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

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Abecma *(idecabtagene vicleucel) generated $118 million U.S. commercial revenue in 1Q 2023, supporting upper end of U.S. revenue guidance of $470-570 million*

U.S. FDA accepted supplemental Biologics License Application (sBLA) based on results from the pivotal phase 3 KarMMa-3 study of Abecma; *PDUFA date December 16, 2023*

Collaboration with Novo Nordisk delivers proof of concept data for in-vivo *gene editing hemophilia A program; triggers $15 million milestone payment from Novo Nordisk*

Ended quarter with $341.4 million cash, cash equivalents, and marketable securities; maintaining cash runway into 2026

Company to host virtual Research and Development Deep Dive session on May 19, 2023

Conference call today at 4:30 PM ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 3, 2023-- 2seventy bio, Inc. (Nasdaq: TSVT), a leading immuno-oncology cell therapy Company, today reported financial results and recent highlights for the first quarter ended March 31, 2023.

"We are off to a strong start in 2023, with a sharp focus on timely execution across our commercial business, clinical programs, and research pipeline," said Nick Leschly, chief kairos officer, 2seventy bio. "*Abecma* revenue remains on a strong growth trajectory as we continue to successfully execute with BMS on manufacturing scale-ups to deliver *Abecma* to myeloma patients. The successful steps taken to date to increase vector and drug product manufacturing support the achievement of the upper end of our U.S. revenue guidance range. With the recent FDA acceptance of our *Abecma* sBLA based on our KarMMa-3 study, we look forward to the opportunity to offer this transformational product to patients in earlier lines of treatment and, if approved, will enable us to serve thousands of additional patients in the U.S. We have made significant progress across our pipeline, and we plan to share initial clinical data from our SC-DARIC33 program for acute myeloid leukemia at the ASGCT Annual Meeting. We also look forward to providing a more in-depth look into both *Abecma* and our pipeline programs, including promising pre-clinical data in our *in-vivo* gene editing hemophilia A program, at our upcoming R&D Deep Dive. We believe 2023 will be a transformative year for 2seventy as we continue in our mission to deliver more time for patients living with cancer."

SELECT COMMERCIAL AND FINANCIAL HIGHLIGHTS

- First quarter *Abecma* U.S. revenues, as reported by Bristol Myers Squibb (BMS), were $118 million, representing 26% growth over the prior quarter and 111% growth over the same quarter last year. Based on strong first quarter performance, the Company believes *Abecma* will achieve the upper end of U.S. revenue guidance of $470-570 million.
- 2seventy bio and BMS share equally in all profits and losses related to development, manufacturing, and commercialization of *Abecma* in the U.S. 2seventy reported collaborative arrangement revenue of $23.0 million for the three months ended March 31, 2023, and share of collaboration loss of $5.4 million for the three months ended March 31, 2022.
- *Abecma* was cash-flow positive in the first quarter and the Company expects the *Abecma* collaboration to be cash flow positive throughout 2023 and to generate between $200 and $300 million of operating income for 2seventy bio during the 2024-2025 period, based on management's current operating plans.
- The Company believes *Abecma* has potential peak U.S. revenues of $2 to 3 billion.
- 2seventy bio successfully completed an equity financing in the first quarter, raising approximately $117 million in net proceeds.
- The Company ended the first quarter of 2023 with cash, cash equivalents and marketable securities of $341.4 million. 2seventy bio believes that this cash position, combined with growing *Abecma* cashflow and disciplined expense management, provides financial runway into 2026 and potentially beyond.

***Abecma* Manufacturing Progress**

- During the first quarter, the Food and Drug Administration (FDA) approved a second adherent vector manufacturing suite, which will further increase vector capacity.
- The FDA approved the Company's plan for establishing comparability between adherent lentiviral vector and suspension-based lentiviral vector (sLVV) manufacturing processes. BMS and 2seventy continue to accelerate the introduction of sLVV manufacturing processes and we expect commercial introduction of sLVV in the first half of 2024.
- BMS recently entered into an agreement for a manufacturing facility to produce viral vectors which is in line with our dual sourcing strategy, leveraging external partners as well as internalizing vector. BMS expects the Libertyville, Illinois site to be contributing by 2025. The combination of this new facility coupled with progress toward transitioning to suspension vector supports bringing more products to patients.
- A successful step-up in drug product manufacturing capacity was completed in the first quarter and additional ramp-ups are planned for later this year.

Abecma Clinical and Regulatory Highlights

- The FDA has accepted BMS and 2seventy bio's supplemental Biologics License Application (sBLA) for *Abecma* in adult patients with triple-class exposed relapsed or refractory multiple myeloma. The FDA assigned a Prescription Drug User Fee Act (PDUFA) goal date of December 16, 2023.
- The sBLA was based on interim results from the KarMMa-3 study evaluating *Abecma* compared with standard combination regimens. The KarMMa-3 study population represents heavily pretreated triple-class exposed patients with high unmet need in their 3rd to 5th line of therapy.
- In this difficult-to-treat population, *Abecma* delivered a 51% risk reduction and clinical benefit compared to the standard of care arm.
- Data from KarMMa-3 were published in *The New England Journal of Medicine* in February 2023.
- Initiation of KarMMa-9 study in patients with newly-diagnosed multiple myeloma is anticipated later this year.

NOVO NORDISK COLLABORATION

- The joint 2seventy bio and Novo Nordisk collaborative research program focused on an *in vivo* gene editing treatment for hemophilia A achieved positive proof of concept data triggering a $15 million milestone payment to 2seventy bio from Novo Nordisk.
- This program represents a natural extension of the Company's gene editing capabilities which are also being applied to its oncology programs, including the bbT369 clinical program for non-Hodgkin lymphoma.
- Proof of concept data to be disclosed during the Company's R&D Deep Dive on May 19, 2023.

ASGCT ABSTRACTS ACCEPTED

- The American Society of Gene & Cell Therapies (ASGCT) released the abstract titles for its 2023 Annual Meeting which will include new data from 2seventy bio's portfolio of preclinical and clinical programs:
    - **Late-Breaking Oral Presentation [#3092]:** First in human studies show activation of SC-DARIC33, a rapamycin-regulated anti-CD33 CAR T cell therapy, in patients with AML
    - **Oral Presentation [#148]:** Enhanced anti-AML potency of DARIC33 by iSynPro-IL-15*: an IL-15 expression module driven by a tightly regulated synthetic promoter activated by

antigen receptor signaling
    - **Poster Presentation [#585]:** bbT369, a clinical-stage dual-targeted and CBLB gene edited autologous CAR T product for non-Hodgkin Lymphoma, shows edit driven enhanced activity in preclinical in vitro and in vivo models
    - **Poster Presentation [#612]:** A novel TGFb switch receptor drives robust MAGE-A4 TCR anti-tumor activity with a favorable safety profile
    - **Poster Presentation [#608]:** RESET: a novel TCR coupled antigen receptor displaying superior targeting sensitivity and pharmacologically controlled anti-tumor activity

UPCOMING ANTICIPATED PIPELINE MILESTONES

- Data update from Phase I CRC-403 study of bbT369 in patients with relapsed and/or refractory B cell non-Hodgkin lymphoma (B-NHL) anticipated by the end of 2023
- Data update from Phase I PLAT-08 study of SC-DARIC33 in patients with acute myeloid leukemia anticipated by the end of 2023
- 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 FIRST QUARTER FINANCIAL RESULTS

- Total 2seventy bio revenues were $41.6 million for the three months ended March 31, 2023, compared to $8.4 million for the three months ended March 31, 2022. The increase for the three-month period was primarily driven by an increase in collaborative arrangement revenue recognized under our collaboration with BMS, as discussed in further detail above.
- Research and development expenses were $68.2 million for the three months ended March 31, 2023, compared to $65.9 million for the three months ended March 31, 2022.
- Selling, general and administrative expenses were $20.7 million for the three months ended March 31, 2023, compared to $23.9 million for the three months ended March 31, 2022. The decrease for the three-month period reflects cost containment measures across overhead and business functions.
- Net loss was $47.0 million for the three months ended March 31, 2023, compared to $85.7 million for the three months ended March 31, 2022.

RESEARCH & DEVELOPMENT (R&D) DEEP DIVE
2seventy bio will host a virtual R&D Deep Dive on Friday, May 19, from 10:00 a.m. – 11:30 a.m. ET to highlight the Company's R&D pipeline, including updates following the 2023 ASGCT Annual Meeting, as well as an *Abecma* commercial update and additional details from the hemophilia A program. Registration and access to the live webcast may be found by visiting the "Events and Presentations" page in the Investors and Media section of the Company's website at https://ir.2seventybio.com/. A replay will be archived on the 2seventy bio website for 30 days following the event.

Conference Call Information
2seventy bio will host a conference call and live webcast today, May 3, at 4:30 p.m. ET to discuss 1Q 2023 financial results and recent business highlights. To join the live conference call, please register at: https://register.vevent.com/register/BI458c3098c2a64310b49e967327a906e7. 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/8migsv6v. 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 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.

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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) 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; 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; 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.

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

	For the three months ended March 31,	
	2023	**2022**
Revenue:		
Service revenue	$ 10,826	$ 4,055
Collaborative arrangement revenue	29,372	3,487
Royalty and other revenue	1,423	887
Total revenues	41,621	8,429
Operating expenses:		
Research and development	68,246	65,879
Cost of manufacturing for commercial collaboration	3,654	3,366
Selling, general and administrative	20,720	23,861
Share of collaboration loss	-	5,352
Cost of royalty and other revenue	641	511
Change in fair value of contingent consideration	73	48
Total operating expenses	93,334	99,017
Loss from operations	(51,713)	(90,588)
Interest income, net	2,049	115
Other income, net	2,643	4,762
Loss before income taxes	(47,021)	(85,711)
Income tax (expense) benefit	-	-
Net loss	$ (47,021)	$ (85,711)
Net loss per share - basic and diluted	$ (1.08)	$ (3.20)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	43,468	26,751

2seventy bio, Inc.
Condensed Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	As of March 31, 2023	As of December 31, 2022
Cash, cash equivalents and marketable securities	$ 341,362	$ 267,684
Total assets	742,437	656,665
Total liabilities	341,113	346,199
Total stockholders' equity	401,324	310,466

View source version on businesswire.com: https://www.businesswire.com/news/home/20230503005950/en/

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