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

August 14, 2023 11:00 AM EDT

Abecma *(idecabtagene vicleucel) generated $115 million U.S. commercial revenue in 2Q 2023, supporting lower end of U.S. revenue guidance of $470-570 million*

2seventy bio provides update on PLAT-08 study in AML with partner Seattle Children's

Ended quarter with $307 million cash, cash equivalents, and marketable securities; maintaining cash runway into 2026

Conference call today at 8:00 AM ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 14, 2023-- 2seventy bio, Inc. (Nasdaq: TSVT), a leading immuno-oncology cell therapy company, today reported financial results and recent highlights for the second quarter ended June 30, 2023.

"We launched 2seventy in late 2021 with the stated mission of delivering more time for people living with cancer through the transformative power of cell therapy," said Nick Leschly, chief kairos officer. Since the creation of 2seventy, our mission has always been dual-pronged: to deliver on the commercial potential of *Abecma* and to leverage our translational engine to develop an innovative cell therapy pipeline. Over the course of this year, we continue to make progress against this goal. We have successfully delivered *Abecma* to an extensive and growing number of patients in need of new treatment options. While the competitive intensity has increased and will have an impact on revenue in the 2nd half of 2023, we believe in the long-term commercial potential of this important therapy, particularly as we move toward earlier lines. On the development side, in June, we paused our PLAT-08 study in AML due to a Grade 5 safety event and this has since been followed by a clinical hold by FDA. We've collaborated with Seattle Children's to conduct a root-cause analysis and developed amendments to the protocol. Seattle Children's will review these amendments with FDA with the goal of resuming the study as soon as possible."

SELECT COMMERCIAL AND FINANCIAL HIGHLIGHTS

- Second quarter *Abecma* U.S. revenues, as reported by Bristol Myers Squibb (BMS), were $115 million. Based on BMS reporting an expected decline in *Abecma* sales in the third quarter, the Company believes *Abecma* will achieve the lower 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 bio reported collaborative arrangement revenue of $24.5 million and $47.5 million for the three months and six months ended June 30, 2023, respectively.
- 2seventy bio believes *Abecma* has potential peak U.S. revenues of $2 to 3 billion.
- The Company ended the second quarter of 2023 with cash, cash equivalents and marketable securities of $307 million. 2seventy bio believes that this cash position, combined with growing *Abecma* cashflow and disciplined expense management, provides financial runway into 2026.

"With the revenue from our *Abecma* collaboration and careful expense management, we significantly reduced our net loss to $42.1 million in the second quarter from $77.4 million for the same period last year," said Chip Baird, chief financial officer. "We are committed to advancing toward breakeven operations for the business while prudently investing in innovation."

***ABECMA* CLINICAL, REGULATORY, AND MANUFACTURING UPDATE**

- 2seventy bio, in collaboration with BMS, continues to build on established manufacturing capacity of *Abecma* with an additional ramp-up planned for later this year.
- The collaboration remains on track for introduction of suspension-based lentiviral vector (sLVV) in 1st half 2024.
- Manufacturing performance metrics remain strong, with greater than 90% in spec rates and an average turnaround time of ~29 days.
- The planned maintenance shutdown of the S12 drug product manufacturing plant was successfully completed in June and the facility is fully operational.

- In addition to increasing manufacturing capacity, commercial efforts are underway to expand the U.S. treatment center footprint.
- We continue to anticipate the December 16 PDUFA goal date for potential label expansion based on the KarMMa-3 data.
- The Company, with BMS, is planning to initiate the KarMMa-9 study in patients with newly diagnosed multiple myeloma later this year.

UPDATE ON PLAT-08 CLINICAL STUDY OF SC-DARIC-33 IN ACUTE MYELOID LEUKEMIA (AML)

In June, the Company announced that because of a fatal (Grade 5) serious adverse event (SAE) in a patient enrolled in the Phase 1 trial of the PLAT-08 study of SC-DARIC33 in AML, the study met protocol-defined pausing rules, pending review of the event by the appropriate regulatory and monitoring boards. On Friday, August 11, 2023, the U.S. Food and Drug Administration (FDA) formally placed the study on clinical hold via email communication. Since the study pause in June, 2seventy bio and Seattle Children's have been conducting an internal investigation and root cause analysis of the SAE. This investigation provided insights into the potential pathobiology of this toxicity which led to several study protocol changes, which the team believes may mitigate this toxicity and allow for the continuation of the PLAT-08 study. 2seventy bio and Seattle Children's will continue to work with FDA to provide the root cause analysis and proposed changes for the clinical study. Based on upcoming discussions with FDA, 2seventy bio and Seattle Children's plan to amend the study accordingly and resume this study as soon as possible.

RECENT DATA HIGHLIGHTS

- ***Abecma* Data at ASCO and EHA:** The Company presented four abstracts at the American Society of Clinical Oncology (ASCO) Annual Meeting and six abstracts at the European Hematology Association (EHA) Congress. The presentations highlighted clinical and correlative data from the KarMMa-2 and KarMMa-3 clinical trials evaluating *Abecma* in patients with relapsed and/or refractory multiple myeloma (RRMM) or newly diagnosed multiple myeloma, reinforcing *Abecma*'s strong clinical profile. Additional data on patient-reported outcomes from the KarMMa-3 trial were also presented. Results showed that patients with triple-class exposed RRMM treated with *Abecma* demonstrated statistically significant and clinically meaningful improvements in health-related quality of life, including key multiple myeloma symptoms and overall functions compared to standard regimens.
- **New Preclinical and Clinical Data at ASGCT:** 2seventy bio presented five abstracts, including one late-breaking oral presentation, at this year's American Society of Gene & Cell Therapy (ASGCT) Annual Meeting.

UPCOMING ANTICIPATED PIPELINE MILESTONES

- 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.
- 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 SECOND QUARTER FINANCIAL RESULTS

- Total 2seventy bio revenues were $36.0 million for the three months ended June 30, 2023, compared to $13.5 million for the three months ended June 30, 2022. Total revenues were $77.7 million for the six months ended June 30, 2023, compared to $21.9 million for the six months ended June 30, 2022.
- Research and development expenses were $60.0 million for the three months ended June 30, 2023, compared to $64.6 million for the three months ended June 30, 2022. Research and development expenses were $128.2 million for the six months ended June 30, 2023, compared to $130.4 million for the six months ended June 30, 2022.
- Selling, general and administrative expenses were $19.5 million for the three months ended June 30, 2023, compared to $17.3 million for the three months ended June 30, 2022. Selling,

general and administrative expenses were $40.2 million for the six months ended June 30, 2023, compared to $41.1 million for the six months ended June 30, 2022.

- Net loss was $42.1 million for the three months ended June 30, 2023, compared to $77.4 million for the three months ended June 30, 2022. Net loss was $89.1 million for the six months ended June 30, 2023, compared to $163.1 million for the six months ended June 30, 2022.

Conference Call Information

2seventy bio will host a conference call and live webcast today, August 14, at 8:00 a.m. ET to discuss 2Q 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.

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 expected ABECMA U.S. revenue and our plans to continue to advance our manufacturing strategy to expand capacity and increase manufacturing efficiency 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 Grade 5 SAE in the PLAT-08 study, resulting trial pause and hold, our and our partner Seattle Children's planned discussions with the FDA regarding the hold and root cause analysis, and the ability of our partner Seattle Children's to resume this study; 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 Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except per share data)

	For the three months ended June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
Revenue:				
Service revenue	$ 5,022	$ 5,666	$ 15,848	$ 9,721
Collaborative arrangement revenue	29,034	7,035	58,406	10,522

Royalty and other revenue	1,992	781	3,415	1,668
Total revenues	36,048	13,482	77,669	21,911
Operating expenses:				
Research and development	59,980	64,557	128,226	130,436
Cost of manufacturing for commercial collaboration	3,610	3,882	7,264	7,248
Selling, general and administrative	19,489	17,278	40,209	41,139
Share of collaboration loss	-	4,290	-	9,642
Cost of royalty and other revenue	907	364	1,548	875
Change in fair value of contingent consideration	53	83	126	131
Total operating expenses	84,039	90,454	177,373	189,471
Loss from operations	(47,991)	(76,972)	(99,704)	(167,560)
Interest income, net	3,090	213	5,139	328
Other income (expense), net	2,812	(661)	5,455	4,101
Loss before income taxes	(42,089)	(77,420)	(89,110)	(163,131)
Income tax (expense) benefit	-	-	-	-
Net loss	$ (42,089)	$ (77,420)	$ (89,110)	$ (163,131)
Net loss per share - basic and diluted	$ (0.83)	$ (2.02)	$ (1.89)	$ (5.00)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	50,966	38,381	47,238	32,598

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

	As of June 30, 2023	As of December 31, 2022
Cash, cash equivalents and marketable securities	$ 306,546	$ 267,684
Total assets	705,713	656,665
Total liabilities	338,218	346,199
Total stockholders' equity	367,495	310,466

View source version on businesswire.com: https://www.businesswire.com/news/home/20230814766402/en/

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