

**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 June 30, 2023  
OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 001-40791

**2seventy bio, Inc.**

*(Exact name of registrant as specified in its charter)*

Delaware

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

60 Binney Street  
Cambridge, MA

*(Address of principal executive offices)*

86-3658454

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

02142

*(Zip Code)*

(339) 499-9300

*(Registrant's telephone number, including area code)*

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

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

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

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

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

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

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

Emerging growth company

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

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

The registrant had outstanding 50,464,578 shares of common stock as of August 8, 2023.

## TABLE OF CONTENTS

	<u>Page</u>
<u>Part I- Financial Information</u>	
<u>Item 1.</u>	<u>1</u>
<u>Condensed Consolidated Balance Sheets as of June 30, 2023 and December 31, 2022</u>	
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2023 and June 30, 2022</u>	<u>2</u>
<u>Condensed Consolidated Statements of Stockholders' Equity for the Three and Six Months Ended June 30, 2023 and June 30, 2022</u>	<u>3</u>
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2023 and June 30, 2022</u>	<u>5</u>
<u>Notes to Condensed Consolidated Financial Statements</u>	<u>6</u>
<u>Item 2.</u>	<u>29</u>
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	
<u>Item 3.</u>	<u>44</u>
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	
<u>Item 4.</u>	<u>45</u>
<u>Controls and Procedures</u>	
<u>Part II. Other Information</u>	
<u>Item 1</u>	<u>46</u>
<u>Legal Proceedings</u>	
<u>Item 1A.</u>	<u>46</u>
<u>Risk Factors</u>	
<u>Item 2.</u>	<u>47</u>
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	
<u>Item 3.</u>	<u>47</u>
<u>Defaults Upon Senior Securities</u>	
<u>Item 4.</u>	<u>47</u>
<u>Mine Safety Disclosures</u>	
<u>Item 5.</u>	<u>48</u>
<u>Other Information</u>	
<u>Item 6.</u>	<u>49</u>
<u>Exhibit Index</u>	
<u>Signatures</u>	<u>51</u>

---

## 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 and Bristol Myers Squibb’s, or BMS, plans for the continued commercialization of *Abecma* and the development and commercialization of earlier lines of therapy;
  - our ability to finance our operations and business initiatives and obtain funding for such activities;
  - the timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching, and commercializing our product candidates;
  - our plans with respect to the development, manufacture or sale of our product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies;
  - the operational capabilities and timelines with respect to our in-house manufacturing facility;
  - sourcing supplies for the materials used to manufacture our product candidates;
  - the safety profile and related adverse events of our product candidates;
  - the perceived therapeutic benefits of our product candidates and the potential indications and market opportunities therefor;
  - U.S. and foreign regulatory requirements for our product candidates, including any post-approval development and regulatory requirements, and the ability of our product candidates to meet such requirements;
  - our ability to attract and retain key employees needed to execute our business plans and strategies and our expectations regarding our ability to manage the impact of any loss of key employees;
  - our ability to obtain and maintain intellectual property protection for our product candidates and the strength thereof;
  - our future financial performance, including estimates of our future revenues, expenses, payments, cash flows, profitability, tax obligations, capital requirements and our needs for additional financing and
-

liquidity sources, real estate needs and concentration of voting control, as well as the timing and drivers thereof, and internal control over financial reporting;

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

See “Risk Factors” for a further description of these and other factors. Although we have attempted to identify important risk factors, there may be other risk factors not presently known to us or that we presently believe are not material that could cause actual results and developments to differ materially from those made in or suggested by the forward-looking statements contained in this Quarterly Report on Form 10-Q. If any of these risks materialize, or if any of the above assumptions underlying forward-looking statements prove incorrect, actual results and developments may differ materially from those made in or suggested by the forward-looking statements contained in this Quarterly Report on Form 10-Q. For the reasons described above, we caution you against relying on any forward-looking statements, which should also be read in conjunction with the other cautionary statements that are included elsewhere in this Quarterly Report on Form 10-Q. Any forward-looking statement made by us in this Quarterly Report on Form 10-Q speaks only as of the date thereof. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update or to revise any forward-looking statement, whether as a result of new information, future developments, or otherwise, except as may be required by law.

---

**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Information**

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

	As of June 30, 2023	As of December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 95,991	\$ 71,032
Marketable securities	186,846	195,238
Prepaid expenses	6,729	13,652
Receivables and other current assets	44,099	20,960
Total current assets	333,665	300,882
Property, plant and equipment, net	61,023	55,735
Marketable securities	23,709	1,414
Intangible assets, net	6,948	7,302
Goodwill	12,056	12,056
Operating lease right-of-use assets	230,712	240,885
Restricted investments and other non-current assets	37,600	38,391
Total assets	\$ 705,713	\$ 656,665
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 6,274	\$ 7,208
Accrued expenses and other current liabilities	36,107	54,678
Operating lease liability, current portion	11,872	11,164
Deferred revenue, current portion	12,642	3,000
Collaboration research advancement	—	3,744
Total current liabilities	66,895	79,794
Deferred revenue, net of current portion	17,213	5,000
Operating lease liability, net of current portion	251,706	259,008
Other non-current liabilities	2,404	2,397
Total liabilities	338,218	346,199
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized, 0 shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 200,000 shares authorized, 50,238 and 37,928 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	5	4
Additional paid-in capital	751,677	606,986
Accumulated other comprehensive loss	(1,430)	(2,877)
Accumulated deficit	(382,757)	(293,647)
Total stockholders' equity	367,495	310,466
Total liabilities and stockholders' equity	\$ 705,713	\$ 656,665

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

2seventy bio, Inc.

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

	For the three months ended June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
<b>Revenue:</b>				
Service revenue	\$ 5,022	\$ 5,666	\$ 15,848	\$ 9,721
Collaborative arrangement revenue	29,034	7,035	58,406	10,522
Royalty and other revenue	1,992	781	3,415	1,668
Total revenues	36,048	13,482	77,669	21,911
<b>Operating expenses:</b>				
Research and development	59,980	64,557	128,226	130,436
Cost of manufacturing for commercial collaboration	3,610	3,882	7,264	7,248
Selling, general and administrative	19,489	17,278	40,209	41,139
Share of collaboration loss	—	4,290	—	9,642
Cost of royalty and other revenue	907	364	1,548	875
Change in fair value of contingent consideration	53	83	126	131
Total operating expenses	84,039	90,454	177,373	189,471
Loss from operations	(47,991)	(76,972)	(99,704)	(167,560)
Interest income, net	3,090	213	5,139	328
Other income (expense), net	2,812	(661)	5,455	4,101
Loss before income taxes	(42,089)	(77,420)	(89,110)	(163,131)
Income tax (expense) benefit	—	—	—	—
Net loss	\$ (42,089)	\$ (77,420)	\$ (89,110)	\$ (163,131)
Net loss per share - basic and diluted	\$ (0.83)	\$ (2.02)	\$ (1.89)	\$ (5.00)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	50,966	38,381	47,238	32,598
<b>Other comprehensive income (loss):</b>				
Other comprehensive income (loss), net of tax benefit (expense) of \$0.0 million and \$0.0 million for the three and six months ended June 30, 2023 and 2022, respectively.	\$ 520	\$ (578)	\$ 1,447	\$ (2,670)
Total other comprehensive income (loss)	\$ 520	\$ (578)	\$ 1,447	\$ (2,670)
Comprehensive loss	\$ (41,569)	\$ (77,998)	\$ (87,663)	\$ (165,801)

See accompanying notes to unaudited condensed consolidated financial statements.

2seventy bio, Inc.

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

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
<b>Balances at December 31, 2022</b>	37,928	\$ 4	\$ 606,986	\$ (2,877)	\$ (293,647)	\$ 310,466
Vesting of restricted stock units	237	—	—	—	—	—
Exercise of stock options	1	—	7	—	—	7
Issuance of common stock in public offering, net of issuance costs	10,870	1	116,968	—	—	116,969
Issuance of common stock to Regeneron	1,115	—	9,859	—	—	9,859
Stock-based compensation	—	—	9,666	—	—	9,666
Purchases of shares under ESPP	39	—	451	—	—	451
Other comprehensive income	—	—	—	927	—	927
Net loss	—	—	—	—	(47,021)	(47,021)
<b>Balances at March 31, 2023</b>	<b>50,190</b>	<b>\$ 5</b>	<b>\$ 743,937</b>	<b>\$ (1,950)</b>	<b>\$ (340,668)</b>	<b>\$ 401,324</b>
Vesting of restricted stock units	48	—	—	—	—	—
Stock-based compensation	—	—	7,740	—	—	7,740
Other comprehensive income	—	—	—	520	—	520
Net loss	—	—	—	—	(42,089)	(42,089)
<b>Balances at June 30, 2023</b>	<b>50,238</b>	<b>\$ 5</b>	<b>\$ 751,677</b>	<b>\$ (1,430)</b>	<b>\$ (382,757)</b>	<b>\$ 367,495</b>

See accompanying notes to unaudited condensed consolidated financial statements.

2seventy bio, Inc.

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

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
<b>Balances at December 31, 2021</b>	23,585	\$ 2	\$ 400,026	\$ (712)	\$ (39,494)	\$ 359,822
Vesting of restricted stock units	97	—	—	—	—	—
Exercise of stock options	—	—	1	—	—	1
Issuance of common stock in private placement, net of issuance costs	13,934	2	165,655	—	—	165,657
Stock-based compensation	—	—	9,739	—	—	9,739
Other comprehensive loss	—	—	—	(2,092)	—	(2,092)
Net loss	—	—	—	—	(85,711)	(85,711)
<b>Balances at March 31, 2022</b>	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)
<b>Balances at June 30, 2022</b>	37,634	\$ 4	\$ 584,987	\$ (3,382)	\$ (202,625)	\$ 378,984

See accompanying notes to unaudited condensed consolidated financial statements.



2seventy bio, Inc.

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

	For the six months ended June 30,	
	2023	2022
<b>Cash flows from operating activities:</b>		
Net loss	\$ (89,110)	\$ (163,131)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of contingent consideration	126	131
Depreciation and amortization	4,493	6,831
Stock-based compensation expense	17,406	19,428
Other non-cash items	(2,581)	1,307
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(14,847)	427
Operating lease right-of-use assets	10,172	10,594
Accounts payable	(496)	1,113
Accrued expenses and other liabilities	(18,431)	9,461
Operating lease liabilities	(6,594)	(5,573)
Deferred revenue	21,855	10,000
Collaboration research advancement	(3,744)	(10,522)
Net cash used in operating activities	(81,751)	(119,934)
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(10,050)	(6,258)
Purchases of marketable securities	(155,524)	(22,450)
Proceeds from maturities of marketable securities	145,476	123,227
Purchases of restricted investments	(4,485)	(971)
Proceeds from maturities of restricted investments	4,500	1,000
Net cash used in investing activities	(20,083)	94,548
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock in public offering, net of issuance costs	117,004	—
Proceeds from issuance of common stock to Regeneron, net of issuance costs	9,859	—
Proceeds from the issuance of common stock in private placement	—	165,554
Proceeds from exercise of stock options and ESPP contributions	349	268
Net cash provided by financing activities	127,212	165,822
Increase in cash, cash equivalents and restricted cash and cash equivalents	25,378	140,436
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	72,290	130,448
Cash, cash equivalents and restricted cash and cash equivalents at end of period	\$ 97,668	\$ 270,884
<b>Reconciliation of cash, cash equivalents, and restricted cash and cash equivalents</b>		
Cash and cash equivalents	\$ 95,991	\$ 269,868
Restricted cash and cash equivalents included in restricted investments and other non-current assets	1,677	1,016
Total cash, cash equivalents, and restricted cash and cash equivalents	\$ 97,668	\$ 270,884
<b>Supplemental cash flow disclosures:</b>		
Purchases of property, plant and equipment included in accounts payable and accrued expenses	\$ 2,302	\$ 6,594
Private placement issuance costs included in accounts payable and accrued expenses	\$ —	\$ 22
Financing issuance costs included in accounts payable or accrued expenses	\$ 35	\$ —

See accompanying notes to unaudited condensed consolidated financial statements.

## 2seventy bio, Inc.

### Notes to Condensed Consolidated Financial Statements (unaudited)

#### 1. Description of the business

2seventy bio, Inc. (the “Company” or “2seventy bio”) was incorporated in Delaware on April 26, 2021 and is a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. The Company’s approach combines its expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. The Company is advancing multiple preclinical and clinical programs in oncology and, together with Bristol-Myers Squibb (“BMS”), delivering the first U.S. Food and Drug Administration (“FDA”)–approved CAR T therapy in multiple myeloma, *Abecma* (idecabtagene vicleucel, or ide-cel), to patients in the United States. Please refer to Note 10, *Collaborative arrangements and strategic partnerships* for further discussion of the collaboration with BMS.

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

#### *The separation from bluebird bio, Inc.*

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

On November 3, 2021, the Company also entered into a separation agreement with bluebird bio, which is referred to in this quarterly report as the “Separation Agreement”, as well as various other agreements with bluebird bio, including a tax matters agreement, an employee matters agreement, an intellectual property license agreement, a transition services agreement under which 2seventy bio temporarily receives certain services from bluebird bio, and a second transition services agreement under which 2seventy bio temporarily provides certain services to bluebird bio. These agreements also govern certain of 2seventy bio’s relationships with bluebird bio after the separation. For additional information regarding the Separation Agreement and the other related agreements, refer to Note 13, *Related-party transactions* and the section captioned “Part III. Item 13. Certain Relationships and Related Transactions, and Director Independence,” included in our annual report on Form 10-K, which was filed with the SEC on March 16, 2023.

#### *Going concern*

In accordance with Accounting Standards Codification 205-40, *Going Concern*, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. The Company has incurred losses and has experienced negative operating cash flows for all historical periods presented. During the six months ended June 30, 2023, the Company incurred a net loss of \$89.1 million and used \$81.8 million of cash in operations. The Company expects to continue to generate operating losses and negative operating cash flows for the next few years. The Company’s continued operations are dependent on its ability to raise additional funding and generate operating cash flows from the commercialization of its product candidates, if approved.

As of June 30, 2023, the Company had cash, cash equivalents, and marketable securities of \$306.5 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. If the Company determines additional cash is needed to support operations, the Company may pursue a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. This includes the potential sale of shares of the Company's common stock of up to \$150.0 million in gross proceeds under the at-the-market ("ATM") facility established in November 2022 with Cowen and Company, LLC. No sales of common stock have occurred under this ATM as of the date of this Quarterly Report on Form 10-Q. There can be no assurance that such financing will be available in sufficient amounts or on acceptable terms, if at all, and some could be dilutive to existing stockholders. If the Company is unable to obtain additional funding on a timely basis, it may be forced to significantly curtail, delay, or discontinue one or more of its planned research or development programs or be unable to expand its operations.

## **2. Summary of significant accounting policies and basis of presentation**

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

The significant accounting policies used in preparation of these condensed consolidated financial statements are consistent with those discussed in Note 2 to the consolidated financial statements for the year ended December 31, 2022 included in the Company's 2022 annual report on Form 10-K.

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

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

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

### ***Correction of immaterial error***

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

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

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

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

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

<i>in thousands</i>	For the six months ended June 30, 2022		
	As previously reported	Adjustment	As revised
<b>Cash flows from operating activities:</b>			
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	\$ (364)	\$ 791	\$ 427
Net cash used in operating activities	\$ (120,725)	\$ 791	\$ (119,934)
<b>Cash flows from investing activities:</b>			
Purchases of restricted investments	\$ —	\$ (971)	\$ (971)
Maturities of restricted investments	\$ —	\$ 1,000	\$ 1,000
Net cash provided by investing activities	\$ 94,519	\$ 29	\$ 94,548
Increase in cash, cash equivalents and restricted cash and cash equivalents	\$ 139,616	\$ 820	\$ 140,436
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	\$ 163,266	\$ (32,818)	\$ 130,448
Cash, cash equivalents and restricted cash and cash equivalents at end of period	\$ 302,882	\$ (31,998)	\$ 270,884
<b>Reconciliation of cash, cash equivalents and restricted cash and cash equivalents</b>			
Restricted cash and cash equivalents included in restricted investments and other non-current assets	\$ 33,014	\$ (31,998)	\$ 1,016
Total cash, cash equivalents and restricted cash and cash equivalents	\$ 302,882	\$ (31,998)	\$ 270,884

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

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

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

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

Estimates and judgments are used in the following areas, among others: future undiscounted cash flows and subsequent fair value estimates used to assess potential and measure any impairment of long-lived assets, including

goodwill and intangible assets, the measurement of right-of-use assets and lease liabilities, contingent consideration, stock-based compensation expense, accrued expenses, income taxes, and the assessment of the Company's ability to fund its operations for at least the next twelve months from the date of issuance of these financial statements. In addition, estimates and judgments are used in the Company's accounting for its revenue-generating arrangements, in particular as it relates to determining the stand-alone selling price of performance obligations, evaluating whether an option to acquire additional goods and services represents a material right, estimating the total transaction price, including estimating variable consideration and the probability of achieving future potential development and regulatory milestones, assessing the period of performance over which revenue may be recognized, and accounting for modifications to revenue-generating arrangements.

### 3. Marketable securities

The following table summarizes the marketable securities held at June 30, 2023 and December 31, 2022 (in thousands):

	Amortized cost/ cost	Unrealized gains	Unrealized losses	Fair Value
<b>June 30, 2023</b>				
U.S. government agency securities and treasuries	\$ 167,370	\$ 18	\$ (611)	\$ 166,777
Corporate bonds	500	—	(3)	497
Commercial paper	43,340	—	(59)	43,281
Total	<u>\$ 211,210</u>	<u>\$ 18</u>	<u>\$ (673)</u>	<u>\$ 210,555</u>
<b>December 31, 2022</b>				
U.S. government agency securities and treasuries	\$ 120,739	\$ 3	\$ (1,963)	\$ 118,779
Corporate bonds	2,524	—	(26)	2,498
Commercial paper	75,491	3	(119)	75,375
Total	<u>\$ 198,754</u>	<u>\$ 6</u>	<u>\$ (2,108)</u>	<u>\$ 196,652</u>

No available-for-sale debt securities held as of June 30, 2023 or December 31, 2022 had remaining maturities greater than five years.

The following table summarizes available-for-sale debt securities in a continuous unrealized loss position for less than and greater than twelve months, and for which an allowance for credit losses has not been recorded at June 30, 2023 and December 31, 2022 (in thousands):

	Less than 12 months		12 months or greater		Total	
	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
<b>June 30, 2023</b>						
U.S. government agency securities and treasuries	\$ 75,411	\$ (226)	\$ 41,110	\$ (385)	\$ 116,521	\$ (611)
Corporate bonds	—	—	497	(3)	497	(3)
Commercial paper	39,846	(59)	—	—	39,846	(59)
Total	<u>\$ 115,257</u>	<u>\$ (285)</u>	<u>\$ 41,607</u>	<u>\$ (388)</u>	<u>\$ 156,864</u>	<u>\$ (673)</u>
<b>December 31, 2022</b>						
U.S. government agency securities and treasuries	\$ 28,749	\$ (159)	\$ 86,176	\$ (1,804)	\$ 114,925	\$ (1,963)
Corporate bonds	—	—	2,498	(26)	2,498	(26)
Commercial paper	62,636	(119)	—	—	62,636	(119)
Total	<u>\$ 91,385</u>	<u>\$ (278)</u>	<u>\$ 88,674</u>	<u>\$ (1,830)</u>	<u>\$ 180,059</u>	<u>\$ (2,108)</u>

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

The following table summarizes restricted investments held at June 30, 2023 and December 31, 2022 (in thousands):

	Amortized cost/ cost	Unrealized gains	Unrealized losses	Fair Value
<b>June 30, 2023</b>				
U.S. government agency securities and treasuries	\$ 32,708	\$ —	\$ (783)	\$ 31,925
Total	<u>\$ 32,708</u>	<u>\$ —</u>	<u>\$ (783)</u>	<u>\$ 31,925</u>
<b>December 31, 2022</b>				
U.S. government agency securities and treasuries	\$ 32,880	\$ —	\$ (1,112)	\$ 31,768
Total	<u>\$ 32,880</u>	<u>\$ —</u>	<u>\$ (1,112)</u>	<u>\$ 31,768</u>

The following table summarizes restricted investments in a continuous unrealized loss position for less than and greater than twelve months, and for which an allowance for credit losses has not been recorded at June 30, 2023 and December 31, 2022 (in thousands):

	Less than 12 months		12 months or greater		Total	
	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
<b>June 30, 2023</b>						
U.S. government agency securities and treasuries	\$ 5,457	\$ (25)	\$ 26,468	\$ (758)	\$ 31,925	\$ (783)
Total	<u>\$ 5,457</u>	<u>\$ (25)</u>	<u>\$ 26,468</u>	<u>\$ (758)</u>	<u>\$ 31,925</u>	<u>\$ (783)</u>
<b>December 31, 2022</b>						
U.S. government agency securities and treasuries	\$ 1,942	\$ (27)	\$ 29,826	\$ (1,085)	\$ 31,768	\$ (1,112)
Total	<u>\$ 1,942</u>	<u>\$ (27)</u>	<u>\$ 29,826</u>	<u>\$ (1,085)</u>	<u>\$ 31,768</u>	<u>\$ (1,112)</u>

Accrued interest receivables on the Company's available-for-sale debt securities and restricted investments, included within receivables and other current assets in the Company's condensed consolidated balance sheet, totaled \$0.5 million and \$0.3 million as of June 30, 2023 and December 31, 2022, respectively. No accrued interest receivable was written off during the three and six months ended June 30, 2023 or 2022.

The amortized cost of available-for-sale debt securities and restricted investments is adjusted for amortization of premiums and accretion of discounts to the earliest call date for premiums or to maturity for discounts. At June 30, 2023 and December 31, 2022, the balance in the Company's accumulated other comprehensive loss was composed primarily of activity related to the Company's available-for-sale debt securities and restricted investments. There were no material realized gains or losses recognized on the sale or maturity of available-for-sale securities or restricted investments during the three and six months ended June 30, 2023 and 2022.

The Company determined that there was no material change in the credit risk of the above investments during the six months ended June 30, 2023. As such, an allowance for credit losses was not recognized. As of June 30, 2023, the Company does not intend to sell such securities and it is not more likely than not that the Company will be required to sell the securities before recovery of their amortized cost bases.

#### 4. Fair value measurements

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of June 30, 2023 and December 31, 2022 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>June 30, 2023</b>				
Assets:				
Cash and cash equivalents	\$ 95,991	\$ 66,797	\$ 29,194	\$ —
Marketable securities:				
U.S. government agency securities and treasuries	166,777	—	166,777	—
Corporate bonds	497	—	497	—
Commercial paper	43,281	—	43,281	—
Restricted cash and cash equivalents	1,677	1,677	—	—
Restricted investments	31,925	—	31,925	—
Total assets	<u>\$ 340,148</u>	<u>\$ 68,474</u>	<u>\$ 271,674</u>	<u>\$ —</u>
Liabilities:				
Contingent consideration	\$ 2,306	\$ —	\$ —	\$ 2,306
Total liabilities	<u>\$ 2,306</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,306</u>
<b>December 31, 2022</b>				
Assets:				
Cash and cash equivalents	\$ 71,032	\$ 71,032	\$ —	\$ —
Marketable securities:				
U.S. government agency securities and treasuries	118,779	—	118,779	—
Corporate bonds	2,498	—	2,498	—
Commercial paper	75,375	—	75,375	—
Restricted cash and cash equivalents	1,257	1,257	—	—
Restricted investments	31,768	—	31,768	—
Total assets	<u>\$ 300,709</u>	<u>\$ 72,289</u>	<u>\$ 228,420</u>	<u>\$ —</u>
Liabilities:				
Contingent consideration	\$ 2,180	\$ —	\$ —	\$ 2,180
Total liabilities	<u>\$ 2,180</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,180</u>

#### *Contingent consideration*

In connection with bluebird bio's prior acquisition of Precision Genome Engineering, Inc. ("Pregen") in 2014, the Company may be required to pay future consideration that is contingent upon the achievement of certain commercial milestone events. Contingent consideration is measured at fair value and is based on significant unobservable inputs, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. Future changes in the fair value of contingent consideration related to updated assumptions and estimates are recognized within the condensed consolidated statements of operations and comprehensive loss. In the absence of



new information related to the probability of milestone achievement, changes in fair value will reflect changing discount rates and the passage of time. Contingent consideration is included in other non-current liabilities on the condensed consolidated balance sheets.

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

	<b>For the six months ended June 30, 2023</b>
Beginning balance	\$ 2,180
Additions	—
Changes in fair value	126
Payments	—
Ending balance	<u>\$ 2,306</u>

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

## 5. Property, plant and equipment, net

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

	<b>As of June 30, 2023</b>	<b>As of December 31, 2022</b>
Computer equipment and software	\$ 5,986	\$ 5,670
Office equipment	6,159	6,159
Laboratory equipment	37,483	36,216
Leasehold improvements	27,862	27,416
Construction-in-progress	35,510	28,112
Total property, plant and equipment	113,000	103,573
Less accumulated depreciation and amortization	(51,977)	(47,838)
Property, plant and equipment, net	<u>\$ 61,023</u>	<u>\$ 55,735</u>

### ***Cambridge, Massachusetts drug product manufacturing facility***

In February 2022, the Company began construction of a drug product manufacturing facility within its Cambridge, Massachusetts headquarters. The facility will enable rapid translational research in clinical trials and the manufacture of drug product for use in Phase 1 clinical development activities. Construction-in-progress as of June 30, 2023 includes \$34.5 million related to the ongoing build-out of the facility. As of December 31, 2022, construction-in-progress included \$27.0 million related to the build-out of the facility. The build out of the facility was substantially completed in February 2023 and is anticipated to be operational in the second half 2023.

## 6. Accrued expenses and other current liabilities

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

	As of June 30, 2023	As of December 31, 2022
Royalties	\$ 13,753	\$ 13,094
Employee compensation	10,308	14,845
Manufacturing costs	4,748	17,962
Property, plant, and equipment	1,407	1,498
Clinical and contract research organization costs	1,555	1,619
Professional fees	336	239
Collaboration research costs	568	2,005
Other	3,432	3,416
Total accrued expenses and other current liabilities	\$ 36,107	\$ 54,678

## 7. Leases

The Company leases certain office and laboratory space, primarily located in Cambridge, Massachusetts and Seattle, Washington, that was assigned to it in connection with the separation. There have been no material changes to the lease obligations from those disclosed in Note 7, *Leases*, to the consolidated financial statements included in the Company's 2022 annual report on Form 10-K.

## 8. Commitments and contingencies

### *Contingent consideration related to business combinations*

On June 30, 2014, bluebird bio acquired 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 from bluebird bio. As of June 30, 2023, 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 10, *Collaborative arrangements and strategic partnerships*, for further information on the BMS, Regeneron

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

Based on the Company’s development plans as of June 30, 2023, the Company may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. When the achievement of these milestones or sales has not occurred, such contingencies are not recorded in the Company’s financial statements. As further discussed in Note 10, *Collaborative arrangements and strategic partnerships*, BMS assumed responsibility for amounts due to licensors as a result of any future ex-U.S. sales of *Abecma*.

In July 2021, bluebird bio and National Resilience, Inc. (“Resilience”) announced a strategic manufacturing collaboration aimed to accelerate the early research, development, and delivery of cell therapies. Agreements related to the collaboration were executed in September 2021. As part of the agreement, Resilience acquired bluebird bio’s North Carolina manufacturing facility and retained all staff employed at the site. Concurrent with the sale of the manufacturing facility in Durham, North Carolina, bluebird bio entered into certain ancillary agreements, including two manufacturing agreements and a license agreement (the “Resilience License Agreement”), among others (together referred to as the “Ancillary Agreements”). One of the manufacturing agreements supports ongoing manufacturing for lentiviral vector for development candidates (the “Development Manufacturing Supply Agreement”). The other manufacturing agreement for the future manufacturing of lentiviral vector for the commercial product marketed in collaboration with BMS, *Abecma* (the “Commercial Supply Agreement”) was assigned by the Company to BMS on June 23, 2023. Certain rights and obligations under the Ancillary 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 committed 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. During the second quarter of 2023, the Company paid a total of \$14.2 million to Resilience for its share of net operating losses. The disposition of the net assets of the manufacturing facility previously assigned to 2seventy bio was reflected as a transfer to bluebird bio via net parent investment as a result of bluebird bio’s sale of such facility in the Company’s 2021 annual report on Form 10-K. As a result of the separation, the Company’s net parent investment balance was reclassified to additional paid-in capital. 2seventy bio is not a party to the sale of the manufacturing facility and, therefore, did not recognize any gain or loss arising from the transaction.

Additionally, 2seventy bio is party to various contracts with contract research organizations and contract manufacturers that generally provide for termination on notice, with the exact amounts in the event of termination to be based on the timing of the termination and the terms of the agreement. As noted above, the Company assigned its Commercial Supply Agreement with Resilience to BMS in June 2023. As a result of the assignment, the Company’s future minimum commitments related to the Commercial Supply Agreement have materially decreased from amounts disclosed as of December 31, 2022 in Note 8, *Commitments and Contingencies*, to the consolidated financial statements included in the Company’s 2022 annual report on Form 10-K. The following table summarizes the Company’s non-cancelable contractual obligations as of June 30, 2023 (in thousands):

Years ended December 31,	Purchase commitment
2023	\$ 4,330
2024	2,240
2025	—
2026 and thereafter	—
Total purchase commitments	<u>\$ 6,570</u>

## **Litigation**

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

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

## **9. Equity**

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

In November 2022, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen"), relating to shares of the Company's common stock through an "at the market" equity offering program under which Cowen will act as the Company's sales agent (the "ATM Facility"). Pursuant to the terms of the sales agreement, the Company may offer and sell shares of common stock, having an aggregate price of up to \$150.0 million, from time to time. As of June 30, 2023, the Company had not made any sales under the ATM Facility.

In January 2023, the Company entered into a Share Purchase Agreement with Regeneron, pursuant to which it sold 1,114,827 shares of its common stock to Regeneron, subject to certain restrictions, for an aggregate cash price of approximately \$20.0 million. The purchase price represents \$9.9 million worth of common stock plus a \$10.1 million premium, which represents collaboration deferred revenue. Details regarding the recognition of this deferred revenue as revenue are included below in Note 10, *Collaborative arrangements and strategic partnerships*.

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

## 10. Collaborative arrangements and strategic partnerships

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

### Bristol-Myers Squibb

#### ***BMS Collaboration Agreement***

In March 2013, bluebird bio entered into a collaboration agreement with BMS. The details of the collaboration agreements and the payments the Company has received, and is entitled to receive, are further described in Note 10, *Collaborative arrangements and strategic partnerships*, to the consolidated financial statements included in the Company's 2022 annual report on Form 10-K. During the second quarter of 2023, the Company entered into an amendment to the collaboration agreement with BMS to assign future manufacturing of lentiviral vector to BMS, as further described in Note 8, *Other funding commitments*.

#### ***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 First Amendment to the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement (the "Amended Ide-Cel CCPS") are within the scope of ASC 808. On a quarterly basis, the Company determines its share of collaboration profit or loss for commercial activities. The Company's share of any collaboration profit for commercial activities is recognized as collaborative arrangement revenue and its share of any collaboration loss for commercial activity is recognized as an operating expense and classified as share of collaboration loss on the Company's condensed consolidated statement of operations and comprehensive loss.

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

The following tables summarize the components utilized in the Company's quarterly calculation of collaborative arrangement revenue or share of collaboration loss under the BMS collaboration arrangement for the three and six months ended June 30, 2023 and 2022 (in thousands). The amounts reported for these periods represent the Company's share of BMS' *Abecma* product revenue, cost of goods sold, and selling costs, along with

reimbursement by BMS of commercial costs incurred by the Company, and exclude expenses related to ongoing development, which are separately reflected in the consolidated statements of operations and comprehensive loss as described below.

	For the three months ended		For the six months ended
	March 31, 2023	June 30, 2023	June 30, 2023
<b>Abecma U.S. Collaboration Profit/Loss Share</b>			
2seventy's share of profits (losses), net of 2seventy's share of BMS costs for commercial activities	\$ 21,581	\$ 23,272	\$ 44,853
Reimbursement from BMS for 2seventy costs of commercial manufacturing and commercial activities	1,380	1,271	2,651
Collaborative arrangement revenue <sup>(1)</sup>	\$ 22,961	\$ 24,543	\$ 47,504

	For the three months ended		For the six months ended
	March 31, 2022	June 30, 2022	June 30, 2022
<b>Abecma U.S. Collaboration Profit/Loss Share</b>			
2seventy's share of profits (losses), net of 2seventy's share of BMS costs for commercial activities	\$ (6,709)	\$ (5,931)	\$ (12,640)
Reimbursement from BMS for 2seventy costs of commercial manufacturing and commercial activities	1,357	1,641	2,998
Collaborative arrangement revenue <sup>(1)</sup>	\$ —	\$ —	\$ —
Share of collaboration loss <sup>(1)</sup>	\$ (5,352)	\$ (4,290)	\$ (9,642)

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

The following tables summarize 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 six months ended June 30, 2023 and 2022 (in thousands):

	For the three months ended		For the six months ended
	March 31, 2023	June 30, 2023	June 30, 2023
<b>Abecma U.S. Collaboration Net R&amp;D Expenses</b>			
2seventy's obligation for its share of BMS research and development expenses	\$ (9,461)	\$ (7,195)	\$ (16,656)
Reimbursement from BMS for 2seventy research and development expenses	4,590	1,543	6,133
Net R&D expense <sup>(1)</sup>	\$ (4,871)	\$ (5,652)	\$ (10,523)

<i>Abecma</i> U.S. Collaboration Net R&D Expenses	For the three months ended		For the six months ended
	March 31, 2022	June 30, 2022	June 30, 2022
2seventy's obligation for its share of BMS research and development expenses	\$ (8,118)	\$ (7,418)	\$ (15,536)
Reimbursement from BMS for 2seventy research and development expenses	1,225	1,955	3,180
Net R&D expense <sup>(1)</sup>	\$ (6,893)	\$ (5,463)	\$ (12,356)

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

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

The Company accounts for any ex-U.S. activities under the Amended *Ide-cel* CCPS pursuant to ASC 606. The following table summarizes the revenue recognized related to *ide-cel* ex-U.S. activities for the three and six months ended June 30, 2023 and 2022 (in thousands). These amounts are reflected in service revenue in the consolidated statements of operations and comprehensive loss:

	For the three months ended June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
ASC 606 <i>ide-cel</i> license and manufacturing revenue – ex-U.S. (included as a component of service revenue) <sup>(1)</sup>	\$ 2,988	\$ 3,525	\$ 9,111	\$ 6,315

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

#### ***bb21217***

In addition to the activities related to *ide-cel*, BMS previously exercised its option to obtain an exclusive worldwide license to develop and commercialize *bb21217*, the second product candidate under the collaboration arrangement with BMS which is further described in Note 10, *Collaborative arrangements and strategic partnerships*, to the consolidated financial statements included in the Company's 2022 annual report on Form 10-K.

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

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

obligations with respect to the arrangement with BMS. The initial performance obligation was for research and development services that were substantially completed in September 2019, associated with the initial phase 1 clinical trial of bb21217. The Company allocated \$5.4 million of consideration to the research and development services performance obligation and fully recognized the consideration through September 2019. The other performance obligation relates to a combined performance obligation for the bb21217 license and vector manufacturing services through development, and the remaining \$37.4 million in consideration was allocated to this combined performance obligation. All of the remaining development, regulatory, and commercial milestones related to U.S. development, regulatory and commercialization activities are fully constrained and are therefore excluded from the transaction price.

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

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

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 six months ended June 30, 2023 (in thousands):

	Balance at December 31, 2022		Additions		Deductions		Balance at June 30, 2023
Receivables	\$ 4,537	\$	46,091	\$	(28,750)	\$	21,878
Contract liabilities:							
Deferred revenue	\$ —	\$	—	\$	—	\$	—

The increase in the receivables balance for the six months ended June 30, 2023 is driven by amounts owed less amounts paid to the Company by BMS in the period under the settlement terms of the collaboration agreement.

### **Regeneron**

#### ***Regeneron Collaboration Agreement***

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

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



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

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

#### ***First Amendment to the Regeneron Collaboration Agreement***

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

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

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

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

#### ***Regeneron Share Purchase Agreements***

A Share Purchase Agreement (“SPA”) was entered into by bluebird bio and Regeneron in August 2018. In August 2018, on the closing date of the transaction, bluebird bio issued to Regeneron 0.4 million shares of bluebird bio’s common stock, subject to certain restrictions, for \$238.10 per share, or \$100.0 million in the aggregate. Following the spin-off, Regeneron held approximately 0.1 million shares of 2seventy bio’s common stock, subject to certain restrictions. The purchase price represents \$63.0 million worth of common stock plus a \$37.0 million

premium, which represents a collaboration research advancement, or credit to be applied to Regeneron's initial 50 percent funding obligation for collaboration research, after which the collaborators will continue to fund ongoing research equally. The collaboration research advancement only applies to pre-IND research activities and is not refundable or creditable against post-IND research activities for any programs where Regeneron exercises its opt-in rights.

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

#### ***Accounting analysis – 2018 Regeneron Collaboration Agreement***

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

The Company analyzed the joint research activities to assess whether they fall within the scope of ASC 808, and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the arrangement as outlined above, for the collaboration research performed prior to submission of an IND application for a potential gene therapy product, both parties are deemed to be active participants in the collaboration. Both parties are performing research and development activities and will share equally in these costs through IND submission. Additionally, Regeneron and the Company are exposed to significant risks and rewards dependent on the commercial success of any product candidates that may result from the collaboration. As such, the collaboration arrangement is deemed to be within the scope of ASC 808.

The \$45.5 million attributed to the joint research activities includes the \$37.0 million creditable against amounts owed to the Company by Regeneron. The collaboration research advancement will be reduced over time for amounts due to the Company by Regeneron as a result of the parties agreeing to share in the costs of collaboration research equally. The remainder of \$8.5 million will be attributed to the joint research activities and recognized over the five-year research collaboration term. As of December 31, 2022, \$1.1 million of the premium remained to be recognized.

Consistent with its collaboration accounting policy, the Company will recognize collaboration revenue or research and development expense related to the joint research activities in future periods depending on the amounts incurred by each party in a given reporting period. That is, if the Company's research costs incurred exceed those research costs incurred by Regeneron in a given quarter, the Company will record collaboration revenue and reduce the original \$37.0 million advance by the amount due from Regeneron until such advancement is fully utilized, after which the Company would record an amount due from Regeneron. If Regeneron's research costs incurred exceed those research costs incurred by the Company in a given quarter, the Company will record research and development expense and record a liability for the amount due to Regeneron. As of December 31, 2022, the Company had \$3.7 million of collaboration research advancement credit attributed to the joint research activities still to be recognized. The research credit was fully utilized in the first quarter of 2023.

#### ***Accounting analysis - Regeneron Amendment***

At the commencement of the Amendment, the Company identified two units of accounting, including the issuance of 1.1 million shares of 2seventy bio common stock and joint research activities under the amended agreement. The Company determined the total transaction price to be \$20.0 million, which comprises \$9.9 million of 2seventy bio equity sold to Regeneron and \$10.1 million attributed to joint research activities. In determining the

fair value of 2seventy bio common stock at closing, the Company considered the closing price of 2seventy bio common stock on the closing date of the transaction and included a lack of marketability discount because Regeneron received shares subject to certain restrictions.

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

The Company analogized to the contract modification guidance in ASC 606 to account for the scope and pricing changes contained in the Amendment. The Company concluded the four targets outlined in the joint research activities within the Amendment are now four distinct performance obligations. Based on this, the Company treated the modification as a termination of the existing contract and a creation of a new contract. The remaining premium of \$1.1 million that had not been recognized as of December 31, 2022 was allocated with the \$10.1 million premium attributed to joint research activities from the Amendment, for a total of \$11.2 million. This amount is recognized through the filing of IND for each individual target, allocated among the four distinct performance obligations based on the stand-alone selling price of each target performance obligation. Future milestones continue to be fully constrained until such time as the achievement of such milestones are considered probable.

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

As discussed, the four targets represent four distinct performance obligations and as such, the Company has allocated the total transaction price of \$11.2 million among the four performance obligations based on the stand-alone selling price of each target.

The following table summarizes the allocation of the transaction price to each performance obligation and the amount of the allocated transaction price that is unsatisfied or partially unsatisfied as of June 30, 2023, which the Company expects to recognized as revenue as the targets progress through each of the target's respective IND filing (in thousands):

Performance Obligation	Allocation of Transaction Price	Unsatisfied Portion of Transaction Price
MUC-16 Mono/Combo & Next Gen Therapies	\$ 1,905	\$ 1,010
MAGE-A4	178	15
Early Research Target (1)	8,701	8,380
Early Research Target (2)	475	450
<b>Total</b>	<b>\$ 11,259</b>	<b>\$ 9,855</b>

As of June 30, 2023, approximately \$9.8 million remains in collaboration deferred revenue, of which \$3.6 million is included in deferred revenue, current portion and \$6.2 million is included in deferred revenue, net of current portion on the condensed consolidated balance sheets.

The Company recognized \$4.5 million and \$10.9 million of collaborative arrangement revenue for the three and six months ended June 30, 2023, respectively. The Company recognized \$7.0 million and \$10.5 million of collaborative arrangement revenue from the Regeneron Collaboration Agreement for the three and six months ended June 30, 2022, respectively. As of June 30, 2023, amounts due from Regeneron total \$6.9 million.

### **JW Therapeutics**

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

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

#### ***Accounting Analysis - JW***

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

At contract inception, the Company determined the unconstrained transaction price was \$7.3 million, consisting of the \$3.0 million up-front consideration and \$4.3 million variable consideration for the reimbursement of vector supply. JW provided the Company with a \$3.0 million upfront payment related to the granting of a license for MAGE-A4 cell therapy and the transfer of technology for the development of the Initial Product in which the Company shared equally with Regeneron. During the first quarter of 2023, the Company completed the full transfer of the license of IP related to MAGEA4 cell therapy along with the technology transfer, and as such, the upfront payment received from JW was recognized as service revenue during the first quarter of 2023. The transaction price of \$4.3 million related to the supply of vector consists of variable consideration based upon the estimated amount of vector needed for the initial Phase 1 clinical trial which the Company will also share equally with Regeneron. In the second quarter of 2023, the Company completed its first transfer of vector to supply to JW of approximately \$0.1 million.

### **Novo Nordisk**

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

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

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

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

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

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

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

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

In April 2023, the Company achieved positive proof of concept, preclinical data related to its joint research and development collaboration with Novo Nordisk. This achievement triggered a \$15.0 million milestone payment to the Company under the terms of the Novo Collaboration Agreement. Following the achievement of this milestone, Novo may elect to exercise an option to in-license technology from a third party in connection with the Novo Collaboration Agreement, for which the Company is responsible in making a \$9.0 million payment. This amount is allocated to the research and development performance obligation. As such, the Company has recorded this as a contract liability as of June 30, 2023, which is included in deferred revenue, current portion on the condensed

consolidated balance sheet. The remaining \$6.0 million, of the \$15.0 million proof of concept milestone, will be allocated to the material right alongside the \$5.0 million upfront payment. The total \$11.0 million is included in deferred revenue, net of current portion, as of June 30, 2023, and will be recognized when Novo exercises its option to obtain a license to commercialize the product developed.

Revenue associated with the research and development performance obligation will be recognized as services are provided and costs are incurred. For the three and six months ended June 30, 2023, the Company recognized \$1.9 million and \$3.6 million of service revenue under this agreement, respectively. For the three and six months ended June 30, 2022, the Company recognized \$2.1 million and \$3.4 million of service revenue under this agreement, respectively.

## **11. Royalty and other revenue**

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

The Company recognized \$2.0 million and \$3.4 million of royalty and other revenue for the three and six months ended June 30, 2023, respectively. The Company recognized \$0.8 million and \$1.7 million of royalty and other revenue in the three and six months ended June 30, 2022, respectively.

### ***Juno Therapeutics***

In May 2020, bluebird bio entered into a non-exclusive license agreement with Juno Therapeutics, Inc. (“Juno”), a wholly-owned subsidiary of BMS, related to lentiviral vector technology to develop and commercialize CD-19-directed CAR T cell therapies. The agreement was assumed by the Company in connection with the separation. Royalty revenue recognized from sales of lisocabtagene maraleucel is included within royalty and other revenue in the condensed consolidated statement of operations and comprehensive loss.

## **12. Stock-based compensation**

In connection with 2seventy bio’s separation from bluebird bio on November 4, 2021, under the provisions of the existing plans, the outstanding bluebird bio equity awards were adjusted in accordance with the terms of the employee matters agreement (equitable adjustment) to preserve the intrinsic value of the awards immediately before and after distribution. Refer to Note 13, *Stock-based compensation*, to the consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2022 for details on the conversion methodology of the equity awards.

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

### ***Stock-based compensation expense***

Stock-based compensation expense includes compensation cost related to 2seventy bio equity awards held by its employees as well as bluebird bio equity awards issued upon separation to its employees.

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

	For the three months ended June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
Stock options	\$ 2,717	\$ 4,654	\$ 6,582	\$ 9,058
Restricted stock units	4,924	4,972	10,651	10,286
Employee Stock Purchase Plan	99	63	173	84
	<u>\$ 7,740</u>	<u>\$ 9,689</u>	<u>\$ 17,406</u>	<u>\$ 19,428</u>

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

	For the three months ended June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
Research and development	\$ 3,372	\$ 4,731	\$ 6,990	\$ 8,949
Selling, general and administrative	4,368	4,958	10,416	10,479
	<u>\$ 7,740</u>	<u>\$ 9,689</u>	<u>\$ 17,406</u>	<u>\$ 19,428</u>

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

During the six months ended June 30, 2023, less than 0.1 million shares of common stock were issued under the Company's 2021 Employee Stock Purchase Plan ("ESPP").

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

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

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

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

#### 14. Income taxes

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

#### 15. Net Loss Per Share

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

	For the three and six months ended June 30,	
	2023	2022
Outstanding stock options <sup>(1)</sup>	3,627	2,716
Restricted stock units <sup>(1)</sup>	2,626	1,608
ESPP shares	—	35
	<u>6,253</u>	<u>4,359</u>

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

As described further in Note 9, *Stockholders' equity*, to the consolidated financial statements included in the Company's 2022 annual report on Form 10-K, in November 2021, the Company issued to certain institutional investors (who previously purchased pre-funded warrants to purchase shares of bluebird bio common stock) pre-funded warrants to purchase 757,575 shares of the Company's common stock at an exercise price of \$0.0001 per share. The pre-funded warrants can be exercised at any time or times on or after November 4, 2021, until exercised in full. Based on the terms of the pre-funded warrants, management concluded that they should be considered outstanding shares in the computation of basic and diluted net loss per share.



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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in the Company's 2022 annual report on Form 10-K, which was most recently filed with the Securities and Exchange Commission, or the SEC, on March 16, 2023.

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

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

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

### Overview

We are a cell and gene therapy company focused on the research, development, and commercialization of transformative treatments for cancer. We were incorporated in Delaware in April 2021 and are led by an accomplished team with significant expertise and experience in this field, from discovery through clinical development to regulatory approval of idecabtagene vicleucel (ide-cel, marketed in the United States as *Abecma*). Our approach combines our expertise in T cell engineering technology and lentiviral vector gene delivery approaches, experience in research, development, and manufacturing of cell therapies and a suite of technologies that can be selectively deployed to develop highly innovative, targeted cellular therapies for patients with cancer. We are advancing multiple preclinical and clinical programs in oncology and, together with our partner, delivering *Abecma* to multiple myeloma patients in the United States following approval by the FDA of *Abecma* in March 2021 for the treatment of adults with multiple myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody.

We have never been profitable and have incurred net losses since inception. Our net loss was \$42.1 million and \$89.1 million for the three and six months ended June 30, 2023, 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; and
- increase research and development-related activities for the discovery and development of product candidates and technologies in oncology.

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

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

On November 4, 2021, bluebird bio completed the separation and spin-off of its oncology portfolio and programs into 2seventy bio, retaining its severe genetic disease portfolio and programs. We did not operate as a separate, stand-alone entity prior to our separation from bluebird bio. In connection with the separation, certain assets and liabilities, including certain accounts receivables and accounts payables, included on the condensed consolidated balance sheets prior to the separation have been retained by bluebird bio post-separation and, therefore, were adjusted through net parent investment in our consolidated financial statements in our 2021 annual report on Form 10-K. In addition, in connection with the separation, certain equity awards were converted in accordance with the employee matters agreement, as further described in Note 12, *Stock-based compensation*. As a result of the separation, our net parent investment balance was reclassified to additional paid-in capital.

### **Financial Operations Overview**

#### **Revenue**

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

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

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

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

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

As we recognize revenue under our collaborative arrangements both within and outside the scope of Topic 606, we present revenue on our consolidated statements of operations and comprehensive loss as follows: service revenue includes revenue from collaborative partners recognized within the scope of Topic 606 and collaborative arrangement revenue includes only revenue from collaborative partners recognized outside the scope of Topic 606.

For the three and six months ended June 30, 2023 and 2022, service revenue consisted of the following (in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
ide-cel ex-U.S. service revenue from BMS	\$ 2,988	\$ 3,525	\$ 9,111	\$ 6,315
Service revenue from December 2021 agreement with Novo Nordisk	1,917	2,141	3,620	3,406
Other	117	—	3,117	—
Total service revenue	<u>\$ 5,022</u>	<u>\$ 5,666</u>	<u>\$ 15,848</u>	<u>\$ 9,721</u>

For the three and six months ended June 30, 2023 and 2022, collaborative arrangement revenue consisted of the following (in thousands):

	For the three months ended		For the six months ended	
	June 30		June 30,	
	2023	2022	2023	2022
U.S. <i>Abecma</i> collaboration with BMS	\$ 24,543	\$ —	\$ 47,504	\$ —
Collaboration with Regeneron	4,491	7,035	10,902	10,522
Total collaborative arrangement revenue	\$ 29,034	\$ 7,035	\$ 58,406	\$ 10,522

To date, *Abecma* is our only commercial product where the collaborator is the principal in the product sales and thus, all amounts shown within our condensed consolidated statements of operations and comprehensive loss for share of collaboration loss relate to *Abecma*. The tables below summarize the impact of the *Abecma* U.S. collaboration profit/loss share on our condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2023 and 2022 (in thousands).

<i>Abecma</i> U.S. Collaboration Profit (Loss) Share	For the three months ended		For the six months ended
	March 31, 2023	June 30, 2023	June 30, 2023
Our share of profits (losses), net of our share of BMS costs for commercial activities	\$ 21,581	\$ 23,272	\$ 44,853
Reimbursement from BMS for our costs of commercial manufacturing and commercial activities	1,380	1,271	2,651
Collaborative arrangement revenue <sup>(1)</sup>	\$ 22,961	\$ 24,543	\$ 47,504
Share of collaboration loss <sup>(1)</sup>	\$ —	\$ —	\$ —
Costs of commercial manufacturing incurred by us, prior to BMS reimbursement	(2,583)	(2,389)	(4,972)
Costs of commercial activities incurred by us, prior to BMS reimbursement	(176)	(153)	(329)
Total impact of <i>Abecma</i> U.S. collaboration profit (loss) on our statements of operations and comprehensive loss	\$ 20,202	\$ 22,001	\$ 42,203

<i>Abecma</i> U.S. Collaboration Profit (Loss) Share	For the three months ended		For the six months ended
	March 31, 2022	June 30, 2022	June 30, 2022
Our share of profits (losses), net of our share of BMS costs for commercial activities	\$ (6,709)	\$ (5,931)	\$ (12,640)
Reimbursement from BMS for our costs of commercial manufacturing and commercial activities	1,357	1,641	2,998
Collaborative arrangement revenue <sup>(1)</sup>	\$ —	\$ —	\$ —
Share of collaboration loss <sup>(1)</sup>	\$ (5,352)	\$ (4,290)	\$ (9,642)
Costs of commercial manufacturing incurred by us, prior to BMS reimbursement	(2,086)	(2,696)	(4,782)
Costs of commercial activities incurred by us, prior to BMS reimbursement	(628)	(587)	(1,215)
Total impact of <i>Abecma</i> U.S. collaboration profit (loss) on our statements of operations and comprehensive loss	\$ (8,066)	\$ (7,573)	\$ (15,639)

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

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

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

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

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

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

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

- KarMMa study – an open label, single-arm, multi-center phase 2 study to examine the efficacy and safety of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- KarMMa-2 study – a multi-cohort, open-label, multicenter phase 2 study to examine the safety and efficacy of ide-cel in the treatment of patients with relapsed and refractory multiple myeloma and in high-risk multiple myeloma. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.
- KarMMa-3 study – a multicenter, randomized, open-label phase 3 study comparing the efficacy and safety of ide-cel versus standard triplet regimens in patients with relapsed and refractory multiple myeloma. The costs incurred by BMS for this study are subject to the cost-sharing provisions of our BMS collaboration arrangement.

- CRC-403 study – an open-label, multi-site Phase 1/2 dose-escalation study to examine the safety and efficacy of bbT369 in relapsed and/or refractory B Cell Non-Hodgkin's Lymphoma (NHL).
- PLAT-08 study – an open-label Phase 1 study to examine the safety and efficacy of SC-DARIC33 in pediatric and young adult relapsed or refractory acute myeloid leukemia (AML).

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

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

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

Our direct research and development expenses consist principally of internal and external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to acquiring and manufacturing clinical study materials. We allocate internal salary and benefits, personnel-related discretionary bonus, and stock-based compensation costs directly related to specific programs. We do not allocate certain general research and platform personnel costs, certain laboratory and related expenses, rent expense,

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

	For the three months ended June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
ide-cel <sup>(1)</sup>	\$ 9,068	\$ 11,155	\$ 26,662	\$ 21,637
bb21217	371	838	1,259	2,838
bbT369	8,877	6,314	18,848	12,773
SC-DARIC33	871	849	2,165	3,011
Preclinical programs	13,155	20,346	27,717	33,779
Total direct research and development expenses	32,342	39,502	76,651	74,038
General research and platform personnel costs	7,438	4,496	12,944	12,140
Unallocated laboratory and manufacturing expenses	4,082	4,387	6,572	10,458
Facility and other support costs	16,118	16,172	32,059	33,800
Total other research and development expenses	27,638	25,055	51,575	56,398
Total research and development expenses	\$ 59,980	\$ 64,557	\$ 128,226	\$ 130,436

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

#### **Cost of Manufacturing for Commercial Collaboration**

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

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

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

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

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

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

### ***Cost of Royalty and Other Revenue***

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

### ***Change in Fair Value of Contingent Consideration***

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

As of June 30, 2023, there were \$99.9 million in future contingent cash payments related to commercial milestones. We estimate future contingent cash payments have a fair value of \$2.3 million as of June 30, 2023, which are classified within other non-current liabilities on our condensed consolidated balance sheet.

### ***Other Income, Net***

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

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies. During the three and six months ended June 30, 2023, there were no material changes to our significant accounting policies as reported in our annual consolidated financial statements included in our 2022 annual report on Form 10-K, except as otherwise described in Note 2, *Basis of presentation, principles of consolidation and significant accounting policies*, in the notes to the condensed consolidated financial statements.

### **Results of Operations**

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



**Comparison of the Three Months Ended June 30, 2023 and 2022:**

	For the three months ended June 30,		Change
	2023	2022	
	(in thousands)		
<b>Revenue:</b>			
Service revenue	\$ 5,022	\$ 5,666	\$ (644)
Collaborative arrangement revenue	29,034	7,035	21,999
Royalty and other revenue	1,992	781	1,211
Total revenues	36,048	13,482	22,566
<b>Operating expenses:</b>			
Research and development	59,980	64,557	(4,577)
Cost of manufacturing for commercial collaboration	3,610	3,882	(272)
Selling, general and administrative	19,489	17,278	2,211
Share of collaboration loss	—	4,290	(4,290)
Cost of royalty and other revenue	907	364	543
Change in fair value of contingent consideration	53	83	(30)
Total operating expenses	84,039	90,454	(6,415)
Loss from operations	(47,991)	(76,972)	28,981
Interest income, net	3,090	213	2,877
Other income (expense), net	2,812	(661)	3,473
Loss before income taxes	(42,089)	(77,420)	35,331
Income tax (expense) benefit	—	—	—
Net loss	\$ (42,089)	\$ (77,420)	\$ 35,331

**Revenue.** Total revenue was \$36.0 million for the three months ended June 30, 2023, compared to \$13.5 million for the three months ended June 30, 2022. The increase of \$22.6 million was primarily attributable to an increase in collaborative arrangement revenue recognized under our collaboration arrangement with BMS, driven by increased *Abecma* net sales and lower cost of goods sold. This resulted in higher profit owed to 2seventy as part of our 50% share of U.S. profit/loss with BMS. The increase was also driven by an increase in royalty and other revenue driven by sales of Breyanzi (lisocabtagene maraleucel) by BMS.

**Research and Development Expenses.** Research and development expenses were \$60.0 million for the three months ended June 30, 2023, compared to \$64.6 million for the three months ended June 30, 2022. The overall decrease of \$4.6 million was primarily attributable to the following:

- \$3.1 million of decreased material production costs, primarily due to decreased plasmid and vector manufacturing activities related to the Regeneron collaboration;
- \$1.4 million of decreased research costs incurred under our partnerships with Gritstone Oncology, Inc. and Seattle Children’s Therapeutics; and
- \$0.9 million of decreased amortization expense associated with the intangible asset acquired in the purchase of Pregenen in 2014. The amortization of this intangible asset was completed in the second quarter of 2022.

These decreases were partially offset by a slight increase of \$0.9 million in employee compensation expenses.

**Cost of Manufacturing for Commercial Collaboration.** Cost of manufacturing for commercial collaboration was \$3.6 million for the three months ended June 30, 2023, compared to \$3.9 million for the three months ended June

30, 2022. The decrease of \$0.3 million was primarily due to a slight decrease in quality testing performed by us on *Abecma* inventory during the second quarter of 2023 compared to the second quarter of 2022. These costs primarily consist of the salaries and benefits for our quality employees and laboratory expenses to support quality testing.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$19.5 million for the three months ended June 30, 2023, compared to \$17.3 million for the three months ended June 30, 2022. The increase of \$2.2 million was primarily due to increased consulting and professional service fees slightly offset by decreased employee compensation costs.

*Cost of Royalty and Other Revenue.* Cost of royalty and other revenue was \$0.9 million for the three months ended June 30, 2023, compared to \$0.4 million for the three months ended June 30, 2022, and represents amounts owed to third-party licensors on revenues recognized under our out-license arrangements. The increase is attributable to increased royalty and other revenue in the same periods driven by sales of Breyanzi (lisocabtagene maraleucel) by BMS.

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

*Other Income (Expense), Net.* For the three months ended June 30, 2023, other income, net primarily consisted of rental income, income recognized under our transition service agreements with bluebird bio, sublease income from bluebird bio and an offset to other expense related to our share of the Resilience net operating loss. Our share of Resilience net operating loss is described in Note 8, Commitment and Contingencies. For the three months ended June 30, 2022, other expense, net primarily consisted of our 50% share of the Resilience net operating loss for the second quarter of 2022 offset by income recognized under our transition services agreements with bluebird bio.

**Comparison of the Six Months Ended June 30, 2023 and 2022:**

	For the six months ended June 30,		Change
	2023	2022	
	(in thousands)		
<b>Revenue:</b>			
Service revenue	\$ 15,848	\$ 9,721	\$ 6,127
Collaborative arrangement revenue	58,406	10,522	47,884
Royalty and other revenue	3,415	1,668	1,747
Total revenues	<u>77,669</u>	<u>21,911</u>	<u>55,758</u>
<b>Operating expenses:</b>			
Research and development	128,226	130,436	(2,210)
Cost of manufacturing for commercial collaboration	7,264	7,248	16
Selling, general and administrative	40,209	41,139	(930)
Share of collaboration loss	—	9,642	(9,642)
Cost of royalty and other revenue	1,548	875	673
Change in fair value of contingent consideration	126	131	(5)
Total operating expenses	<u>177,373</u>	<u>189,471</u>	<u>(12,098)</u>
Loss from operations	(99,704)	(167,560)	67,856
Interest income, net	5,139	328	4,811
Other income, net	5,455	4,101	1,354
Loss before income taxes	<u>(89,110)</u>	<u>(163,131)</u>	<u>74,021</u>
Income tax (expense) benefit	—	—	—
Net loss	<u>\$ (89,110)</u>	<u>\$ (163,131)</u>	<u>\$ 74,021</u>

*Revenue.* Total revenue was \$77.7 million for the six months ended June 30, 2023, compared to \$21.9 million for the six months ended June 30, 2022. The increase of \$55.8 million was primarily attributable to an increase in collaborative arrangement revenue recognized under our collaboration arrangement with BMS, driven by increased *Abecma* net sales and lower cost of goods sold. This resulted in higher profit owed to 2seventy bio as part of our 50% share of U.S. profit/loss with BMS. The increase was also driven by an increase in service revenue in the first quarter of 2023, attributable to an increase of *ide-cel* ex-U.S. service revenue of approximately \$3.3 million, along with the recognition of revenue on the upfront payment received from the JW agreement of \$3.0 million. Finally, increased royalty and other revenue driven by sales of *Breyanzi* (*lisocabtagene maraleucel*) by BMS contributed to the increase in the first half of 2023 compared to the first half of 2022.

*Research and Development Expenses.* Research and development expenses were \$128.2 million for the six months ended June 30, 2023, compared to \$130.4 million for the six months ended June 30, 2022. The overall decrease of \$2.2 million was primarily attributable to the following:

- \$7.8 million of decreased research costs incurred under our partnerships with Gritstone Oncology, Inc. and Seattle Children's Therapeutics, as well as a decrease in net research and development expenses recognized under our collaboration with BMS;
- \$1.9 million of decreased amortization expense associated with the intangible asset acquired in the purchase of Pregenen in 2014. The amortization of this intangible asset was completed in the second quarter of 2022;
- \$1.3 million of decreased IT and other facility-related costs; and
- \$1.0 million of decreased consulting and professional service fees.

These decreases were partially offset by:

- \$7.1 million of increased material production costs, primarily due to increased manufacturing activities of suspension lentiviral vector for ide-cel development in the first half of 2023; and
- \$2.7 million of increased license and milestone fees associated with a milestone paid to Medigene in the first quarter of 2023 for the continued development of our MAGE-A4 TCR program in solid tumors, which is being developed as part of our collaboration with Regeneron.

*Cost of Manufacturing for Commercial Collaboration.* Cost of manufacturing for commercial collaboration was \$7.3 million for the six months ended June 30, 2023, compared to \$7.2 million for the six months ended June 30, 2022. These costs primarily consist of the salaries and benefits for our quality employees and laboratory expenses incurred to support quality testing on *Abecma* inventory.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$40.2 million for the six months ended June 30, 2023, compared to \$41.1 million for the six months ended June 30, 2022. The decrease of \$0.9 million was primarily due to decreased consulting and professional service fees in the first quarter of 2023 compared to the first quarter of 2022, associated with our spin-off from bluebird bio, as well as decreased employee compensation costs.

*Cost of Royalty and Other Revenue.* Cost of royalty and other revenue was \$1.5 million for the six months ended June 30, 2023, compared to \$0.9 million for the six months ended June 30, 2022, and represents amounts owed to third-party licensors on revenues recognized under our out-license arrangements. The increase is attributable to increased royalty and other revenue in the same periods driven by sales of Breyanzi (lisocabtagene maraleucel) by BMS.

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

*Other Income, Net.* For the six months ended June 30, 2023, other income, net primarily consisted of rental income, income recognized under our transition service agreements with bluebird bio, and sublease income from bluebird bio. For the six months ended June 30, 2022, other income, net consisted of income recognized under our transition services agreements with bluebird bio offset by our 50% share of the Resilience net operating loss for the second quarter of 2022.

## Liquidity and Capital Resources

As of June 30, 2023, we had cash, cash equivalents, and marketable securities of approximately \$306.5 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. If we determine that additional cash is needed to support operations, we may pursue a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. This includes the potential sale of shares of our common stock of up to \$150.0 million in gross proceeds under the at-the-market (“ATM”) facility established in November 2022 with Cowen and Company, LLC. No sales of common stock have occurred under this ATM facility as of the date of this Quarterly Report on Form 10-Q. There can be no assurance that such financing will be available in sufficient amounts or on acceptable terms, if at all, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned research or development programs or be unable to expand our operations.

We have incurred losses and have experienced negative operating cash flows for all periods presented. During the six months ended June 30, 2023, we incurred a loss of \$89.1 million and used \$81.8 million of cash in operations. We will continue to incur research and development and selling, general and administrative expenses and we expect to continue to generate operating losses and negative operating cash flows for the next few years.

### Sources of Liquidity

#### Cash Flows

The following table summarizes our cash flow activity:

	For the six months ended June 30,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	\$ (81,751)	\$ (119,934)
Net cash (used in) provided by investing activities	(20,083)	94,548
Net cash provided by financing activities	127,212	165,822
Increase in cash, cash equivalents and restricted cash and cash equivalents	\$ 25,378	\$ 140,436

*Cash Flows from Operating Activities.* Net cash used in operating activities was \$81.8 million for the six months ended June 30, 2023 and primarily consisted of a net loss of \$89.1 million adjusted for non-cash items, including stock-based compensation of \$17.4 million, depreciation and amortization of \$4.5 million, and the change in fair value of contingent consideration of \$0.1 million, as well as the change in our net working capital.

Net cash used in operating activities was \$119.9 million for the six months ended June 30, 2022 and primarily consisted of net loss of \$163.1 million adjusted for non-cash items, including stock-based compensation of \$19.4 million and depreciation and amortization of \$6.8 million, and the change in fair value of contingent consideration of \$0.1 million, as well as the change in our net working capital.

*Cash Flows from Investing Activities.* Net cash used in investing activities for the six months ended June 30, 2023 was \$20.1 million and was due to purchase of marketable securities of \$155.5 million, purchase of restricted investments of \$4.5 million, and the purchase of property, plant and equipment of \$10.1 million, offset by proceeds from maturities of marketable securities of \$145.5 million and proceeds from maturities of restricted investments of \$4.5 million.

Net cash provided by investing activities for the six months ended June 30, 2022 was \$94.5 million and was due to proceeds from maturities of marketable securities of \$123.2 million and proceeds from the maturities of restricted

investments of \$1.0 million, offset by the purchase of marketable securities of \$22.5 million, the purchase of restricted investments of \$1.0 million, and the purchase of property, plant and equipment of \$6.3 million.

*Cash Flows from Financing Activities.* Net cash provided by financing activities for the six months ended June 30, 2023 was \$127.2 million and was primarily due to net proceeds received of \$117.0 million from the issuance of common stock in a public offering in March 2023 along with net proceeds of \$9.9 million from the issuance of common stock to Regeneron from the January 2023 Share Purchase Agreement.

Net cash provided by financing activities for the six months ended June 30, 2022 was \$165.8 million and was primarily due to gross proceeds received of \$165.6 million from the issuance of common stock in a private placement in March 2022.

## Funding Requirements

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

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

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

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

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including medical affairs, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;

- the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

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

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

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

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

### **Contractual Obligations and Commitments**

As discussed in Note 8, *Commitments and contingencies*, we assigned our Commercial Supply Agreement with Resilience to BMS in June 2023. This resulted in our future minimum commitments related to the Commercial Supply Agreement to materially decrease from amounts disclosed as of December 31, 2022 in Note 8, *Commitments and Contingencies*, to the consolidated financial statements included in the Company's 2022 annual report on Form 10-K. There have been no other material changes to our contractual obligations and commitments as included in our audited consolidated financial statements included in our 2022 annual report on Form 10-K.

### **Emerging Growth Company Status**

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

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### ***Interest rate fluctuation risk***

We are exposed to market risk related to changes in interest rates. As of June 30, 2023 we had cash, cash equivalents and marketable securities of \$306.5 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 June 30, 2023, the net fair value of our interest-sensitive marketable securities and restricted investments 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 six months ended June 30, 2023. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future (especially if inflation rates continue to rise) due to an impact on the costs to conduct clinical trials, labor costs we incur to attract and retain qualified personnel, and other operational costs, inflationary costs could adversely affect our business, financial condition and results of operations.



## ITEM 4. CONTROLS AND PROCEDURES

### *Evaluation of Disclosure Controls and Procedures*

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

### *Changes in Internal Control*

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

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 1A. Risk Factors

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, 2022. In addition to the other information set forth in this report, you should carefully consider the factors discussed in the section captioned “Part I, Item 1A. Risk Factors” in our annual report on Form 10-K for the year ended December 31, 2022, which could materially affect our business, financial condition, or future results. The risks described in our annual report on Form 10-K and our Quarterly Reports on Form 10-Q are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may have a material adverse effect on our business, financial condition, and/or operating results.

***Patients receiving T cell-based immunotherapies such as Abecma may experience serious adverse events, including neurotoxicity and cytokine release syndrome. Serious adverse events or undesirable side effects associated with Abecma or our product candidates may result in delays, clinical holds, or terminations of our clinical trials, impact our ability to obtain or maintain marketing approval, and impact market acceptance and commercial sales, which will significantly harm our business, financial condition and prospects.***

*Abecma* is a chimeric antigen receptor, or CAR, T cell-based immunotherapy. In previous and ongoing clinical studies involving CAR T cell products, including those involving ide-cel, patients experienced side effects such as neurotoxicity and cytokine release syndrome. There have been life-threatening events related to severe neurotoxicity and cytokine release syndrome, requiring intense medical intervention such as intubation or vasopressor support, and in several cases, resulted in death. Severe neurotoxicity is a condition that is currently defined clinically by cerebral edema, confusion, drowsiness, speech impairment, tremors, seizures, or other central nervous system side effects, when such side effects are serious enough to lead to intensive care. In some cases, severe neurotoxicity was thought to be associated with the use of certain lymphodepletion regimens used prior to the administration of the CAR T cell products. Cytokine release syndrome is a condition that is currently defined clinically by certain symptoms related to the release of cytokines, which can include fever, chills, low blood pressure, when such side effects are serious enough to lead to intensive care with mechanical ventilation or significant vasopressor support. The exact cause or causes of cytokine release syndrome and severe neurotoxicity in connection with treatment of CAR T cell products is not fully understood at this time. In addition, patients have experienced other adverse events in these studies, such as a reduction in the number of blood cells (in the form of neutropenia, thrombocytopenia, anemia or other cytopenias), febrile neutropenia, chemical laboratory abnormalities (including elevated liver enzymes), and renal failure.

Undesirable side effects caused by *Abecma*, other CAR T product candidates targeting B cell maturation antigen, or BCMA, or our other engineered cell therapy product candidates, could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in restrictions on the labeling, distribution, or marketing of our approved products or a requirement to conduct potentially costly post-approval studies or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authorities. For example, the prescribing information for *Abecma* includes a boxed warning for cytokine release syndrome, neurologic toxicities, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome, and *Abecma* is only available in the U.S. through a REMS program. Additionally, FDA has imposed a post-marketing requirement for *Abecma* that requires completion of an observational study to assess the long-term safety of *Abecma* and the risk of secondary malignancies occurring after treatment by following patients for a 15-year period. Side effects and toxicities

associated with *Abecma*, as well as the warnings, precautions, and requirements listed in the prescribing information, could affect the willingness of physicians to prescribe, and patients to use, *Abecma* and negatively affect market acceptance and commercial sales. In some cases, side effects such as neurotoxicity or cytokine release syndrome have resulted in clinical holds of ongoing clinical trials and/or discontinuation of the development of the product candidate. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In addition, in June 2023, the Phase 1 trial of the PLAT-08 study of SC-DARIC33 in AML was placed on hold by Seattle Children’s Research Institute following a fatal (Grade 5) serious adverse event in a patient enrolled in the study and in August 2023 the FDA placed a clinical hold on the study. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the studies or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from engineered cell therapies are not normally encountered in the general patient population and by medical personnel. Medical personnel may need additional training regarding engineered cell therapies to understand their side effects. Inadequate training in recognizing or failure to effectively manage the potential side effects of engineered cell therapies could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- regulatory authorities may withdraw or limit their approval of *Abecma* or our product candidates;
- regulatory authorities may require the addition of labeling statements, including a “boxed” warning or contraindications, such as the “boxed” warning included in the product label for *Abecma*;
- we and/or BMS may be required to change the way *Abecma* or such product candidates are distributed or administered, conduct additional clinical trials or change the labeling for *Abecma* or such product candidates;
- regulatory authorities may require a REMS plan to mitigate risks, such as the REMS program for *Abecma*;
- we may be subject to regulatory investigations and government enforcement actions;
- we or BMS may decide to remove *Abecma* or such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking *Abecma* or our product candidates; and
- our reputation may suffer.

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

None

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

None

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

None

**Item 5. Other Information**

None

## Item 6. Exhibit Index

<u>Exhibit Number</u>	<u>Exhibit Description</u>
<a href="#">3.1</a>	<a href="#">Amended and Restated Certificate of Incorporation of 2seventy bio, Inc. (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed on November 4, 2021).</a>
<a href="#">3.2</a>	<a href="#">Amended and Restated Bylaws of 2seventy bio, Inc. (incorporated by reference to Exhibit 3.2 to Annual Report on Form 10-K filed on March 16, 2023).</a>
<a href="#">4.1</a>	<a href="#">Form of Pre-Funded Warrant (incorporated by reference to Exhibit 10.7 to Current Report on Form 8-K filed on November 4, 2021).</a>
<a href="#">10.1**†</a>	<a href="#">Second Amendment to Amended and Restated Co-Development, Co-Promote and Profit Share Agreement, between 2seventy bio, Inc., Celgene Corporation and Celgene Investment Company LLC, dated June 23, 2023.</a>
<a href="#">31.1*</a>	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">31.2*</a>	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">32.1**</a>	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

\* 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.

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



**SIGNATURES**

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

2seventy bio, Inc.

Date: August 14, 2023

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

Date: August 14, 2023

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

SECOND AMENDMENT TO  
AMENDED AND RESTATED CO-DEVELOPMENT, CO-PROMOTE AND PROFIT SHARE AGREEMENT

By and Between 2SEVENTY BIO, INC.

and

CELGENE CORPORATION

and

CELGENE EUROPEAN INVESTMENT COMPANY LLC

Dated as of June 23, 2023



## SECOND AMENDMENT TO CCPS AGREEMENT

### **This Second Amendment to Amended and Restated Co-Development, Co-Promote**

**AND PROFIT SHARE AGREEMENT** (this “**Second Amendment**”) is entered into as of June 23, 2023 (the “**Second Amendment Effective Date**”) by and between **2seventy Bio, Inc.** (as assignee of Bluebird Bio, Inc.), a Delaware corporation having its principal place of business at 60 Binney Street, Cambridge, MA 02142 (“**2seventy**”) and **CELGENE CORPORATION, INC.**, a corporation organized under the laws of Delaware and having a principal place of business at 86 Morris Avenue, Summit, NJ 07901 (“**Celgene Corp**”), with respect to all rights and obligations under the CCPS Agreement (as defined below) in the United States (subject to Section 18.18 of the **CCPS Agreement**), and **CELGENE EUROPEAN INVESTMENT COMPANY LLC**, a limited liability company organized under the laws of Delaware and having a principal place of business at Route de Perreux 1, 2017 Boudry, Switzerland, with respect to all rights and obligations under the CCPS Agreement outside of the United States (subject to Section 18.18 of the CCPS Agreement) (“**Celgene Europe**” and together with Celgene Corp, “**Celgene**”). Celgene and 2seventy are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”. Capitalized terms not defined herein shall have the meaning provided in the CCPS Agreement, and if not defined in the CCPS Agreement, in the Master Collaboration Agreement.

### **Background**

**WHEREAS**, Celgene and Bluebird Bio, Inc. (“**Bluebird**”) entered into that certain Amended and Restated Co-Development, Co-Promote and Profit Share Agreement dated March 26, 2018, as amended by the First Amendment to the CCPS agreement dated May 8, 2020 (the “**CCPS Agreement**”);

**Whereas**, Bluebird separated out its oncology business (the “**Separation**”) and formed 2seventy, a differentiated publicly traded company, and in connection with the Separation, Bluebird assigned of all of its rights and obligations under the CCPS Agreement to 2seventy;

**Whereas**, the Parties wish to amend the CCPS Agreement with respect to the Manufacture and Supply of Vectors, and to assign the Resilience Supply Agreements (as defined below) to Celgene in accordance with the terms and conditions set forth below.

**Now Therefore**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Second Amendment, the Parties agree as follows:

## **ARTICLE 1**

### **ASSIGNMENT AND AMENDMENTS**

**1.1** 2seventy shall assign and Celgene shall accept assignment of the Clinical and Commercial Supply Agreement between 2seventy (as assignee of Bluebird) and Resilience Boston, Inc. dated September 27, 2021 (the “**Resilience Supply Agreement**”) according to the terms of the Assignment and Assumption Agreement executed contemporaneously herewith.

**1.2** Section 7.1 of the CCPS Agreement is hereby amended by deleting the existing text and replacing it with the following text:

“7.1 Generally.

(a) As of and after the CCPS Agreement Effective Date, subject to the terms and conditions of this CCPS Agreement, (i) the Parties will assume through the JGC joint responsibility for (1) Manufacture of Elected Candidate and Licensed Product for Development and (2) Manufacture of Licensed Product for Commercialization for U.S. Administration, each under the Development & U.S. Commercialization Program, and (ii) Celgene will assume sole responsibility for Manufacturing Licensed Product for

Commercialization for ROW Administration. The Joint Manufacturing Committee (JMC), established by the JGC in accordance with Section 3.1(c)(iv) of the CCPS Agreement, shall be maintained during the CCPS Agreement Term.

(b) Subject to the terms and conditions of this CCPS Agreement (and including without limitation the Transition Plan), as of and after the Second Amendment Effective Date, Celgene will assume sole responsibility for Manufacturing Vector for Development and Commercialization of Elected Candidate and Licensed Product in the Field for U.S. Administration (with respect to such U.S. Administration under the supervision of the JGC in accordance with Article 3) and ROW Administration.”

**1.1** Section 7.4 of the CCPS Agreement is hereby amended by deleting the existing text and replacing it with the following text:

“7.4 Vector Manufacturing. Notwithstanding anything else in this Section 7:

(a) *Generally*. As of the Second Amendment Effective Date, but subject to the other clauses of this Section 7.4, (and with respect to U.S. Administration under the supervision of the JGC in accordance with Article 3), Celgene will be solely responsible for the Manufacture and supply of Vector and associated Payload for the Development and Commercialization of Elected Candidate and Licensed Products in the Field for U.S. Administration and ROW Administration.

(i) Each Party shall use Commercially Reasonable Efforts to perform activities ascribed to it in the transition plan set forth in Appendix 1, (the “**Transition Plan**”), attached hereto, to transfer to Celgene Suspension Vector Manufacturing (including associated Payloads) responsibilities. All costs incurred by the Parties in relation to the execution of the Transition Plan will be apportioned in accordance with Schedule 4.3(b). If Celgene requires any particular transition service following the expiration of the service timeline for such transition service as set forth in the Transition Plan, the Parties shall discuss in good faith the potential for 2seventy to continue providing such service beyond such time period.

(ii) The Manufacturing Cost of Suspension Vector Supply for Commercialization for U.S. Administration will be included in the Cost of Goods Sold (for clarity, as a component of the Manufacturing Costs). The cost of Suspension Vector Supply for Development will be included in the U.S. Development Costs, subject to adjustment as provided therein.

(iii) As provided in the Quality Agreement by and between 2seventy and Bristol Myers Squibb Company (“**BMS**”), dated March 17, 2022 (the “**Quality Agreement**”) as may be amended by the Parties, 2seventy shall continue to provide the quality testing activities consistent with the terms therein.

**1.2** Sections 10.1(b), 10.1(c) and the last paragraph of Section 10.1 of the CCPS Agreement are hereby amended by deleting the existing text and replacing it with the following text:

“(b) a worldwide, exclusive (even as to 2seventy) fully paid up, royalty-free license, with the right to sublicense only as permitted by Section 10.3, under Bluebird Licensed IP and Bluebird Regulatory Rights to, (i) Develop (including for clarity, Manufacture) Elected Candidate and Licensed Product in the Field for ROW Administration and (ii) to Commercialize (including for clarity Manufacture) Licensed Product in the Field for ROW Administration; and

(c) a worldwide, exclusive, royalty-free license, with the right to sublicense only as permitted by Section 10.3, under Bluebird Licensed IP and Bluebird Regulatory Rights, to Manufacture Vectors and associated Payloads for Licensed Product in the Field for U.S. Administration and ROW Administration.

Further, (i) the foregoing licenses to Bluebird Regulatory Rights include the right to reference same, (ii) the licenses to Commercialize granted in this Section 10.1 will cover only the sale and offer for sale of Licensed Product in finished form and not the **sale** or offer for sale of Vectors and associated Payloads (other than as and to the extent incorporated in the Licensed Product), and (iii) rights to Manufacture Vectors and associated Payloads are included within the scope of the licenses granted to Celgene under this Section 10.1, which rights are subject to the terms and conditions of Section 7.4.”

1.5 Section 10.2 of the CCPS Agreement is hereby amended by deleting Section 10.2(a)(iii) “Manufacture of Vectors and associated Payloads for Licensed Product for ROW Administration”.

## ARTICLE 2

### REPRESENTATIONS AND WARRANTIES; OTHER TERMS

2.1 Each Party represents and warrants to the other as of the date hereof that:

(a) Corporate Power. It is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation, and has full corporate power and authority to enter into this First Amendment and to carry out the provisions hereof.

(b) Due Authorization. It is duly authorized to execute and deliver this First Amendment and to perform its obligations hereunder, and the person executing this First Amendment on its behalf has been duly authorized to do so by all requisite corporate action.

(c) Binding Agreement. This First Amendment is legally binding upon it and enforceable against it in accordance with its terms. The execution, delivery and performance of this Amendment by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any applicable Laws.

2.2 Except as otherwise expressly set forth herein, the Agreement shall continue, in full force and effect, in accordance with its terms.

*[Signature Page Follows]*

**In Witness Whereof**, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Second Amendment Effective Date.

**2SEVENTY BIO, INC.**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**CELGENE CORPORATION**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**CELGENE EUROPEAN INVESTMENT COMPANY, LLC**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**Appendix 1**

**Manufacturing Transition Plan**

Following the Second Amendment Effective Date and the assignment to Celgene of the Resilience Supply Agreement, 2seventy will continue to provide the below manufacturing related services to Celgene during the timelines set forth below:

<b><i>Activity</i></b>	<b><i>Duration</i></b>
Provision of sLLV scale down model (lab) and process knowledge support	Until Celgene's designated lab successfully has qualified the applicable processes (target December 2023, but no later than March 31, 2024)
Support for characterization assays	Until agreed upon commercial batches and reference standard batch has been tested and Celgene plan of assay ownership is fully developed (target December 2023, but no later than March 31, 2024)
Support to enable EGT as a plasmid supplier to BMS and to ensure adequate plasmid/cell bank supply to meet RESL production requirements	Until agreed inventory is successfully transferred to Celgene and Celgene has obtained reliable plasmid supplier (target December 2023, but no later than March 31, 2024)
Ad hoc advisory support for custom critical reagent sourcing	Ad hoc support, but no later than March 31, 2024)
Provision of regulatory support activities as may be needed to ensure regulatory approval	Ongoing

**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: August 14, 2023

/s/ Nick Leschly

Nick Leschly  
Chief Executive Officer  
(Principal Executive Officer)

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

I, Chip Baird, certify that:

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

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

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

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

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

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

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

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

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

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



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

Dated: August 14, 2023

/s/ Chip Baird

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

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

In connection with the quarterly report on Form 10-Q of 2seventy bio, Inc. (the “Company”) for the quarter ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to his knowledge, that:

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

Dated: August 14, 2023    /s/ Nick Leschly

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

Dated: August 14, 2023    /s/ Chip Baird

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