

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): November 14, 2023

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, par value \$0.0001 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 November 14, 2023, 2seventy bio, Inc. announced its financial results for the three months ended September 30, 2023 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

Exhibit No.	Description
99.1	Press release issued by 2seventy bio, Inc. on November 14, 2023.
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 14, 2023

2seventy bio, Inc.

By:

/s/ Chip Baird

Chip Baird

Chief Operating Officer

(Principal Financial and Accounting Officer)



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

Abecma (idecabtagene vicleucel) data to be presented at ASH 2023; multiple new analyses of KarMMA-3 and KarMMA-2c add to growing body of data supporting the potential safety and efficacy of Abecma in earlier lines of treatment

Abecma generated \$69 million U.S. commercial revenue in the third quarter of 2023; \$302 million U.S. commercial revenue year-to-date

Two solid tumor programs positioned to enter clinical trials in 2024

Ended quarter with \$284.3 million cash, cash equivalents, and marketable securities

Conference call today at 8:00 AM ET

CAMBRIDGE, Mass.— (BUSINESS WIRE)—November 14, 2023—[2seventy bio, Inc.](https://www.2seventybio.com) (Nasdaq: TSVT), a leading immuno-oncology cell therapy company, today reported financial results and recent highlights for the third quarter ended September 30, 2023.

“This quarter, 2seventy completed a significant reshaping of our organization, enabling us to advance our pipeline in an efficient and more cost-effective manner. We are also supporting BMS’ efforts to return *Abecma* to growth through a variety of commercial and medical affairs initiatives, including adding more treatment sites and boots on the ground,” said Nick Leschly, chief kairos officer. “Collectively, we believe these measures will give us the ability to continue our mission of delivering time to patients, operate within a more disciplined cost structure and deliver value for our shareholders.”

SELECT COMMERCIAL AND FINANCIAL HIGHLIGHTS

- Third quarter *Abecma* U.S. revenues, as reported by Bristol Myers Squibb (BMS), were \$69 million. The decline in third quarter sales was due to increased competition from other BCMA-targeted therapies in addition to the planned manufacturing maintenance in June. The Company anticipates that competitive dynamics will continue to impact *Abecma* sales in the fourth quarter. Based on year-to-date results and current expectations for the fourth quarter, 2seventy does not expect to achieve the original revenue guidance of \$470-570 million for 2023.
- In order to restore growth in *Abecma*, BMS and 2seventy are focused on rapidly expanding the treating site footprint, competitively differentiating *Abecma*’s real-world data and safety profile, and educating on treatment sequencing and the emerging data supporting the use of *Abecma* before T cell engagers and antibody drug conjugates, including those targeting BCMA.
- 2seventy bio and BMS share equally in all profits and losses related to development, manufacturing, and commercialization of *Abecma* in the United States. 2seventy bio reported collaborative arrangement revenue of \$0.5 million and \$48.0 million for the three months and nine months ended September 30, 2023, respectively.
- In September, the Company announced a restructuring of its business operations and research and development model to significantly reduce costs while supporting the execution of a prioritized plan for the long-term growth of the Company. This restructuring is expected to achieve \$130+ million savings in 2024-2025 period.
- The Company anticipates staying within the previously-guided net cash spend range of \$180-220 million for 2023.
- The Company ended the third quarter of 2023 with cash, cash equivalents and marketable securities of \$284.3 million. While the Company has sufficient cash to fund current planned operations for at least 12 months, we are no longer providing specific cash runway guidance.

“While *Abecma* performance was impacted due to the evolving competitive landscape, we and our partners at BMS believe in the long-term potential of *Abecma* to meaningfully impact the lives of multiple myeloma patients. We support BMS’ efforts to improve the commercial performance for the

product,” said Chip Baird, chief operating officer. “As we gain more visibility to the commercial trajectory for Abecma, we will continue to carefully manage our cash to preserve our financial runway.”

SELECTED ABECMA DATA TO BE PRESENTED AT ASH

Oral Presentation: Idecabtagene Vicleucel (ide-cel) Versus Standard Regimens in Patients (pts) with Triple-Class Exposed (TCE) Relapsed and Refractory Multiple Myeloma (RRMM): Updated Analysis from KarMMa-3

Presenter: Paula Rodriguez-Otero

Date & Time: Monday, December 11, 4:45pm PT

In the final progression-free survival (PFS) analysis from the Phase 3 KarMMa-3 study in patients with RRMM who received 2-4 prior regimens, significantly longer PFS was maintained with ide-cel versus standard regimens. In pts who received ide-cel (n = 225) or a standard regimen (n = 126), median PFS (95% CI) was 15.7 (12.5–18.9) vs 4.4 (3.4–5.8) months, respectively. The ide-cel safety profile was consistent with previous reports, with no parkinsonism or Guillain-Barré syndrome reported. Ide-cel continued to demonstrate durable, clinically meaningful improvements in pt-reported outcomes, including symptoms, functioning, and quality of life (QOL) vs standard regimens. Interim overall survival (OS) will be included in the presentation.

Poster Presentation: Efficacy and Safety of Idecabtagene Vicleucel (ide-cel) in Patients with Clinical High-Risk Newly Diagnosed Multiple Myeloma (MM) with an Inadequate Response to Frontline Autologous Stem Cell Transplantation (ASCT): KarMMa-2 Cohort 2c Extended Follow-up

Presenters: Madhav Dhodapkar; Melissa Alsina

Date & Time: Saturday, December 9, 5:30 – 7:30 PM

In updated data from the KarMMa-2 cohort 2c study, ide-cel continued to demonstrate deep, durable responses in patients with an inadequate response to frontline ASCT. No new safety signals were observed with extended follow-up, and no deaths were reported. No patients who received lenalidomide maintenance post ide-cel experienced disease progression.

“The updated clinical data to be presented on *Abecma* reinforces the potential of this therapy to play an important role in earlier lines,” said Steve Bernstein, chief medical officer. “In the extended follow-up from the KarMMa-3 study, we saw responses from some patients continue to deepen. The additional data from the KarMMa-2, cohort 2c study is supportive of our registrational KarMMa-9 study in a similar patient population which is now open and enrolling. We look forward to presenting these data at ASH along with additional sub-analyses that reinforce the impact of *Abecma* on patient-reported outcomes, quality of life and clinical use.”

RECENT UPDATES

- **MUC16 DATA PRESENTED AT SITC** – In November, 2seventy presented new pre-clinical data on its MUC16-targeted CAR T-cell therapy in ovarian cancer, being developed as part of our expanded collaboration with Regeneron, in a poster presentation at the 38th Annual Meeting of the Society for Immunotherapy of Cancer (SITC). These preclinical data support the IND submission for MUC16, which is on track for end of year. The Company recently completed 270-MPH, an in-house clinical drug product manufacturing site, to more effectively support growing U.S. clinical needs. MUC16 will be the first program to be manufactured in this facility.
- **EXPANSION OF PARTNERSHIP WITH JW THERAPEUTICS** – In September, 2seventy and JW Therapeutics announced their intention to expand their strategic alliance. The expansion, based on the partnership that was established last year, builds upon the companies’ translational and clinical cell therapy development platform originally designed to more rapidly explore T cell-based immunotherapy therapy products in Greater China. Specifically, the companies intend to add up to two additional candidates from the 2seventy portfolio, one in solid tumor indications using T-cell receptor (TCR) based technology and a second in autoimmune disease using a CAR T cell approach.

UPCOMING ANTICIPATED PIPELINE MILESTONES



- Submission of an Investigational New Drug (IND) application for MUC-16 program in ovarian cancer, being developed in partnership with Regeneron, anticipated by end of 2023.
- Led by JW Therapeutics, initiation of an investigator-initiated study in China of 2seventy bio's potency enhanced MAGE-A4 T cell receptor (TCR) program in solid tumors anticipated by end of 2023.

SELECT THIRD QUARTER FINANCIAL RESULTS

- Total 2seventy bio revenues were \$12.0 million for the three months ended September 30, 2023, compared to \$13.4 million for the three months ended September 30, 2022. Total revenues were \$89.7 million for the nine months ended September 30, 2023, compared to \$35.3 million for the nine months ended September 30, 2022.
- Research and development expenses were \$51.3 million for the three months ended September 30, 2023, compared to \$58.2 million for the three months ended September 30, 2022. Research and development expenses were \$179.5 million for the nine months ended September 30, 2023, compared to \$188.6 million for the nine months ended September 30, 2022.
- Selling, general and administrative expenses were \$13.0 million for the three months ended September 30, 2023, compared to \$19.6 million for the three months ended September 30, 2022. Selling, general and administrative expenses were \$53.2 million for the nine months ended September 30, 2023, compared to \$60.7 million for the nine months ended September 30, 2022.
- Net loss was \$71.6 million for the three months ended September 30, 2023, compared to \$67.9 million for the three months ended September 30, 2022. Net loss was \$160.7 million for the nine months ended September 30, 2023, compared to \$231.0 million for the nine months ended September 30, 2022.

Conference Call Information

2seventy bio will host a conference call and live webcast today, November 14, at 8:00 a.m. ET to discuss 3Q 2023 financial results and recent business highlights. To join the live conference call, please register at:

<https://register.vevent.com/register/Bia4096e5acd24407e8d1e2a5e32ba2e14>. Upon registering, each participant will be provided with call details and access codes. The live webcast may be accessed by visiting the event link at: <https://edge.media-server.com/mmc/p/ovopwzwn>. A replay of the webcast may be accessed from the "News and Events" page in the Investors and Media section of the Company's website at <https://ir.2seventybio.com/> and will be available for 30 days following the event.

ABECMA U.S. INDICATION

ABECMA (idecabtagene vicleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, AND PROLONGED CYTOPENIA

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with ABECMA. Do not administer ABECMA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- Neurologic Toxicities, which may be severe or life-threatening, occurred following treatment with ABECMA, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with ABECMA. Provide supportive care and/or corticosteroids as needed.
- Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS) including fatal and life-threatening reactions, occurred in patients following treatment with ABECMA. HLH/MAS can occur with CRS or neurologic toxicities.
- Prolonged Cytopenia with bleeding and infection, including fatal outcomes following stem cell transplantation for hematopoietic recovery, occurred following treatment with ABECMA.

- ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.

Warnings and Precautions:

Cytokine Release Syndrome (CRS): CRS, including fatal or life-threatening reactions, occurred following treatment with ABECMA in 85% (108/127) of patients. Grade 3 or higher CRS occurred in 9% (12/127) of patients, with Grade 5 CRS reported in one (0.8%) patient. The median time to onset of CRS, any grade, was 1 day (range: 1 – 23 days) and the median duration of CRS was 7 days (range: 1 – 63 days). The most common manifestations included pyrexia, hypotension, tachycardia, chills, hypoxia, fatigue, and headache. Grade 3 or higher events that may be associated with CRS include hypotension, hypoxia, hyperbilirubinemia, hypofibrinogenemia, acute respiratory distress syndrome (ARDS), atrial fibrillation, hepatocellular injury, metabolic acidosis, pulmonary edema, multiple organ dysfunction syndrome, and HLH/MAS.

Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. CRS has been reported to be associated with findings of HLH/MAS, and the physiology of the syndromes may overlap. In patients with progressive symptoms of CRS or refractory CRS despite treatment, evaluate for evidence of HLH/MAS.

Fifty four percent (68/127) of patients received tocilizumab (single dose: 35%; more than 1 dose: 18%). Overall, 15% (19/127) of patients received at least 1 dose of corticosteroids for treatment of CRS. All patients that received corticosteroids for CRS received tocilizumab.

Ensure that a minimum of 2 doses of tocilizumab are available prior to infusion of ABECMA.

Monitor patients at least daily for 7 days following ABECMA infusion at the REMS-certified healthcare facility for signs or symptoms of CRS and monitor patients for signs or symptoms of CRS for at least 4 weeks after ABECMA infusion. At the first sign of CRS, institute treatment with supportive care, tocilizumab and/or corticosteroids as indicated.

Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.

Neurologic Toxicities: Neurologic toxicities, which may be severe or life-threatening, occurred following treatment with ABECMA in 28% (36/127) of patients receiving ABECMA, including Grade 3 in 4% (5/127) of patients. One patient had ongoing Grade 2 neurotoxicity at the time of death. Two patients had ongoing Grade 1 tremor at the time of data cutoff. The median time to onset of neurotoxicity was 2 days (range: 1 – 42 days). CAR T cell-associated neurotoxicity resolved in 92% (33/36) of patients with a median time to resolution of 5 days (range: 1 – 61 days). The median duration of neurotoxicity was 6 days (range: 1 – 578) in all patients including 3 patients with ongoing neurotoxicity. Thirty-four patients with neurotoxicity had CRS with onset in 3 patients before, 29 patients during, and 2 patients after CRS. The most frequently reported manifestations of CAR T cell-associated neurotoxicity include encephalopathy, tremor, aphasia, and delirium. Grade 4 neurotoxicity and cerebral edema in 1 patient, Grade 3 myelitis, and Grade 3 parkinsonism have been reported with ABECMA in another study in multiple myeloma.

Monitor patients at least daily for 7 days following ABECMA infusion at the REMS-certified healthcare facility for signs or symptoms of neurologic toxicities and monitor patients for signs or symptoms of neurologic toxicities for at least 4 weeks after ABECMA infusion and treat promptly. Rule out other causes of neurologic symptoms. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed.

Counsel patients to seek immediate medical attention should signs or symptoms occur at any time.

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS): HLH/MAS occurred in 4% (5/127) of patients receiving ABECMA. One patient developed fatal multi-organ HLH/MAS with CRS and another patient developed fatal bronchopulmonary aspergillosis with contributory HLH/MAS. Three cases of Grade 2 HLH/MAS resolved. All events of HLH/MAS had onset within 10 days

of receiving ABECMA with a median onset of 7 days (range: 4 - 9 days) and occurred in the setting of ongoing or worsening CRS. Two patients with HLH/MAS had overlapping neurotoxicity. The manifestations of HLH/MAS include hypotension, hypoxia, multiple organ - dysfunction, renal dysfunction, and cytopenia. HLH/MAS is a potentially life-threatening condition with a high mortality rate if not recognized early and treated. Treatment of HLH/MAS should be administered per institutional guidelines.

ABECMA REMS: Due to the risk of CRS and neurologic toxicities, ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS. Further information is available at www.AbecmaREMS.com or 1-888-423-5436.

Hypersensitivity Reactions: Allergic reactions may occur with the infusion of ABECMA. Serious hypersensitivity reactions, including anaphylaxis, may be due to dimethyl sulfoxide (DMSO) in ABECMA.

Infections: ABECMA should not be administered to patients with active infections or inflammatory disorders. Severe, life-threatening, or fatal infections occurred in patients after ABECMA infusion. Infections (all grades) occurred in 70% of patients. Grade 3 or 4 infections occurred in 23% of patients. Overall, 4 patients had Grade 5 infections (3%); 2 patients (1.6%) had Grade 5 events of pneumonia, 1 patient (0.8%) had Grade 5 bronchopulmonary aspergillosis, and 1 patient (0.8%) had cytomegalovirus (CMV) pneumonia associated with *Pneumocystis jirovecii*. Monitor patients for signs and symptoms of infection before and after ABECMA infusion and treat appropriately. Administer prophylactic, pre-emptive, and/or therapeutic antimicrobials according to standard institutional guidelines.

Febrile neutropenia was observed in 16% (20/127) of patients after ABECMA infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care.

Viral Reactivation: CMV infection resulting in pneumonia and death has occurred following ABECMA administration. Monitor and treat for CMV reactivation in accordance with clinical guidelines. Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients treated with drugs directed against plasma cells. Perform screening for CMV, HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines before collection of cells for manufacturing.

Prolonged Cytopenias: In the clinical study, 41% of patients (52/127) experienced prolonged Grade 3 or 4 neutropenia and 49% (62/127) experienced prolonged Grade 3 or 4 thrombocytopenia that had not resolved by Month 1 following ABECMA infusion. In 83% (43/52) of patients who recovered from Grade 3 or 4 neutropenia after Month 1, the median time to recovery from ABECMA infusion was 1.9 months. In 65% (40/62) of patients who recovered from Grade 3 or 4 thrombocytopenia, the median time to recovery was 2.1 months.

Three patients underwent stem cell therapy for hematopoietic reconstitution due to prolonged cytopenia. Two of the three patients died from complications of prolonged cytopenia. Monitor blood counts prior to and after ABECMA infusion. Manage cytopenia with myeloid growth factor and blood product transfusion support.

Hypogammaglobulinemia: Hypogammaglobulinemia was reported as an adverse event in 21% (27/127) of patients; laboratory IgG levels fell below 500 mg/dl after infusion in 25% (32/127) of patients treated with ABECMA.

Monitor immunoglobulin levels after treatment with ABECMA and administer IVIG for IgG <400 mg/dl. Manage appropriately per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

The safety of immunization with live viral vaccines during or after ABECMA treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of



lymphodepleting chemotherapy, during ABECMA treatment, and until immune recovery following treatment with ABECMA.

Secondary Malignancies: Patients treated with ABECMA may develop secondary malignancies. Monitor life-long for secondary malignancies. If a secondary malignancy occurs, contact Bristol-Myers Squibb at 1-888-805-4555 to obtain instructions on patient samples to collect for testing of secondary malignancy of T cell origin.

Effects on Ability to Drive and Operate Machinery: Due to the potential for neurologic events, patients receiving ABECMA are at risk for altered or decreased consciousness or coordination in the 8 weeks following ABECMA infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

Adverse Reactions: The most common nonlaboratory adverse reactions include CRS, infections – pathogen unspecified, fatigue, musculoskeletal pain, hypogammaglobulinemia, diarrhea, upper respiratory tract infection, nausea, viral infections, encephalopathy, edema, pyrexia, cough, headache, and decreased appetite.

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide.

About Bristol Myers Squibb and 2seventy bio

Abecma is being jointly developed and commercialized in the U.S. as part of a Co-Development, Co-Promotion, and Profit Share Agreement between Bristol Myers Squibb and 2seventy bio. Bristol Myers Squibb assumes sole responsibility for *Abecma* drug product manufacturing and commercialization outside of the U.S. The companies' broad clinical development program for *Abecma* includes ongoing and planned clinical studies (KarMMA-2, KarMMA-3, KarMMA-9) in earlier lines of treatment for patients with multiple myeloma. For more information visit clinicaltrials.gov.

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 immunology 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.

Follow 2seventy bio on social media: [X \(Twitter\)](#) 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 concerning our expected revenues and net cash spend for 2023; statements about our financial position and cash runway; statements about the expected cash savings resulting from the recent restructuring of our business operations and research and development model; 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, including the expected MUC-16 IND filing and initiation of an investigator-initiated study of our MAGE-A4 TCR program; statements regarding our plans to continue to advance our manufacturing strategy to expand capacity and increase manufacturing efficiency for ABECMA across the supply chain and our plans to increase the number of ABECMA treating sites; statements regarding expected benefits from our strategic collaboration; statements about the efficacy and perceived therapeutic benefits of our product candidates and the potential indications; 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, 2022 and our quarterly report on Form 10-Q for the quarter ended September 30, 2023, 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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2seventy bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2023	2022	2023	2022
Revenue:				
Service revenue	\$ 4,948	\$ 4,642	\$ 20,796	\$ 14,363
Collaborative arrangement revenue	5,859	7,903	64,265	18,425
Royalty and other revenue	1,227	863	4,642	2,531
Total revenues	12,034	13,408	89,703	35,319
Operating expenses:				
Research and development	51,315	58,155	179,541	188,591
Cost of manufacturing for commercial collaboration	4,408	3,584	11,672	10,832
Selling, general and administrative	13,004	19,610	53,213	60,749
Share of collaboration loss	-	-	-	9,642
Restructuring expenses	8,614	-	8,614	-
Cost of royalty and other revenue	551	377	2,099	1,252
Change in fair value of contingent consideration	54	50	180	181
Goodwill impairment charge	12,056	-	12,056	-
Total operating expenses	90,002	81,776	267,375	271,247
Loss from operations	(77,968)	(68,368)	(177,672)	(235,928)
Interest income, net	3,626	1,113	8,765	1,441
Other income (expense), net	2,704	(624)	8,159	3,477
Loss before income taxes	(71,638)	(67,879)	(160,748)	(231,010)
Income tax (expense) benefit	-	-	-	-
Net loss	\$ (71,638)	\$ (67,879)	\$ (160,748)	\$ (231,010)
Net loss per share - basic and diluted	\$ (1.40)	\$ (1.76)	\$ (3.31)	\$ (6.67)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	51,179	38,573	48,566	34,612



2seventy bio, Inc.

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

	As of September 30, 2023	As of December 31, 2022
Cash, cash equivalents and marketable securities	\$ 284,278	\$ 267,684
Total assets	640,806	656,665
Total liabilities	334,384	346,199
Total stockholders' equity	306,422	310,466