2seventy bio Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Operational Progress

March 22, 2022 11:00 AM EDT

Closed $170M private placement with leading healthcare investors

ABECMA generated $158M U.S. commercial revenue in 2021; tracking toward upper end of $250-300M U.S. revenue guidance for 2022

Internal cost reduction measures reduce net cash spend guidance to $190-220M for 2022

Cash runway into 2025

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 22, 2022-- 2seventy bio, Inc. (Nasdaq: TSVT), a leading immuno-oncology cell therapy company, today reported financial results and recent highlights for the fourth quarter and year ended December 31, 2021.

“We launched 2seventy bio at the end of 2021 with incredible starting material. We have a transformative commercial product in ABECMA, a pipeline with multiple clinical stage programs, next-generation technologies that will enable us to continue to be at the forefront of cell therapy innovation, and a passionate team that is committed to the cause,” said Nick Leschly, chief kairos officer. “We’ve had a strong start to 2022. We have reshaped our operating model and taken important steps to reduce our overhead costs. We are taking a disciplined approach to our budgets to ensure that we optimize our R&D investment and drive towards value-creating milestones. Together with our partner Bristol Myers Squibb, we have made important progress on unlocking additional ABECMA manufacturing capacity and expect additional increases to capacity in the second half of the year as we continue to deliver for multiple myeloma patients in need of treatment options. And, we have secured additional capital during challenging market conditions from leading life sciences investors in the business. Taken together, we expect that we will have a sufficient financial foundation to execute on our patient mission into 2025. We are fired up and look forward to great things this year and beyond!”

PIPE FINANCING

On March 17, 2022, the company closed a $170 million private placement. The private placement included top healthcare investors, including 683 Capital, Armistice Capital, Bain Capital Life Sciences, Boxer Capital, CaaS Capital, Casdin Capital, Cowen Healthcare Investments, EcoR1 Capital, Heights Capital, Janus Henderson Investors, Madison Avenue Partners, Newtyn Management, Nick Leschly & family, RTW Investments, LP, and existing investors.

COMMERCIAL PROGRESS

Bristol Myers Squibb reported total U.S. ABECMA (idecabtagene vicleucel; ide-cel) fourth quarter revenues of $67 million and full year 2021 U.S. ABECMA revenues of $158 million. 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 tracking to the high end of the range bolstered by a significant patient backlog, continued high demand for a proven treatment and increasing manufacturing capacity.

Given the high unmet medical need and strong patient demand, we believe there is meaningful opportunity for multiple BCMA CAR-T products. Our primary focus for the next one to two years is on increasing our manufacturing capacity in partnership with regulators. The U.S. business will fully utilize the expanding capacity as it becomes available, and we will build on our experience in the commercial setting to deliver ABECMA for multiple myeloma patients in need. We continue to anticipate that ABECMA will be sustainably cash flow positive for 2seventy bio, inclusive of R&D costs, by the end of 2022, and will continue to grow in 2023 and beyond.

UPDATED CASH SPEND GUIDANCE

2seventy bio has taken important steps to reduce overhead costs and streamline our operating model. We expect that these changes, combined with an improved outlook for ABECMA, will enable us to decrease net cash spend for 2022. We are reducing our original net cash spend guidance of $220-250 million down to a lower range of $190-220 million. Together with the proceeds from the recently completed private placement, the company now anticipates that it has sufficient cash to fund current planned operations into 2025. The increased financial runway is expected to bring 2seventy bio through meaningful clinical data updates, new INDs and additional commercial progress.

RECENT HIGHLIGHTS

- **bbT369 PRECLINICAL DATA AT AACR –** Today, 2seventy bio is announcing that preclinical data from bbT369, an investigational dual-targeted CAR T cell therapy with a *CBLB* gene edit for patients with relapsed/refractory B cell non-Hodgkin lymphoma (B-NHL), has been accepted for poster presentation at the American Association of Cancer Research (AACR) Annual Meeting 2022 on Sunday, April 10 in New Orleans, LA. Mike Certo, Ph.D., VP of Genome Editing at 2seventy bio, will present Poster 581, titled “bbT369, a dual-targeted and *CBLB* gene-edited autologous CART product, demonstrates anti-lymphoma activity in preclinical mouse models,” on Sunday, April 10, 1:30-5:30 PM CT. An E-Poster will be

available on the AACR website starting Friday, April 8 at 1:00 PM ET through Wednesday, July 13.

- **MANAGEMENT APPOINTMENTS –** On February 14, 2022, 2seventy bio announced that Steven Bernstein, M.D. joined the company in the role of chief medical officer. Additionally, Susan Abu-Absi, Ph.D. was appointed chief technology & manufacturing officer.

UPCOMING ANTICIPATED MILESTONES

ABECMA

- Anticipated $250-300 million total U.S. commercial revenue in 2022, 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

- Presentation of preclinical data from bbT369 program in B-NHL at AACR Annual Meeting 2022
- Infusion of first patients in CRC-403 study of bbT369 in B-NHL in 2022
- Initial assessment of feasibility of bbT369 drug product manufacturing and patient safety in 2H 2022
- Infusion of first patients in PLAT-08 study of SC-DARIC33 in AML in 2022
- Initial assessment of feasibility of SC-DARIC33 drug product manufacturing and drug regulated anti-CD33 activity in 2H 2022

SELECT FOURTH QUARTER AND FULL YEAR 2021 FINANCIAL RESULTS

- Bristol Myers Squibb reported total U.S. revenues of $67 million and $158 million for ABECMA for the three and twelve months ended December 31, 2021, respectively. 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 collaborative arrangement revenue of $11.4 million and $26.9 million for the three and twelve months ended December 31, 2021, respectively, which includes our share of gross profit less costs associated with the commercialization of ABECMA in the U.S.
- Total revenues were $16.0 million for the three months ended December 31, 2021, compared to $9.9 million for the three months ended December 31, 2020. Total revenues were $54.5 million for the twelve months ended December 31, 2021 compared to $248.1 million for the twelve months ended December 31, 2020. The increase for the three-month period was primarily driven by collaborative arrangement revenue recognized as a result of sales of ABECMA in the fourth quarter of 2021. The decrease for the twelve-month period was driven by one-time revenue recorded in connection with the May 2020 Bristol Myers Squibb contract modification in the second quarter of 2020.
- Research and development expenses were $59.5 million for the three months ended December 31, 2021, compared to $68.9 million for the three months ended December 31, 2020. Research and development expenses were $261.9 million for the twelve months ended December 31, 2021 compared to $296.5 million for the twelve months ended December 31, 2020. The decrease for the three-month period was primarily driven by decreased development costs under our agreement with Bristol Myers Squibb due to a focus on directing manufacturing capacity to commercial ABECMA patients following approval in 2021. The decrease for the twelve-month period was primarily driven by decreased manufacturing expenses as a result of Bristol Myers Squibb’s assumption of the contract manufacturing

agreement relating to ide-cel adherent lentiviral vector as part of the May 2020 Bristol Myers Squibb contract modification and an overall decrease in drug product manufacturing for the CRB-402 study, as the study has come to conclusion.

- Selling, general and administrative expenses were $24.5 million for the three months ended December 31, 2021, compared to $21.9 million for the three months ended December 31, 2020. Selling, general and administrative expenses were $93.5 million for the twelve months ended December 31, 2021 compared to $90.9 million for the twelve months ended December 31, 2020. The increase for both periods was primarily driven by increased commercial costs to support the commercialization of ABECMA and IT and other facility-related costs in connection with the spin-off from bluebird bio.
- Net loss was $61.0 million for the three months ended December 31, 2021, compared to $76.8 million for the year ended December 31, 2020. Net loss was $292.2 million for the twelve months ended December 31, 2021, compared to $120.1 million for the twelve months ended December 31, 2020.
- 2seventy bio ended 2021 with cash, cash equivalents and marketable securities of $362.2 million.

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 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 the information statement contained in our Registration Statement on Form 10, 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 Combined Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands)

	For the three months ended December 31,		For the year ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Service revenue	$ 3,836	$ 4,720	$ 21,381	$ 111,452

Collaborative arrangement revenue	11,394	1,196	26,921	115,594
Royalty and other revenue	803	3,990	6,220	21,076
Total revenues	16,033	9,906	54,522	248,122
Operating expenses:				
Research and development	59,544	68,882	261,937	296,467
Selling, general and administrative	24,480	21,946	93,506	90,897
Share of collaboration loss	-	-	10,071	-
Cost of royalty and other revenue	405	1,499	2,517	5,396
Change in fair value of contingent consideration	(25)	(877)	439	(6,468)
Total operating expenses	84,404	91,450	368,470	386,292
Loss from operations	(68,371)	(81,544)	(313,948)	(138,170)
Interest income, net	88	-	88	-
Other income, net	7,309	4,744	21,647	18,056
Loss before income taxes	(60,974)	(76,800)	(292,213)	(120,114)
Income tax (expense) benefit	-	-	-	-
Net loss	$ (60,974)	$ (76,800)	$(292,213)	$(120,114)
Net loss per share - basic and diluted	$ (2.55)	$ (3.29)	$ (12.44)	$ (5.14)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	23,884	23,369	23,499	23,369

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

	As of December 31, 2021	As of December 31, 2020
Cash, cash equivalents and marketable securities	$ 362,181	$ -
Total assets	759,675	12,620
Total liabilities	399,853	237,991
Total stockholder's equity	359,822	74,629

View source version on businesswire.com: https://www.businesswire.com/news/home/20220322005508/en/

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Source: 2seventy bio, Inc.