

**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, 2023
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)

60 Binney Street
Cambridge, MA

(Address of principal executive offices)

86-3658454

(I.R.S. Employer Identification No.)

02142

(Zip Code)

(339) 499-9300

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer

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 50,199,268 shares of common stock as of May 4, 2023.

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and other materials we have filed or will file with the SEC include, or will include, forward-looking statements. All statements in this Quarterly Report on Form 10-Q, 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 post-separation relationships with bluebird bio, Inc., or bluebird bio, third parties, collaborators and our employees;
 - our and Bristol Myers Squibb’s, or BMS, plans for the continued commercialization of *Abecma* and the development and commercialization of earlier lines of therapy;
 - 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 operational capabilities and timelines with respect to our in-house manufacturing facility;
 - sourcing supplies for the materials used to manufacture our product candidates;
 - the safety profile and related adverse events of our product candidates;
 - the perceived therapeutic benefits of our product candidates and the potential indications and market opportunities therefor;
 - 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, including estimates of our future revenues, expenses, payments, cash flows, profitability, tax obligations, capital requirements and our needs for additional financing and liquidity sources, real estate needs and concentration of voting control, as well as the timing and drivers thereof, and internal control over financial reporting;
- our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;
- the status of government regulation in the life sciences industry, particularly with respect to healthcare reform;
- the potential benefits of strategic collaboration agreements;
- potential indemnification liabilities we may owe to bluebird bio after the separation;
- our business and operations following the separation and any benefits or costs of the separation, including the tax treatment of the separation, the tax treatment of the distribution, and limitations imposed on us under the tax matters agreement that we entered into with bluebird bio in connection with the separation and distribution;
- the impact of rising inflation rates on our business, financial condition and results of operations;
- the fluctuation of the market price of our shares; and
- trends and challenges in our current and 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q. Any forward-looking statement made by us in this Quarterly Report on Form 10-Q 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.

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, 2023	As of December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 193,629	\$ 71,032
Marketable securities	146,301	195,238
Prepaid expenses	8,635	13,652
Receivables and other current assets	41,252	20,960
Total current assets	<u>389,817</u>	<u>300,882</u>
Property, plant and equipment, net	59,153	55,735
Marketable securities	1,432	1,414
Intangible assets, net	7,125	7,302
Goodwill	12,056	12,056
Operating lease right-of-use assets	235,264	240,885
Restricted investments and other non-current assets	37,590	38,391
Total assets	<u>\$ 742,437</u>	<u>\$ 656,665</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 13,399	\$ 7,208
Accrued expenses and other current liabilities	43,568	54,678
Operating lease liability, current portion	11,482	11,164
Deferred revenue, current portion	8,480	3,000
Collaboration research advancement	—	3,744
Total current liabilities	<u>76,929</u>	<u>79,794</u>
Deferred revenue, net of current portion	6,311	5,000
Operating lease liability, net of current portion	255,472	259,008
Other non-current liabilities	2,401	2,397
Total liabilities	<u>341,113</u>	<u>346,199</u>
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, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 200,000 shares authorized, 50,190 and 37,928 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	5	4
Additional paid-in capital	743,937	606,986
Accumulated other comprehensive loss	(1,950)	(2,877)
Accumulated deficit	(340,668)	(293,647)
Total stockholders' equity	<u>401,324</u>	<u>310,466</u>
Total liabilities and stockholders' equity	<u>\$ 742,437</u>	<u>\$ 656,665</u>

See accompanying notes to unaudited condensed consolidated financial statements.

2seventy bio, Inc.

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

	For the three months ended March 31,	
	2023	2022
Revenue:		
Service revenue	\$ 10,826	\$ 4,055
Collaborative arrangement revenue	29,372	3,487
Royalty and other revenue	1,423	887
Total revenues	<u>41,621</u>	<u>8,429</u>
Operating expenses:		
Research and development	68,246	65,879
Cost of manufacturing for commercial collaboration	3,654	3,366
Selling, general and administrative	20,720	23,861
Share of collaboration loss	—	5,352
Cost of royalty and other revenue	641	511
Change in fair value of contingent consideration	73	48
Total operating expenses	<u>93,334</u>	<u>99,017</u>
Loss from operations	(51,713)	(90,588)
Interest income, net	2,049	115
Other income, net	2,643	4,762
Loss before income taxes	<u>(47,021)</u>	<u>(85,711)</u>
Income tax (expense) benefit	—	—
Net loss	<u>\$ (47,021)</u>	<u>\$ (85,711)</u>
Net loss per share - basic and diluted	<u>\$ (1.08)</u>	<u>\$ (3.20)</u>
Weighted-average number of common shares used in computing net loss per share - basic and diluted	<u>43,468</u>	<u>26,751</u>
Other comprehensive income (loss):		
Other comprehensive income (loss), net of tax benefit (expense) of \$0.0 million and \$0.0 million for the three months ended March 31, 2023 and 2022, respectively.	\$ 927	\$ (2,092)
Total other comprehensive income (loss)	<u>\$ 927</u>	<u>\$ (2,092)</u>
Comprehensive loss	<u>\$ (46,094)</u>	<u>\$ (87,803)</u>

See accompanying notes to unaudited condensed consolidated financial statements.

2seventy bio, Inc.

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

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balances at December 31, 2022	37,928	\$ 4	\$ 606,986	\$ (2,877)	\$ (293,647)	\$ 310,466
Vesting of restricted stock units	237	—	—	—	—	—
Exercise of stock options	1	—	7	—	—	7
Issuance of common stock in public offering, net of issuance costs	10,870	1	116,968	—	—	116,969
Issuance of common stock to Regeneron	1,115	—	9,859	—	—	9,859
Stock-based compensation	—	—	9,666	—	—	9,666
Purchases of shares under ESPP	39	—	451	—	—	451
Other comprehensive income	—	—	—	927	—	927
Net loss	—	—	—	—	(47,021)	(47,021)
Balances at March 31, 2023	<u>50,190</u>	<u>\$ 5</u>	<u>\$ 743,937</u>	<u>\$ (1,950)</u>	<u>\$ (340,668)</u>	<u>\$ 401,324</u>

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balances at December 31, 2021	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)
Balances at March 31, 2022	<u>37,616</u>	<u>\$ 4</u>	<u>\$ 575,421</u>	<u>\$ (2,804)</u>	<u>\$ (125,205)</u>	<u>\$ 447,416</u>

See accompanying notes to unaudited condensed consolidated financial statements.

2seventy bio, Inc.

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

	For the three months ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (47,021)	\$ (85,711)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of contingent consideration	73	48
Depreciation and amortization	2,255	3,530
Stock-based compensation expense	9,666	9,739
Other non-cash items	(1,204)	1,227
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(14,103)	(7,186)
Operating lease right-of-use assets	5,621	4,710
Accounts payable	7,072	6,228
Accrued expenses and other liabilities	(11,276)	280
Operating lease liabilities	(3,218)	(2,860)
Deferred revenue	6,791	—
Collaboration research advancement	(3,744)	(3,487)
Net cash used in operating activities	(49,088)	(73,482)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(6,079)	(3,585)
Purchases of marketable securities	(36,093)	(22,450)
Proceeds from maturities of marketable securities	86,976	70,784
Purchases of restricted investments	(2,506)	—
Proceeds from maturities of restricted investments	2,500	—
Net cash provided by investing activities	44,798	44,749
Cash flows from financing activities:		
Proceeds from issuance of common stock in public offering, net of issuance costs	117,058	—
Proceeds from issuance of common stock to Regeneron, net of issuance costs	9,876	—
Proceeds from the issuance of common stock in private placement	—	170,000
Proceeds from exercise of stock options and ESPP contributions	150	99
Net cash provided by financing activities	127,084	170,099
Increase in cash, cash equivalents and restricted cash and cash equivalents	122,794	141,366
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	72,290	130,448
Cash, cash equivalents and restricted cash and cash equivalents at end of period	\$ 195,084	\$ 271,814
Reconciliation of cash, cash equivalents, and restricted cash and cash equivalents		
Cash and cash equivalents	\$ 193,629	\$ 270,893
Restricted cash and cash equivalents included in restricted investments and other non-current assets	1,455	921
Total cash, cash equivalents, and restricted cash and cash equivalents	\$ 195,084	\$ 271,814
Supplemental cash flow disclosures:		
Purchases of property, plant and equipment included in accounts payable and accrued expenses	\$ 2,342	\$ 2,925
Private placement issuance costs included in accounts payable and accrued expenses	\$ —	\$ 4,343
Financing issuance costs included in accounts payable or accrued expenses	\$ 106	\$ —

See accompanying notes to unaudited condensed consolidated financial statements.

2seventy bio, Inc.

Notes to Condensed Consolidated 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 U.S. Food and Drug Administration (“FDA”)–approved CAR T therapy in multiple myeloma, *Abecma* (idecabtagene vicleucel, or ide-cel), to patients in the United States. Please refer to Note 10, *Collaborative arrangements and strategic partnerships* for further discussion of the collaboration with BMS.

2seventy bio Securities Corporation is a wholly-owned subsidiary of the Company which was incorporated in Massachusetts on December 13, 2021 and was granted securities corporation status in Massachusetts beginning in 2021. 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 “Part III. 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 16, 2023.

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 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, 2023, the Company incurred a net loss of \$47.0 million and used \$49.1 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 and generate operating cash flows from the commercialization of its product candidates, if approved.

As of March 31, 2023, the Company had cash, cash equivalents, and marketable securities of \$341.4 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. This includes the potential sale of shares of our common stock of up to \$150.0 million in gross proceeds under the at-the-market (“ATM”) facility established in November 2022 with Cowen and Company, LLC. No sales of common stock have occurred under this ATM as of the date of this Quarterly Report on Form 10-Q. 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 financial statements are consistent with those discussed in Note 2 to the consolidated financial statements for the year ended December 31, 2022 included in the Company’s 2022 annual report on Form 10-K.

Basis of presentation

The accompanying condensed consolidated 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”).

In the opinion of management, the unaudited interim condensed consolidated 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.

Correction of immaterial error

During the first quarter of 2023, the Company identified two immaterial errors in its previously issued 2022 quarterly reports on Form 10-Q and 2021 and 2022 annual reports on Form 10-K related to: 1) restricted investments previously presented as restricted cash on its consolidated balance sheets and consolidated statements of cash flows; and 2) cash outflows related to the purchase of property, plant and equipment previously presented within operating cash outflows instead of investing cash outflows in its 2022 annual consolidated statements of cash flows.

Based on the analysis of quantitative and qualitative factors in accordance with SEC Staff Accounting Bulletin (SAB) Topic 1.M “Assessing Materiality” and SAB Topic 1.N “Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements”, the Company concluded that these errors were immaterial, individually and in the aggregate, to its consolidated balance sheets and consolidated statements of cash flows as presented in its previously filed quarterly and annual financial statements. There was no impact to any other statements for any period presented.

To correct for the immaterial error related to restricted investments, the Company:

- changed the caption “Restricted cash and other non-current assets” to “Restricted investments and other non-current assets” on the balance sheet;

- included additional disclosures around the restricted investments within Note 3, *Marketable securities* and Note 4, *Fair value measurements*; and
- adjusted its previously filed consolidated statement of cash flows as follows:

<i>in thousands</i>	For the three months ended March 31, 2022		
	As previously reported	Adjustment	As revised
Cash flows from operating activities:			
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	\$ (7,768)	\$ 582	\$ (7,186)
Net cash used in operating activities	\$ (74,064)	\$ 582	\$ (73,482)
Increase in cash, cash equivalents and restricted cash and cash equivalents	\$ 140,784	\$ 582	\$ 141,366
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	\$ 163,266	\$ (32,818)	\$ 130,448
Cash, cash equivalents and restricted cash and cash equivalents at end of period	<u>\$ 304,050</u>	<u>\$ (32,236)</u>	<u>\$ 271,814</u>
Reconciliation of cash, cash equivalents and restricted cash and cash equivalents			
Restricted cash and cash equivalents included in restricted investments and other non-current assets	\$ 33,157	\$ (32,236)	\$ 921
Total cash, cash equivalents and restricted cash and cash equivalents	<u>\$ 304,050</u>	<u>\$ (32,236)</u>	<u>\$ 271,814</u>

The Company will correct its prior period presentation for this error in its future 2023 quarterly financial statements on Form 10-Q and 2023 annual report on Form 10-K.

To correct for the immaterial misclassification of cash outflows noted above, the Company will adjust its 2022 statement of cash flows within its 2023 annual report on Form 10-K by reclassifying \$8.0 million of cash outflows from net cash used in operating activities to net cash provided by investing activities.

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: 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, 2023 and December 31, 2022 (in thousands):

	Amortized cost/ cost	Unrealized gains	Unrealized losses	Fair Value
March 31, 2023				
U.S. government agency securities and treasuries	\$ 97,174	\$ 13	\$ (1,020)	\$ 96,167
Corporate bonds	1,001	—	(14)	987
Commercial paper	50,651	1	(73)	50,579
Total	<u>\$ 148,826</u>	<u>\$ 14</u>	<u>\$ (1,107)</u>	<u>\$ 147,733</u>
December 31, 2022				
U.S. government agency securities and treasuries	\$ 120,739	\$ 3	\$ (1,963)	\$ 118,779
Corporate bonds	2,524	—	(26)	2,498
Commercial paper	75,491	3	(119)	75,375
Total	<u>\$ 198,754</u>	<u>\$ 6</u>	<u>\$ (2,108)</u>	<u>\$ 196,652</u>

No available-for-sale debt securities held as of March 31, 2023 or December 31, 2022 had remaining maturities greater than five years.

The following table summarizes available-for-sale debt securities in a continuous unrealized loss position for less than and greater than twelve months, and for which an allowance for credit losses has not been recorded at March 31, 2023 and December 31, 2022 (in thousands):

	Less than 12 months		12 months or greater		Total	
	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
March 31, 2023						
U.S. government agency securities and treasuries	\$ 1,952	\$ (1)	\$ 74,463	\$ (1,019)	\$ 76,415	\$ (1,020)
Corporate bonds	—	—	987	(14)	987	(14)
Commercial paper	43,580	(73)	—	—	43,580	(73)
Total	<u>\$ 45,532</u>	<u>\$ (74)</u>	<u>\$ 75,450</u>	<u>\$ (1,033)</u>	<u>\$ 120,982</u>	<u>\$ (1,107)</u>
December 31, 2022						
U.S. government agency securities and treasuries	\$ 28,749	\$ (159)	\$ 86,176	\$ (1,804)	\$ 114,925	\$ (1,963)
Corporate bonds	—	—	2,498	(26)	2,498	(26)
Commercial paper	62,636	(119)	—	—	62,636	(119)
Total	<u>\$ 91,385</u>	<u>\$ (278)</u>	<u>\$ 88,674</u>	<u>\$ (1,830)</u>	<u>\$ 180,059</u>	<u>\$ (2,108)</u>

As discussed further in Note 7, *Leases*, to the consolidated financial statements included in the Company's 2022 annual report on Form 10-K, the Company maintains letters of credit related to its leases in Cambridge and Seattle. A portion of this collateral is classified as restricted investments and included within restricted investments and other non-current assets on the condensed consolidated balance sheets.

The following table summarizes restricted investments held at March 31, 2023 and December 31, 2022 (in thousands):

	Amortized cost/ cost	Unrealized gains	Unrealized losses	Fair Value
March 31, 2023				
U.S. government agency securities and treasuries	\$ 32,806	\$ —	\$ (865)	\$ 31,941
Total	<u>\$ 32,806</u>	<u>\$ —</u>	<u>\$ (865)</u>	<u>\$ 31,941</u>
December 31, 2022				
U.S. government agency securities and treasuries	\$ 32,880	\$ —	\$ (1,112)	\$ 31,768
Total	<u>\$ 32,880</u>	<u>\$ —</u>	<u>\$ (1,112)</u>	<u>\$ 31,768</u>

The following table summarizes restricted investments in a continuous unrealized loss position for less than and greater than twelve months, and for which an allowance for credit losses has not been recorded at March 31, 2023 and December 31, 2022 (in thousands):

	Less than 12 months		12 months or greater		Total	
	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
March 31, 2023						
U.S. government agency securities and treasuries	\$ 4,450	\$ (27)	\$ 27,491	\$ (838)	\$ 31,941	\$ (865)
Total	<u>\$ 4,450</u>	<u>\$ (27)</u>	<u>\$ 27,491</u>	<u>\$ (838)</u>	<u>\$ 31,941</u>	<u>\$ (865)</u>
December 31, 2022						
U.S. government agency securities and treasuries	\$ 1,942	\$ (27)	\$ 29,826	\$ (1,085)	\$ 31,768	\$ (1,112)
Total	<u>\$ 1,942</u>	<u>\$ (27)</u>	<u>\$ 29,826</u>	<u>\$ (1,085)</u>	<u>\$ 31,768</u>	<u>\$ (1,112)</u>

Accrued interest receivables on the Company's available-for-sale debt securities and restricted investments, included within receivables and other current assets in the Company's condensed consolidated balance sheet, totaled \$0.7 million and \$0.3 million as of March 31, 2023 and December 31, 2022, respectively. No accrued interest receivable was written off during the three months ended March 31, 2023 or 2022.

The amortized cost of available-for-sale debt securities and restricted investments is adjusted for amortization of premiums and accretion of discounts to the earliest call date for premiums or to maturity for discounts. At March 31, 2023 and December 31, 2022, the balance in the Company's accumulated other comprehensive loss was composed primarily of activity related to the Company's available-for-sale debt securities and restricted investments. There were no material realized gains or losses recognized on the sale or maturity of available-for-sale securities or restricted investments during the three months ended March 31, 2023 and 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, 2023. As such, an allowance for credit losses was not recognized. As of

March 31, 2023, the Company does not intend to sell such securities and it is not more likely than not that the Company will be required to sell the securities before recovery of their amortized cost bases.

4. Fair value measurements

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2023 and December 31, 2022 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2023				
Assets:				
Cash and cash equivalents	\$ 193,629	\$ 175,713	\$ 17,916	\$ —
Marketable securities:				
U.S. government agency securities and treasuries	96,167	—	96,167	—
Corporate bonds	987	—	987	—
Commercial paper	50,579	—	50,579	—
Restricted cash and cash equivalents	1,455	1,455	—	—
Restricted investments	31,941	—	31,941	—
Total assets	<u>\$ 374,758</u>	<u>\$ 177,168</u>	<u>\$ 197,590</u>	<u>\$ —</u>
Liabilities:				
Contingent consideration	\$ 2,253	\$ —	\$ —	\$ 2,253
Total liabilities	<u>\$ 2,253</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,253</u>
December 31, 2022				
Assets:				
Cash and cash equivalents	\$ 71,032	\$ 71,032	\$ —	\$ —
Marketable securities:				
U.S. government agency securities and treasuries	118,779	—	118,779	—
Corporate bonds	2,498	—	2,498	—
Commercial paper	75,375	—	75,375	—
Restricted cash and cash equivalents	1,257	1,257	—	—
Restricted investments	31,768	—	31,768	—
Total assets	<u>\$ 300,709</u>	<u>\$ 72,289</u>	<u>\$ 228,420</u>	<u>\$ —</u>
Liabilities:				
Contingent consideration	\$ 2,180	\$ —	\$ —	\$ 2,180
Total liabilities	<u>\$ 2,180</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,180</u>

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 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):

	For the three months ended March 31, 2023
Beginning balance	\$ 2,180
Additions	—
Changes in fair value	73
Payments	—
Ending balance	<u>\$ 2,253</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):

	As of March 31, 2023	As of December 31, 2022
Computer equipment and software	\$ 5,899	\$ 5,670
Office equipment	6,159	6,159
Laboratory equipment	36,534	36,216
Leasehold improvements	27,428	27,416
Construction-in-progress	33,048	28,112
Total property, plant and equipment	<u>109,068</u>	<u>103,573</u>
Less accumulated depreciation and amortization	<u>(49,915)</u>	<u>(47,838)</u>
Property, plant and equipment, net	<u>\$ 59,153</u>	<u>\$ 55,735</u>

Cambridge, Massachusetts drug product manufacturing facility

In February 2022, the Company began construction of a drug product manufacturing facility within its Cambridge, Massachusetts headquarters. The facility will enable rapid translational research in clinical trials and the manufacture of drug product for use in Phase 1 clinical development activities. Construction-in-progress as of March 31, 2023 includes \$31.7 million related to the ongoing build-out of the facility. As of December 31, 2022, construction-in-progress included \$27.0 million related to the build-out of the facility. The build out of the facility was substantially completed in February 2023 and is anticipated to be operational by mid-2023.

6. Accrued expenses and other current liabilities

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

	As of March 31, 2023	As of December 31, 2022
Manufacturing costs	\$ 19,244	\$ 17,962
Royalties	11,629	13,094
Employee compensation	4,547	14,845
Property, plant, and equipment	1,858	1,498
Clinical and contract research organization costs	1,692	1,619
Professional fees	858	239
Collaboration research costs	505	2,005
Other	3,235	3,416
Total accrued expenses and other current liabilities	\$ 43,568	\$ 54,678

7. Leases

The Company leases certain office and laboratory space, primarily located in Cambridge, Massachusetts and Seattle, Washington, that was assigned 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 financial statements included in the Company's 2022 annual report on Form 10-K.

8. Commitments and contingencies

Contingent consideration related to business combinations

On June 30, 2014, bluebird bio acquired Pregonen. All assets, liabilities and future obligations related to the Pregonen acquisition, including the resulting goodwill and contingent consideration, were assumed by the Company in connection with the separation. As of March 31, 2023, the Company may be required to make up to \$99.9 million in contingent cash payments to the former equity holders of Pregonen upon the achievement of certain commercial milestones related to the Pregonen 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. Please refer to Note 4, *Fair value measurements*, for further information.

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. 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 10, *Collaborative arrangements and strategic partnerships*, for further information on the BMS, Regeneron

Pharmaceuticals, Inc. (“Regeneron”), and Novo Nordisk A/S (“Novo”) agreements and to Note 11, *Royalty and other revenue*, for further information on license agreements.

Based on the Company’s development plans as of March 31, 2023, the Company may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. When the achievement of these milestones or sales has not occurred, such contingencies are not recorded in the Company’s financial statements. As further discussed in Note 10, *Collaborative arrangements and strategic partnerships*, BMS assumed responsibility for amounts due to licensors as a result of any future ex-U.S. sales of *Abecma*.

In July 2021, bluebird bio and National Resilience, Inc. (“Resilience”) announced a strategic manufacturing collaboration aimed to accelerate the early research, development, and delivery of cell therapies. Agreements related to the collaboration were executed in September 2021. As part of the agreement, Resilience acquired bluebird bio’s North Carolina manufacturing facility and retained all staff employed at the site. Concurrent with the sale of the manufacturing facility in Durham, North Carolina, bluebird bio entered into certain ancillary agreements, including two manufacturing agreements and a license agreement (the “Resilience License Agreement”), among others (together referred to as the “Ancillary Agreements”). One manufacturing agreement will support the future manufacturing of lentiviral vector for the commercial product marketed in collaboration with BMS, *Abecma* (the “Commercial Supply Agreement”), while the other will support ongoing manufacturing for lentiviral vector for development candidates (the “Development Manufacturing Supply Agreement”). Certain rights and obligations under these agreements were assigned by bluebird bio to 2seventy bio on November 4, 2021 upon the separation of 2seventy bio from bluebird bio. The assignments under the asset purchase agreement and the development manufacturing supply agreement commit the Company to reimburse Resilience for an amount equal to 50% of the net operating losses of and relating to the manufacturing facility’s business incurred during the twelve-month period ending on the first anniversary of the closing of the transaction, as calculated in accordance with the asset purchase agreement, subject to a cap of \$15.0 million. In exchange, under the terms of the development manufacturing supply agreement, the Company was entitled to receive up to eight batches of lentiviral vector during the twelve-month period ending on the first anniversary of the closing of the transaction. The Company therefore committed to a minimum purchase of at least the Company’s 50% share of the net operating losses during the twelve-month period ending on the first anniversary of the closing of the transaction, which occurred in September 2022. As of March 31, 2023, the Company has accrued \$14.8 million representing our estimated share of the net operating losses of Resilience. The disposition of the net assets of the manufacturing facility previously assigned to 2seventy bio was reflected as a transfer to bluebird bio via net parent investment as a result of bluebird bio’s sale of such facility in the Company’s 2021 annual report on Form 10-K. As a result of the separation, the Company’s net parent investment balance was reclassified to additional paid-in capital. 2seventy bio is not a party to the sale of the manufacturing facility and, therefore, did not recognize any gain or loss arising from the transaction.

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 financial statements included in the Company’s 2022 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. 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 \$165.5 million, after deducting placement agent fees and other offering expenses payable by the Company.

In November 2022, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen"), relating to shares of the Company's common stock through an "at the market" equity offering program under which Cowen will act as the Company's sales agent (the "ATM Facility"). Pursuant to the terms of the sales agreement, the Company may offer and sell shares of common stock, having an aggregate price of up to \$150.0 million, from time to time. As of March 31, 2023, the Company had not made any sales under the ATM Facility.

In January 2023, the Company entered into a Share Purchase Agreement with Regeneron, pursuant to which it sold 1,114,827 shares of its common stock to Regeneron, subject to certain restrictions, for an aggregate cash price of approximately \$20.0 million. The purchase price represents \$9.9 million worth of common stock plus a \$10.1 million premium, which represents collaboration deferred revenue.

In March 2023, the Company sold 10,869,566 shares of common stock through an underwritten public offering at a price per share of \$11.50. This resulted in aggregate net proceeds to the Company of approximately \$117.0 million, after deducting underwriting fees and offering expenses. The underwriters did not exercise their option to purchase up to 1,630,434 additional shares of common stock and therefore no additional proceeds were received.

10. Collaborative arrangements and strategic partnerships

To date, the Company's service and collaborative arrangement revenue has been primarily generated from collaboration arrangements with BMS, Regeneron, and Novo, each as further described below. 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 financial statements included in the Company's 2022 annual report on Form 10-K. During the first quarter of 2023, 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 (marketed as *Abecma*). The Company has no remaining financial rights with respect to the development or commercialization of ide-cel outside of the United States. The Company accounts for its collaborative arrangement efforts with BMS in the United States within the scope of ASC 808 given that both parties are active participants in the activities and both parties are exposed to significant risks and rewards dependent on the commercial success of the activities. The calculation of collaborative activity to be recognized for joint *Abecma* efforts in the United States is performed on a quarterly basis and is independent of previous quarterly activity. This may result in fluctuations between revenue and expense recognition period over period, depending on the varying extent of effort performed by each party during the period. The Company recognizes revenue related to the combined unit of accounting for the ex-U.S. license and lentiviral vector manufacturing services under Topic 606.

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

The U.S. commercial and development activities under the Amended Ide-Cel CCPS are within the scope of ASC 808. On a quarterly basis, the Company determines its share of collaboration profit or loss for commercial activities. 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 statement of operations and comprehensive loss.

The Company is also responsible for equally sharing in the ongoing ide-cel research and development activities being conducted by BMS in the United States as BMS continues conducting ongoing clinical studies to support the use of *Abecma* in earlier lines of therapy and both companies continue to develop suspension lentiviral vector to be used in the manufacture of *Abecma*. The net amount owed to BMS for research and development activities determined on a quarterly basis is classified as research and development expense on the statements of operations and comprehensive loss. If BMS is obligated to reimburse the Company because the Company's research and development costs exceeds BMS' research and development costs in a particular quarterly period, the net amount is recorded as collaborative arrangement revenue.

The following tables summarize the components utilized in the Company's quarterly calculation of collaborative arrangement revenue or share of collaboration loss under the BMS collaboration arrangement for the three months ended March 31, 2023, and 2022 (in thousands). The amounts reported for these periods represent the Company's share of BMS' *Abecma* product revenue, cost of goods sold, and selling costs, along with reimbursement by BMS of commercial costs incurred by the Company, and exclude expenses related to ongoing development, which are separately reflected in the consolidated statements of operations and comprehensive loss as described below.

Abecma U.S. Collaboration Profit/Loss Share	For the three months ended March 31,	
	2023	2022
2seventy's share of profits (losses), net of 2seventy's share of BMS costs for commercial activities	\$ 21,581	\$ (6,709)
Reimbursement from BMS for 2seventy costs of commercial manufacturing and commercial activities	1,380	1,357
Collaborative arrangement revenue ⁽¹⁾	\$ 22,961	\$ —
Share of collaboration loss ⁽¹⁾	\$ —	\$ (5,352)

(1) As noted above, the calculation is performed on a quarterly basis and consists of 2seventy's share of profits, net of 2seventy's share of BMS costs for commercial activities, offset by reimbursement from BMS for 2seventy commercial activities. The calculation is independent of previous activity, which may result in fluctuations between revenue and expense recognition period over period.

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, 2023 and 2022 (in thousands):

<i>Abecma</i> U.S. Collaboration Net R&D Expenses	For the three months ended March 31,	
	2023	2022
2seventy's obligation for its share of BMS research and development expenses	\$ (9,461)	\$ (8,118)
Reimbursement from BMS for 2seventy research and development expenses	4,590	1,225
Net R&D expense ⁽¹⁾	\$ (4,871)	\$ (6,893)

(1) As noted above, the calculation is performed on a quarterly basis and consists of 2seventy bio's obligation for its share of BMS research and development expenses, offset by reimbursement from BMS for 2seventy bio's research and development expenses.

Ide-cel ex-U.S. Service Revenue

The Company accounts for any ex-U.S. activities under the Amended Ide-cel CCPS pursuant to ASC 606. The following table summarizes the revenue recognized related to ide-cel ex-U.S. activities for the three months ended March 31, 2023 and 2022 (in thousands). These amounts are reflected in service revenue in the consolidated statements of operations and comprehensive loss:

ASC 606 ide-cel license and manufacturing revenue – ex-U.S. (included as a component of service revenue) ⁽¹⁾	For the three months ended March 31,	
	2023	2022
	\$ 6,123	\$ 2,790

(1) These amounts include reimbursements from BMS to the Company for the Company's ex-U.S. quality and other manufacturing costs associated with the manufacture of *Abecma* inventory.

bb21217

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 financial statements included in the Company's 2022 annual report on Form 10-K.

Under the collaboration arrangement with BMS, the Company had an option to co-develop and co-promote bb21217 within the United States. However, following completion of the CRB-402 clinical trial, in January 2022 the Company, along with BMS, evaluated its plans with respect to bb21217. Based in part on the strength of *Abecma* clinical data and commercial sales to date, the Company and BMS elected to discontinue development of bb21217 and, as such, the Company did not exercise its option to co-develop and co-promote bb21217 within the United States. The Company is still eligible to receive U.S. milestones and royalties for U.S. sales of bb21217, if further developed by BMS. Additionally, pursuant to the terms of the collaboration agreement, because it did not exercise its option to co-develop and co-promote bb21217, the Company received an additional fee in the amount of \$10.0 million from BMS during the second quarter of 2022. Pursuant to the variable consideration allocation exception, the \$10.0 million of consideration received was allocated to the combined performance obligation for the bb21217 license and vector manufacturing services through development, described further below.

The transaction price associated with the collaboration arrangement consisted of \$31.0 million of upfront payments and option payments received from BMS, the \$10.0 million bb21217 opt-out payment discussed above, and \$1.8 million in variable consideration which represented reimbursement to be received from BMS for manufacturing vector and associated payloads through development (which will never be received by the Company given the decision to discontinue development of bb21217 in 2022). The Company 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 \$37.4 million in consideration was allocated to this combined performance obligation. 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.

In December 2022, BMS formally notified the Company that its license and vector manufacturing services for bb21217 will no longer be required, thus releasing it from the combined performance obligation for the bb21217 license and vector manufacturing services through development. As a result, the Company recognized the remaining deferred revenue of \$35.8 million associated with bb21217 performance obligations as a component of service revenue during the fourth quarter of 2022.

Contract assets and liabilities – ide-cel and bb21217

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

The following table presents changes in the balances of the Company's BMS receivables and contract liabilities during the three months ended March 31, 2023 (in thousands):

	Balance at December 31, 2022	Additions	Deductions	Balance at March 31, 2023
Receivables	\$ 4,537	\$ 24,212	\$ (4,537)	\$ 24,212
Contract liabilities:				
Deferred revenue	\$ —	\$ —	\$ —	\$ —

The increase in the receivables balance for the three months ended March 31, 2023 is driven by amounts owed less amounts paid to the Company by 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.

First Amendment to the Regeneron Collaboration Agreement

In January 2023, 2seventy bio and Regeneron announced an amendment to the Regeneron Collaboration Agreement (the “Amendment”), to amend and extend their current agreement, applying their respective technology platforms to the discovery, development and commercialization of novel immune cell therapies for cancer. Under the Amendment, the parties have identified four research targets to advance the next stage of research therapies. The parties will continue sharing costs for these activities in a manner largely consistent with the existing agreement, with Regeneron now covering 75% of eligible late-stage research costs to study combinations and 100% of the costs for the arms of clinical studies that include Regeneron agents through regulatory approval of two of the four targets. For other programs, cost-sharing will follow the existing 50/50 cost sharing agreement.

Additionally, Regeneron will make one-time milestone payments for each of the first Clinical Candidate directed to MUC-16 and the first Clinical Candidate directed to a selected early stage research target to achieve the applicable milestones. Clinical Candidate milestone events and payments include:

- \$2.0 million payment from Regeneron for Development Candidate Nomination;
- \$3.0 million payment from Regeneron for IND Acceptance; and
- \$5.0 million pay from Regeneron for the Earlier of (i) last patient dosed with a Monotherapy Regimen and (ii) dosing of the 10th patient in a Clinical Trial included in an Approved Research/ Development Plan.

The Development Candidate Nomination for MUC-16 has already occurred and will not be due until the Clinical Candidate milestone event (IND Acceptance) is achieved for MUC-16 at which time the first milestone will be reduced to \$1.0 million for a total amount due for the two milestones related to MUC-16 of \$4.0 million.

Regeneron Share Purchase Agreements

A Share Purchase Agreement (“SPA”) was entered into by bluebird bio and Regeneron in August 2018. In August 2018, on the closing date of the transaction, bluebird bio issued to Regeneron 0.4 million shares of bluebird bio’s common stock, subject to certain restrictions, for \$238.10 per share, or \$100.0 million in the aggregate. Following the spin-off, Regeneron held approximately 0.1 million shares of 2seventy bio’s common stock, subject to certain restrictions. The purchase price represents \$63.0 million worth of common stock plus a \$37.0 million premium, which represents a collaboration research advancement, or credit to be applied to Regeneron’s initial 50 percent funding obligation for collaboration research, after which the collaborators will continue to fund ongoing research equally. The collaboration research advancement only applies to pre-IND research activities and is not refundable or creditable against post-IND research activities for any programs where Regeneron exercises its opt-in rights.

In connection with the Amendment, the Company entered into a Share Purchase Agreement with Regeneron pursuant to which the Company sold 1.1 million shares of its common stock, subject to certain restrictions, for \$17.94 per share, to Regeneron for an aggregate cash price of approximately \$20.0 million. The purchase price represents \$9.9 million worth of common stock plus a \$10.1 million premium, which represents deferred revenue.

Accounting analysis – 2018 Regeneron Collaboration Agreement

At the commencement of the original Regeneron Collaboration Agreement, 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 submission. 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 \$8.5 million will be attributed to the joint research activities and recognized over the five-year research collaboration term.

Consistent with its collaboration accounting policy, the Company will recognize collaboration revenue or research and development expense related to the joint research activities in future periods depending on the amounts incurred by each party in a given reporting period. That is, if the Company’s research costs incurred exceed those research costs incurred by Regeneron in a given quarter, the Company will record collaboration revenue and reduce the original \$37.0 million advance by the amount due from Regeneron until such advancement is fully utilized, after which the Company would record an amount due from Regeneron. If Regeneron’s research costs incurred exceed those research costs incurred by the Company in a given quarter, the Company will record research and development expense and record a liability for the amount due to Regeneron. As of December 31, 2022, the Company had \$3.7 million of collaboration research advancement credit attributed to the joint research activities still to be recognized. As of March 31, 2023, this amount was fully utilized and there is no collaboration research advancement credit remaining.

Accounting analysis - Regeneron Amendment

At the commencement of the Amendment, the Company identified two units of accounting, including the issuance of 1.1 million shares of 2seventy bio common stock and joint research activities under the amended agreement. The Company determined the total transaction price to be \$20.0 million, which comprises \$9.9 million of 2seventy bio equity sold to Regeneron and \$10.1 million attributed to joint research activities. In determining the fair value of 2seventy bio common stock at closing, the Company considered the closing price of 2seventy bio common stock on the closing date of the transaction and included a lack of marketability discount because Regeneron received shares subject to certain restrictions.

Consistent with the original Regeneron Collaboration Agreement, the Company assessed whether the joint research activities under the Amendment fell within the scope of ASC 808 and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the amended arrangement as outlined above, for the collaboration research performed prior to submission of an IND application for a potential gene therapy product, both parties continue to be active participants in the collaboration. Both parties continue to perform research and development activities and will share in these costs through IND submission. Additionally, Regeneron and the Company continue to be exposed to significant risks and rewards dependent on the commercial success of any product candidates that may result from the collaboration. As such, the collaboration arrangement is deemed to be within the scope of ASC 808. The Company continues to apply ASC 606 by analogy to determine the measurement and recognition of the consideration received from Regeneron.

The Company analogized to the contract modification guidance in ASC 606 to account for the scope and pricing changes contained in the Amendment. The Company concluded the performance obligation under the Amended Agreement continues to be a single performance obligation and the remaining services under the Amendment are not distinct from those already provided. The Company therefore accounted for the modification by updating the transaction price and measure of progress prospectively with a cumulative catch-up entry recorded as of the effective date of the Amendment. The updated transaction price is based on the Company's total spend from the original agreement and total estimated spend until the targets outlined in the Amendment clear IND filing, at which point, the Company will reassess whether the collaboration is still within the scope of ASC 808. The Company then combined the \$10.1 million premium attributed to the joint research activities in the Amendment with the \$8.5 million premium from the original Regeneron Collaboration Agreement for a total of \$18.6 million. Future milestones continue to be fully constrained until such time as the achievement of such milestones are considered probable.

The Company concluded that it continues to satisfy its obligations over-time as Regeneron receives the benefit of the research activities as the activities are performed. The Company determined the most appropriate method to track progress towards completion of the performance obligation is an input method that is based on costs incurred. There are significant judgments and estimates inherent in the determination of the costs to be incurred for the research and development activities related to the collaboration with Regeneron. These estimates and assumptions include a number of objective and subjective factors, including the likelihood that a target will be successfully developed through its IND filing and the estimated costs associated with such development, including the potential third-party costs related to each target's IND-enabling study.

As of March 31, 2023, the Company estimates the contract is approximately 47% complete and therefore approximately \$9.8 million remains in collaboration deferred revenue, of which \$3.5 million is included in short-term deferred revenue and \$6.3 million is included in long-term deferred revenue on the condensed consolidated balance sheets.

The Company recognized \$6.4 million of collaborative arrangement revenue, including a \$0.7 million catch-up adjustment under the Amendment, for the three months ended March 31, 2023. The Company recognized \$3.5 million of collaborative arrangement revenue from the Regeneron Collaboration Agreement for the three months ended March 31, 2022. As of March 31, 2023, amounts due from Regeneron include \$2.3 million of receivables from the collaborative arrangement revenue recognized in the first quarter of 2023.

JW Therapeutics

In October 2022, the Company entered into a strategic alliance with JW (Cayman) Therapeutics Co., Ltd. (“JW”) to establish a translational and clinical cell therapy development platform designed to more rapidly explore T cell-based immunotherapy therapy products in the Chinese mainland, Hong Kong (China), and Macao (China). The initial focus of the collaboration is the Company’s MAGE-A4 TCR program in solid tumors which is being developed as part of its collaboration with Regeneron.

Under the terms of the agreement, the Company will grant JW a license for the MAGE-A4 cell therapy in the Chinese mainland, Hong Kong (China), and Macao (China). JW will be responsible for development, manufacturing, and commercialization of the Initial Product within China. The Company is eligible to receive milestones and royalties on product revenues in China. The Company and Regeneron will equally share all payments received from JW, including but not limited to all upfront, milestone and royalty payments made by JW to the Company. The Company and Regeneron will also equally share all costs for any eligible expenses incurred in accordance with the terms of the Regeneron Collaboration Agreement. Additionally, the Company may leverage the early clinical data generated under the collaboration to support development in other geographies.

Accounting Analysis - JW

The Company concluded JW is a customer, and as such, the arrangement falls within the scope of Topic 606. Two performance obligations were identified within the contract consisting of (i) a license for the MAGE-A4 cell therapy, including a transfer of technology as agreed upon by both parties and (ii) vector supply necessary to conduct a Phase 1 clinical trial. The Company has concluded the manufacturing and supply of vector is a distinct performance obligation from the license for MAGE-A4 cell therapy because there are other vendors that could provide the necessary supply.

At contract inception, the Company determined the unconstrained transaction price was \$7.3 million, consisting of the \$3.0 million up-front consideration and \$4.3 million variable consideration for the reimbursement of vector supply. JW provided the Company with a \$3.0 million upfront payment related to the granting of a license for MAGE-A4 cell therapy and the transfer of technology for the development of the Initial Product in which the Company will share equally with Regeneron. During the first quarter of 2023, the Company completed the full transfer of the license of IP related to MAGEA4 cell therapy along with the technology transfer, and as such, the upfront payment received from JW was recognized as service revenue during the first quarter of 2023. The transaction price of \$4.3 million related to the supply of vector consists of variable consideration based upon the estimated amount of vector needed for the initial Phase 1 clinical trial. As of March 31, 2023, the manufacturing and transfer of vector to JW has not yet occurred and therefore the Company has not received any payments related to this performance obligation.

Novo Nordisk

Novo Collaboration and License Agreement

In December 2021, the Company entered into a Collaboration and License Agreement (the “Novo Collaboration Agreement”) with Novo 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 research program up to a mutually agreed upon amount. If Novo exercises its option to obtain a license to commercialize the product developed during the initial research program, the Company is also eligible to receive mid-single digit royalties on product sales on a country-by-country and product-by-product basis, subject to certain royalty step-down provisions set forth in the agreement.

Accounting Analysis - Novo

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

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

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, 2023, and 2022 the Company recognized \$1.7 million and \$1.3 million of service revenue under this agreement, respectively.

11. Royalty and other revenue

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

The Company recognized \$1.4 million and \$0.9 million of royalty and other revenue in the three months ended March 31, 2023 and 2022, respectively.

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. Royalty revenue recognized from sales of lisocabtagene maraleucel is included within royalty and other revenue in the condensed consolidated statement of operations and comprehensive loss.

12. Stock-based compensation

In connection with 2seventy bio’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 financial statements included in our annual report on Form 10-K for the year ended December 31, 2022 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

Stock-based compensation expense includes compensation cost related to 2seventy bio 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,	
	2023	2022
Stock options	\$ 3,865	\$ 4,404
Restricted stock units	5,727	5,314
Employee stock purchase plan and other	74	21
	<u>\$ 9,666</u>	<u>\$ 9,739</u>

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

	For the three months ended March 31,	
	2023	2022
Research and development	\$ 3,618	\$ 4,218
Selling, general and administrative	6,048	5,521
	<u>\$ 9,666</u>	<u>\$ 9,739</u>

Employee Stock Purchase Plan

During the three months ended March 31, 2023, less than 0.1 million shares of common stock were issued under the Company's 2021 Employee Stock Purchase Plan.

13. Related-party transactions

Relationship with bluebird bio

In connection with the separation from bluebird bio, Inc, the Company entered into certain agreements pursuant to which the separation of its business from bluebird bio was effected and that govern its relationship with bluebird bio going forward. The separation agreement, tax matters agreement, employee matters agreement, intellectual property license agreement ("License Agreement") and two transition services agreements are described in Note 14, Related-party transactions, to the consolidated financial statements included in the Company's 2022 annual report on Form 10-K. Aside from a Partial Assignment and Assumption Agreement entered in February 2023, as described below, there have been no material changes to the existing agreements from those previously disclosed. Prior to the separation, all of Company's outstanding shares of common stock were owned by bluebird bio and therefore the transactions under those agreements were considered and disclosed as related party transactions. Following the completion of the separation and distribution, the Company and bluebird bio have operated separately, each as independent public company and bluebird bio no longer owns any shares of the Company's common stock. Therefore, transactions under those agreements are no longer accounted for as related party transactions.

On February 23, 2023, the Company entered into a Partial Assignment and Assumption Agreement (the "Assignment and Assumption Agreement") with Institut Pasteur ("Institut Pasteur") and bluebird bio. Pursuant to the Assignment and Assumption Agreement, bluebird bio assigned to the Company bluebird bio's rights, obligations and interests under a license agreement with Institut Pasteur that were previously licensed to the Company by bluebird bio under the License Agreement. The Company will pay Institut Pasteur an annual maintenance payment, a percentage of income received in the event of sublicensing arrangements and, upon commercialization of certain products, a percentage of net sales as a royalty, which varies depending on the indication of the product.

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,	
	2023	2022
Outstanding stock options ⁽¹⁾	3,571	2,780
Restricted stock units ⁽¹⁾	2,678	1,655
ESPP shares and other	—	35
	<u>6,249</u>	<u>4,470</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 financial statements included in the Company's 2022 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.

16. Subsequent events

In April 2023, the Company achieved positive proof of concept, preclinical data related to its joint research and development collaboration with Novo Nordisk, which is focused on an *in vivo* gene editing treatment for hemophilia A. This achievement triggered a \$15.0 million milestone payment under the terms of the Novo Collaboration Agreement. Following the achievement of this milestone, the Company and/or Novo Nordisk may elect to exercise an option to in-license technology from a third party in connection with the Novo Collaboration Agreement, which would result in the Company making a \$9.0 million payment to the third party.

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 2022 annual report on Form 10-K, which was most recently filed with the Securities and Exchange Commission, or the SEC, on March 16, 2023.

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 Delaware 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 in the United States as *Abecma*). Our approach combines our expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. We are advancing multiple preclinical and clinical programs in oncology and, together with our partner, delivering *Abecma* to multiple myeloma patients in the United States following approval by the FDA of *Abecma* in March 2021 for the treatment of adults with multiple myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody.

We have never been profitable and have incurred net losses since inception. Our net loss was \$47.0 million for the three months ended March 31, 2023. 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;
- continue to develop and commercialize *Abecma* with our partner, BMS;

- seek regulatory approval for our product candidates and advance our preclinical programs into clinical development; and
- increase research and development-related activities for the discovery and development of product candidates and technologies in oncology.

In February 2023, we substantially completed the construction of our drug product manufacturing facility at our existing headquarters in Cambridge, Massachusetts for our future Phase 1 clinical trials. We anticipate the facility to be operational by mid-2023. In the meantime, all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize third-party contract research organizations, or CROs, to carry out our clinical development activities. As we continue to develop and seek to obtain regulatory approval for our product candidates, we expect to incur significant expenses. Accordingly, until we generate significant revenues from product sales, we will continue to seek to fund our operations through public or private equity or debt financings, strategic collaborations, or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates. Refer to sections *Liquidity and Capital Resources* and *Funding Requirements* below for further discussion.

Separation from bluebird bio, Inc.

On November 4, 2021, bluebird bio completed the separation and spin-off of its oncology portfolio and programs into 2seventy bio, retaining its severe genetic disease portfolio and programs. We did not operate as a separate, stand-alone entity prior to our separation from bluebird bio. In connection with the separation, certain assets and liabilities, including certain accounts receivables and accounts payables, included on the condensed consolidated 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 financial statements in our 2021 annual report on Form 10-K. 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, all revenue we have recognized relating to the sale of products has been the collaboration revenue derived from commercial sales of *Abecma* by BMS, and we have not recognized any revenue from the sale of products by us.

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

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* (“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 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 to us for research and development expenses	Collaborative arrangement revenue
Net reimbursement to the collaborator for research and development expenses	Research and development expense

Where the collaborator is the principal in the product sales, 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.

As we recognize revenue under our collaborative arrangements both within and outside the scope of Topic 606, we present revenue on our consolidated 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.

For the three months ended March 31, 2023 and 2022, service revenue consisted of the following (in thousands):

	For the three months ended March 31,	
	2023	2022
ide-cel ex-U.S. service revenue from BMS	\$ 6,123	\$ 2,790
Service revenue from December 2021 agreement with Novo Nordisk	1,703	1,265
Other	3,000	—
Total service revenue	<u>\$ 10,826</u>	<u>\$ 4,055</u>

For the three months ended March 31, 2023 and 2022, collaborative arrangement revenue consisted of the following (in thousands):

	For the three months ended March 31,	
	2023	2022
U.S. <i>Abecma</i> collaboration with BMS	\$ 22,961	\$ —
Collaboration with Regeneron	6,411	3,487
Total collaborative arrangement revenue	\$ 29,372	\$ 3,487

To date, *Abecma* is our only commercial product where the collaborator is the principal in the product sales and thus, all amounts shown within our condensed consolidated statements of operations and comprehensive loss for share of collaboration loss relate to *Abecma*. The table below summarizes the impact of the *Abecma* U.S. collaboration profit/loss share on our condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2023 and 2022 (in thousands).

<i>Abecma</i> U.S. Collaboration Profit (Loss) Share	For the three months ended March 31,	
	2023	2022
Our share of profits (losses), net of our share of BMS costs for commercial activities	\$ 21,581	\$ (6,709)
Reimbursement from BMS for our costs of commercial manufacturing and commercial activities	1,380	1,357
Collaborative arrangement revenue ⁽¹⁾	\$ 22,961	\$ —
Share of collaboration loss ⁽¹⁾	\$ —	\$ (5,352)
Costs of commercial manufacturing incurred by us, prior to BMS reimbursement	(2,583)	(2,086)
Costs of commercial activities incurred by us, prior to BMS reimbursement	(176)	(628)
Total impact of <i>Abecma</i> U.S. collaboration profit (loss) on our statements of operations and comprehensive loss	\$ 20,202	\$ (8,066)

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

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:

- 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. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- KarMMA-2 study – a multi-cohort, open-label, multicenter phase 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. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- KarMMA-3 study – a multicenter, randomized, open-label phase 3 study comparing the efficacy and safety of ide-cel versus standard triplet regimens in patients with relapsed and refractory multiple myeloma. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- KarMMA-4 study – a multi-cohort, open-label, multicenter phase 1 study intended to determine the optimal target dose and safety of ide-cel in subjects with newly-diagnosed multiple myeloma. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- KarMMA-7 study – an open label, multi-arm, multi-cohort phase 1/2 study intended to determine the optimal target dose, safety and efficacy of ide-cel combinations in subjects with relapsed and/or refractory multiple myeloma. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- CRB-402 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 following our election to discontinue development of bb21217 in 2022.
- 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 both our clinical and preclinical programs. Clinical programs include our advancement of the SC-DARIC33 and bbT369 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 of clinical study materials in support of our clinical studies.

Our direct research and development expenses consist principally of internal and 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 internal 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:

	For the three months ended March 31,	
	2023	2022
ide-cel ⁽¹⁾	\$ 17,594	\$ 10,482
bb21217	888	2,000
bbT369	9,971	6,459
SC-DARIC33	1,294	2,162
Preclinical programs	14,562	13,433
Total direct research and development expenses	44,309	34,536
General research and platform personnel costs	5,506	7,644
Unallocated laboratory and manufacturing expenses	2,490	6,071
Facility and other support costs	15,941	17,628
Total other research and development expenses	23,937	31,343
Total research and development expenses	\$ 68,246	\$ 65,879

(1) ide-cel research and development expenses included above are substantially global in nature and benefit both U.S. and ex-U.S. territories.

Cost of Manufacturing for Commercial Collaboration

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

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

Selling, General and Administrative Expenses

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

Share of Collaboration Loss

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

Cost of Royalty and Other Revenue

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

Change in Fair Value of Contingent Consideration

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

As of March 31, 2023, there were \$99.9 million in future contingent cash payments related to commercial milestones. We estimate future contingent cash payments have a fair value of \$2.3 million as of March 31, 2023, which are classified within other non-current liabilities on our condensed consolidated balance sheet.

Other Income, Net

Other income, net consists primarily of rental income along with income recognized under our transition service agreements with bluebird bio and gains and losses on disposal of assets. For the 2022 comparative periods, other income, net included these items as well as our 50% share of the Resilience net operating losses.

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 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, 2023, there were no material changes to our significant accounting policies as reported in our annual consolidated financial statements included in our 2022 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 financial statements.

Results of Operations

The following discussion summarizes the key factors we believe are necessary for an understanding of our condensed consolidated financial statements.

Comparison of the Three Months Ended March 31, 2023 and 2022:

	For the three months ended March 31,		Change
	2023	2022	
(in thousands)			
Revenue:			
Service revenue	\$ 10,826	\$ 4,055	\$ 6,771
Collaborative arrangement revenue	29,372	3,487	25,885
Royalty and other revenue	1,423	887	536
Total revenues	41,621	8,429	33,192
Operating expenses:			
Research and development	68,246	65,879	2,367
Cost of manufacturing for commercial collaboration	3,654	3,366	288
Selling, general and administrative	20,720	23,861	(3,141)
Share of collaboration loss	—	5,352	(5,352)
Cost of royalty and other revenue	641	511	130
Change in fair value of contingent consideration	73	48	25
Total operating expenses	93,334	99,017	(5,683)
Loss from operations	(51,713)	(90,588)	38,875
Interest income, net	2,049	115	1,934
Other income, net	2,643	4,762	(2,119)
Loss before income taxes	(47,021)	(85,711)	38,690
Income tax (expense) benefit	—	—	—
Net loss	\$ (47,021)	\$ (85,711)	\$ 38,690

Revenue. Total revenue was \$41.6 million for the three months ended March 31, 2023, compared to \$8.4 million for the three months ended March 31, 2022. The increase of \$33.2 million was primarily attributable to an increase in collaborative arrangement revenue recognized under our collaboration arrangement with BMS, driven by increased *Abecma* net sales and lower cost of goods sold. This resulted in higher profit owed to 2seventy as part of our 50% share of U.S. profit/loss with BMS. The increase was also driven by an increase in service revenue attributable to an increase of ide-cel ex-U.S. service revenue of approximately \$3.3 million along with the recognition of revenue on the upfront payment received from the JW agreement of \$3.0 million in the first quarter of 2023.

Research and Development Expenses. Research and development expenses were \$68.2 million for the three months ended March 31, 2023, compared to \$65.9 million for the three months ended March 31, 2022. The overall increase of \$2.4 million was primarily attributable to the following:

- \$10.1 million of increased material production costs, primarily due to increased manufacturing activities of suspension lentiviral vector for ide-cel development; and
- \$3.1 million of increased license and milestone fees associated with a milestone paid to Medigene for the continued development of our MAGE-A4 TCR program in solid tumors, which is being developed as part of our collaboration with Regeneron.

These increases were partially offset by:

- \$6.4 million of decreased collaboration research funding costs incurred under our partnerships with Gritstone Oncology, Inc. and Seattle Children's Therapeutics, as well as a decrease in net research and development expenses recognized under our collaboration with BMS;
- \$1.5 million of decreased IT and other facility-related costs;
- \$1.3 million of decreased employee compensation expenses, primarily due to a decrease in stock-based compensation expense driven by an overall decrease in the value of stock-based compensation awards; and
- \$0.9 million of decreased amortization expense associated with the intangible asset acquired in our purchase of Pregenen in 2014. The amortization of this intangible asset was completed in the second quarter of 2022.

Cost of Manufacturing for Commercial Collaboration. Cost of manufacturing for commercial collaboration was \$3.7 million for the three months ended March 31, 2023, compared to \$3.4 million for the three months ended March 31, 2022. The increase of \$0.3 million was primarily due to a slight increase in quality testing performed by us on *Abecma* inventory during the first quarter of 2023 compared to the first quarter of 2022. These costs primarily consist of the salaries and benefits for our quality employees and laboratory expenses incurred to support quality testing.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$20.7 million for the three months ended March 31, 2023, compared to \$23.9 million for the three months ended March 31, 2022. The decrease of \$3.1 million was primarily due to decreased consulting and professional service fees associated with our spin-off from bluebird bio as well as decreased employee compensation costs.

Cost of Royalty and Other Revenue. Cost of royalty and other revenue was \$0.6 million for the three months ended March 31, 2023, compared to \$0.5 million for the three months ended March 31, 2022, and represents amounts owed to third-party licensors on revenues recognized under our out-license arrangements. The increase is attributable to increased royalty and other revenue in the same periods driven by sales of Breyanzi (lisocabtagene maraleucel) by BMS.

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

Other Income, Net. For the three months ended March 31, 2023, other income, net primarily consisted of rental income along with income recognized under our transition service agreements with bluebird bio. For the three months ended March 31, 2022, other income, net primarily consisted of income recognized under our transition services agreements with bluebird bio.

Liquidity and Capital Resources

As of March 31, 2023, we had cash, cash equivalents, and marketable securities of approximately \$341.4 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. This includes the potential sale of shares of our common stock of up to \$150.0 million in gross proceeds under the at-the-market (“ATM”) facility established in November 2022 with Cowen and Company, LLC. No sales of common stock have occurred under this ATM facility as of the date of this Quarterly Report on Form 10-Q. 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, 2023, we incurred a loss of \$47.0 million and used \$49.1 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:

	For the three months ended March 31,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	\$ (49,088)	\$ (73,482)
Net cash provided by investing activities	44,798	44,749
Net cash provided by financing activities	127,084	170,099
Increase in cash, cash equivalents and restricted cash and cash equivalents	<u>\$ 122,794</u>	<u>\$ 141,366</u>

Cash Flows from Operating Activities. Net cash used in operating activities was \$49.1 million for the three months ended March 31, 2023 and primarily consisted of a net loss of \$47.0 million adjusted for non-cash items, including stock-based compensation of \$9.7 million, depreciation and amortization of \$2.3 million, and the change in fair value of contingent consideration of \$0.1 million, as well as the change in our net working capital.

Net cash used in operating activities was \$73.5 million for the three months ended March 31, 2022 and primarily consisted of 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.

Cash Flows from Investing Activities. Net cash provided by investing activities for the three months ended March 31, 2023 was \$44.8 million and was due to proceeds from maturities of marketable securities of \$87.0 million and proceeds from maturities of restricted investments of \$2.5 million, offset by the purchases of marketable securities of \$36.1 million, purchases of restricted investments of \$2.5 million, and the purchase of property, plant and equipment of \$6.1 million.

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.

Cash Flows from Financing Activities. Net cash provided by financing activities for the three months ended March 31, 2023 was \$127.1 million and was primarily due to net proceeds received of \$117.1 million from the issuance of common stock in a public offering in March 2023 along with net proceeds of \$9.9 million from the issuance of common stock to Regeneron from the January 2023 Share Purchase Agreement.

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, as issuance costs had not yet been paid as of March 31, 2022.

Funding Requirements

We intend to incur costs in support of the following activities:

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

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

Because of the numerous risks and uncertainties associated with research, 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 financial statements, there have been no material changes to our contractual obligations and commitments as included in our audited consolidated financial statements included in the Company's 2022 annual report on Form 10-K.

Emerging Growth Company Status

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

ITEM 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, 2023 we had cash, cash equivalents and marketable securities of \$341.4 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, 2023, the net fair value of our interest-sensitive marketable securities and restricted investments would have resulted in a hypothetical decline of \$0.7 million.

Foreign currency fluctuation risk

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

Inflation fluctuation risk

Inflation generally affects us by increasing our cost of labor and operating expenses. 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, 2023. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future (especially if inflation rates continue to rise) due to an impact on the costs to conduct clinical trials, labor costs we incur to attract and retain qualified personnel, and other operational costs, inflationary costs could adversely affect our business, financial condition and results of operations.

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

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, 2022. 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, 2022, 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.

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>
3.1	Amended and Restated Certificate of Incorporation of 2seventy bio, Inc. (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed on November 4, 2021).
3.2	Amended and Restated Bylaws of 2seventy bio, Inc. (incorporated by reference to Exhibit 3.2 to Annual Report on Form 10-K filed on March 16, 202).
4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 10.7 to Current Report on Form 8-K filed on November 4, 2021).
10.1*†	License Agreement by and between bluebird bio, Inc. and Institut Pasteur, dated September 8, 2011, as amended.
10.2#	Severance Agreement between Globalization Partners Switzerland SA and Nicola Heffron, dated February 17, 2023 (incorporated by reference to Exhibit 10.17 to Annual Report on Form 10-K filed on March 16, 2023).
10.3#	Consulting Agreement between 2seventy bio, Inc. and Nicola Heffron, dated February 21, 2023 (incorporated by reference to Exhibit 10.18 to Annual Report on Form 10-K filed on March 16, 2023).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.*)

* 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 10, 2023

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

Date: May 10, 2023

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

LICENSE AGREEMENT

Between

INSTITUT PASTEUR, a non profit private foundation organized under the laws of France with offices at 25-28 rue du Docteur Roux, 75 724 Paris Cedex 15, France, VAT FR 65 775 684 897, represented by M. Christophe Mauriet, Senior Executive Vice-President for Administration, and M. Jean Derégnaucourt, Executive Vice President Business Development

Hereinafter referred to as “Institut Pasteur”

On one hand,

And

BLUEBIRDBIO INC., a company incorporated under the laws of Massachusetts, with offices at 840 Memorial Drive, Cambridge, MA 02139, United States, represented by Nick Leschly, Chief Executive Officer

Hereinafter referred to as “Licensee”,

On the other hand,

Hereinafter mentioned as a Party or the Parties.

Recitals

1. Institut Pasteur has identified and patented a specific nucleotide sequence having a triplex structure, hereinafter referred to as “DNA flap”, covered by patents and patent applications.
2. Institut Pasteur has granted several exclusive or non exclusive licenses on the DNA flap under several fields to companies.
3. Licensee is a company developing innovative gene therapies for severe genetic disorders.
4. Licensee wishes to obtain a license of such patents and commercialize products for gene therapy.
5. Licensee and Institut Pasteur have decided to discuss terms of a license agreement according to the terms and conditions of this Agreement.

Now, therefore, the Parties hereby agree as follow:

Article 1. Definitions

For the purpose of this Agreement, the terms used in this Agreement, in singular or in plural, shall have the respective meanings set forth below:

- “Affiliate” means with respect to Licensee any party which (directly or indirectly) is controlled by, controls, or is under common control with, Licensee. For the purposes of this definition, the terms “control” and “controlled” mean the direct or indirect ownership of more than fifty percent (50%) of the outstanding voting securities of an entity, or such other relationship as results in actual control over the management, assets, business and affairs of such entity.
- “Agreement” shall mean this license agreement together with its appendices which make integral part of it.
- “Confidential Information” shall mean any and all confidential information, whatever its nature or its format, which is disclosed by one Party to the other Party hereunder and that is marked confidential or with similar term, if disclosed in writing, or if disclosed orally, identified as confidential at the time of disclosure. Notwithstanding the foregoing, any information which, by its nature and under the circumstances surrounding its disclosure is generally considered proprietary and confidential shall be

deemed Confidential Information regardless of whether it is properly marked with legends or properly reduced to writing.

- “Development Plan” shall mean a document defining the research and development of the Licensee and/or Affiliates as well as the commercial and financial development estimates of Licensee and/or Affiliates for its Product(s) using the Technology in the Field.
- “Effective Date” shall mean the date of the last signature of this Agreement by the Parties.
- “Ex vivo gene therapy” shall mean that cells are extracted from a patient, corrected by placing a healthy or functional gene(s) and transplanted back into patient.
- “Field” shall mean ex vivo gene therapy for human disorders limited to adrenoleukodystrophy (ALD) (including but not limited to AMN, CCALD, and all other variants of this disease caused by genetic mutations), beta hemoglobinopathies (including but not limited to beta-thalassemia and sickle cell anemia), [***], the “Field” includes in vivo as well as ex vivo gene therapy. Licensee and/or Affiliates shall have the right to request Institut Pasteur to expand the definition of “Field” to include additional clinical areas. [***] For clarity, the Field excludes any other fields and specifically prophylactic and therapeutic human and veterinary vaccination against all kind of pathogens, and the field of services of production and commercialisation of Good Manufacturing Practice (GMP) batches of lentiviral vectors for clinical trials. For clarity, the Field shall include production of GMP batches, by Licensee and its Affiliates [***]. For clarity, Institut Pasteur has already granted exclusive rights for services of production and commercialisation of Good Manufacturing Practice (GMP) batches of lentiviral vectors for clinical trials. [***]
- “Improvement” shall mean any new invention, patentable or not, patented or not, of the Technology, which under applicable law, depends on, at least, one claim of the Patents. For clarity, an Improvement does not include any Product.
- “Net Sales” shall mean the gross amount, excluded taxes, invoiced for sale of Products manufactured or sold in the Territory, in finish or semi finish form by Licensee and/or Affiliates less the following items, consistent with U.S. GAAP:
 - a) trade, quantity and cash discounts actually allowed;
 - b) commissions, discounts, refunds, rebates, charge backs, retroactive price adjustments, and any other allowances paid to non-governmental Third Parties that effectively reduce net selling price;
 - c) credits, allowances and refunds for actual Product rejections, returns and allowances;
 - d) taxes, duties and other governmental charges on the sale, shipment or transfer of the Product; and
 - e) duly justified governmental discounts, refunds, rebates, charge backs, retroactive price adjustments and any other allowances that effectively reduce net selling price.

It is understood that deductions set forth in a), b) and c) herein above shall not exceed [***] of gross revenue, excluded taxes, invoiced for sale of Products in the Territory.

- “Patents” shall mean the patents and patents applications listed in Appendix 1, along with all other patent rights (including but not limited to continuations, continuations-in-part (but only for those claims of such continuations-in-part that are fully supported by the patents and patent applications listed in Appendix 1 as of the Effective Date), divisionals, renewals, reissues, re-examinations, patent term extensions) that claim priority in whole or in part to any such patents and patent applications.
- “Product” shall mean all composition or product for gene therapy or method in the Field that incorporate the Technology.
- “Rare Diseases” shall include adrenoleukodystrophy (ALD) (including but not limited to AMN, CCALD, and all other variants of this disease caused by genetic mutations), beta hemoglobinopathies (including but

not limited to beta-thalassemia and sickle cell anemia), [***]. Whether in the case of [***], such diseases shall be considered on a case-by-case basis and considered a Rare Diseases if the incidence or prevalence is similar to those diseases listed as Rare Diseases above. In these situations, Licensee and/or Affiliates shall provide justification as to whether such disease is a Rare Disease, in writing, prior to payment of the Milestone #4 or #5 as applicable.

- “Technology” shall mean lentivirus vector containing DNA flap sequence covered by whole or part of the claims of the Patents.
- “Territory” shall mean [***].
- “Third Party” shall mean any party which is not Institut Pasteur or Licensee or its Affiliates.

Article 2. Scope

1.1 Under this Agreement, Institut Pasteur grants to Licensee and its Affiliates, that Licensee and its Affiliates accepts at their own risks, a license under the Patents in the Field and in the Territory for research and development, and to manufacture, have manufactured, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import or have imported the Products, to the exclusion of any other rights, which is:

- exclusive for Products containing human (HIV-1 and HIV-2) lentivirus vector, and ;
- non exclusive for Products containing non-human lentivirus vector.

1.2 No right granted herein shall prevent Institut Pasteur or its licensees or research partners to conduct research in the Field.

1.3 This Agreement includes the right for Licensee and/or Affiliates to grant sublicenses in the Field and the Territory to and through multiple tier(s) of Third Party(ies).

Article 3. Licensee’s obligation

1.1 Licensee shall make, or shall cause its Affiliates and sublicensee to make, all reasonable commercial efforts (by reference to a company of similar size and scope to Licensee as of the Effective Date) to develop and commercialize one or more Products in the Field and to obtain any necessary governmental approvals in respect of, and market the Product(s) in the Field, if any. It is expressly agreed that fulfillment of the above obligation is an absolute requirement for this Agreement to be maintained into force.

1.2 Licensee shall provide annually, upon each anniversary date of the Effective Date, to Institut Pasteur an updated Development Plan, which will be Confidential Information of Licensee. [***]

1.3 Licensee is the sole responsible for securing the compliance of Products with applicable laws, rules and regulations, in particular, but without limitation, such as relating to ethics, the treatment of animals, and genetically modified organisms, if any.

Article 4. Intellectual property

1.1 The provisions of this Agreement shall not modify the ownership of the Technology and Patents.

1.2 Any Improvement of the Technology made without Institut Pasteur by the Licensee shall belong to Licensee.

1.3 Any Improvement of the Technology made with the help of Institut Pasteur will be co-owned by Institut Pasteur and Licensee. A specific agreement shall be established between the co-owners within six (6) months following the identification of the joint Improvement.

1.4 Upon request of Institut Pasteur, Institut Pasteur and Licensee agrees to meet in view to determine the conditions under which Licensee shall grant Institut Pasteur, a non exclusive, free license on the Improvement if possible and available mentioned in articles 4.2 and 4.3 above, for internal research purpose. Licensee and/or Affiliates shall ask to Institut Pasteur to submit a supplementary protection certificate (SPC) for any Product. To this

aim, Licensee shall provide Institut Pasteur all necessary information. This SPC shall automatically be part of the Agreement.

1.5 From the Effective Date, Licensee shall pay to Institut Pasteur [***] of future external expenses engaged by Institut Pasteur for securing issuance of, and maintaining Patents or extending the duration of the Patents. Institut Pasteur shall not abandon any Patent without the prior notice of Licensee.

1.6 Upon written request, but at most once a year, Institut Pasteur shall keep Licensee informed of the status of issuance procedures of Patents, and shall update Appendix 1 accordingly.

1.7 Licensee acknowledges that Institut Pasteur has expended significant resources and efforts to develop the Patents, and that the Patents represents highly valuable interests, [***].

1.8 In the case a Patent is challenged (including but not limited to a re-examination, opposition or interference proceeding, but not including when part of an infringement action described above), the Parties shall make available to the other all information they have, and shall meet to decide the defense strategy. [***]

Article 5. Infringement

1.1 Institut Pasteur and Licensee shall as soon as they become aware thereof mutually advise each other of any infringement of Patents by a Third Party in the Field. Institut Pasteur and Licensee shall make available to the other all information at their disposal on the basis of which nature and extend can be assessed.

1.2 [***]

1.3 In the case Licensee is sued by a Third Party regarding Technology in a Product, the Parties shall make available to the other all information they have, and shall meet to decide the defense strategy, if any, with respect to such Technology.

Article 6. Consideration

1.1 Within thirty (30) days of the Effective Date, Licensee shall pay to Institut Pasteur a one-time, non-refundable license issuance fee [***] exclusive of taxes. This amount cannot be set-off against future royalties.

1.2 For the development of each Product indication by indication, except in the case mentioned below, Licensee and/or Affiliates shall pay to Institut Pasteur the following milestones:

	[***]	[***]	[***]	[***]
Milestone 1: [***]	[***]	[***]	[***]	[***]
Milestone 2: [***]	[***]	[***]	[***]	[***]
Milestone 3: [***]	[***]	[***]	[***]	[***]
Milestone 4: [***]	[***]	[***]	[***]	[***]
Milestone 5: [***]	[***]	[***]	[***]	[***]
Milestone 6: [***]	[***]	[***]	[***]	[***]

For the foregoing table:

- [***]
- For each Product (including multiple indications for the same Product), only one column is applied and each milestone in such column is paid only once at the first occurrence of such event
- [***]
- [***]
- [***]

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.

- [***]
- [***]

For further clarity, with respect to the second tabbed paragraph above, if the same Product is developed or approved for more than one indication, the specified milestones for a column shall be paid one time only at the first occurrence of such event. As a specific example, [***].

1.3 Until the expiration of the last Patent claiming a Product in the Territory, Licensee and/or Affiliates shall pay to Institut Pasteur the following yearly royalty fees:

- [***] of Net Sales for a Product with an indication in a Rare Disease, without stacking clause, and
- [***] of Net Sales for a Product with an indication in a disease other than a Rare Disease, without stacking clause;

[***].

1.4 If the combined royalties Licensee and/or Affiliates would be required to pay to Institut Pasteur and Third Parties, is higher than [***] for one Product, Licensee and/or Affiliates may ask Institut Pasteur to negotiate the royalty fees of the article 6.3.

1.5 Licensee and/or Affiliates shall pay to Institut Pasteur a minimum annual fee [***] exclusive of taxes per twelve (12) month period and due at the end of such period which shall start from the fifth anniversary of the Effective Date of this Agreement for all Products. For clarity, such payment shall be offset by the royalties payments made to Institut Pasteur during such 12 month period. If no Product is on the market after the fifth anniversary of the Effective Date, this minimum annual fee shall be reduced [***] exclusive of taxes until the first Product shall be on the market, date on which the minimum annual fee shall be again [***] exclusive of taxes per twelve (12) month period.

1.6 Licensee and/or Affiliates shall pay to Institut Pasteur [***] of all cash and cash-equivalent consideration, whatever its nature, and in particular without limitation, all sums, milestones, royalties, exchange value of any counterpart in kind or in industry (but not duly justified payments for research and development) received by Licensee and/or Affiliates from its all sublicenses agreements granted by Licensee and/or Affiliates on the sole Technology.

1.7 On a indication-by-indication basis, in case of sublicenses relating to a Product, Licensee and/or Affiliates shall pay to Institut Pasteur on any and all cash and cash-equivalent consideration, whatever its nature, and in particular without limitation, all sums, milestones, royalties, exchange value of any counterpart in kind or in industry (but not duly justified payments for research and development) received by Licensee and/or Affiliates from a sublicensee:

- [***] if the sublicense is signed for Product(s) in a preclinical stage development, or,
- [***] if the sublicense is signed for Product(s) in a clinical stage of development.

1.8 If the combined royalties Licensee and/or Affiliates would be required to pay to Institut Pasteur and Third Parties, is higher than [***] for one Product, Licensee and/or Affiliates may ask Institut Pasteur to negotiate the royalty fees of the article 6.7.

1.9 Notwithstanding the foregoing, in the case of a sublicense of the Technology for a Product for ALD (including but not limited to AMN, CCALD, and all other variants of this disease caused by genetic mutations), beta-thalassemia and/or sickle cell anemia, Institut Pasteur shall receive the same Milestones and Royalties as if Licensee and/or Affiliates itself were developing and commercializing such Product(s) (and thus no amounts shall be payable to Institut Pasteur under Article 6.7). Licensee and/or Affiliates shall be liable for ensuring such payment in accordance with the terms of this Agreement.

Article 7. Payment

1.1 Payment of royalties due under this Agreement shall be made within forty-five (45) days from the invoice date, after the end of each six-month period's Net Sales (ending 30 June and 31 December) for the sum corresponding to that period.

1.2 Any payment due by Licensee, pursuant to this Agreement, shall be made in euros by check or by wire transfer to a bank account as designated by Institut Pasteur from time to time.

1.3 Royalties arising out of Net Sales achieved in currencies other than the Euro shall be converted at the current average exchange rate one month prior to the date upon which the royalties report is due, and shall be borne by Licensee.

1.4 Notwithstanding the provisions of this Agreement, sums paid to Institut Pasteur shall in any event be retained by Institut Pasteur. Any VAT (Value Added Tax) due, if any, shall be added to the invoiced amount at the then current rate, and shall be borne by Licensee.

1.5 Any withholding tax payable by Licensee on royalties due hereunder shall be deducted from royalties due for the relevant country. Licensee shall be responsible for obtaining and providing to Institut Pasteur evidence of the payment of such withholding taxes. Licensee shall assist Institut Pasteur to prevent any double taxation and shall provide Institut Pasteur on request with any document necessary to that end.

1.6 The royalties and other payments set forth in this Agreement shall, if overdue, bear interest until paid at a per annum rate of [***]. The payment of such interest shall not foreclose Institut Pasteur from exercising any other rights or actions it may have as a consequence of the lateness of any payment.

Article 8. Accounts

1.1 Licensee shall simultaneously with payments of royalties deliver to Institut Pasteur a report reflecting its accounts and sub-licenses accounts, pertaining to royalties calculated, on Net Sales, including:

- [***];
- [***]; and
- [***].

Such report maybe delivered by email to the following email address (which address may be updated by written notice from Institut Pasteur to Licensee): Service de Transfert de Technologie, [***].

1.2 When no royalty is payable, a report so attesting shall be submitted to Institut Pasteur. The aforesaid reports shall be treated as Confidential Information of Licensee.

Such report maybe delivered by email to the following email address (which address may be updated by written notice from Institut Pasteur to Licensee): Service de Transfert de Technologie, [***].

1.3 Licensee shall keep complete and accurate records of all Net Sales, allowing a computation and checking of the royalty amount due to Institut Pasteur hereunder. Once a year and upon prior notice to Licensee and/or Affiliates, Institut Pasteur shall, throughout the term of this Agreement, and for a period of three (3) years following the end of this Agreement, be entitled to have at its own expense and during regular business hours Licensee's records pertaining to this Agreement checked by an independent certified public accountant chosen by Institut Pasteur and reasonably acceptable to Licensee, which accountant shall enter into a confidentiality agreement with Licensee. Such accountant shall be appointed for the sole purpose of determining the amount of royalties due to Institut Pasteur hereunder, covering a period not to exceed the past three (3) years, provided that [***] such accountant shall report to Institut Pasteur only as to the accuracy of royalty statements and payments and that such reported information shall be considered to be Confidential Information of Licensee.

1.4 If, as a result of such audit, an adjustment is determined to be made in favor of Institut Pasteur, the accountant's fees and expenses shall be borne by Licensee, if the sums underpaid by Licensee exceed [***] of what was actually paid by Licensee to Institut Pasteur; otherwise such fees and expenses shall be paid by Institut Pasteur. Licensee shall pay any underpaid royalties to Institut Pasteur.

Article 9. Confidentiality

1.1 Confidential Information does not include information for which it is evidenced that:

- is publicly known and made generally available in the public domain prior to the time of disclosure by the providing Party,
- becomes publicly known and made generally available after disclosure by the providing Party to the receiving Party through no action or inaction of the receiving Party,
- is already in the possession of the receiving Party at the time of disclosure by the providing Party as shown by the receiving Party's documentary evidence,
- is obtained by the receiving Party from a Third Party without breach of such Third Party's obligations of confidentiality, as shown by the receiving Party's documentary evidence,
- is required by law to be disclosed by the receiving Party.

1.2 In the event that the receiving Party is notified of a requirement to disclose the providing Party's Confidential Information, the receiving Party shall notify the providing Party immediately upon receipt of such notice and not release the Confidential Information until such time as the providing Party has taken reasonable steps to seek an order of a court of competent jurisdiction to prevent the disclosure, or limit the extent of disclosure, of the providing Party's Confidential Information.

1.3 During the term of this Agreement and five (5) years thereafter, the receiving Party agrees to keep confidential and cause its employees, consultants or students to keep confidential, all Confidential Information of the providing Party that is disclosed to it, or to any of its employees, consultants or students under or in connection with this Agreement.

1.4 Neither the receiving Party nor any of its respective employees, consultants or students, shall use Confidential Information for any other purpose whatsoever except as expressly permitted by this Agreement.

1.5 The receiving Party may not disclose providing Party's Confidential Information to a Third Party without the prior written consent of the providing Party, other than for Licensee and/or Affiliates in connection with a proposed or actual sublicense or transaction permitted by Article 13.7 or for other reasonable business purposes, subject to the confidentiality protections stated above, for the purpose of this Agreement.

1.6 Following expiration or termination of this Agreement, the receiving Party shall return all the Confidential Information to the providing Party, or destroy such Confidential Information at the providing Party request, with the exception that (1) one copy of the Confidential Information that may be retained by the receiving Party's legal counsel for the purpose of verifying its obligations under this Agreement.

Article 10. Representations and Warranties

1.1 At the Effective Date, each Party represents and warrants to the other Party that it has the right to enter into this Agreement.

1.2 Licensee agrees that all Confidential Information or any other information or data communicated or provided by Institut Pasteur under this Agreement are communicated "as is", without any warranty, expressed or implied, regarding accuracy, completeness, merchantability, fitness, patentability and/or performance. Any hazards, costs and risks that may be incurred by Licensee in connection with the use of all or part of the Products, resulting, in particular, from possible defects or from the eviction risk, are the sole responsibility of Licensee. Institut Pasteur shall not be liable for any consequential, indirect or punitive damages or lost profits of Licensee.

1.3 Institut Pasteur gives no warranty whatsoever express or implied, in respect of the Patents, in particular as regards of its usefulness, safety or fitness for a particular purpose. Institut Pasteur does not, either expressly or tacitly warrant that the use of the Patents granted under this Agreement shall allow the production of Product, as well as the manufacture, sale, use, importation, exportation and holding of Products shall not infringe a Third Party's intellectual proprietary rights or violate any rights in particular license rights, already granted to a Third Party. Licensee undertakes not to enforce any remedy, including a claim under any guarantee against Institut Pasteur, for compensation of whatever damage which might arise out of or in connection with the use or non use of the Patents.

1.4 Nothing in the Agreement shall be construed as: (a) a warranty or representation by Institut Pasteur as to the validity or scope of any Patents; (b) a warranty or representation by Institut Pasteur that the practice under the Patents is or will be free from infringement of patents of any Third Party or rights granted to Third Party; (c) except as expressly set forth herein, an obligation to Institut Pasteur to sue Third Party for infringement; or (d) conferring by implication, estoppels or otherwise any license, immunity or right under any patent owned by or licensed to Institut Pasteur other than the Patents.

1.5 Institut Pasteur shall under no circumstances be held liable to Licensee, whether expressly or impliedly, for any direct, indirect, consequential or special damages in relation to the use or sale of Patents and/or Products by Licensee. Licensee shall indemnify and hold Institut Pasteur harmless from all costs and expenses of any kind, arising from or resulting of any Third Party claim against Institut Pasteur relating to the use, handling or storage by Licensee of the Patents or Confidential Information, as well as the manufacture, sale, use, importation, exportation and holding of Product, except where such claims arise from a finding of gross negligence or willful misconduct by Institut Pasteur only with respect to the Patents or Confidential Information, to the exclusion of Products. [***]

1.6 Institut Pasteur may terminate this Agreement with immediate effect in the event that Licensee, either directly or indirectly, or its Affiliates challenges the validity of any of the Patents.

Article 11. Term and Termination

1.1 This Agreement shall be effective from the Effective Date.

1.2 Unless sooner terminated under the articles below, this Agreement shall be effective until the last Patents to expire in the Territory.

1.3 This Agreement may be terminated without any indemnification, by either Party at any time during this Agreement if the other Party is in substantial breach of its obligations hereunder and has not cured such breach within sixty (60) days after a registered letter notifying such substantial breach, without prejudice of any right to pursue an action for damages as a result of such breach.

1.4 Institut Pasteur may also terminate this Agreement without fault where collective proceedings – bankruptcy, suspension of proceedings – are opened against Licensee and not dismissed within sixty (60) days thereafter.

1.5 Licensee may terminate this Agreement by a written notice sent ninety (90) days in advance.

1.6 Termination of this Agreement for any reason shall not affect each Party's continuing obligations to the other Party under this Agreement or pursuing provisions. Upon termination of this Agreement, as long as there are always unexpired Patents under the Territory, this license shall automatically terminate and Licensee shall promptly cease any use of the Patents and shall cease manufacturing, importing, using and selling Products within [***] form the effective date of the termination.

1.7 Upon termination of this Agreement, Institut Pasteur shall have the right to retain any sums already paid by Licensee hereunder, and Licensee shall pay all sums accrued hereunder which are then due, including all sums generated during the three month period mentioned in Article 11.6 of this Agreement.

1.8 Articles 1, 3.3, 4.1 to 4.3, 7 to 10, 11.6, 11.7, 11.8 and 12 shall survive any termination or expiration of this Agreement.

Article 12. Litigation and governing law

1.1 This Agreement shall be construed and governed by the Laws of France. The language of this Agreement shall be English.

1.2 The Parties shall attempt to settle any dispute relating to this Agreement, its validity and/or its interpretation and/or its enforceability and/or its termination, in an amicable way. Should such attempts fails, the litigation will be held in the court of the competent jurisdiction in France.

Article 13. Miscellaneous

1.1 This Agreement contains the entire understanding and agreement between the Parties hereto with respect to its subject matter, and except where otherwise provided herein, supersedes any prior or contemporaneous written or oral agreement between them relating to the subject matter hereof.

1.2 The Parties agree to keep the existence and the terms and conditions of this Agreement strictly confidential, and shall not disclose the existence and the terms and conditions of this Agreement to any Third Party, except as required by law (including but not limited to in connection with a public securities offering) or by Licensee in connection with a proposed or actual sublicense or transaction permitted by Article 13.7 or for other reasonable business purposes. Moreover, nothing contained in this Agreement shall grant to Licensee a right to use for advertising, publicity or any promotional activity whatsoever Institut Pasteur's names, trademarks, logo or any other designations, including in contracted or abbreviated form or by imitation, subject to a prior express written consent of Institut Pasteur. Notwithstanding the foregoing, Licensee may disclose the existence of this Agreement and the fact that Institut Pasteur has granted an exclusive license under the Patents to Licensee.

1.3 This Agreement may be amended only by a written amendment signed by the Parties.

1.4 If any term, provision or condition of this Agreement shall be held by a court of competent jurisdiction to be invalid, unenforceable or void, the remainder of this Agreement shall remain in full force and effect.

1.5 Any notice required or permitted to be given under this Agreement shall be sufficient if sent by commercial courier or certified mail (return receipt requested), facsimile, or postage prepaid, addressed to the address mentioned in first page of this Agreement.

1.6 Neither Party shall be liable to the other for any default under this Agreement caused by war, riot, fire, flood, drought, act of God or any other cause which is beyond the reasonable control of the defaulting Party, as acknowledged by the court of competent jurisdiction.

1.7 This Agreement being entered into for the benefit of consideration of the Parties, shall not be assigned or transferred, whether in whole or in part, without the other Party's prior written consent; provided that Licensee may assign this Agreement to an Affiliate or in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement, and the assignee shall notify Institut Pasteur of such assignment and shall agree in writing to be bound to the terms of this Agreement as "Licensee" hereunder.

1.8 The relationship created by this Agreement shall be that of independent contractors.

1.9 The failure or neglect of a Party at any time, to require performance of the other Party of any provision hereof, shall not in any way affect the right to require such performance at any time thereafter. The waiver by a Party of any breach of any provision hereof shall not be held to be a waiver of any subsequent breach of the same provision or of any other provisions hereof.

[remainder of this page intentionally left blank]

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.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their authorized respective representative.

Made in Paris,
In duplicate.

Date: 08 SEP. 2011
/s/ Christophe Mauriet
INSTITUT PASTEUR
Christophe Mauriet
Senior Executive Vice-President

Date: 13-Sept 2011
/s/ Nick Leschly
BLUEBIRDBIO INC.
Nick Leschly
Chief Executive Officer

Date: 26/8/11
/s/ Jean Derégnacourt
INSTITUT PASTEUR
Jean Derégnacourt
Executive Vice-President Business Development

Appendix 1

Patents

<u>Invention</u> [***]	<u>Priority/Filing date</u> <u>Extension/Filing date</u>	<u>Territories / Filing date</u> <u>Legal Status</u>
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Institut Pasteur hereby confirms that the foregoing is a complete and accurate list of all the Patents as the Date of August 11,2011.

AMENDMENT N°1 TO THE LICENSE AGREEMENT

Between

INSTITUT PASTEUR, a non profit private foundation organized under the laws of France with offices at 25-28 rue du Docteur Roux, 75 724 Paris Cedex 15, France, VAT FR 65 775 684 897, represented by M. Christophe Mauriet, Senior Executive Vice-President for Administration

Hereinafter referred to as “Institut Pasteur”

On one hand,

And

BLUEBIRDBIO INC., a company incorporated under the laws of Massachusetts, with offices at 840 Memorial Drive, Cambridge, MA 02139, United States, represented by Nick Leschly, Chief Executive Officer

Hereinafter referred to as “Licensee”,

On the other hand,

Hereinafter mentioned as a Party or the Parties.

Recitals

1. The Parties have signed a license agreement on September 13, 2011 on a patented specific nucleotide sequence having a triplex structure, referred to as “DNA flap”.
2. Institut Pasteur has granted several exclusive or non exclusive licenses on the DNA flap under several fields to companies, [***].
3. Institut Pasteur has negotiated with a licensee to obtain rights for the Licensee in this field of services of production and commercialization of Good Manufacturing Practice (GMP) batches of lentiviral vectors for clinical trials, according to the terms and conditions of this Amendment n°1.

Now, therefore, the Parties hereby agree as follow:

Article 1. Scope

The scope of this Amendment n°1 is to extend the Field of the Agreement and the license grants by Institut Pasteur.

Article 2. Modifications

2.1. The definition of the Field in the article 1 of the Agreement is replaced by the following definition as from the effective date of this Amendment n°1:

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.

- “Field” shall mean ex vivo gene therapy for human disorders limited to adrenoleukodystrophy (ALD) (including but not limited to AMN, CCALD, and all other variants of this disease caused by genetic mutations), beta hemoglobinopathies (including but not limited to beta-thalassemia and sickle cell anemia), [***] for [***] the “Field” includes in vivo as well as ex vivo gene therapy. [***]

2.2. The article 2.1 of the Agreement is modified as follow, as from the effective date of this Amendment n°1:

“2.1. Institut Pasteur hereby grants to Licensee, its Affiliates, that Licensee, its Affiliates accept at their own risk, a license under the Patents in the Field and in the Territory for research and development, and to manufacture, have manufactured, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import or have imported the Products, to the exclusion of any other rights, the said license being:

- exclusive for Products containing human (HIV-1 and HIV-2) lentivirus vector;
- nonexclusive for Products containing non-human lentivirus vector.

In addition, Institut Pasteur hereby grants to Licensee, its Affiliates and sublicensees, that Licensee, its Affiliates and sublicensees accept at their own risk, a nonexclusive license under the Patents in the Field and in the Territory to make or to have made by a Third Party Good Manufacturing Practice (GMP) batches of lentiviral vectors for its/their own clinical trials on Products, provided that such Third Party makes Good Manufacturing Practice (GMP) batches of lentiviral vectors solely for the Licensee, its Affiliates and sublicensees clinical trials of Products above mentioned.

2.3. The article 10.5 of the Agreement is modified as follow, as from the effective date of this Amendment n° 1: the last sentence of such article 10.5 is modified as follow: [***]

Article 3. Miscellaneous

3.1. All the other provisions of the Agreement remain unchanged and fully applicable between the Parties.

3.2. This Amendment n°1 is effective from the date of signature by the Parties.

3.3. This Amendment n°1 makes integral part of the Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their authorized respective representative.

Made in Paris,
In duplicate.

Date: 27 AVR. 2012
/s/ Christophe Mauriet
INSTITUT PASTEUR
Christophe Mauriet
Senior Executive Vice-President

Date:
/s/ Nick Leschly
BLUEBIRDBIO INC.
Nick Leschly
Chief Executive Officer

AMENDMENT N°2 TO THE LICENSE AGREEMENT

Between

INSTITUT PASTEUR, a non profit private foundation organized under the laws of France with offices at 25-28 rue du Docteur Roux, 75 724 Paris Cedex 15, France, VAT FR 65 775 684 897, represented by M. Christophe Mauriet, Senior Executive Vice-President for Administration

Hereinafter referred to as “Institut Pasteur”

On one hand,

And

BLUEBIRDBIO INC., a company incorporated under the laws of Delaware, with offices at 840 Memorial Drive, Cambridge, MA 02139, United States, represented by Nick Leschly, Chief Executive Officer

Hereinafter referred to as “Licensee”,

On the other hand,

Hereinafter mentioned as a Party or the Parties.

Recitals

1. The Parties have signed a license agreement on September 13, 2011 on a patented specific nucleotide sequence having a triplex structure, referred to as “DNA flap”, modified by an amendment n°1 dated April 27, 2012 (the “Agreement”).
2. The Licensee has initiated a program to treat cancerous and/or pre-cancerous conditions by genetically modifying T cells to express antigen binding domain(s) on their surface that target tumor associated antigen(s).
3. Institut Pasteur agrees to extend the Field as follows, and the Parties agree to modify some definitions, according to the terms and conditions of this Amendment n°2.

Now, therefore, the Parties hereby agree as follow:

Article 1. Scope

The scope of this Amendment n°2 is to extend the Field of the Agreement and the license granted by Institut Pasteur, and to make some modifications.

Article 2. Modifications

2.1. The following definitions shall replace the definitions of the Agreement:

- “Gene therapy” shall mean the use of a vector containing at least one DNA sequence that encodes at least one protein, in order to restore the functional activity of one or more resident non-functional gene copies, or provide for the introduction and expression of novel protein(s) not normally expressed in the cell type or expression of protein(s) that do not exist normally in nature. The introduced protein(s) are not intended to generate a prophylactic and/or therapeutic immune response against the protein encoded by the introduced DNA sequence of interest for use in Vaccination.
- “Ex vivo” shall mean that cells are extracted from a patient, corrected or otherwise modified by Gene Therapy, and transplanted or dosed back into patient.
- “Vaccination” shall mean the use of a vector containing at least one DNA sequence that encodes at least one protein with the intent to generate an immune response against the protein encoded by the DNA sequence of interest to cause a prophylactic or therapeutic effect in humans and other animals. The protein

encoded by the DNA sequence of interest shall not restore an altered or non existing protein function or, modify existing protein function.

- “Field” shall mean ex vivo Gene therapy for human disorders limited to adrenoleukodystrophy (ALD) (including but not limited to AMN, CCALD, and all other variants of this disease caused by genetic mutations), beta hemoglobinopathies (including but not limited to beta-thalassemia and sickle cell anemia), [***] leukemias, lymphomas, B-cell malignancies and solid tumors by producing chimeric antigen receptor T-cells [***] for [***] and [***] the “Field” includes in vivo as well as ex vivo Gene therapy. [***]

2.2. The following sentence is hereby added to the end of Article 2.1 of the Agreement: “At Licensee’s request, the Parties agree to discuss in good faith about the [***].”

2.3. The following sentence is hereby added to the end of Article 4.4 of the Agreement: “Further, Licensee shall have the right to seek patent term extension according to the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) for any Patent based on Product(s) (in addition to an SPC(s) as provided in Article 4.4). Institut Pasteur will reasonably assist Licensee if Licensee elects to initiate to obtain any such patent term extension”.

Article 3. Other Terms

3.1. Upon signature of this Amendment 2 by the Parties, Licensee shall pay Institut Pasteur [***] exclusive of taxes. This amount cannot be set-off against future royalties.

Article 4. Miscellaneous

4.1. All the other provisions of the Agreement remain unchanged and fully applicable between the Parties.

4.2. This Amendment n°2 is effective from the date of signature by the Parties.

4.3. This Amendment n°2 makes integral part of the Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their authorized respective representative.

Made in Paris,
In duplicate.

Date: 16 OCT. 2012
/s/ Christophe Mauriet
INSTITUT PASTEUR
Christophe Mauriet
Senior Executive Vice-President

Date: 16 OCT. 2012
/s/ Nick Leschly
BLUEBIRDBIO INC.
Nick Leschly
Chief Executive Officer

**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 10, 2023

/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 10, 2023

/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, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to his knowledge, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 10, 2023 /s/ Nick Leschly

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

Dated: May 10, 2023 /s/ Chip Baird

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