UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

☒

For the quarterly period ended September 30, 2022

OR

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

☐

For the transition period from _________ to ________

Commission file number 001-40791

2seventy bio, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

The registrant had outstanding 37,916,693 shares of common stock as of November 1, 2022.

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

- our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;
- the status of government regulation in the life sciences industry, particularly with respect to healthcare reform;
- the potential benefits of strategic collaboration agreements;
- potential indemnification liabilities 2seventy bio may owe to bluebird bio after the separation;
- the tax treatment of the distribution and the limitations imposed on 2seventy bio under the tax matters agreement that 2seventy bio entered into with bluebird bio in connection with the separation and distribution;
- the impact of rising inflation rates on our business, financial condition and results of operation;
- the fluctuation of the market price of our shares; and
- trends and challenges in our potential markets.

See “Risk Factors” for a further description of these and other factors. Although we have attempted to identify important risk factors, there may be other risk factors not presently known to us or that we presently believe are not material that could cause actual results and developments to differ materially from those made in or suggested by the forward-looking statements contained in this 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 September 30, 2022	As of December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 127,021	$ 130,414
Marketable securities	196,089	134,643
Prepaid expenses	14,270	9,512
Receivables and other current assets	12,037	16,995
Total current assets	349,417	291,564
Property, plant and equipment, net	46,650	34,913
Marketable securities	1,407	97,124
Intangible assets, net	7,479	9,892
Goodwill	12,056	12,056
Operating lease right-of-use assets	253,458	275,534
Restricted cash and other non-current assets	38,277	38,592
Total assets	$ 708,744	$ 759,675
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,983	$ 6,024
Accrued expenses and other current liabilities	52,156	55,410
Operating lease liability, current portion	10,798	9,769
Deferred revenue, current portion	—	5,000
Collaboration research advancement, current portion	8,960	22,185
Total current liabilities	79,897	98,388
Deferred revenue, net of current portion	40,762	25,762
Collaboration research advancement, net of current portion	—	1,135
Operating lease liability, net of current portion	262,490	272,446
Other non-current liabilities	2,415	2,122
Total liabilities	385,564	399,853
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000 shares authorized, 0 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 200,000 shares authorized, 37,912 and 23,585 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	4	2
Additional paid-in capital	597,566	400,026
Accumulated other comprehensive loss	(3,886)	(712)
Accumulated deficit	(270,504)	(39,494)
Total stockholders' equity	323,180	359,822
Total liabilities and stockholders' equity	$ 708,744	$ 759,675

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

2seventy bio, Inc.

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
Revenue:				
Service revenue	$ 4,642	$ 6,312	$ 14,363	$ 17,544
Collaborative arrangement revenue	7,903	12,337	18,425	15,527
Royalty and other revenue	863	608	2,531	5,417
Total revenues	13,408	19,257	35,319	38,488
Operating expenses:				
Research and development	61,739	61,131	199,423	202,394
Selling, general and administrative	19,610	22,996	60,749	69,025
Share of collaboration loss	—	—	9,642	10,071
Cost of royalty and other revenue	377	320	1,252	2,111
Change in fair value of contingent consideration	50	48	181	464
Total operating expenses	81,776	84,495	271,247	284,065
Loss from operations	(68,368)	(65,238)	(235,928)	(245,577)
Interest income, net	1,113	—	1,441	—
Other (loss) income, net	(624)	5,237	3,494	14,340
Loss before income taxes	(67,879)	(60,001)	(230,993)	(231,237)
Income tax (expense) benefit	—	—	(17)	—
Net loss	$ (67,879)	$ (60,001)	$ (231,010)	$ (231,237)
Net loss per share - basic and diluted	$ (1.76)	$ (2.57)	$ (6.67)	$ (9.90)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	38,573	23,369	34,612	23,369
Other comprehensive loss:				
Other comprehensive loss, net of tax benefit (expense) of $0.0 million and $0.0 million for the three and nine months ended September 30, 2022 and 2021, respectively.	$ (504)	$ —	$ (3,174)	$ —
Total other comprehensive loss	$ (504)	$ —	$ (3,174)	$ —
Comprehensive loss	$ (68,383)	$ (60,001)	$ (234,184)	$ (231,237)

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

2seventy bio, Inc.

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

	Common stock		Net parent investment	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount					
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	37,616	$ 4	$ —	$ 575,421	$ (2,804)	$ (125,205)	$ 447,416
Vesting of restricted stock units	18	$ —	$ —	$ —	$ —	$ —	$ —
Exercise of stock options	—	—	—	1	—	—	1
Additional issuance costs related to issuance of common stock in private placement	—	—	—	(124)	—	—	(124)
Stock-based compensation	—	—	—	9,689	—	—	9,689
Other comprehensive loss	—	—	—	—	(578)	—	(578)
Net loss	—	—	—	—	—	(77,420)	(77,420)
Balances at June 30, 2022	37,634	$ 4	$ —	$ 584,987	$ (3,382)	$ (202,625)	$ 378,984
Vesting of restricted stock units	245	$ —	$ —	$ —	$ —	$ —	$ —
Exercise of stock options	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	12,207	—	—	12,207
Purchase of common stock under ESPP	33	—	—	372	—	—	372
Other comprehensive loss	—	—	—	—	(504)	—	(504)
Net loss	—	—	—	—	—	(67,879)	(67,879)
Balances at September 30, 2022	37,912	$ 4	$ —	$ 597,566	$ (3,886)	$ (270,504)	$ 323,180

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

2seventy bio, Inc.

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

	Common stock						
	Shares	**Amount**	**Net parent investment**	**Additional paid-in capital**	**Accumulated other comprehensive loss**	**Accumulated deficit**	**Total stockholders' equity**
Balances at December 31, 2020	—	$ —	$ 74,629	$ —	$ —	$ —	$ 74,629
Stock-based compensation - bluebird bio allocation	—	—	17,109	—	—	—	17,109
Transfers from bluebird bio, net	—	—	71,101	—	—	—	71,101
Net loss	—	—	(87,196)	—	—	—	(87,196)
Balances at March 31, 2021	—	$ —	$ 75,643	$ —	$ —	$ —	$ 75,643
Stock-based compensation - bluebird bio allocation	—	—	11,967	—	—	—	11,967
Transfers from bluebird bio, net	—	—	45,119	—	—	—	45,119
Net loss	—	—	(84,040)	—	—	—	(84,040)
Balances at June 30, 2021	—	$ —	$ 48,689	$ —	$ —	$ —	$ 48,689
Stock-based compensation - bluebird bio allocation	—	—	11,230	—	—	—	11,230
Transfers to bluebird bio, net	—	—	(58,325)	—	—	—	(58,325)
Net loss	—	—	(60,001)	—	—	—	(60,001)
Balances at September 30, 2021	—	$ —	$ (58,407)	$ —	$ — —	$ —	$ (58,407)

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

2seventy bio, Inc.

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

	For the nine months ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (231,010)	$ (231,237)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of contingent consideration	181	464
Depreciation and amortization	9,208	12,815
Stock-based compensation expense	31,635	40,306
Other non-cash items	1,074	247
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(354)	3,036
Operating lease right-of-use assets	22,076	11,146
Accounts payable	422	607
Accrued expenses and other liabilities	(1,598)	32,066
Operating lease liabilities	(8,927)	(13,305)
Deferred revenue	10,000	(820)
Collaboration research advancement	(14,361)	(4,920)
Net cash used in operating activities	(181,654)	(149,595)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(19,676)	(10,600)
Purchases of marketable securities	(115,692)	—
Proceeds from maturities of marketable securities	147,597	—
Purchase of intangible assets	—	(8,000)
Net cash provided by (used in) investing activities	12,229	(18,600)
Cash flows from financing activities:		
Transfers from bluebird bio	—	168,195
Proceeds from issuance of common stock in private placement, net of issuance costs	165,531	—
Proceeds from exercise of stock options and ESPP contributions	466	—
Net cash provided by financing activities	165,997	168,195
Decrease in cash, cash equivalents and restricted cash	(3,428)	—
Cash, cash equivalents and restricted cash at beginning of period	163,266	—
Cash, cash equivalents and restricted cash at end of period	$ 159,838	$ —
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 127,021	$ —
Restricted cash included in restricted cash and other non-current assets	32,817	—
Total cash, cash equivalents, and restricted cash	$ 159,838	$ —
Supplemental cash flow disclosures:		
Purchases of property, plant and equipment included in accounts payable and accrued expenses	$ 2,828	$ 321
Non-cash return of bRT related assets to bluebird bio	$ —	$ 110,300

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

2seventy bio, Inc.

Notes to Condensed Consolidated and Combined Financial Statements
(unaudited)

1. Description of the business

2seventy bio, Inc. (the "Company" or "2seventy bio") was incorporated in Delaware on April 26, 2021 and is a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. The Company's approach combines its expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. The Company is advancing multiple preclinical and clinical programs in oncology and, together with Bristol-Myers Squibb ("BMS"), delivering the first 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 9, *Collaborative arrangements and strategic partnerships* for further discussion of the collaboration with BMS.

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

The separation from bluebird bio, Inc.

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

On November 3, 2021, the Company also entered into a separation agreement with bluebird bio, which is referred to in this quarterly report as the "Separation Agreement", as well as various other agreements with bluebird bio, including a tax matters agreement, an employee matters agreement, an intellectual property license agreement, a transition services agreement under which 2seventy bio temporarily receives certain services from bluebird bio, and a second transition services agreement under which 2seventy bio temporarily provides certain services to bluebird bio. These agreements also govern certain of 2seventy bio's relationships with bluebird bio after the separation. For additional information regarding the Separation Agreement and the other related agreements, refer to Note 13, *Related-party transactions* and the section captioned "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 22, 2022.

Going concern

In accordance with Accounting Standards Codification 205-40, *Going Concern*, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the condensed consolidated and combined financial statements are issued. The Company has incurred losses and has experienced negative operating cash flows for all historical periods presented. During the nine months ended September 30, 2022, the Company incurred a net loss of $231.0 million and used $181.7 million of cash in operations. The Company expects to continue to generate operating losses and negative operating cash flows for the next few years. The Company's continued operations are dependent on its ability to raise additional funding.

As of September 30, 2022, the Company had cash, cash equivalents, and marketable securities of $324.5 million. The Company expects that its cash, cash equivalents, and marketable securities will be sufficient to fund current planned operations for at least the next twelve months from the date of issuance of these financial statements. The Company intends to pursue additional cash resources through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. There can be no assurance that such financing will be available in sufficient amounts or on acceptable terms, if at all, and some could be dilutive to existing stockholders. If the Company is unable to obtain additional funding on a timely basis, it may be forced to significantly curtail, delay, or discontinue one or more of its planned research or development programs or be unable to expand its operations.

2. Summary of significant accounting policies and basis of presentation

Significant accounting policies

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

Basis of presentation

The Company did not operate as a separate, stand-alone entity prior to its separation from bluebird bio. Accordingly, the Company’s consolidated and combined statements of operations and comprehensive loss, stockholders’ equity and cash flows for the three and nine months ended September 30, 2021, have been prepared on a carve out basis, derived from bluebird bio’s consolidated financial statements and accounting records.

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

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

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

Use of estimates

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

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

3. Marketable securities

The following table summarizes the marketable securities held at September 30, 2022 and December 31, 2021 (in thousands):

	Amortized cost/ cost	Unrealized gains	Unrealized losses	Fair Value
September 30, 2022				
U.S. government agency securities and treasuries	$ 124,212	$ —	$ (2,700)	$ 121,512
Corporate bonds	6,397	—	(75)	6,322
Commercial paper	69,786	—	(124)	69,662
Total	$ 200,395	$ —	$ (2,899)	$ 197,496
December 31, 2021				
U.S. government agency securities and treasuries	$ 128,899	$ —	$ (507)	$ 128,392
Corporate bonds	49,368	—	(58)	49,310
Commercial paper	54,065	—	—	54,065
Total	$ 232,332	$ —	$ (565)	$ 231,767

No available-for-sale debt securities held as of September 30, 2022 or December 31, 2021 had remaining maturities greater than five years.

Accrued interest receivable on the Company's available-for-sale debt securities totaled $0.2 million and $0.4 million as of September 30, 2022 and December 31, 2021, respectively. No accrued interest receivable was written off during the three and nine months ended September 30, 2022 or 2021.

The Company determined that there was no material change in the credit risk of the above investments during the nine months ended September 30, 2022. As such, an allowance for credit losses was not recognized. As of September 30, 2022, the Company does not intend to sell such securities and it is not more likely than not that the Company will be required to sell the securities before recovery of their amortized cost bases.

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 September 30, 2022 and December 31, 2021 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2022				
Assets:				
Cash and cash equivalents	$ 127,021	$ 99,349	$ 27,672	$ —
Marketable securities:				
U.S. government agency securities and treasuries	121,512	—	121,512	—
Corporate bonds	6,322	—	6,322	—
Commercial paper	69,662	—	69,662	—
Total assets	$ 324,517	$ 99,349	$ 225,168	$ —
Liabilities:				
Contingent consideration	$ 2,129	$ —	$ —	$ 2,129
Total liabilities	$ 2,129	$ —	$ —	$ 2,129
December 31, 2021				
Assets:				
Cash and cash equivalents	$ 130,414	$ 130,414	$ —	$ —
Marketable securities:				
U.S. government agency securities and treasuries	128,392	—	128,392	—
Corporate bonds	49,310	—	49,310	—
Commercial paper	54,065	—	54,065	—
Total assets	$ 362,181	$ 130,414	$ 231,767	$ —
Liabilities:				
Contingent consideration	$ 1,948	$ —	$ —	$ 1,948
Total liabilities	$ 1,948	$ —	$ —	$ 1,948

Contingent consideration

In connection with bluebird bio's prior acquisition of Precision Genome Engineering, Inc. (“Pregenen”), the Company may be required to pay future consideration that is contingent upon the achievement of certain commercial milestone events. Contingent consideration is measured at fair value and is based on significant unobservable inputs, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. Future changes in the fair value of contingent consideration related to updated assumptions and estimates are recognized within the condensed consolidated and combined statements of operations and comprehensive loss. In the absence of new information related to the probability of milestone achievement, changes in fair value will reflect changing discount rates and the passage of time. Contingent consideration is included in other non-current liabilities on the condensed consolidated balance sheets.

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

		For the nine months ended September 30, 2022
Beginning balance	$	1,948
Additions		—
Changes in fair value		181
Payments		—
Ending balance	$	2,129

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 September 30, 2022		As of December 31, 2021
Laboratory equipment	$	35,238	$	31,710
Leasehold improvements		26,709		28,479
Construction-in-progress		18,688		3,462
Office equipment		6,080		6,080
Computer equipment and software		5,625		5,260
Total property, plant and equipment		92,340		74,991
Less accumulated depreciation and amortization		(45,690)		(40,078)
Property, plant and equipment, net	$	46,650	$	34,913

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 September 30, 2022 includes $16.8 million related to the ongoing build-out of the facility.

6. Accrued expenses and other current liabilities

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

	As of September 30, 2022	As of December 31, 2021
Manufacturing costs	$ 15,516	$ 5,459
Collaboration research costs	9,889	2,576
Employee compensation	9,657	24,655
Royalties	7,828	6,768
Clinical and contract research organization costs	2,285	3,229
Property, plant and equipment	683	2,241
Separation related costs	405	762
Professional fees	349	1,688
Other	5,544	8,032
Accrued expenses and other current liabilities	$ 52,156	$ 55,410

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 and combined financial statements included in the Company's 2021 Annual Report on Form 10-K.

8. Commitments and contingencies

Contingent consideration related to business combinations

On June 30, 2014, bluebird bio acquired Pregenen. All assets, liabilities and future obligations related to the Pregenen acquisition, including the resulting goodwill and contingent consideration, were assumed by the Company in connection with the separation. As of September 30, 2022, the Company may be required to make up to $99.9 million in contingent cash payments to the former equity holders of Pregenen upon the achievement of certain commercial milestones related to the Pregenen technology. In accordance with accounting guidance for business combinations, contingent consideration liabilities are required to be recognized on the condensed consolidated balance sheets at fair value. Estimating the fair value of contingent consideration requires the use of significant assumptions primarily relating to probabilities of successful achievement of certain clinical and commercial milestones, the expected timing in which these milestones will be achieved and discount rates. The use of different assumptions could result in materially different estimates of fair value. 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 9, *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 10, *Royalty and other revenue*, for further information on license agreements.

Based on the Company's development plans as of September 30, 2022, the Company may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. When the achievement of these milestones or sales has not occurred, such contingencies are not recorded in the Company’s financial statements. As further discussed in Note 9, *Collaborative arrangements and strategic partnerships*, BMS assumed responsibility for amounts due to licensors as a result of any future ex-U.S. sales of ABECMA.

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 September 30, 2022, 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 has been reflected as a transfer to bluebird bio via net parent investment as a result of bluebird bio’s sale of such facility. 2seventy bio is not a party to the sale of the manufacturing facility and, therefore, did not recognize any gain or loss arising from the transaction.

Additionally, 2seventy bio is party to various contracts with contract research organizations and contract manufacturers that generally provide for termination on notice, with the exact amounts in the event of termination to be based on the timing of the termination and the terms of the agreement. There have been no material changes in future minimum purchase commitments from those disclosed in Note 8, *Commitments and Contingencies*, to the consolidated and combined financial statements included in the Company's 2021 Annual Report on Form 10-K.

Litigation

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

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

9. Collaborative arrangements and strategic partnerships

To date, the Company’s service and collaborative arrangement revenue has been primarily generated from collaboration arrangements with BMS, 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 and combined financial statements included in the Company's 2021 Annual Report on Form 10-K. During 2022, there have been no changes to the terms of the collaboration agreement with BMS.

ABECMA

Under the collaboration agreement with BMS, the Company shares equally in the profit and loss related to the development and commercialization of ide-cel in the United States (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 (i.e., commercial sales of ABECMA by BMS). The Company’s share of any collaboration profit for commercial activities is recognized as collaborative arrangement revenue and its share of any collaboration loss for commercial activity is recognized as an operating expense and classified as share of collaboration loss on the Company's condensed consolidated and combined statement of operations and comprehensive loss.

The Company recognized the following on the 2022 and 2021 condensed consolidated and combined statements of operations and comprehensive loss, respectively, related to its share of collaboration profit or loss associated with ide-cel commercial activities following approval (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 condensed consolidated and combined statements of operations and comprehensive loss as described below.

	Three months ended			Nine months ended
	March 31, 2022	June 30, 2022	September 30, 2022	September 30, 2022
Collaborative arrangement revenue from ide-cel commercial activities [1]	$ —	$ —	$ 4,064	$ 4,064
Share of collaboration loss from ide-cel commercial activities [1]	$ (5,352)	$ (4,290)	$ —	$ (9,642)

(1) As noted above, the calculation is performed on a quarterly basis. The calculation is independent of previous activity, which may result in fluctuations between revenue and expense recognition period over period.

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

(1) As noted above, the calculation is performed on a quarterly basis. The calculation is independent of previous activity, which may result in fluctuations between revenue and expense recognition period over period.

The Company is also responsible for equally sharing in the ongoing ide-cel research and development activities being conducted by BMS in the United States as BMS continues conducting ongoing clinical studies to support the use of ABECMA in earlier lines of therapy. The net amount owed to BMS for research and development activities determined on a quarterly basis is classified as research and development expense on the condensed consolidated and combined statement of operations and comprehensive loss. If BMS is obligated to reimburse the Company because the Company's research and development costs exceeds BMS' research and development costs in a particular quarterly period, the net amount is recorded as collaborative arrangement revenue.

The following table summarizes the amounts associated with the research activities under the collaboration included in research and development expense or recognized as collaborative arrangement revenue for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
Net expense (included as a component of research and development expense)	$ (9,252)	$ (5,660)	$ (21,608)	$ (31,678)

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 and nine months ended September 30, 2022 and 2021 (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
ASC 606 ide-cel license and manufacturing revenue - ex-U.S. (included as a component of service revenue)	$ 3,122	$ 5,314	$ 9,437	$ 14,698

bb21217

In addition to the activities related to ide-cel, BMS previously exercised its option to obtain an exclusive worldwide license to develop and commercialize bb21217, the second product candidate under the collaboration arrangement with BMS which is further described in Note 10, *Collaborative arrangements and strategic partnerships*, to the consolidated and combined financial statements included in the Company's 2021 Annual Report on Form 10-K.

Under the collaboration arrangement with BMS, the Company 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. As the Company has not yet commenced manufacturing, the entire $10.0 million payment received is included within deferred revenue, net of current portion on the September 30, 2022 condensed consolidated balance sheet.

The transaction price associated with the collaboration arrangement consists 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 represents reimbursement to be received from BMS for manufacturing vector and associated payloads through development which has not yet been received. 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. The Company will satisfy this combined performance obligation as the bb21217 manufacturing services are performed. All of the remaining development, regulatory, and commercial milestones related to U.S. development, regulatory and commercialization activities are fully constrained and are therefore excluded from the transaction price.

As of September 30, 2022, the Company has not commenced manufacturing and the full amount of the allocated transaction price remains unsatisfied. The Company had $35.8 million and $25.8 million of deferred revenue as of September 30, 2022 and December 31, 2021, respectively, associated with the combined performance obligation consisting of the bb21217 license and manufacturing services. The Company expects to recognize the remaining $35.8 million as these services are performed or upon BMS's formal notification to the Company that these services will no longer be required.

Contract assets and liabilities – ide-cel and bb21217

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

The following table presents changes in the balances of the Company's BMS receivables and contract liabilities during the nine months ended September 30, 2022 (in thousands):

	Balance at December 31, 2021	Additions	Deductions	Balance at September 30, 2022
Receivables	$ 652	$ 10,000	$ (10,652)	$ —
Contract liabilities:				
Deferred revenue	$ 25,762	$ 10,000	$ —	$ 35,762

The decrease in the receivables balance for the nine months ended September 30, 2022 is driven by amounts paid to the Company from BMS in the period under the settlement terms of the collaboration agreement. The increase in the deferred revenue balance for the nine months ended September 30, 2022 is driven by the $10.0 million payment made to the Company by BMS upon the Company opting out of co-development and co-promotion of bb21217 in the United States.

Regeneron

Regeneron Collaboration Agreement

In August 2018, bluebird bio entered into a Collaboration Agreement (the "Regeneron Collaboration Agreement") with Regeneron pursuant to which the parties will apply their respective technology platforms to the discovery, development, and commercialization of novel immune cell therapies for cancer. In August 2018, following the completion of required regulatory reviews, the Regeneron Collaboration Agreement became effective. As noted above, the agreement was assumed by the Company in connection with the separation. Under the terms of the agreement, the parties will leverage Regeneron's proprietary platform technologies for the discovery and characterization of fully human antibodies, as well as T cell receptors directed against tumor-specific proteins and peptides and the Company will contribute its field-leading expertise in gene therapy.

In accordance with the Regeneron Collaboration Agreement, the parties jointly selected six initial targets and intend to equally share the costs of research up to the point of submitting an IND application for a potential gene therapy product directed to a particular target. Additional targets may be selected to add to or replace any of the initial targets during the five-year research collaboration term as agreed to by the parties.

Regeneron will accrue a certain number of option rights exercisable against targets as the parties reach certain milestones under the terms of the agreement. Upon the acceptance of an IND for the first product candidate directed to a target, Regeneron will have the right to exercise an option for co-development/co-commercialization of product candidates directed to such target on a worldwide or applicable opt-in territory basis, with certain exceptions. Where Regeneron chooses to opt-in, the parties will share equally in the costs of development and commercialization and will share equally in any profits or losses therefrom in applicable opt-in territories. Outside of the applicable opt-in territories, the target becomes a licensed target and Regeneron would be eligible to receive, with respect to any resulting product, milestone payments of up to $130.0 million per product and royalties on net sales outside of the applicable opt-in territories at a rate ranging from the mid-single digits to low-double digits. A target would also become a licensed target in the event Regeneron does not have an option to such target, or Regeneron does not exercise its option with respect to such target.

Either party may terminate a given research program directed to a particular target for convenience, and the other party may elect to continue such research program at its expense, receiving applicable cross-licenses. The terminating party will receive licensed product royalties and milestone payments on the potential applicable gene therapy products. Where the Company terminates a given research program for convenience, and Regeneron elects to continue such research program, the parties will enter into a transitional services agreement. Under certain conditions, following its opt-in, Regeneron may terminate a given collaboration program and the Company may elect to continue the development and commercialization of the applicable potential gene therapy products as licensed products.

Regeneron Share Purchase Agreement

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

Accounting analysis – Regeneron

At the commencement of the arrangement, two units of accounting were identified, which are the issuance of 0.4 million shares of bluebird bio’s common stock and joint research activities during the five-year research collaboration term. The Company determined the total transaction price to be $100.0 million, which comprises $54.5 million attributed to the bluebird bio equity sold to Regeneron and $45.5 million attributed to the joint research activities. In determining the fair value of the bluebird bio common stock at closing, the Company considered the closing price of the bluebird bio common stock on the closing date of the transaction and included a lack of marketability discount because Regeneron received shares subject to certain restrictions.

The Company analyzed the joint research activities to assess whether they fall within the scope of ASC 808, and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the arrangement as outlined above, for the collaboration research performed prior to submission of an IND application for a potential gene therapy product, both parties are deemed to be active participants in the collaboration. Both parties are performing research and development activities and will share equally in these costs through IND 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 the amount attributed to the joint research activities will be recognized over the five-year research collaboration term.

Consistent with its collaboration accounting policy, the Company will recognize collaboration revenue or research and development expense related to the joint research activities in future periods depending on the amounts incurred by each party in a given reporting period. That is, if the Company’s research costs incurred exceed those research costs incurred by Regeneron in a given quarter, the Company will record collaboration revenue and reduce the original $37.0 million advance by the amount due from Regeneron until such advancement is fully utilized, after which the Company would record an amount due from Regeneron. If Regeneron’s research costs incurred exceed those research costs incurred by the Company in a given quarter, the Company will record research and development expense and record a liability for the amount due to Regeneron. As of September 30, 2022 and December 31, 2021, the Company has $9.0 million and $23.3 million, respectively, of the amount attributed to the joint research activities remaining to be recognized, which is classified as collaboration research advancement, current portion and collaboration research advancement, net of current portion on the condensed consolidated balance sheets.

The Company recognized $3.8 million and $14.4 million of collaborative arrangement revenue from the Regeneron Collaboration Agreement during the three and nine months ended September 30, 2022, respectively. The Company recognized $1.7 million and $4.9 million of collaborative arrangement revenue from the Regeneron Collaboration Agreement during the three and nine months ended September 30, 2021, respectively.

Novo Nordisk

Novo Collaboration and License Agreement

On December 23, 2021, the Company entered into a Collaboration and License Agreement (the "Novo Collaboration Agreement") with Novo 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, based on an updated budget of $13.2 million. If Novo exercises its option to obtain a license to commercialize the product developed during the initial research program, the Company is also eligible to receive mid-single digit royalties on product sales on a country-by-country and product-by-product basis, subject to certain royalty step-down provisions set forth in the agreement.

Accounting Analysis - Novo

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

The Company has determined the updated unconstrained transaction price is $18.2 million, consisting of the $5.0 million in up-front consideration and $13.2 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 $13.2 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 continue to 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 and nine months ended September 30, 2022, the Company recognized $1.5 million and $4.9 million of revenue under this agreement, respectively.

10. Royalty and other revenue

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

The Company recognized $0.9 million and $2.5 million of royalty and other revenue in the three and nine months ended September 30, 2022, respectively. The Company recognized $0.6 million and $5.4 million of royalty and other revenue in the three and nine months ended September 30, 2021, respectively.

Novartis Pharma AG

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

Juno Therapeutics

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

Resilience

The Resilience License Agreement, entered into concurrently with the sale of bluebird bio's North Carolina manufacturing facility, grants Resilience a worldwide, co-exclusive license to intellectual property controlled by the Company to perform Resilience's obligations and exercise Resilience's rights under the supply agreements, and a worldwide, nonexclusive right to offer certain manufacturing services to third-party customers under certain of the Company's intellectual property. Under the terms of the Resilience License Agreement, the Company may receive a high single-digit to low double-digit percentage tiered royalty based on Resilience's gross margins for transactions entered into with parties other than the Company in which the Company's proprietary intellectual property is utilized as part of such transaction.

Future royalty payments under the Resilience License Agreement are considered part of the consideration associated with the disposition of the manufacturing facility. In accordance with ASC 450, the Company will recognize future royalties received under the Resilience License Agreement in the period the contingencies are resolved as an adjustment to the consideration received as other (loss) income, net in the condensed consolidated and combined statements of operations and comprehensive loss. As of September 30, 2022, the Company has not recognized any royalties from Resilience under the Resilience License Agreement.

11. Equity

In March 2022, the Company entered into stock purchase agreements with certain investors, pursuant to which the Company agreed to sell and issue, in a private placement, an aggregate of 13,934,427 shares of the Company's common stock at a purchase price per share of $12.20. This resulted in aggregate net proceeds to the Company of $165.5 million, after deducting placement agent fees and other offering expenses payable by the Company.

12. Stock-based compensation

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

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

Stock-based compensation expense

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

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
Stock options	$ 4,519	$ 5,090	$ 13,577	$ 19,140
Restricted stock units	7,615	4,659	17,901	15,578
Employee stock purchase plan and other	73	1,481	157	5,588
	$ 12,207	$ 11,230	$ 31,635	$ 40,306

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
Research and development	$ 5,314	$ 5,523	$ 14,263	$ 22,429
Selling, general and administrative	6,893	5,707	17,372	17,877
	$ 12,207	$ 11,230	$ 31,635	$ 40,306

Employee Stock Purchase Plan

During the three and nine months ended September 30, 2022, 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

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

In connection with the separation, the Company entered into the Separation Agreement with bluebird bio, dated as of November 3, 2021, that, among other things, set forth bluebird bio's agreements with 2seventy bio regarding the principal actions to be taken in connection with the separation, including the distribution. The effective time of the distribution was 12:01 a.m. on November 4, 2021. The Separation Agreement identifies assets transferred to, liabilities assumed by and contracts assigned to 2seventy bio as part of the separation, and it provides for when and how these transfers, assumptions and assignments occur. The purpose of the Separation Agreement is to provide 2seventy bio and bluebird bio with assets to operate their respective businesses and retain or assume liabilities related to those assets. Each of 2seventy bio and bluebird bio agreed to releases, with respect to pre-separation claims, and cross indemnities with respect to post-separation claims, that are principally designed to place financial responsibility for the obligations and liabilities allocated to 2seventy bio under the Separation Agreement with 2seventy bio and financial responsibility for the obligations and liabilities allocated to bluebird bio under the Separation Agreement. bluebird bio and 2seventy bio are also each subject to mutual 12-month employee non-solicit and non-hire restrictions, subject to certain customary exceptions. In accordance with the Separation Agreement with bluebird bio, there were certain other transactions and adjustments post-Separation between the Company and bluebird bio. For the three and nine months ended September 30, 2022, the Company recorded an expense of $0.3 million and income of $2.8 million related to the Separation Agreement, respectively.

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

In connection with the separation, the Company also entered into an employee matters agreement with bluebird bio, dated as of November 3, 2021. The employee matters agreement allocates assets, liabilities and responsibilities relating to the employment, compensation and employee benefits of bluebird bio and 2seventy bio employees, and other related matters, in connection with the separation, including the treatment of outstanding bluebird bio incentive equity awards and certain retirement and welfare benefit obligations. The employee matters agreement generally provides that, unless otherwise specified, 2seventy bio is responsible for liabilities associated with employees who transfer to 2seventy bio and employees whose employment terminated prior to the distribution but who primarily supported the 2seventy bio business, and bluebird bio is responsible for liabilities associated with other employees, including employees retained by bluebird bio. Included in the agreement are also specific clauses relating to liabilities assumed by bluebird bio for the costs incurred prior to the separation. For the three and nine months ended September 30, 2022, the Company recorded a net charge to operating expense of $0.0 million and $0.2 million for costs stipulated by the employee matters agreement, respectively.

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

The Company and bluebird bio entered into two transition services agreements on November 3, 2021, pursuant to which bluebird bio will provide 2seventy bio with corporate and shared services and resources related to corporate functions such as finance, human resources, internal audit, research and development, financial reporting, and information technology, and to which 2seventy bio will provide certain services to bluebird bio, each for an initial term of two years, unless earlier terminated or extended according to the terms of the transition services agreement. For the three and nine months ended September 30, 2022, the Company recorded $1.9 million and $8.1 million, respectively, in other (loss) income, net reflecting services provided to bluebird bio and $0.1 million and $1.0 million, respectively, of operating expenses reflecting services received from bluebird bio, for activities related to the transition services agreement.

Additionally, under the transition services agreements, 2seventy bio was subleasing 30% of its headquarters at 60 Binney Street in Cambridge, Massachusetts to bluebird bio through the first quarter of 2022. Beginning in the second quarter of 2022, this percentage decreased to 23% for the remainder of the year. The Company recorded $1.2 million and $3.6 million in other (loss) income, net related to sublease income from bluebird under this arrangement during the three and nine months ended September 30, 2022, respectively.

As of September 30, 2022, amounts due to bluebird bio under the above agreements were $0.4 million and are included in accrued expenses. As of September 30, 2022, amounts due from bluebird bio under the above agreements were $1.9 million and are included in receivables and other current assets.

Corporate allocations

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

For periods prior to the separation, the condensed consolidated and combined financial statements reflect allocations of certain expenses from bluebird bio, including, but not limited to, general corporate expenses, such as senior management, legal, human resources, accounting, other financial services (such as treasury, audit and purchasing), tax, information technology, and corporate employee benefits, incentives and stock-based compensation included within selling, general and administrative expense.

These expenses have been allocated to the Company based on direct usage or benefit where specifically identifiable, with the remainder allocated based on employee time spent on projects, square footage or other measures that management believes are consistent and reasonable. Allocations for management costs and corporate support services provided to the Company totaled $14.5 million and $49.9 million for the three and nine months ended September 30, 2021.

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

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

Certain assets have been reflected in these condensed consolidated and combined financial statements as the underlying assets were assumed by the Company; however, bluebird bio has historically utilized a portion of the underlying asset as part of its operations. Accordingly, the expense related to the underlying asset has been reflected in the 2021 condensed consolidated and combined financial statements. The Company has also recorded an imputed charge to bluebird bio to reflect the cost of bluebird bio's proportional usage. In addition, the Company has recorded as an expense an imputed charge to reflect the cost of the Company's proportional usage of certain underlying assets not reflected in the condensed consolidated and combined financial statements but for which the Company has historically utilized a portion of the underlying asset as part of its operations. The income and expense recognized by the Company resulting from these imputed charges is recorded as other (loss) income, net in the 2021 condensed consolidated and combined financial statements and was as follows (in thousands):

	For the three months ended September 30,	For the nine months ended September 30,
	2021	2021
Imputed charge to bluebird bio for leases	$ 4,519	$ 13,440
Imputed charge from bluebird bio for leases	(209)	(836)
Imputed charge to bluebird bio for property, plant and equipment	507	1,714
Imputed charge from bluebird bio for property, plant and equipment	(13)	(1,125)
Imputed charge to bluebird bio for intangible assets	9	82
Other	—	(1)
	$ 4,813	$ 13,274

Other components of other (loss) income, net, that are not shown in the table above primarily include immaterial rental income and gains and losses on disposals of fixed assets. There are no such imputed charges in 2022 as the Company recognized all post separation income and costs related pursuant to the terms of the various transition agreements between the Company and bluebird bio, as discussed in previous section.

Stock-based compensation

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

Retirement plans

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

Transaction costs

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

Centralized cash management

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

14. Income taxes

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets.

15. Net Loss Per Share

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

	For the three and nine months ended September 30,	
	2022	2021
Outstanding stock options [(1)]	2,607	—
Restricted stock units [(1)]	1,332	—
ESPP shares and other	30	—
	3,969	—

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

As described further in Note 9, *Stockholders' equity*, to the consolidated and combined financial statements included in the Company's 2021 Annual Report on Form 10-K, in November 2021, the Company issued to certain institutional investors (who previously purchased pre-funded warrants to purchase shares of bluebird bio common stock) pre-funded warrants to purchase 757,575 shares of the Company's common stock at an exercise price of $0.0001 per share. The pre-funded warrants can be exercised at any time or times on or after November 4, 2021, until exercised in full. Based on the terms of the pre-funded warrants, management concluded that they should be considered outstanding shares in the computation of basic and diluted net loss per share.

16. Subsequent events

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 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. The closing of the transaction will be subject to the approval of the JW shareholders and other customary closing conditions.

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in the Company's 2021 Annual Report on Form 10-K, which was most recently filed with the Securities and Exchange Commission, or the SEC, on March 22, 2022.

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

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

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

Overview

We are a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. We were incorporated in 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 $67.9 million and $231.0 million for the three and nine months ended September 30, 2022, respectively. We expect to continue to incur operating losses for at least the next several years as we:

- advance our next-generation programs in B-NHL, AML, and multiple myeloma through the clinic;
- manufacture clinical study drug product and materials and establish the infrastructure necessary to support and develop manufacturing capabilities;
- 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;
- increase research and development-related activities for the discovery and development of product candidates and technologies in oncology; and
- incur costs related to our separation from bluebird bio into an independent, publicly traded company.

We are in the process of building a facility at our existing headquarters in Cambridge, Massachusetts to manufacture drug product for our future Phase 1 clinical trials, but currently, all of our manufacturing activities are contracted out to third parties, including Resilience. Additionally, we currently utilize third-party contract research organizations, or CROs, to carry out our clinical development activities. As we seek to obtain regulatory approval for our product candidates and begin commercialization following marketing approval, if obtained, we expect to incur significant commercialization expenses as we prepare for and begin product sales, marketing, commercial manufacturing, and distribution at such time. Accordingly, until we generate significant revenues from product sales, we will continue to seek to fund our operations through public or private equity or debt financings, strategic collaborations, or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

As of September 30, 2022, we had cash, cash equivalents and marketable securities of $324.5 million. Based on our current operating plans, including with respect to the ongoing commercialization of ABECMA, we expect that our cash, cash equivalents and marketable securities will be sufficient to fund current planned operations for at least the next twelve months, although we intend to pursue additional cash resources through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties.

Separation from bluebird bio, Inc.

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

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

Financial Operations Overview

Revenue

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

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

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* (“ASC 808”), which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606, *Revenue from Contracts with Customers* (“Topic 606” or "ASC 606"). For those elements of the arrangement that are accounted for pursuant to Topic 606, we apply the five-step model prescribed in Topic 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606. In arrangements where we do not deem our collaborator to be our customer, payments to and from our collaborator are presented in the consolidated and combined statements of operations and comprehensive loss based on the nature of the payments, as summarized in the table and further described below.

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

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

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

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

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

Research and Development Expenses

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

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

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

- CRB-401 study – an open label, single-arm, multi-center, phase 1 study to examine the safety and efficacy of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma. The estimated study completion date is the end of 2022.
- KarMMa study – an open label, single-arm, multi-center phase 2 study to examine the efficacy and safety of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma.
- KarMMa-2 study – a multi-cohort, open-label, multicenter phase 2 study to examine the safety and efficacy of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma and in high-risk multiple myeloma.
- KarMMa-3 study – a multicenter, randomized, open-label phase 3 study comparing the efficacy and safety of ide-cel versus standard triplet regimens in patients with relapsed and refractory multiple myeloma.
- KarMMa-4 study – a multi-cohort, open-label, multicenter phase 1 study intended to determine the optimal target dose and safety of ide-cel in subjects with newly-diagnosed multiple myeloma.

- 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.

- CRB-402 study – an open label, single-arm, multicenter, phase 1 study to examine the safety and efficacy of the bb21217 product candidate in the treatment of patients with relapsed and refractory multiple myeloma. We are winding down the study in 2022 following our election to discontinue development of bb21217.

- CRC-403 study – an open-label, multi-site Phase 1/2 dose-escalation study to examine the safety and efficacy of bbT369 in relapsed and/or refractory B Cell Non-Hodgkin's Lymphoma (NHL).

- PLAT-08 study – an open-label Phase 1 study to examine the safety and efficacy of SC-DARIC33 in pediatric and young adult relapsed or refractory acute myeloid leukemia (AML).

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

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical studies and other research and development activities we undertake;

- future clinical study results;

- uncertainties in clinical study enrollment rates;

- new manufacturing processes or protocols that we may choose to or be required to implement in the manufacture of our lentiviral vector or drug product;

- regulatory feedback on requirements for regulatory approval, as well as changing standards for regulatory approval; and

- the timing and receipt of any regulatory approvals.

We expect our ongoing research and development expenses to be driven mainly by our advancement of the SC-DARIC33 and bbT369 clinical programs through phase 1 studies, funding our share of the costs of development of ABECMA, including clinical expansion to earlier lines of therapy, through our collaboration with BMS and manufacture of clinical study materials in support of our clinical studies.

Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to acquiring and manufacturing clinical study materials. We allocate salary and benefits, personnel-related discretionary bonus, and stock-based compensation costs directly related to specific programs. We do not allocate certain general research and platform personnel costs, certain laboratory and related expenses, rent expense, depreciation or other indirect costs that are deployed across multiple projects under development and, as such, the costs are separately classified as other research and development expenses in the table below:

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
ide-cel	$ 16,510	$ 14,199	$ 45,395	$ 68,585
bb21217	336	1,578	3,174	8,198
bbT369	8,406	4,871	21,179	15,351
SC-DARIC33	843	3,162	3,854	6,467
Preclinical programs	11,414	11,130	45,193	26,583
Total direct research and development expense	37,509	34,940	118,795	125,184
General research and platform personnel costs	4,633	8,591	16,773	26,552
Unallocated laboratory and manufacturing expenses	2,461	3,690	12,919	10,838
Facility and other support costs	17,136	13,910	50,936	39,820
Total other research and development expenses	24,230	26,191	80,628	77,210
Total research and development expense	$ 61,739	$ 61,131	$ 199,423	$ 202,394

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

Selling, General and Administrative Expenses

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

Share of Collaboration Loss

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

Cost of Royalty and Other Revenue

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

Change in Fair Value of Contingent Consideration

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

As of September 30, 2022, there were $99.9 million in future contingent cash payments related to commercial milestones. We estimate future contingent cash payments have a fair value of $2.1 million as of September 30, 2022, which are classified within other non-current liabilities on our condensed consolidated balance sheet.

Other (Loss) Income, Net

Other (loss) income, net consisted primarily of our 50% share of the Resilience net operating loss for the third quarter of 2022. This was partially offset by rental income along with income recognized under our transition service agreements with bluebird bio. Other (loss) income, net also includes gains and losses on disposal of assets. For the 2021 comparative periods, other (loss) income, net consists primarily of income resulting from the allocation of facility-related, depreciation and amortization expense to bluebird bio for its proportional use of assets that were assumed by us, as well as expense resulting from the allocation of facility-related, depreciation and amortization expense to us for our proportional use of assets that were not assumed by us.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our combined financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies. During the three and nine months ended September 30, 2022, there were no material changes to our significant accounting policies as reported in our annual consolidated and combined financial statements included in our 2021 Annual Report on Form 10-K, except as otherwise described in Note 2, *Basis of presentation, principles of consolidation and significant accounting policies*, in the notes to the condensed consolidated and combined financial statements.

Results of Operations

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

Comparison of the Three Months Ended September 30, 2022 and 2021:

	For the three months ended September 30,		
	2022	2021	Change
		(in thousands)	
Revenue:			
Service revenue	$ 4,642	$ 6,312	$ (1,670)
Collaborative arrangement revenue	7,903	12,337	(4,434)
Royalty and other revenue	863	608	255
Total revenues	13,408	19,257	(5,849)
Operating expenses:			
Research and development	61,739	61,131	608
Selling, general and administrative	19,610	22,996	(3,386)
Share of collaboration loss	—	—	—
Cost of royalty and other revenue	377	320	57
Change in fair value of contingent consideration	50	48	2
Total operating expenses	81,776	84,495	(2,719)
Loss from operations	(68,368)	(65,238)	(3,130)
Interest income, net	1,113	—	1,113
Other (loss) income, net	(624)	5,237	(5,861)
Loss before income taxes	(67,879)	(60,001)	(7,878)
Income tax (expense) benefit	—	—	—
Net loss	$ (67,879)	$ (60,001)	$ (7,878)

Revenue. Total revenue was $13.4 million for the three months ended September 30, 2022, compared to $19.3 million for the three months ended September 30, 2021. The decrease of $5.8 million was primarily attributable to a decrease in collaborative arrangement revenue recognized under our collaboration arrangement with BMS, driven by increased ABECMA manufacturing costs. This has resulted in higher charges to 2seventy as part of our 50% share of U.S. costs with BMS. We are continuing to invest in increasing manufacturing capacity in the future.

Research and Development Expenses. Research and development expenses were $61.7 million for the three months ended September 30, 2022, compared to $61.1 million for the three months ended September 30, 2021. The overall increase of $0.6 million was primarily attributable to the following:

- $3.4 million of increased IT and other facility-related costs, mainly driven by higher rent charges under the assigned and amended 60 Binney Street lease. This increase is also attributable to a higher allocation of these costs to research and development expense based on headcount and facility square footage;
- $2.2 million of increased collaboration research funding costs, which is primarily driven by an increase in our share of research and development costs under our collaboration with BMS; and
- $1.8 million of increased material production costs associated with CRC-403, the phase 1/2 Study of bbT369.

These increases were partially offset by:

- $3.9 million of decreased license and milestone fees associated with oncology research, the SC-DARIC33 program and our collaboration with Novo; and
- $1.2 million of decreased consultant, clinical trial and medical research fees.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $19.6 million for the three months ended September 30, 2022, compared to $23.0 million for the three months ended September 30, 2021. The decrease of $3.4 million was primarily due to the following:

- $2.4 million of decreased IT and other facility-related costs, mainly driven by a lower allocation of these costs to selling, general and administrative expense based on headcount and facility square footage; and
- $2.3 million of decreased employee compensation expenses, driven mainly by reduced headcount, reflective of efforts to streamline 2seventy's operating model.

These decreases were partially offset by an increase in stock-based compensation expense of $1.2 million, primarily due to expense recognized on executive retention grants with performance conditions that were met during the third quarter of 2022.

Cost of Royalty and Other Revenue. Cost of royalty and other revenue was $0.4 million for the three months ended September 30, 2022, compared to $0.3 million for the three months ended September 30, 2021. 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 (Loss) Income, Net. For the three months ended September 30, 2022, other (loss) income, net primarily consisted of our 50% share of the Resilience net operating loss for the third quarter of 2022. This was partially offset by rental income along with income recognized under our transition service agreements with bluebird bio. For the three months ended September 30, 2021, other (loss) income, net consisted primarily of income resulting from the allocation of facility-related, depreciation and amortization expense to bluebird bio for its proportional use of assets that were assumed by us, as well as expense resulting from the allocation of facility-related, depreciation and amortization expense to us for our proportional use of assets that were not assumed by us.

Comparison of the Nine Months Ended September 30, 2022 and 2021:

	For the nine months ended September 30,		
	2022	**2021**	**Change**
		(in thousands)	
Revenue:			
Service revenue	$ 14,363	$ 17,544	$ (3,181)
Collaborative arrangement revenue	18,425	15,527	2,898
Royalty and other revenue	2,531	5,417	(2,886)
Total revenues	35,319	38,488	(3,169)
Operating expenses:			
Research and development	199,423	202,394	(2,971)
Selling, general and administrative	60,749	69,025	(8,276)
Share of collaboration loss	9,642	10,071	(429)
Cost of royalty and other revenue	1,252	2,111	(859)
Change in fair value of contingent consideration	181	464	(283)
Total operating expenses	271,247	284,065	(12,818)
Loss from operations	(235,928)	(245,577)	9,649
Interest income, net	1,441	—	1,441
Other income, net	3,494	14,340	(10,846)
Loss before income taxes	(230,993)	(231,237)	244
Income tax (expense) benefit	(17)	—	(17)
Net loss	$ (231,010)	$ (231,237)	$ 227

Revenue. Total revenue was $35.3 million for the nine months ended September 30, 2022, compared to $38.5 million for the nine months ended September 30, 2021. The decrease of $3.2 million was primarily attributable to a decrease in Idel-cel ex-U.S. service revenue along with a decrease in royalty and other revenue as a result of the termination of our license agreement with Novartis in the first quarter of 2021. This decrease was partially offset by an increase in collaborative arrangement revenue, driven by an increase in collaborative related activities with Regeneron in the second quarter of 2022.

Research and Development Expenses. Research and development expenses were $199.4 million for the nine months ended September 30, 2022, compared to $202.4 million for the nine months ended September 30, 2021. The overall decrease of $3.0 million was primarily attributable to the following:

- $12.5 million of decreased collaboration research funding costs, which is primarily driven by a decrease in our share of research and development costs under our collaboration with BMS;
- $4.2 million of decreased license and milestone fees associated with oncology research, the SC-DARIC33 program and our collaboration with Novo; and
- $4.0 million of decreased employee compensation expenses, primarily due to decreased stock-based compensation expense resulting from the completion of our employee retention plan at the end of 2021 and an overall decrease in the value of stock-based compensation awards. This was partially offset by increased employee salary expense.

These decreased costs were partially offset by:

- $10.8 million of increased IT and other facility-related costs, mainly driven by higher rent charges under the assigned and amended 60 Binney Street lease. This increase is also attributable to a higher allocation of these costs to research and development expense based on headcount and facility square footage; and

- $7.7 million of increased material production costs associated with CRC-403, the phase 1/2 Study of bbT369.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $60.7 million for the nine months ended September 30, 2022, compared to $69.0 million for the nine months ended September 30, 2021. The decrease of $8.3 million was primarily due to the following:

- $6.1 million of decreased IT and other facility-related costs, mainly driven by a lower allocation of these costs to selling, general and administrative expense based on headcount and facility square footage; and

- $5.8 million of decreased employee compensation expenses, driven mainly by reduced headcount, reflective of efforts to streamline 2seventy's operating model.

The decreased costs were partially offset by $3.0 million of increased legal fees related to patent applications and maintenance and increased consulting costs as we began incurring costs to operate as standalone company during the first quarter of 2022.

Share of Collaboration Loss. Share of collaboration loss for the nine months ended September 30, 2022 represents our share of net loss arising from the commercialization of ABECMA under the BMS collaboration during both the first and second quarters of 2022, as we recorded collaborative arrangement revenue related to this collaboration in the third quarter of 2022. Share of collaboration loss for the nine months ended September 30, 2021 represents our share of loss for only the second quarter of 2021, as ABECMA was approved in the U.S. at the end of March 2021 and sales did not begin until April 2021, and we recorded collaborative arrangement revenue related to this collaboration in the third quarter of 2021. The decrease in share of collaboration loss period over period is attributable to increased net sales partially offset by increased vector manufacturing costs incurred by BMS during the first half of 2022.

Cost of Royalty and Other Revenue. Cost of royalty and other revenue was $1.3 million for the nine months ended September 30, 2022, compared to $2.1 million for the nine months ended September 30, 2021. The decrease is attributable to decreased royalty and other revenue in the same periods, primarily as a result of the termination of our license agreement with Novartis in March 2021.

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 nine months ended September 30, 2022, other income, net primarily consisted of income recognized under our transition services agreements with bluebird bio and rental income. For the nine months ended September 30, 2021, other income, net consisted primarily of income resulting from the allocation of facility-related, depreciation and amortization expense to bluebird bio for its proportional use of assets that were assumed by us, as well as expense resulting from the allocation of facility-related, depreciation and amortization expense to us for our proportional use of assets that were not assumed by us. Other income, net also included rental income and gains and losses on disposal of assets for the nine months ended September 30, 2021.

Note on the COVID-19 Pandemic

As a result of the impacts of the novel coronavirus (“COVID-19”), we continue to experience disruptions and increased risk in our operations and those of third parties upon whom we rely, which may materially and adversely affect our business. These include disruptions and risks related to the conduct of our clinical trials, manufacturing, and commercialization efforts, as policies at various clinical sites and federal, state, local and foreign laws, rules and regulations continue to evolve, including quarantines, travel restrictions, and direction of healthcare resources toward pandemic response efforts. The COVID-19 pandemic and its effects continue to evolve and the extent to which the pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence. We continue to evaluate the impact of the COVID-19 pandemic on patients, healthcare providers and our employees, as well as our operations and the operations of our business partners and healthcare communities.

Liquidity and Capital Resources

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

As of September 30, 2022, we had cash, cash equivalents, and marketable securities of approximately $324.5 million. Based on our current operating plans, including with respect to the ongoing commercialization of ABECMA, we expect our cash, cash equivalents and marketable securities will be sufficient to fund current planned operations for at least the next twelve months from the date of filing these financial statements. We intend to pursue additional cash resources through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. There can be no assurance that such financing will be available in sufficient amounts or on acceptable terms, if at all, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned research or development programs or be unable to expand our operations.

We have incurred losses and have experienced negative operating cash flows for all periods presented. During the nine months ended September 30, 2022, we incurred a loss of $231.0 million and used $181.7 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:

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (181,654)	$ (149,595)
Net cash provided by (used in) investing activities	12,229	(18,600)
Net cash provided by financing activities	165,997	168,195
Increase (decrease) in cash, cash equivalents and restricted cash	$ (3,428)	$ —

Cash Flows from Operating Activities. Net cash used in operating activities was $181.7 million for the nine months ended September 30, 2022 and primarily consisted of a net loss of $231.0 million adjusted for non-cash items, including stock-based compensation of $31.6 million and depreciation and amortization of $9.2 million, as well as the change in our net working capital.

Net cash used in operating activities was $149.6 million for the nine months ended September 30, 2021 and primarily consisted of net loss of $231.2 million adjusted for non-cash items, including stock-based compensation of $40.3 million and depreciation and amortization of $12.8 million, as well as the change in our net working capital.

Cash Flows from Investing Activities. Net cash provided by investing activities for the nine months ended September 30, 2022 was $12.2 million and was due to proceeds from maturities of marketable securities of $147.6 million, offset by the purchase of marketable securities of $115.7 million and the purchase of property, plant and equipment of $19.7 million.

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

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

Net cash provided by financing activities for the nine months ended September 30, 2022 was $166.0 million and was primarily due to net proceeds received of $165.5 million from the issuance of common stock in a private placement in March 2022.

Net cash provided by financing activities for the nine months ended September 30, 2021 was $168.2 million and was due to cash transferred to us from bluebird bio based on changes in our cash used for operating activities and investing activities.

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 ide-cel in additional indications, pursuant to our cost sharing arrangements with BMS;
- development of our pipeline of early research programs;

- the build-out of our drug product manufacturing capabilities at our Cambridge, Massachusetts headquarters, which will enable rapid translational research in our clinical trials and the manufacture of drug product for preclinical and Phase 1 clinical development activities; and

- additional research discovery efforts, other capital expenditures, working capital requirements, and other general corporate activities.

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

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

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

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;

- the costs, timing and outcome of regulatory review of our product candidates;

- the costs of future activities, including medical affairs, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;

- the cost and timing of hiring new employees to support our continued growth;

- the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and

- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

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

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

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

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

Contractual Obligations and Commitments

Except as discussed in Note 7, *Leases*, and Note 8, *Commitments and contingencies*, in the notes to condensed consolidated and combined financial statements, there have been no material changes to our contractual obligations and commitments as included in our audited consolidated and combined financial statements included in the Company's 2021 Annual Report on Form 10-K.

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 September 30, 2022 we had cash, cash equivalents and marketable securities of $324.5 million, primarily invested in U.S. government agency securities and treasuries, corporate bonds and commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points, or one percentage point, from levels at September 30, 2022, the net fair value of our interest-sensitive marketable securities would have resulted in a hypothetical decline of $1.1 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 and nine months ended September 30, 2022. 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 reporting within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Except as set forth below, there have been no material changes to the risk factors described in the section captioned "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021 and updated in our Quarterly Report on Form 10-Q for the quarterly period ended March 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, 2021 and Quarterly Report on Form 10-Q for the quarterly period ended March 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.

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

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

Inflation rates have increased and may continue to rise. If continued inflation causes the cost of labor to increase or our suppliers and vendors to raise prices, our operational expenses may increase, which could have an adverse impact on our business, financial condition and results of operation.

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

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

The market price of our shares of common stock may fluctuate widely, depending upon many factors, some of which are beyond our control, including the following:

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

- results of clinical studies of our competitors' products;
- failure to adequately protect our trade secrets;
- our inability to raise additional capital and the terms on which we raise it;
- commencement or termination of any strategic partnership or licensing arrangement;
- regulatory developments with respect to our products or our competitors' products, including any developments, litigation or public concern about the safety of such products;
- announcements concerning product development results, including clinical trial results, the introduction of new products or intellectual property rights of us or others;
- actual or anticipated fluctuations in our financial condition and our quarterly and annual operating results;
- deviations in our operating results from any guidance we may provide or the estimates of securities analysts;
- additions and departures of key personnel;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- announcement or expectation of additional financing efforts;
- publication of research reports by securities analysts about us or our competitors or our industry and speculation regarding our company or our stock price in the financial or scientific press or in online investor communities;
- changes in market conditions in the pharmaceutical and biotechnology sector; and
- changes in general credit and financial markets and economic conditions.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, results of operations, financial condition and prospects. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management. In addition, a decline or volatility in the market price of our common stock may affect our willingness and ability to raise equity capital through the sale of our common shares in public and/or private offerings, which may adversely affect our ability to fund our business operations.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on the Company's product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of third-party suppliers and manufacturers to manufacture ABECMA as well as clinical trial materials for product candidates.

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

Exhibit Number	Exhibit Description
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 Current Report on Form 8-K filed on November 4, 2021).
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).
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.

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: November 7, 2022	By:	/s/ Nick Leschly
		Nick Leschly
		President and Chief Executive Officer (Principal Executive Officer and Duly Authorized Officer)
Date: November 7, 2022	By:	/s/ Chip Baird
		Chip Baird
		Chief Financial Officer (Principal Financial Officer, Principal Accounti Officer and Duly Authorized Officer)

Exhibit 31.1

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

I, Nick Leschly, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: November 7, 2022 /s/ Nick Leschly

Nick Leschly
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Chip Baird, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: November 7, 2022 /s/ Chip Baird

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

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of 2seventy bio, Inc. (the “Company”) for the quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to his knowledge, that:

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

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

Dated: November 7, 2022 /s/ Nick Leschly

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

Dated: November 7, 2022 /s/ Chip Baird

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