

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

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

**Date of Report (Date of earliest event reported): November 7, 2022**

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**2seventy bio, Inc.**

(Exact name of Registrant as Specified in Its Charter)

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**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)

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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

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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.

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

On November 7, 2022, 2seventy bio, Inc. announced its financial results for the three months ended September 30, 2022 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.

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 November 7, 2022.</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.

Dated: November 7, 2022

**2seventy bio, Inc.**

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



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

*Strategic partnership with JW Therapeutics to accelerate development of cell therapies targeted to solid tumors*

*Abecma generated \$75M U.S. commercial revenue in 3Q; continues to track toward upper end of \$250-\$300M revenue guidance for 2022*

*Ended quarter with \$324.5M cash, cash equivalents, and marketable securities; continues to anticipate 2022 net cash spend to \$245-265M; maintaining cash runway into 2025*

**CAMBRIDGE, Mass.**— (BUSINESS WIRE)—November 7, 2022—2seventy bio, Inc. (Nasdaq: TSVT), a leading immuno-oncology cell therapy company, today reported financial results and recent highlights for the third quarter ended September 30, 2022.

“In our first year of operations, 2seventy bio has made tremendous progress in our mission of delivering more time to patients with cancer,” said Nick Leschly, chief kairo officer. “*Abecma* has exceeded our expectations and is gaining momentum with potential to become a multi-billion dollar product. We now have hundreds of patients treated in the commercial setting and importantly we continue to see consistent efficacy and safety results between our clinical trials and our real-world data. We are excited to share our plans to initiate the KarMMA-9 study in newly diagnosed patients, in partnership with BMS. In addition, we have made important progress towards establishing a highly differentiated pipeline and sustainable product engine: our DARIC-33 and bbT369 studies in AML and B-NHL, respectively, are enrolling patients and our solid tumor programs with Regeneron are fast approaching the starting line with our MUC-16 CAR program. More broadly, we have made great progress on building translational throughput capacity with our internal drug product manufacturing facility nearing completion and we expect our strategic collaboration with JW Therapeutics to accelerate solid tumor development starting with putting our MAGE-A4 program into the clinic. Taken together, we believe we are on track to establishing a unique end to end cell therapy product engine, exploring four clinical-stage assets by 2024 and continuing to expand *Abecma* into earlier lines. As we wrap up 2022, we look forward to presenting important *Abecma* data at ASH and more broadly on our pipeline in 2023.”

### RECENT PIPELINE HIGHLIGHTS

- **STRATEGIC PARTNERSHIP WITH JW THERAPEUTICS** – Last month, 2seventy bio and JW Therapeutics announced a strategic alliance 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 2seventy bio’s MAGE-A4 t cell receptor (TCR) program in solid tumors which is being developed as part of a collaboration with Regeneron. Under the terms of the agreement, 2seventy bio will grant JW Therapeutics a license for the MAGE-A4 cell therapy in the Chinese mainland, Hong Kong (China), and Macao (China). JW Therapeutics will be responsible for development, manufacturing, and commercialization within China. 2seventy bio is eligible to receive milestones and royalties on product revenues in China.

- **ADDITIONAL PROGRESS** - 2seventy bio's clinical studies of DARIC-33 in acute myeloid leukemia (AML) and bbT369 in B cell non-Hodgkin lymphoma (B-NHL) are open and enrolling. We plan to share clinical data from these programs in the future. The company continues to execute pre-investigational new drug (IND) work to support a MUC-16 IND in 2023.

### **Abecma Commercial Summary**

Our partner, Bristol Myers Squibb (BMS) reported total U.S. *Abecma* (idecabtagene vicleucel; ide-cel) third quarter revenues of \$75 million. Based on strong commercial demand for *Abecma*, we remain on track to achieve the upper end of our stated 2022 U.S. *Abecma* revenue guidance of \$250-300 million. Given the continued strong demand for *Abecma* and our growing belief in its potential to play an important role in earlier lines of therapy, we plan to initiate the KarMMa-9 study in partnership with BMS in patients with newly diagnosed multiple myeloma who have a suboptimal response to transplant and we are continuing to advance our manufacturing strategy to expand capacity across the supply chain.

We reported collaborative arrangement revenue of \$4.1 million for the third quarter, which includes our share of gross profit/loss less costs associated with the commercialization of *Abecma* in the U.S. Vector and drug product supply remains on track to meet our commercial plan for 2022 and we are continuing to invest in increasing manufacturing capacity in the future.

### **ABECMA HIGHLIGHTS**

- **KARMMA-2 DATA AT ASH** – Earlier this month, 2seventy bio announced that data from two cohorts of the KarMMa-2 study of *Abecma* (idecabtagene vicleucel), conducted in partnership with BMS, in patients who have suboptimal response to transplant or early relapse will be presented at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition. Data from KarMMa-2 Cohorts 2a and 2c suggest the potential for early treatment with *Abecma* in patients with second-line and newly diagnosed multiple myeloma, and that promising outcomes can be achieved treating patients with suboptimal response after transplant. These results support further evaluation of *Abecma* in patients with newly diagnosed multiple myeloma in the KarMMa-9 study.
- **KARMMA-9 STUDY IN NEWLY-DIAGNOSED MULTIPLE MYELOMA** – In September, 2seventy bio announced plans to initiate the KarMMa-9 study, in partnership with BMS, to evaluate *Abecma* in newly diagnosed multiple myeloma patients who have suboptimal response to transplant. The company intends to provide additional information about the design and timing of the study at the earliest upcoming opportunity

### **SELECT THIRD QUARTER 2022 FINANCIAL RESULTS**

- Our partner, BMS, reported total U.S. revenues of \$75 million for *Abecma* for the three months ended September 30, 2022. 2seventy bio and BMS share equally in all profits and losses related to development, manufacture and commercialization of *Abecma* in the U.S. We reported collaborative arrangement revenue of \$4.1 million for the three months ended September 30, 2022. For the first and second quarters of 2022, we reported a share of collaboration loss of \$5.4 million and \$4.3 million, respectively.
- Total 2seventy bio revenues were \$13.4 million for the three months ended September 30, 2022 compared to \$19.3 million for the three months ended September 30, 2021. Total revenues were \$35.3 million for the nine months ended September 30, 2022 compared to \$38.5 million for the nine months ended September 30, 2021. The decrease for the three-month period was

primarily driven by a decrease in *Abecma* collaborative arrangement revenue and the decrease for the nine-month period was largely attributable to a decrease in ide-cel ex-U.S. service revenue and royalty and other revenue.

- Research and development expenses were \$61.7 million for the three months ended September 30, 2022 compared to \$61.1 million for the three months ended September 30, 2021. Research and development expenses were \$199.4 million for the nine months ended September 30, 2022, compared to \$202.4 million for the nine months ended September 30, 2021. The slight increase for the three-month period was primarily driven by increases in IT and other facility-related costs and collaboration research funding costs, partially offset by decreased license and milestone fees. The decrease for the nine-month period was primarily driven by decreased collaboration research funding costs due to a decrease in our share of research and development costs under our collaboration with BMS, partially offset by an increase in IT and other facility-related costs.
- Selling, general and administrative expenses were \$19.6 million for the three months ended September 30, 2022, compared to \$23.0 million for the three months ended September 30, 2021. Selling, general and administrative expenses were \$60.7 million for the nine months ended September 30, 2022, compared to \$69.0 million for the nine months ended September 30, 2021. The decrease for both the three- and nine-month periods was primarily driven by decreased employee compensation expenses, reflective of efforts to streamline 2seventy bio's operating model and a decrease in IT and other facility-related costs.
- Net loss was \$67.9 million for the three months ended September 30, 2022, compared to \$60.0 million for the three months ended September 30, 2021. Net loss was \$231.0 million for the nine months ended September 30, 2022, compared to \$231.2 million for the nine months ended September 30, 2021.
- 2seventy bio ended the third quarter of 2022 with cash, cash equivalents and marketable securities of \$324.5 million.

### **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 applicable laws and regulations. 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 results and expected timing of ongoing and planned clinical trials for our product candidates and for ABECMA (ide-cel) in additional indications and in earlier line settings; statements about our plans, strategies, timelines and expectations with respect to regulatory approval and related filings for our product candidates; statements regarding our plans to continue to advance our manufacturing strategy to expand capacity for ABECMA across the supply chain; statements regarding expected benefits from our strategic collaboration with JW Therapeutics; statements regarding our projected timing for disclosing data from our ongoing clinical trials; statements about the efficacy and perceived therapeutic benefits of our product candidates and the potential indications, market opportunities and demand therefor; statements about the strategic plans for 2seventy bio and potential corporate development opportunities including collaboration arrangements; statements regarding the company’s financial condition, expenses, results of operations, expectations regarding use of capital, cash runway and other future financial results; and statements about our ability to 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, our limited independent operating history and the risk that our 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 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 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 our annual report on Form 10-K for the year ended December 31, 2021, 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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#### **Investors:**

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#### **Media:**

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

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



2seventy bio, Inc.

Condensed Consolidated Balance Sheet Data  
(unaudited)  
(in thousands)

	As of September 30, 2022	As of December 31, 2021
Cash, cash equivalents and marketable securities	\$ 324,517	\$ 362,181
Total assets	708,744	759,675
Total liabilities	385,564	399,853
Total stockholders' equity	323,180	359,822