

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): December 1, 2021**

**2seventy bio, Inc.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-40791**  
(Commission File Number)

**86-3658454**  
(IRS Employer  
Identification No.)

**60 Binney Street,  
Cambridge, MA**  
(Address of principal executive offices)

**02142**  
(Zip Code)

**Registrant's telephone number, including area code: (339) 499-9300**

**Not Applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

**Item 2.02 Results of Operations and Financial Condition.**

On December 1, 2021, 2seventy bio, Inc. announced its financial results for the three months ended September 30, 2021 and other business highlights. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press release issued by 2seventy bio, Inc. on December 1, 2021.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and incorporated as Exhibit 101)

## SIGNATURES

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

Date: December 1, 2021

2seventy bio, Inc.

By: /s/ Chip Baird  
*Chip Baird*  
*Chief Financial Officer*

**2seventy bio Reports Third Quarter Financial Results and Recent Operational Progress**

– SC-DARIC33 IND accepted by FDA; Phase 1 study now enrolling

**CAMBRIDGE, Mass.**— (BUSINESS WIRE)—December 1, 2021—[2seventy bio, Inc.](#) (Nasdaq: TSVT), an emerging immunology company, today reported financial results and recent highlights for the third quarter ended September 30, 2021.

“We launched 2seventy bio a few short weeks ago and I’m highly encouraged by the way our team has taken this challenge head on,” said Nick Leschly, chief kairios officer. “Our urgency to bring transformative cell therapies forward is driven by the ultimate goal, which is to provide more time to patients and their families devastated by cancer. We have hit the ground running, with the first IND acceptance for our program in AML, and another anticipated in the bNHL program by the end of the year. Exciting times are ahead, and we are fired up for 2022 as ABECMA continues to deliver for MM patients and our product engine drives more disruptive next-gen cell therapies forward in both liquid and solid tumors.”

**RECENT HIGHLIGHTS**

- **COMPANY LAUNCH** – On November 4, 2021, 2seventy bio launched as an independent, publicly traded company with a robust cell therapy pipeline across a range of hematologic and solid tumors including the SC-DARIC33 and bbT369 candidates that are planned, subject to IND acceptance, to enter the clinic by the first half of 2022. 2seventy bio’s portfolio also includes a development and 50/50 U.S. commercialization partnership with Bristol Myers Squibb (BMS) for ABECMA, a first-in-class B-cell maturation antigen (BCMA)-directed CAR T cell immunotherapy, in relapsed or refractory multiple myeloma.
- **SC-DARIC33 IND** – Today, 2seventy bio is announcing that the FDA has accepted the IND for SC-DARIC33, an investigational, pharmacologically controlled CD33-targeted autologous T cell product, developed in collaboration with Seattle Children’s Therapeutics for the potential treatment of acute myeloid leukemia (AML). PLAT-08, the Phase 1 study of SC-DARIC33 in relapsed/refractory pediatric AML, led by Seattle Children’s Therapeutics, is now open and enrolling patients (NCT: 05105152). This study is a first-in-human investigation of the DARIC T cell platform.
- **ASH PRESENTATIONS** – On November 4, 2021, 2seventy bio announced that it will present data from its portfolio of oncology cell therapies at the 63rd American Society of Hematology (ASH) Annual Meeting. These presentations include new pre-clinical data on SC-DARIC33, and in partnership with BMS, updated results from the ongoing Phase 1 CRB-402 study of the BCMA-targeted CAR T cell therapy bb21217 in patients with relapsed and refractory multiple myeloma (RRMM). In addition, a range of analyses will be presented from the pivotal KarMMa trial of ide-cel, in partnership with BMS.

**UPCOMING ANTICIPATED MILESTONES**

- Acceptance of investigational new drug (IND) application for bbT369 in bNHL by the end of 2021.
- Presentation of new preclinical data from the SC-DARIC33 program at the 63rd ASH Annual Meeting in December 2021.
- Presentation of clinical data from the ongoing CRB-402 study of bb21217 at the 63rd ASH Annual Meeting in December 2021.

**SELECT THIRD QUARTER AND YEAR-TO-DATE 2021 FINANCIAL RESULTS**

- The results for the period ended September 30, 2021, have been prepared on a carve-out basis and are derived from bluebird bio, Inc.’s consolidated financial statements and accounting records. Upon separation on November 4, 2021, bluebird bio made a contribution to 2seventy bio of approximately \$441.5 million in cash and cash equivalents, which is expected to be sufficient to fund current planned operations for at least the next twelve months.



- **Revenues:** Total revenues were \$19.3 million for the three months ended September 30, 2021 compared to \$18.4 million for the three months ended September 30, 2020. Total revenues were \$38.5 million for the nine months ended September 30, 2021 compared to \$238.2 million for the nine months ended September 30, 2020. The increase for the three-month period was primarily driven by revenue recognized under our collaboration arrangement with BMS. The decrease in the nine-month period was primarily driven by revenue recorded in connection with the May 2020 BMS contract modification in the second quarter of 2020.
- **ABECMA Revenue:** BMS reported total U.S. revenues of \$67 million for ABECMA (idecabtagene vicleucel; ide-cel) in the third quarter of 2021. 2seventy bio reported net collaboration revenue of \$12.3 million for the third quarter of 2021, which includes our share of revenue and costs associated with the commercialization of ABECMA in the U.S.
- **R&D Expenses:** Research and development expenses were \$61.1 million for the three months ended September 30, 2021 compared to \$72.3 million for the three months ended September 30, 2020. Research and development expenses were \$202.4 million for the nine months ended September 30, 2021 compared to \$227.6 million for the nine months ended September 30, 2020. The decrease for the three-month period was primarily driven by decreased R&D costs under our collaboration with BMS and decreased manufacturing expenses. The decrease for the nine-month period was primarily driven by decreased manufacturing expenses.
- **SG&A Expenses:** Selling, general and administrative expenses were \$23.0 million for the three months ended September 30, 2021 compared to \$22.1 million for the three months ended September 30, 2020. Selling, general and administrative expenses were \$69.0 million for the nine months ended September 30, 2021 and September 30, 2020. The increase for the three-month period was primarily driven by an increase in employee compensation, benefit, and other headcount related expenses.
- **Net Loss:** Net loss was \$60.0 million for the three months ended September 30, 2021 compared to \$72.1 million for the three months ended September 30, 2020. Net loss was \$231.2 million for the nine months ended September 30, 2021 compared to \$43.3 million for the nine months ended September 30, 2020.

### **About 2seventy bio**

Our name, 2seventy bio, reflects why we do what we do - TIME. Cancer rips time away and our goal is to work at the maximum speed of translating human thought into action – 270 miles per hour—to give the people we serve more time. We are building the leading immuno-oncology cell therapy company, focused on discovering and developing new therapies that truly disrupt the cancer treatment landscape. With a deep understanding of the human body's immune response to tumor cells and how to translate cell therapies into practice, we're applying this knowledge to deliver next generation cellular therapies that focus on a broad range of hematologic malignancies, including the first FDA-approved CAR T cell therapy for multiple myeloma, as well as solid tumors. Our research and development is focused on delivering therapies that are designed with the goal to "think" smarter and faster than the disease. Importantly, we remain focused on accomplishing these goals by staying genuine and authentic to our "why" and keeping our people and culture top of mind every day.

For more information, visit [www.2seventybio.com](http://www.2seventybio.com).

Follow 2seventy bio on social media: [Twitter](#) and [LinkedIn](#).

2seventy bio is a trademark of 2seventy bio, Inc.

### **Cautionary Note Regarding Forward-Looking Statements**

*This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to: statements about our plans, strategies, timelines and expectations with respect to the development, manufacture or sale of our product candidates, including the design and results of pre-clinical and clinical studies and timelines for the initiation and enrollment of clinical trials or the results of ongoing and planned clinical trials for our product candidates and for Abecma (ide-cel) in additional indications; statements about our expectations for the submission of an IND for bbT369 in bNHL, including the timing thereof; statements about the efficacy and perceived therapeutic benefits of our product candidates and the potential indications and*



*market opportunities therefor; statements about the strategic plans for 2seventy bio and potential corporate development opportunities; and statements about our ability to operate as a stand-alone company and execute our strategic priorities. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, the risk that we may not achieve the expected benefits of the separation; the risk that the separation could harm our business, results of operations and financial condition; our lack of independent operating history and the risk that its accounting and other management systems may not be prepared to meet the financial reporting and other requirements of operating as an independent public company; the risk that we may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as an independent company; the risk that dedicated financial and/or strategic funding sources may not be available on favorable terms or at all; the risk that the separation may adversely impact our ability to attract or retain key personnel; the risk that the separation may adversely impact the effectiveness of development and commercialization efforts by us and our partners; the risk of possible disruption to our business as a result of the separation; the risk that our BLAs and INDs will not be accepted for filing by the FDA on the timeline that we expect, or at all; the risk that our plans with respect to the preclinical and clinical development and regulatory approval of our product candidates may not be successfully achieved on the planned timeline, or at all; the risk that ABECMA will not be as commercially successful as we may anticipate; and the risk that we are unable to manage our operating expenses or cash use for operations. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the information statement contained in our Registration Statement on Form 10, as supplemented and/or modified by our most recent Quarterly Report on Form 10-Q and any other filings that we have made or will make with the Securities and Exchange Commission in the future. All information in this press release is as of the date of the release, and 2seventy bio undertakes no duty to update this information unless required by law.*

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**2seventy bio, Inc.**  
**Condensed Combined Statements of Operations and Comprehensive Loss**  
**(unaudited)**  
**(in thousands)**

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