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

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First patients enrolled in clinical studies in bNHL and AML

ABECMA generated $56M U.S. commercial revenue in 1Q; continues to track toward upper end of $250-$300M U.S. ABECMA revenue guidance for 2022

Ended quarter with $452.5M cash, cash equivalents, and marketable securities; anticipated cash runway into 2025

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 12, 2022-- 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, 2022.

“2seventy bio has started 2022 in a strong position, and we’ve already begun to execute on some key clinical milestones,” said Nick Leschly, chief kairos officer. “This quarter, we enrolled the first patients in clinical studies of SC-DARIC33 and bbT369. We look forward to continuing to enroll patients in these studies and providing an update at the appropriate time. In addition, we continue to focus on other foundational elements of 2seventy bio: growth of ABECMA and a sound financial position. Despite a challenging external environment, I’m pleased with the steady progress on both fronts with continued demand for ABECMA as well securing additional capital in March that we anticipate will provide cash runway into 2025. We’re proud of the momentum we’ve established as a team at 2seventy bio because we know that every day matters as we focus on delivering more time to patients with cancer and their families.”

COMMERCIAL PROGRESS
Bristol Myers Squibb reported total U.S. ABECMA (idecabtagene vicleucel; ide-cel) first quarter revenues of $56 million, consistent with our 2022 plan. 2seventy bio and Bristol Myers Squibb share equally in all profits and losses related to developing, manufacturing and commercializing ABECMA in the U.S. In 2022, 2seventy anticipates total U.S. ABECMA revenues of $250-$300 million and we are continuing to track to the high end of the range bolstered by continued high demand for a proven treatment and increasing manufacturing capacity.

Demand for ABECMA is expected to continue to fully utilize the expanding manufacturing capacity throughout 2022 and 2023.

RECENT HIGHLIGHTS

- **SC-DARIC33 FIRST PATIENT ENROLLED** – Last quarter, the first patient with acute myeloid leukemia (AML) was enrolled in PLAT-08, a phase 1 study of SC-DARIC33 led by Seattle Children’s Therapeutics in relapsed or refractory pediatric and young adult AML. This is the first-in-human application of 2seventy bio’s proprietary DARIC T cell platform.
- **BBT369 FIRST PATIENT ENROLLED** – Last quarter, the first patient with B cell non-Hodgkin lymphoma (B-NHL) was enrolled in CRC-403, a phase 1/2 study of bbT369 in patients with relapsed and/or refractory B-NHL. This study serves as a safety and proof-of-concept assessment of 2seventy bio’s proprietary megaTAL™ gene editing platform, dual-targeting strategies and split co-stimulation signaling technology.
- **bbT369 PRECLINICAL DATA AT AACR –** New preclinical data on bbT369 was presented in a poster session (poster #581) at the American Association for Cancer Research (AACR) Annual Meeting 2022 in New Orleans, LA on Sunday, April 10. The data presented at AACR show the anti-lymphoma activity of bbT369 observed to date and suggest that, as intended in the design, bbT369 has the potential to overcome failure modes of anti-CD19 CAR therapies.
- **ASCO ABSTRACTS ACCEPTED**– In April 2022, the American Society of Clinical Oncology (ASCO) released the abstract titles for its 2022 Annual Meeting. 2seventy bio will present updates from its portfolio of oncology cell therapies at the meeting, including a correlative analysis, in partnership with Bristol Myers Squibb, defining patient profiles associated with manufacturing and clinical endpoints in patients treated with ide-cel, and a trial in progress poster on CRB-403, a phase 1/2 study on bbT369.
    - **Poster Discussion [#8021]:** Correlative analysis to define patient profiles associated with manufacturing and clinical endpoints in relapsed/refractory multiple myeloma (RRMM) patients treated with idecabtagene vicleucel (ide-cel; bb2121), an anti-BCMA

CAR T cell therapy.
    - **Presenting Author:** Julie Rytlewski, PhD, Bristol Myers Squibb
    - **Date/Time:** Saturday, June 4, 2022, 5:30 PM – 7:00 PM ET
- **Poster [#TPS7580]:** CRC-403: A phase 1/2 study of bbT369, a dual targeting CAR T-cell drug product with a gene edit, in relapsed and/or refractory B-cell non-Hodgkin lymphoma (NHL).
    - **Presenting Author:** Frederick L. Locke, MD, H. Lee Moffitt Cancer Center & Research Institute
    - **Date/Time:** Saturday, June 4, 2022, 9:00 AM – 12:00 PM ET

UPCOMING ANTICIPATED MILESTONES

ABECMA

- Anticipated $250-300 million total U.S. commercial revenue in 2022; profits and losses shared with Bristol Myers Squibb
- Increasing manufacturing capacity expected over 2022 and 2023
- KarMMa-2 study in high-risk multiple myeloma proof-of-concept data in 2022
- KarMMa-3 study in 3L+ registrational data in 2023 with potential FDA approval in 2023-2024

Pipeline

- Initial assessment of feasibility of bbT369 drug product manufacturing and patient safety in 2H 2022
- Initial assessment of feasibility of SC-DARIC33 drug product manufacturing and drug regulated anti-CD33 activity in 2H 2022

SELECT FIRST QUARTER 2022 FINANCIAL RESULTS

- Bristol Myers Squibb reported total U.S. revenues of $56 million for ABECMA for the three months ended March 31, 2022. 2seventy bio and Bristol Myers Squibb share equally in all profits and losses related to development, manufacturing and commercializing ABECMA in the U.S. We reported share of collaboration loss of $5.4 million for the three months ended March 31, 2022, which includes our share of gross profit/loss less costs associated with the commercialization of ABECMA in the U.S. The collaboration reported a loss this quarter due to continued investment in manufacturing scale-up and commercialization.
- Total revenues were $8.4 million for the three months ended March 31, 2022, compared to $11.9 million for the three months ended March 31, 2021. The decrease for the three-month period was primarily driven by a decrease in royalty and other revenue as a result of the termination of the Company's license agreement with Novartis in March 2021.
- Research and development expenses were $69.2 million for the three months ended March 31, 2022, compared to $77.6 million for the three months ended March 31, 2021. The decrease for the period was primarily driven by decreased collaboration research costs, which represent the Company's share of research and development costs under the collaboration with Bristol Myers Squibb.
- Selling, general and administrative expenses were $23.9 million for the three months ended March 31, 2022, compared to $24.6 million for the three months ended March 31, 2021. The slight decrease was primarily driven by a decrease in employee compensation expense. In 2021, the Company recorded higher stock-based compensation and bonus expense related to a retention plan that was enacted during the separation of 2seventy bio from bluebird bio. The retention plan was completed at the end of 2021.
- Net loss was $85.7 million for the three months March 31, 2022, compared to $87.2 million for

the three months ended March 31, 2021.

- 2seventy bio ended the first quarter of 2022 with cash, cash equivalents and marketable securities of $452.5 million, including net proceeds from our March 2021 private placement of $165.7 million, after deducting placement agent fees and other offering expenses payable by the Company.

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 the Private Securities Litigation Reform Act of 1995. 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; 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; statements regarding the company's financial condition, expenses, results of operations, expectations regarding use of capital, 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.

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

	For the three months ended March 31,	
	2022	**2021**
Revenue:		
Service revenue	$ 4,055	$ 5,918
Collaborative arrangement revenue	3,487	1,519
Royalty and other revenue	887	4,464
Total revenues	8,429	11,901
Operating expenses:		
Research and development	69,245	77,571
Selling, general and administrative	23,861	24,627
Share of collaboration loss	5,352	-
Cost of royalty and other revenue	511	1,704
Change in fair value of contingent consideration	48	369
Total operating expenses	99,017	104,271
Loss from operations	(90,588)	(92,370)
Interest income, net	115	-
Other income, net	4,762	5,174
Loss before income taxes	(85,711)	(87,196)
Income tax (expense) benefit	-	-
Net loss	$ (85,711)	$ (87,196)
Net loss per share - basic and diluted	$ (3.20)	$ (3.73)

Weighted-average number of common shares used in computing net loss per share - basic and diluted	26,751	23,369

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

	As of March 31, 2022	As of December 31, 2021
Cash, cash equivalents and marketable securities	$ 452,549	$ 362,181
Total assets	851,921	759,675
Total liabilities	404,505	399,853
Total stockholders' equity	447,416	359,822

View source version on businesswire.com: https://www.businesswire.com/news/home/20220512006000/en/

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