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

Except as set forth below, there have been no material changes to the risk factors described in the section captioned “Part I, Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021. In addition to the other information set forth in this report, you should carefully consider the factors discussed in the section captioned “Part I, Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021, which could materially affect our business, financial condition, or future results. The risks described in our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may have a material adverse effect on our business, financial condition, and/or operating results.

***Our business has incurred significant losses and we anticipate that we will incur continued 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, including a net loss of \$85.7 million for the three months ended March 31, 2022. We expect to incur operating losses for several years, as we continue our research activities and conduct development of, and seek regulatory approvals for, our product candidates.

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 ABECMA and any future products in those markets.

We expect to continue to incur significant expenses and continued operating losses for the foreseeable future. We will continue to incur expenses and our expenses may increase 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.

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.***

As of March 31, 2022, we had cash, cash equivalents, and marketable securities of \$452.5 million. We expect that our cash, cash equivalents, and marketable securities will be sufficient to fund our current planned operations for at least the next twelve months from the date of issuance of these financial statements. We will, however, require significant additional funding to continue advancing 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. We also may elect to raise additional funds sooner because we believe market conditions are attractive or as a risk mitigation measure.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our approved product and product candidates. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Regardless of the terms of any debt or equity financing, our agreements and obligations under the tax matters agreement with bluebird bio may limit our ability to issue stock. See “—Risks Related to the Separation” in our Annual Report on Form 10-K.

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. In addition, if we are unable to obtain necessary funding on a

timely basis, we may have to liquidate some or all of our assets and may receive less than the value at which those assets are carried on our audited financial statements, which could cause investors to lose all or part of their investment.

***We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize ABECMA and any future products. If our competitors obtain orphan drug exclusivity for products that regulatory authorities determine constitute the same drug and treat the same indications as ABECMA or any future products, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.***

We are engaged in the development of gene therapies for cancer and this field is competitive and rapidly changing. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, one such competitive product, Janssen and Legend Biotech's ciltacabtagene autoleucel, an anti-BCMA CAR T cell therapy marketed as Carvykti, was approved by the FDA in February 2022. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, manufacturing capabilities, experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective, safer, or less costly than any products that we may develop, or achieve patent protection, marketing approval, product commercialization and market penetration earlier than us. Additionally, technologies developed by our competitors may render our 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 has been granted orphan drug status by the FDA and EMA, there are limitations to the exclusivity. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In the United States, the exclusivity period for orphan drugs is seven years (with limited exceptions), and pediatric exclusivity adds six months to any existing patents or exclusivity periods. In Europe, orphan drugs may be able to obtain 10 years of marketing exclusivity and up to an additional two years on the basis of qualifying pediatric studies. However, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria. Additionally, a marketing authorization holder may lose its orphan exclusivity for a number of reasons, including if it consents to a second orphan drug application, its request for designation is found to be materially defective, or if the marketing

authorization holder cannot supply enough drug. Orphan drug exclusivity also can be lost when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug, in that it is shown to be safer, more effective, or makes a major contribution to patient care compared with the product that has orphan exclusivity. Generally, if a product with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the European Commission from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for our product for the exclusivity period for the applicable indication.

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

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

We are co-developing and co-promoting ide-cel, being marketed as ABECMA in the United States, with BMS under our amended and restated co-development and co-promotion agreement with BMS, or the Ide-cel CCPS. Under the Ide-cel CCPS, we and BMS share the obligation to develop and commercialize ide-cel in the United States.

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

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

- BMS has wide discretion in determining the efforts and resources that it will apply to its partnership with us. The timing and amount of any downstream commercial profits, milestones and royalties that we may receive under such partnership will depend on, among other things, BMS’s efforts, allocation of resources and successful development and commercialization of ide-cel.
- BMS may develop and commercialize, either alone or with others, products that are similar to or competitive with ide-cel. For example, BMS is currently commercializing a number of its existing products, including lenalidomide and pomalidomide, for certain patients with relapsed and refractory multiple myeloma, as well as our CAR-T product candidate targeting BCMA.

- BMS may terminate its partnership with us without cause and for circumstances outside of our control, which could make it difficult for us to attract new strategic partners or adversely affect how we are perceived in scientific and financial communities.
- BMS may develop or commercialize ABECMA in such a way as to elicit litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability.
- BMS may not comply with all applicable regulatory and compliance requirements, including failing to report safety data in accordance with all applicable regulatory requirements.
- If BMS were to breach its arrangements with us, we may need to enforce our right to terminate the agreement in legal proceedings, which could be costly and cause delay in our ability to receive ABECMA rights back. If we were to terminate an agreement with BMS due to BMS's breach or if BMS were to terminate an agreement without cause, the development and commercialization of ABECMA could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of these product candidates on our own if we choose not to, or are unable to, enter into a new collaboration for these product candidates.
- BMS may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or other change in control, which could divert the attention of its management and adversely affect BMS's ability to retain and motivate key personnel who are important to the continued development of ABECMA. In addition, the third-party to any such transaction could determine to re-prioritize BMS's development programs such that BMS ceases to diligently pursue the development of ABECMA and/or cause the respective collaboration with us to terminate.

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

None

## **Item 3. Defaults Upon Senior Securities**

None

## **Item 4. Mine Safety Disclosures**

None

## **Item 5. Other Information**

None



## Item 6. Exhibit Index

<u>Exhibit Number</u>	<u>Exhibit Description</u>
<a href="#">3.1</a>	<a href="#">Amended and Restated Certificate of Incorporation of 2seventy bio, Inc. (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed on November 4, 2021).</a>
<a href="#">3.2</a>	<a href="#">Amended and Restated Bylaws of 2seventy bio, Inc. (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed on November 4, 2021).</a>
<a href="#">4.1</a>	<a href="#">Form of Pre-Funded Warrant (incorporated by reference to Exhibit 10.7 to Current Report on Form 8-K filed on November 4, 2021).</a>
<a href="#">10.1*#†</a>	<a href="#">First Addendum Executive Employment Agreement between Globalization Partners Switzerland SA and Nicola Heffron, dated as of March 7, 2022.</a>
<a href="#">10.2*#†</a>	<a href="#">Second Addendum to Executive Employment Agreement between Globalization Partners Switzerland SA and Nicola Heffron, dated as of March 25, 2022.</a>
<a href="#">10.3*†</a>	<a href="#">Patent License Agreement, dated August 31, 2015, by and between bluebird bio, Inc. and the National Institutes of Health.</a>
<a href="#">10.4*†</a>	<a href="#">Amendment to License Agreement, dated April 25, 2022, by and between 2seventy bio, Inc. and the National Institutes of Health.</a>
<a href="#">10.5</a>	<a href="#">Form of Share Purchase Agreement, dated March 15, 2022, by and between 2seventy bio, Inc. and purchasers in the March 2022 private placement (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on March 16, 2022).</a>
<a href="#">10.6</a>	<a href="#">Form of Registration Rights Agreement, dated March 15, 2022, by and between 2seventy bio, Inc. and purchasers in the March 2022 private placement (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed on March 16, 2022).</a>
<a href="#">31.1*</a>	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">31.2*</a>	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">32.1**</a>	<a href="#">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.</a>
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

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\* Filed herewith.

\*\* The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

# Indicates a management contract or compensatory plan, contract or arrangement.

† Portions of this exhibit (indicated by asterisks) were omitted in accordance with the rules of the Securities and Exchange Commission.

**SIGNATURES**

Pursuant to the requirements of 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: May 12, 2022

By: /s/ Nick Leschly  
Nick Leschly  
*President and Chief Executive Officer (Principal Executive Officer and Duly Authorized Officer)*

Date: May 12, 2022

By: /s/ Chip Baird  
Chip Baird  
*Chief Financial Officer (Principal Financial Officer, Principal Accounting Officer and Duly Authorized Officer)*

**EXHIBIT 10.1**

Nicola Heffron

[\*\*\*]

7<sup>th</sup> March 2022

<p><b>Re: Avenant au contrat de travail – augmentation de salaire:</b></p> <p>Chère Nicola,</p> <p>J'ai le plaisir de vous confirmer qu'à compter du 29/11/2021, votre salaire annuel de base a été porté à 501072 CHF et qu'à compter du 03/01/2022, votre salaire annuel de base a été porté à 536748.33 CHF.</p> <p>Ce montant sera assujetti aux cotisations d'assurance sociale habituels et aux impôts à la source, si vous y êtes soumis personnellement. Votre fiche de paie sera établie en conséquence.</p> <p>La présente lettre constitue une modification officielle à vos conditions d'emploi. Toutes les autres conditions générales resteront en vigueur conformément à votre contrat existant.</p> <p>Meilleures salutations,</p>	<p><b>RE: Addendum for Salary increase:</b></p> <p>Dear Nicola,</p> <p>I am pleased to confirm that effective from 29/11/2021, your annual base salary was increased to 501072 CHF and effective from 03/01/2022, your annual base salary was increased to 536748.33 CHF.</p> <p>This will be subject to the usual Social Insurance contributions and to tax at source, if applicable in your case. Your payslip will be issued accordingly.</p> <p>This letter is a formal amendment to your terms and conditions of employment. All other terms and conditions will remain as per your existing contract.</p> <p>Yours sincerely,</p>
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/s/ Todd Goffman  
**Globalization Partners Switzerland SA**

Globalization Partners Switzerland SA	
Nicola Heffron [***]	
25th March 2022	
<b>Avenant au contrat de travail – Allocation scolaire et allocation Générale</b>	<b>Addendum to employment contract: Education Allowance and General Allowance</b>
Chère Nicola,	Dear Nicola,
Globalization Partners Switzerland SA (la “Société”) est ravie de vous informer d’un changement récent de vos données d’emploi.	Globalization Partners Switzerland SA (the “Company”) is pleased to inform you about a recent change to your employment data.
Pour donner suite à ce changement, votre contrat de travail est mis à jour à la date effective du 01.12.2021 avec des modalités suivantes:	In accordance with this change, your Contract of Employment is hereby amended effective 01.12.2021 with the following changes:
Toutes les autres clauses de votre Contrat de travail de la date 01.12.2021 demeurent inchangées.	All other terms and conditions outlined in your Contract of Employment dated 01.12.2021 remain in full force and effect.
Montant de l’allocation brute: 900 Allocation: Allocation scolaire Fréquence: Monthly Monnaie: CHF	New gross allowance amount: 900 Allowance type: Education allowance Frequency of payment: Monthly Currency: CHF
Montant de l’allocation brute: 530 Allocation: Allocation générale Fréquence: Monthly Monnaie: CHF	New gross allowance amount: 530 Allowance type: General allowance Frequency of payment: Monthly Currency: CHF
Sincères salutations,	Kind regards,

**Globalization Partners Switzerland SA**

Signature /s/ Valentina Pedroso Date 25 March 2022 | 09:19 PDT

**Nicola Heffron**

Signature /s/ Nicola Heffron Date 25 March 2022 | 12:16 EDT

THE NATIONAL INSTITUTES OF HEALTH  
PATENT LICENSE AGREEMENT – *EXCLUSIVE*

COVER PAGE

For the **NIH** internal use only:

License Number: [\*\*\*]

License Application Number: [\*\*\*]

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

[\*\*\*]

Licensee: bluebird bio, Inc.

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention): n/a

Additional Remarks: none

Public Benefit(s):

Autologous cell therapy has shown the potential to result in a significant and durable clinical benefit to patients with advanced tumors; the newest iteration of this approach uses engineered chimeric antigen receptors (CAR) to activate T cell response to the tumor. B cell maturation antigen (BCMA) is an attractive target for application of CAR technology due to its expression in different tumor types (especially hematological cancers) and lack of expression in non-transformed tissues; therefore, development of BCMA CAR products by the **Licensee**, in partnership with the **NIH**, has the potential to generate new, efficacious, and safe therapies for patients that have not responded to all other therapies.

This Patent License Agreement, hereinafter referred to as the “**Agreement**”, consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options). The Parties to this **Agreement** are:

- 1) The National Institutes of Health (“**NIH**”), an agency within the Department of Health and Human Services (“**HHS**”); and

- 2) The person, corporation, or institution identified above or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as the “**Licensee**”.

The **NIH** and the **Licensee** agree as follows:

1. BACKGROUND

- 1.1 In the course of conducting biomedical and behavioral research, the **NIH** or the **FDA** investigators made inventions that may have commercial applicability.
- 1.2 By assignment of rights from **NIH** or **FDA** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **NIH** or the **FDA**.
- 1.3 The Secretary of **HHS** has delegated to the **NIH** the authority to enter into this **Agreement** for the licensing of rights to these inventions.
- 1.4 The **NIH** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.
- 1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

- 2.1 “**Affiliate(s)**” means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term “control” shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.
- 2.2 “**Benchmarks**” mean the performance milestones that are set forth in Appendix D.
- 2.3 “**Combination Product**” means a product that contains a **Licensed Product(s)** and at least one other active therapeutic component or device other than a **Licensed Product(s)** that is not claimed or covered by the **Licensed Patent Rights**.
- 2.4 “**Commercial Development Plan**” means the written commercialization plan attached as Appendix E.
- 2.5 “**CRADA**” means a Cooperative Research and Development Agreement.
- 2.6 “**FDA**” means the Food and Drug Administration.
- 2.7 “**First Commercial Sale**” means the initial transfer by or on behalf of the **Licensee**, its **Affiliates** or sublicensees of the **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Licensee**, its **Affiliates**, or sublicensees in a country or other jurisdiction, in each case, after all applicable marketing and pricing approvals (if any) have been granted by the applicable governing regulatory authority in such country or other jurisdiction, in exchange for cash or some equivalent consideration to which value can be assigned for the purpose of determining **Net Sales**.
- 2.8 “**Government**” means the Government of the United States of America.
- 2.9 “**Licensed Fields of Use**” means the fields of use identified in Appendix B
- 2.10 “**Licensed Patent Rights**” shall mean, subject to Paragraph 6.6:
  - (a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;
  - (b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.10(a):
    - (i) continuations-in-part of 2.10(a);
    - (ii) all divisions and continuations of these continuations-in-part;

- (iii) all patents issuing from these continuations-in-part, divisions, and continuations;
  - (iv) priority patent application(s) of 2.10(a); and
  - (v) any reissues, reexaminations, and extensions of these patents;
  - (c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.10(a): all counterpart foreign and U.S. patent applications and patents to 2.10(a) and 2.10(b), including those listed in Appendix A; and
  - (d) **Licensed Patent Rights** shall *not* include claims included in patents or applications identified in 2.10(b) or 2.10(c) to the extent that such claims are directed to new matter which is not the subject matter disclosed in 2.10(a).
- 2.11 “**Licensed Processes**” means processes which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights**.
- 2.12 “**Licensed Products**” means tangible materials which, in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights**.
- 2.13 “**Licensed Territory**” means the geographical area identified in Appendix B.
- 2.14 (a) “**Net Sales**” means [\*\*\*]
- 2.15 “**Practical Application**” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.
- 2.16 “**Research License**” means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or the **Licensed Processes** as defined by the **Licensed Patent Rights** for purposes of research and not for purposes of commercial manufacture, sale, or distribution in lieu of purchase.
- 2.17 [\*\*\*].
- 2.18 “**Licensee’s Development Partner**” means Celgene Corporation, which was identified in **Licensee’s** commercial development plan included with its license application as **Licensee’s** partner for developing and commercializing the **Licensed Patent Rights**.
- 2.19 “**Notice**” means a legal notification by **Licensee** to **NIH** that is delivered in a written format to **NIH’s** official mailing address for **Agreement** notices and reports.
- 2.20 “**Collaboration and Option Agreement**” means the amended and restated master collaboration agreement between **Licensee** and **Licensee’s Development Partner**, dated as of June 3, 2015, focused on anti-BCMA product candidates, and as may be amended from time to time.

### 3. GRANT OF RIGHTS

- 3.1 The **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Field of Use I** and to practice and have practiced any **Licensed Process(es)** in the **Licensed Field of Use I**.
- 3.2 The **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a non-exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Field of Use II** and to practice and have practiced any **Licensed Process(es)** in the **Licensed Field of Use II**. [\*\*\*]
- 3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **NIH** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

### 4. SUBLICENSING

- 4.1 Upon written approval, which shall include prior review of any sublicense agreement by the **NIH** and which shall not be unreasonably withheld, the **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**. With respect to any proposed sublicense agreement, if the **NIH** does not provide the **Licensee** with a written objection thereof within [\*\*\*] after the date the **NIH** receives **Notice** of **Licensee’s** intent to sublicense and a copy of the proposed sublicense



from the **Licensee**, the **NIH** shall be deemed to have given its approval of such sublicense agreement and the **Licensee** shall have the right to enter into such sublicense agreement.

The **NIH** hereby provides written approval for the **Collaboration and Option Agreement** with the following stipulations:

[\*\*\*]

- 4.2 The **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to the **NIH** of Paragraphs 5.1-5.4, 8.1, 10.1, 10.2, 12.5, 13.6-13.8 of this **Agreement** shall be explicitly binding to sublicensee as if it were a party to this **Agreement**.
- 4.3 Any sublicenses granted by the **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and the **NIH**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to the **NIH** approval, which will not be unreasonably withheld, and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.
- 4.4 The **Licensee** agrees to forward to the **NIH** a complete copy of each fully executed sublicense agreement postmarked within [\*\*\*] of the execution of the agreement. To the extent permitted by law, the **NIH** agrees to maintain each sublicense agreement in confidence.

## 5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

- 5.1 (a) the **NIH** reserves on behalf of the **Government** an irrevocable, non-exclusive, non-transferable, royalty-free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory; and  
(b) in the event that the **Licensed Patent Rights** are Subject Inventions made under **CRADA**, the **Licensee** grants to the **Government**, to the extent set forth in 15 U.S.C. §3710a(b)(1)(A), a non-exclusive, non-transferable, irrevocable, paid-up license to practice the **Licensed Patent Rights** or have the **Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this license, the **Government** shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party.
- 5.2 The **Licensee** agrees that products used or sold in the United States embodying the **Licensed Products** or produced through use of the **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **NIH**, which written waiver will not be unreasonably withheld or denied.
- 5.3 The **Licensee** acknowledges that the **NIH** may enter into future **CRADAs** under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. The **Licensee** agrees not to unreasonably deny requests for a **Research License** from future collaborators with the **NIH** when acquiring these rights is necessary in order to make a **CRADA** project feasible. The **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.
- 5.4 (a) in addition to the reserved license of Paragraph 5.1, the **NIH** reserves the right to grant **Research Licenses** directly or to require the **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, the **NIH** shall consult with the **Licensee** before granting to commercial entities a **Research License** or providing to them research samples of materials made through the **Licensed Processes**; and  
(b) in exceptional circumstances, and in the event that the **Licensed Patent Rights** are Subject Inventions made under a **CRADA**, the **Government**, to the extent set forth in 15 U.S.C. §3710a(b)(1)(B), retains the right to require the **Licensee** to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the **Licensed Patent Rights** in the **Licensed Field of Use** on terms that are reasonable under the circumstances, or if the **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these rights by the **Government** shall only be in exceptional circumstances and only if the **Government** determines:
  - (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the **Licensee**;

- (ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by the **Licensee**; or
  - (iii) the **Licensee** has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B); and
  - (c) the determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(b).
  - (d) The **NIH** acknowledges and agrees that a **Research License** or other right granted pursuant to this Paragraph 5.4 shall only pertain to the **Licensed Patent Rights** and shall not include a right or license to any patent or other intellectual property right solely owned or solely controlled by the **Licensee** or its **Affiliates** other than the **Licensed Patent Rights**. Without limiting the foregoing, except as expressly provided herein, nothing contained in this **Agreement** shall be construed as granting, by implication, estoppel or otherwise, any licenses or rights under any patents or other intellectual property rights other than the **Licensed Patent Rights**.
- 5.5 Notwithstanding anything to the contrary set forth in this **Agreement**, the **NIH** shall not grant to any third party any rights under the **Licensed Patent Rights** within the **Licensed Field of Use I** and shall not provide any **Licensed Products** or materials made through the **Licensed Processes** to any third party for any commercial purpose within the **Licensed Field of Use I**.

## 6. ROYALTIES AND REIMBURSEMENT

- 6.1 The **Licensee** agrees to pay the **NIH** a non-creditable, non-refundable license issue royalty as set forth in Appendix C.
- 6.2 The **Licensee** agrees to pay the **NIH** a non-refundable, fully creditable (against earned royalties due for sales made in that specific year under Paragraph 6.3 below) minimum annual royalty as set forth in Appendix C.
- 6.3 The **Licensee** agrees to pay the **NIH** earned royalties as set forth in Appendix C.
- 6.4 The **Licensee** agrees to pay the **NIH** benchmark royalties as set forth in Appendix C.
- 6.5 The **Licensee** agrees to pay the **NIH** sublicensing royalties as set forth in Appendix C.
- 6.6 A patent or patent application, in any given country or other jurisdiction, licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments on the earliest of the dates that, in such country or other jurisdiction:
  - (a) the application has lapsed or been rejected, revoked or abandoned and not continued;
  - (b) the patent expires or irrevocably lapses, or
  - (c) the patent has been held to be revoked, invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.
  - (d) one or more claims have been pending before the United States Patent and Trademark Office for more than [\*\*\*] as of the date of **Licensee's** signature found at the Signature Page of this **Agreement**, except that such [\*\*\*] period shall be extended by a period equal to the time the examination of the claim(s) has been interrupted by (i) a derivation proceeding under 35 U.S.C. Section 135 or (ii) the claim(s) are the subject of an appeal filed by the **NIH** of a decision of a patent examiner pursuant to 37 C.F.R Part 1; provided, however, that if the claim(s) issue in a form substantially similar to the form in which they were originally filed, the claim(s) shall be deemed to fall within the scope of the **Licensed Patent Rights** on which royalties on **Net Sales** are due.
- 6.7 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.
- 6.8 On sales of the **Licensed Products** by the **Licensee** to its **Affiliates** or sublicensees or on sales made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.
- 6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIH** prior to the effective date of this **Agreement**, an amount equal to [\*\*\*], the **Licensee** shall pay the **NIH**, as an additional royalty, within sixty (60) days of

the **NIH's** submission of a statement and request for payment to the **Licensee** an amount equivalent to these unreimbursed expenses previously paid by the **NIH**, or a *pro rata* share thereof if there are multiple commercial licensees of the **Licensed Patent Rights** prior to the end of the sixty (60) day period for such payment by **Licensee**.

6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIH** on or after the effective date of this **Agreement** and during the term of this **Agreement**, the **NIH**, at its sole option, may require the **Licensee**:

[\*\*\*]

6.11 The **NIH** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **NIH** has requested payment from the **Licensee** under Paragraphs 6.9 and 6.10. The **Licensee** agrees that all information provided by the **NIH** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party except as required by law or a court of competent jurisdiction.

6.12 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon thirty (30) days written notice to the **NIH** and owe no payment obligation under Paragraph 6.10 for patent-related expenses paid in that country after thirty (30) days of the effective date of the written notice.

## 7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 Except as otherwise provided in this Article 7, the **NIH** agrees to take responsibility for the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all relevant patent-related documents to the **Licensee**. **NIH** shall instruct the law firm prosecuting the **Licensed Patent Rights** to furnish, upon execution of this **Agreement** and on a continuous basis thereafter as long as the **Agreement** is in effect, copies of relevant patent-related documents to **Licensee**, including all drafts of patent applications filings, domestic and foreign, amendments thereto, related correspondence and other related documents, sufficiently in advance to allow **Licensee** to comment thereon prior to filing or submission. **NIH** shall, in good faith, take into consideration all reasonable comments provided by **Licensee** relating to the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**, provided however, that if **Licensee** has not commented prior to the relevant action deadline, **NIH** shall be free to act without consideration of **Licensee's** comments.

7.2 Upon the **NIH's** written request or upon any determination by the **NIH** not to proceed or continue with the preparation, filing, prosecution, or maintenance (or combination thereof) of any patent application or patent included in the **Licensed Patent Rights**, the **NIH** shall provide the **Licensee** with written notice of such determination at least sixty (60) days prior to the deadline for taking any action for such patent application or patent or the date on which the abandonment of any such patent or application would become effective, whichever is earlier, and the **Licensee** shall have the right but not the obligation to assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all relevant patent-related documents to the **NIH**. In this event, the **Licensee** shall select registered patent attorneys or patent agents to provide these services on behalf of the **Licensee** and the **NIH**. The **NIH** shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The **Licensee** and its attorneys or agents shall consult with the **NIH** in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the **Licensed Patent Rights** and shall provide the **NIH** sufficient opportunity to comment on any document that the **Licensee** intends to file or to cause to be filed with the relevant intellectual property or patent office. If **Licensee** notifies **NIH** that **Licensee** does not intend to pursue or pay (or both) the costs of an application, then **NIH** may file such application at its own expense and **Licensee's** rights derived from this **Agreement** to that application will terminate.

7.3 **NIH** may provide **Licensee** with written notice that **NIH** wishes to reassume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** only if **NIH** determines that the **Licensee**:

- (a) is not executing the **Commercial Development Plan** submitted with **Licensee's** request for a license and the **Licensee** cannot otherwise demonstrate to **NIH's** satisfaction that

the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**;

- (b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2; or
- (c) is not fulfilling its obligations regarding diligent preparation, filing, prosecutions, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**.

7.4 In making the determination referenced in Paragraph 7.3, **NIH** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.2. Prior to resuming control under Paragraph 7.3, **NIH** shall give written notice to **Licensee** providing **Licensee** specific notice of, and a [\*\*\*] opportunity to respond to, **NIH's** concerns as to the items referenced in 7.3(a)-7.3(c). If **Licensee** fails to initiate corrective action to **NIH's** satisfaction, **NIH** may reassume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**.

7.5 Each party shall promptly inform the other as to all matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of the **Licensed Patent Rights**, which comments and suggestions shall be considered by the other party.

## 8. RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of the **Licensed Products** made, used, sold, or imported and the **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **NIH**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours, but not more than once per year, for inspection, at the expense of the **NIH**, by an accountant or other designated auditor selected by the **NIH** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only have the right to audit those records that have not previously been audited pursuant to this Paragraph 8.1, unless the **NIH** determines that there is just cause for an additional audit, and shall only disclose to the **NIH** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the **Licensee** shall reimburse the **NIH** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date the **NIH** provides to the **Licensee** notice of the payment due. The **Licensee** shall have the right to require that any accountant or auditor, prior to conducting an audit under this Paragraph 8.1, enter into an appropriate non-disclosure agreement with the **Licensee** regarding such financial information.

## 9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **NIH** with the **Commercial Development Plan** in Appendix E, under which the **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 The **Licensee** shall provide written summary annual reports on [\*\*\*] for each of the **Licensed Fields of Use** within [\*\*\*] These progress reports shall include, but not be limited to: [\*\*\*]The **NIH** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights**. [\*\*\*] the **Licensee** shall [\*\*\*] In the annual report, the **Licensee** may [\*\*\*] The **Licensee** agrees to provide any additional information reasonably required by the **NIH** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by the **NIH**, which approval shall not be unreasonably withheld. The **NIH** shall not unreasonably withhold approval of any request of the **Licensee** to [\*\*\*]

9.3 The **Licensee** shall report to the **NIH** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within [\*\*\*] of such occurrences.

9.4 Following **First Commercial Sale**, the **Licensee** shall submit to the **NIH**, within [\*\*\*] after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed**

**Products** sold or **Licensed Processes** practiced by or on behalf of the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **NIH** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** [\*\*\*]. The royalty report shall also identify the site of manufacture for the **Licensed Product(s)** sold in the United States.

- 9.5 The **Licensee** agrees to forward semi-annually to the **NIH** a copy of these reports received by the **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to the **NIH** by the **Licensee** for activities under the sublicense.
- 9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. [\*\*\*] The royalty report required by Paragraph 9.4 shall be mailed to the **NIH** at its address for **Agreement** Notices indicated on the Signature Page.
- 9.7 [\*\*\*]
- 9.8 [\*\*\*] may be assessed by the **NIH** on any payment that is more than ninety (90) days overdue, and not the subject of a good faith dispute, at the rate of [\*\*\*]
- 9.9 All plans and reports required by this Article 9 and marked “confidential” by the **Licensee** shall, to the extent permitted by law, be treated by the **NIH** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **NIH** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

#### 10. PERFORMANCE

- 10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and the **Licensed Processes** to **Practical Application**. “Reasonable commercial efforts” for the purposes of this provision shall include reasonable efforts to adhere to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D. The efforts of a sublicensee shall be considered the efforts of the **Licensee**.
- 10.2 Upon the **First Commercial Sale**, until the expiration or termination of this **Agreement**, the **Licensee** shall use its reasonable commercial efforts to make the **Licensed Products** and the **Licensed Processes** reasonably accessible to the United States public. The efforts of a sublicensee shall be considered the efforts of the **Licensee**.
- 10.3 The **Licensee** agrees that, to the extent commercially reasonable or possible, after its **First Commercial Sale**, to make reasonable quantities of the **Licensed Products** or materials produced through the use of the **Licensed Processes** available to patient assistance programs.
- 10.4 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians reasonably detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.
- 10.5 The **Licensee** agrees to supply to **NIH**, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, samples of the marketing brochures for the **Licensed Products** or the **Licensed Processes** for educational and display purposes only.

#### 11. INFRINGEMENT AND PATENT ENFORCEMENT

- 11.1 The **NIH** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.
- 11.2 Pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29, the **Licensee** may:
  - (a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **Licensed Patent Rights**;
  - (b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or
  - (c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that the **NIH** and appropriate **Government** authorities shall have the first right to take such actions; and

- (d) if the **Licensee** desires to initiate a suit for patent infringement, the **Licensee** shall notify the **NIH** in writing. If the **NIH** does not notify the **Licensee** of its intent to pursue legal action within [\*\*\*], the **Licensee** shall be free to initiate suit. The **NIH** shall have a continuing right to intervene in the suit at its own expense. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any suit for patent infringement; provided, however, that the **Government** will participate in the suit if required for legal standing purposes. The **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit brought by the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including all costs incurred by the **Government** in opposing the motion or other action. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.3 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against the **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by the **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29 or other statutes, the **Licensee** may:

- (a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **Licensed Patent Rights**;
- (b) in any suit, ultimately to enjoin infringement and to collect for its use, sue for damages, profits, and awards of whatever nature recoverable for the infringement; and
- (c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights** provided, however, that the **NIH** and appropriate **Government** authorities shall have a continuing right to intervene in the suit at its own expense; and
- (d) if the **NIH** does not notify the **Licensee** of its intent to respond to the legal action within a reasonable time, the **Licensee** shall be free to do so. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. The **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit by motion or any other action brought by the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. If the **Licensee** elects not to defend against the declaratory judgment action, the **NIH**, at its option, may do so at its own expense. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.4 Except as otherwise set forth above, in any action under Paragraphs 11.2 or 11.3 the expenses including costs, fees, attorney fees, and disbursements, shall be paid by [\*\*\*]

11.5 The **NIH** shall cooperate fully with [\*\*\*] in connection with any action under Paragraphs 11.2 or 11.3. The **NIH** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by [\*\*\*].

## 12. NEGATION OF WARRANTIES AND INDEMNIFICATION

- 12.1 The **NIH** offers no other warranties than those specified in Article 1: (i) **HHS**, by assignment of rights from **NIH** employees, on behalf of the **Government**, owns all intellectual property rights claimed in the United States and foreign patent applications and patents in the **Licensed Patent Rights**, (ii) **HHS** owns tangible embodiments of inventions actually reduced to practice, and (iii) **NIH** has the authority, by delegation from the Secretary of **HHS**, to enter into this **Agreement**.
- 12.2 The **NIH** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

- 12.3 THE **NIH** MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.
- 12.4 The **NIH** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.
- 12.5 The **Licensee** shall indemnify and hold the **NIH**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage to the extent arising out of any suit or proceeding brought by a third party for:
- (a) the use by or on behalf of the **Licensee**, its sublicensees, their respective directors or employees, or third parties acting by the direction of **Licensee** of any **Licensed Patent Rights**; or
  - (b) the design, manufacture, distribution, or use of any **Licensed Products, Licensed Processes** or other materials, products or processes developed by or on behalf of the **Licensee** or its sublicensees in connection with or arising out of the **Licensed Patent Rights**.
- 12.6 **Licensee** shall have no obligation to indemnify hereunder with respect to any liability, demands, damages, expenses, and losses to the extent arising out of any negligence or willful misconduct of the **NIH** or its employees, students, fellows, agents or consultants, or any breach by the **NIH** of the warranty set forth in Section 12.1 above.
- 12.7 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13 TERM, TERMINATION, AND MODIFICATION OF RIGHTS

- 13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.
- 13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within [\*\*\*] after the date of notice in writing of the default, the **NIH** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.
- 13.3 In the event that the **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, the **Licensee** shall immediately notify the **NIH** in writing.
- 13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** or any licenses in any **Licensed Fields of Use** in any country or territory by giving the **NIH** [\*\*\*] written notice to that effect.
- 13.5 The **NIH** shall specifically have the right to terminate or modify, at its option, this **Agreement** by written notice to the **Licensee**, if the **NIH** reasonably determines that the **Licensee**:
- (a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to the **NIH's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve the **Practical Application** of the **Licensed Products** or the **Licensed Processes**;
  - (b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;
  - (c) has willfully made a false statement of, or willfully omitted a material fact in the license application or in any report required by this **Agreement**;
  - (d) has committed a material breach of a covenant or agreement contained in this **Agreement** that has not been remedied within the [\*\*\*] period set forth in Paragraph 13.2 above;
  - (e) is not keeping the **Licensed Products** or the **Licensed Processes** reasonably available to the public after commercial use commences;
  - (f) cannot reasonably satisfy unmet health and safety needs;

- (g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.
- 13.6 In making the determination referenced in Paragraph 13.5, the **NIH** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **NIH** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a [\*\*\*] opportunity to respond to, the **NIH's** concerns as to the items referenced in 13.5(a)-13.5(g). If the **Licensee** fails to alleviate the **NIH's** concerns as to the items referenced in 13.5(a)-13.5(g) or within [\*\*\*] following written notice from the **NIH** or otherwise fails to initiate corrective action to the **NIH's** satisfaction, the **NIH** may terminate this **Agreement** upon written notice to the **Licensee**.
- 13.7 When the public health and safety so require, and after written notice to the **Licensee** providing the **Licensee** a [\*\*\*] opportunity to respond, the **NIH** shall have the right to require the **Licensee** to grant sublicenses to responsible applicants, on reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights**, unless the **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights**. The **NIH** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with the **Licensee**.
- 13.8 The **NIH** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** upon written notice to the **Licensee** if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee** within [\*\*\*] following written notice from the **NIH**.
- 13.9 Within [\*\*\*] of receipt of written notice of the **NIH's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated **NIH** official. The decision of the designated **NIH** official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.
- 13.10 Within [\*\*\*] of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expenses, due to the **NIH** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with the **NIH** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall have the right to offer for sale and sell any existing inventory of **Licensed Products** for a period of [\*\*\*] following the effective termination date of this **Agreement**, subject to the royalty obligations as set forth in Appendix C. The **Licensee** may not be granted additional **NIH** licenses if the final reporting requirement is not fulfilled.

#### 14 GENERAL PROVISIONS

- 14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of a party to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by that party or excuse a similar subsequent failure to perform any of these terms or conditions by the other party.
- 14.2 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, the **Licensed Products** and the **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.
- 14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
- 14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.



- 14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.
- 14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- [\*\*\*]
- 14.7 The **Licensee** agrees in its use of any **NIH**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying the **NIH**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **NIH** of research involving human subjects or clinical trials outside of the United States shall be given no later than [\*\*\*] prior to commencement of the research or trials.
- 14.8 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of this agency. The **NIH** neither represents that a license is or is not required or that, if required, it shall be issued.
- 14.9 The **Licensee** agrees to mark the **Licensed Products** or their packaging or containers in accordance with the applicable patent marking laws.
- 14.10 By entering into this **Agreement**, the **NIH** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, the **NIH**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **NIH**, the **FDA** or the **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature in connection with this **Agreement** or the **Licensed Patent Rights** without the prior written approval of the **NIH**.
- 14.11 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **NIH** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available. Notwithstanding anything to the contrary in this **Agreement**, the **Licensee** shall have the right, without waiving any right or remedy available under this **Agreement** or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of the **Licensee**, pending any such settlement or the determination of any such appeal.
- 14.12 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 14.13 Any formal recordation of this **Agreement** required by the laws of any **Licensed Territory** as a prerequisite to enforceability of the **Agreement** in the courts of any foreign jurisdiction or for other reasons shall be carried out by the **Licensee** at its expense, and appropriately verified proof of recordation shall be promptly furnished to the **NIH**.

- 14.14 Paragraphs 4.3, 8.1, 9.5-9.9, 12.1-12.5, 13.9, 13.10, 14.11 and 14.14 of this **Agreement** shall survive termination of this **Agreement**.
- 14.15 The terms and conditions of this **Agreement** shall, at the **NIH's** sole option, be considered by the **NIH** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **NIH** within sixty (60) days from the date of the **NIH's** signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

**SIGNATURE PAGE**

For the **NIH**:

/s/ Richard U. Rodriguez

Richard U. Rodriguez

Director, Division of Technology Development and Transfer

Office of Technology Transfer

National Institutes of Health

Mailing Address or E-mail Address for **Agreement** notices and reports:

Chief, Monitoring & Enforcement Branch

Office of Technology Transfer

National Institutes of Health

6011 Executive Boulevard, Suite 325

Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices\_Reports@mail.nih.gov

8/21/2015

Date

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

by:

/s/ Jason F. Cole

Signature of Authorized Official

Jason F. Cole

Printed Name

SVP, General Counsel

Title

8/31/2015

Date

I. Official and Mailing Address for **Agreement** notices:

Jason Cole

\_\_\_\_\_  
Name

SVP, General Counsel

\_\_\_\_\_  
Title

Mailing Address

bluebird bio, Inc.

\_\_\_\_\_  
150 Second Street, Third Floor

\_\_\_\_\_  
Cambridge, MA 02141

Email Address: [\*\*\*]

Phone:

Fax:

II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments)

Amber Casares

\_\_\_\_\_  
Name

\_\_\_\_\_  
Title

Mailing Address:

Accounts Payable

\_\_\_\_\_  
bluebirdbio, Inc.

\_\_\_\_\_  
150 Second Street, Third Floor

\_\_\_\_\_  
Cambridge, MA 02141

Email Address: [\*\*\*]

Phone:

Fax:

**Certain information indicated with [\*\*\*] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.**

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

[\*\*\*]

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

[\*\*\*]

APPENDIX C – ROYALTIES

[\*\*\*]



APPENDIX D – BENCHMARKS AND PERFORMANCE

[\*\*\*]

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

[\*\*\*]

APPENDIX F – EXAMPLE ROYALTY REPORT

[\*\*\*]

APPENDIX G – ROYALTY PAYMENT OPTIONS

[\*\*\*]

NATIONAL INSTITUTES OF HEALTH

1st AMENDMENT TO [\*\*\*]

[\*\*\*] No.: [\*\*\*]

This is the first amendment (“**First Amendment**”) of the agreement by and between the National Institutes of Health (“**NIH**”) within the Department of Health and Human Services (“**HHS**”), and 2seventy bio, Inc. having an effective date of 31 August 2015 and having **NIH** Reference Number [\*\*\*] (“**Agreement**”). This **First Amendment**, having **NIH** Reference Number [\*\*\*], is made between the **NIH** through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A., and 2seventy bio, Inc. having an office at 60 Binney St., Cambridge, MA 02142 (the “**Licensee**”). This **First Amendment** includes, in addition to the amendments made below, 1) a Signature Page, and 2) Attachment 1 (Royalty Payment Information).

WHEREAS, the **NIH** and the **Licensee** desire that the **Agreement** be amended a first time as set forth below in order to modify the terms that relate to sublicense agreements.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, the **NIH** and the **Licensee**, intending to be bound, hereby mutually agree to the following:

1) **Sublicense Terms:**

- a. Appendix C, Section III (a) of the **Agreement** shall be amended by deleting the words “and its sublicensees”.
- b. Appendix C, Section III of the **Agreement** shall be amended by adding a new subsection (c) which shall read as follows:
  - (c) Notwithstanding Section III(a) above, the royalties for any **Licensed Products** by a sublicensee shall be paid to **NIH** at the rate [\*\*\*].
- c. Appendix C, Section V(a) of the **Agreement** will be amended and restated in its entirety as follows:
  - (a) For each sublicense of a **Licensed Product** by **Licensee** to a third party other than **Licensee’s Development Partner** for sole development and commercialization by the third party, a sublicense royalty will be owed to **NIH** in the amount that is [\*\*\*].

- 2) Within sixty (60) days of the execution of this **First Amendment**, the **Licensee** shall pay the **NIH** an amendment issue royalty in the sum of [\*\*\*], and payment options may be found in Attachment 2.
- 3) In the event any provision(s) of the **Agreement** is/are inconsistent with Attachment 1, such provision(s) is/are hereby amended to the extent required to avoid such inconsistency and to give effect to the shipping and payment information in such Attachment 1.
- 4) All terms and conditions of the **Agreement** not herein amended remain binding and in effect.
- 5) The terms and conditions of this **First Amendment** shall, at the **NIH’s** sole option, be considered by the **NIH** to be withdrawn from the **Licensee’s** consideration and the terms and conditions of this **First Amendment**, and the **First Amendment** itself, to be null and void, unless this **First Amendment** is executed by the **Licensee** and a fully executed original is received by the **NIH** within sixty (60) days from the date of the **NIH’s** signature found at the Signature Page.
- 6) This **First Amendment** is effective upon execution by all parties.

Certain information indicated with [\*\*\*] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

**SIGNATURES BEGIN ON NEXT PAGE**

**1ST AMENDMENT TO L-XXX-200X/0**

**SIGNATURE PAGE**

In Witness Whereof, the parties have executed this **First Amendment** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the **NIH**:

/s/ Richard U. Rodriguez    4-13-22  
Richard U. Rodriguez, M.B.A.    Date  
Associate Director  
Technology Transfer Center  
The National Cancer Institute  
National Institutes of Health  
Address for Agreement notices and reports:

E-mail: [LicenseNotices\\_Reports@mail.nih.gov](mailto:LicenseNotices_Reports@mail.nih.gov) (preferred)

Mail:    License Compliance and Administration  
          Monitoring & Enforcement  
          Office of Technology Transfer  
          National Institutes of Health  
          6701 Rockledge Drive, Suite 700, MS 7788  
          Bethesda, Maryland 20892 U.S.A.

(For courier deliveries please check <https://www.ott.nih.gov/licensing/license-noticesreports>)

For the **Licensee** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

/s/ Teresa Jurgensen    4-25-22  
Signature of Authorized Official    Date

Name: Teresa Jurgensen  
Title: SVP, General Counsel

I. Official and Mailing Address for **Agreement** notices:

[\*\*\*]

Mailing Address:

60 Binney St.

Cambridge, MA 02142

Email Address: [\*\*\*]

Phone: [\*\*\*]

II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments):

[\*\*\*]

Mailing Address:

60 Binney St.

Cambridge, MA 02142

Email Address: [\*\*\*]

Phone: [\*\*\*]

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes [31 U.S.C. §§3801-3812](#) (civil liability) and [18 U.S.C. §1001](#) (criminal liability including fine(s) or imprisonment).



**ATTACHMENT 1 – ROYALTY PAYMENT OPTIONS**  
New Payment Options Effective March 2018

[\*\*\*]

**Agency Contacts:**

[\*\*\*]

**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: May 12, 2022

/s/ Nick Leschly

Nick Leschly  
Chief Executive Officer  
(Principal Executive Officer)

**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: May 12, 2022

/s/ Chip Baird

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

**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 March 31, 2022, 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: May 12, 2022 /s/ Nick Leschly

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

Dated: May 12, 2022 /s/ Chip Baird

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