

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): September 8, 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 X

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. O

Item 2.05 Costs Associated with Exit or Disposal Activities.

On September 12, 2023, 2seventy bio, Inc. (the “Company”) announced a strategic restructuring, including plans to reduce its workforce by approximately 40%. The Company expects this workforce reduction and restructuring will preserve its cash runway into 2026 and will be substantially completed by the fourth quarter of 2023.

In connection with this workforce reduction and restructuring, the Company expects to incur one-time costs of approximately \$9 million, primarily in the third quarter of 2023, relating to severance and retention packages and related benefits. The estimates of expenses and cash costs that the Company expects to incur, and the timing thereof, are subject to a number of assumptions and actual results may differ. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the actions described above.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On September 11, 2023, Nick Leschly, the Company’s president and chief executive officer, notified the Company’s board of directors of his intent to resign as president and chief executive officer upon the Board’s identification of his successor.

On September 10, 2023, the board of directors of the Company appointed William D. Baird, III as the chief operating officer of the Company. Mr. Baird will continue to serve as the Company’s principal financial officer and principal accounting officer. Mr. Baird, 52, has served as the Company’s chief financial officer since 2021. Previously, Mr. Baird served as chief financial officer of bluebird bio, Inc. from February 2019 until November 2021 and served as chief financial officer of Amicus Therapeutics, Inc. from April 2012 until February 2019. Mr. Baird has served on the board of directors of Axcella Health Inc. since June 2018.

There are no (i) family relationships, as defined in Item 401 of Regulation S-K, between Mr. Baird and any of the Company’s executive officers or directors, or any person nominated to become a director or executive officer, (ii) arrangements or understandings between Mr. Baird and any other person pursuant to which Mr. Baird was appointed as chief operating officer, or (iii) transactions in which Mr. Baird has an interest requiring disclosure under Item 404(a) of Regulation S-K.

Item 7.01 Regulation FD Disclosure.

On September 12, 2023, the Company issued a press release related to the strategic restructuring. The full text of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by 2seventy bio, Inc. on September 12, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and incorporated as Exhibit 101)

Cautionary Statement Concerning Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including the Company’s expectations regarding the timing and results of the Company’s restructuring and workforce reduction; the estimated charges and costs expected to be incurred therewith; and expectation that the restructuring and workforce reduction will preserve its cash runway into 2026. The use of words such as “anticipate,” “believe,” “continue,” “could,” “endeavor,”

“estimate,” “expect,” “anticipate,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will” or “would” or the negative of such words or other similar expressions can be used to identify forward-looking statements. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. These and other risks and uncertainties are described in additional detail in the section entitled “Risk Factors” in the Company’s Annual Report on Form 10-K filed March 16, 2023, its Quarterly Report on Form 10-Q filed on May 10, 2023, and its other filings made with the SEC from time to time. Although the Company’s forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by the Company. As a result, you are cautioned not to rely on these forward-looking statements. Any forward-looking statement made in this Current Report on Form 8-K speaks only as of the date on which it is made. Except as required by applicable law, the Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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: September 12, 2023

2seventy bio, Inc.

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



2seventy bio Announces Strategic Restructuring to Prioritize Growth of Abecma, Streamline Pipeline Advancement and Preserve Financial Runway

Approximately 40% workforce reduction combined with related actions expected to achieve \$130+ million savings in the 2024-2025 period; projected cash runway into at least 2026 to support focus on long-term mission

Company to internally advance fewer pipeline programs while expanding collaboration with JW Therapeutics to include new solid tumor and autoimmune programs; Company to gate at-risk investment in bbT369 (NHL) and SC-DARIC33 (AML) programs pending further clinical data readouts

CEO Nick Leschly announces plans to step down as CEO and transition to Chairman of Board of Directors; CEO search process has been initiated; CFO Chip Baird promoted to Chief Operating Officer

Conference call today at 8:00 AM ET

CAMBRIDGE, Mass. — (BUSINESS WIRE) — September 12, 2023 — [2seventy bio, Inc.](https://www.2seventybio.com) (Nasdaq: TSVT), today 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.

“2seventy’s mission remains the same: to unleash the power of the T-cell and develop un-incremental treatments for people living with cancer,” said Nick Leschly, chief kairos officer. “However, the macro environment for oncology cell therapy companies and the near-term headwinds we have seen in our own business have led us to examine how we pursue our mission. Today we are taking hard but necessary steps to streamline our team and optimize our R&D approach and cost structure. In this process, we have focused on how to move efficiently and more cost effectively to develop innovative therapies for patients and create value for shareholders. Unfortunately, we will be saying goodbye to many highly talented and committed members of our team. I want to thank each of them for their amazing dedication to 2seventy and our mission to help those in need, doing everything we can to deliver more TIME.”

“The difficult but necessary changes we are making to our workforce, our programs and our cost structure reflect our commitment to advancing our pipeline and achieving value creating milestones with existing cash,” said Chip Baird, chief operating officer. “Our U.S. Abecma collaboration provides a source of revenue to offset investment in our pipeline programs, and while we continue to be optimistic about Abecma’s future, particularly given the potential third-line label expansion at the end of the year, we are planning conservatively. We expect today’s changes will preserve runway into at least 2026, and we will continue to focus on careful expense management and thoughtful capital allocation while staying true to our mission of driving programs forward for patients in need. I echo Nick’s gratitude to the members of our team who will be departing 2seventy and look forward to continuing to uphold 2seventy’s unwavering focus on patients as we move into a new chapter.”

Business Updates, Restructure Actions and Financial Impacts

- Elimination of 176 roles, representing approximately 40% of our workforce
- Expected annualized cost savings of at least \$65 million, or approximately \$130 million in the 2024-2025 period; additional savings possible as we continue rigorous efforts to right-size facilities and related external spend by 2025 to better reflect our current needs.
- One-time restructuring costs of approximately \$9 million, primarily incurred in the third quarter of 2023.
- Implemented a capital-efficient translational development paradigm blending internal manufacturing (270-MPH), our expanded JW Therapeutics collaboration as well as select academic centers to efficiently explore our innovative cell therapies in the clinic

- Current balance of cash, cash equivalents, and marketable securities expected to support operations into 2026

Abecma and Pipeline Portfolio Updates

- **Abecma “Return to Growth:”**
 - **Revenue and impact to 2seventy:** Based on an anticipated decline in *Abecma* sales in the third quarter, we believe full-year 2023 U.S. revenue for *Abecma* could be lower than the \$470-\$570 million range previously projected. 2seventy continues to expect *Abecma* to remain profitable this year and contribute significantly toward our cash runway into at least 2026 and remains confident in *Abecma*’s long-term commercial potential.
 - **Upcoming Milestones:** The December 16, 2023 PDUFA date for potential label expansion based on the KarMMa-3 data in adult patients with triple-class exposed relapsed or refractory multiple myeloma and the planned initiation of the KarMMa-9 study in patients with newly diagnosed multiple myeloma with sub-optimal response post-ASCT later this year provide both short- and medium-term grounds for continued optimism in the commercial potential of *Abecma*.
- **Updates on bbT369 and SC-DARIC-33 Programs**
 - **Phase I CRC-403 study of bbT369** in patients with relapsed and/or refractory B cell non-Hodgkin lymphoma (B-NHL) (wholly-owned)

Clinical Data Update: Today, 2seventy is disclosing that the safety profile, CAR expansion kinetics, including the potential role of the CBL-B gene edit, and the clinical efficacy data, including complete responses in some patients observed to date is supportive of the Company’s decision to continue the Phase I study.

Future Development: While interest and enrollment at clinical study sites has been strong and initial data are encouraging, the Phase I dose escalation study of bbT369 has progressed slower than anticipated, due in part to the FDA mandated safety stagger and the often-aggressive nature of relapsed and/or refractory B-NHL, which can result in patients becoming ineligible for treatment. Despite these challenges, the study is actively enrolling at the third dose level. Given the anticipated pace of accrual and treatment, the Company expects to present the first data from the bbT369 study at a medical meeting in 2024.

Consistent with the rest of the pipeline, the Company has markedly streamlined the cost structure for this program, gating further investment beyond Phase I on the achievement of transformational efficacy.
 - **PLAT-08 clinical study of SC-DARIC-33** in acute myeloid leukemia (AML) and next generation AML program (wholly-owned)

The Company is working with the FDA to enable restart of the Phase 1 study, which is currently on clinical hold. 2seventy plans to limit financial commitment to the current Phase I trial.

The Company will provide the next update on the PLAT-08 study upon completion of the Phase I dose escalation.
- **Partnered pipeline continues to develop and expand – two new programs approaching the clinic at year end**
 - **MUC-16 program in ovarian cancer (Regeneron partnership)**

IND submission is on track and anticipated by the end of 2023
 - **MAGE-A4 T cell receptor (TCR) program in solid tumors (led by JW Therapeutics)**



Led by JW Therapeutics, initiation of an investigator-initiated study in China is ahead of schedule and anticipated by end of 2023.

o **JW Therapeutics Partnership Expansion**

As announced in a separate press release [today](#), 2seventy bio and JW Therapeutics are planning to expand their collaboration to include an additional solid tumor program and the first-in-human assessment of 2seventy's proprietary autoimmune-directed CAR T cell product.

Leadership Transitions

Nick Leschly has informed the Company's Board of Directors that he intends to step down as CEO upon the Board's identification of his successor. The Company expects that Mr. Leschly will be appointed Chairman of the Board upon this transition. The Board has retained an executive recruitment firm to assist with the search for Mr. Leschly's successor as CEO.

"After nearly 14 years as CEO of bluebird and 2seventy I feel beyond grateful and humbled to have had the opportunity to help bring four cell therapies to patients and do our part to advance the field," said Nick Leschly, chief kairos officer. "I very much look forward to continuing to work closely with the board and leadership team to advance 2seventy's mission for patients."

Additionally, Chip Baird, formerly Chief Financial Officer, is now Chief Operating Officer expanding his responsibilities to include finance, corporate development, investor relations and corporate communications as well as portfolio and program/alliance management.

Conference Call Information

2seventy bio will host a conference call and live webcast today, September 12, at 8:00 a.m. ET to discuss today's announcement. To join the live conference call, please register at: <https://register.vevent.com/register/B1c10c340a7f244db5a5fc17394a8f3552>. 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/rd7agmkn>. 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.

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](#).

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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) timelines and expectations with respect to regulatory approval and related filings for our product candidates; statements regarding expected ABECMA U.S. revenue; statements regarding expected benefits from our strategic collaborations; 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; statements about the strategic plans for 2seventy bio and potential corporate development opportunities including collaboration arrangements; the implementation, timing and results of our strategic restructuring efforts; the estimated charges and costs expected to be incurred in connection with such restructuring efforts and the projected cost savings resulting from such restructuring efforts; the anticipated resignation of our CEO and the Company’s expectation regarding his appointment as Chairman; 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, 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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