2seventy bio Reports Fourth Quarter and Full Year 2022 Financial Results and Recent Operational Progress

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Abecma *(idecabtagene vicleucel) generated $94M U.S. commercial revenue in 4Q 2022, $297M in FY 2022; anticipate $470-$570M U.S. revenue in 2023*

Positive data from Phase 3 KarMMa-3 study published in New England Journal of Medicine

Ended 2022 with $268M cash, cash equivalents, and marketable securities; continue to anticipate 2023 net cash spend of $180-220M

Raised $117M in net proceeds in underwritten follow-on public offering in 1Q 2023 to extend cash runway into 2026

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 16, 2023-- 2seventy bio, Inc. (Nasdaq: TSVT), a leading immuno-oncology cell therapy company, today reported financial results and recent highlights for the fourth quarter and full year ended December 31, 2022.

"In our first full year of operations, 2seventy made tremendous strides across all aspects of our business: from advancing early-stage research, building out manufacturing capabilities, initiating clinical studies, and delivering to patients in the commercial setting with *Abecma*," said Nick Leschly, chief kairos officer. "Bolstered by strong growth in the fourth quarter, we delivered *Abecma* to hundreds of patients with multiple myeloma in the U.S. and expect continued strong growth in 2023. With our partners at BMS, we continue to develop this product into earlier lines of multiple myeloma treatment on the back of positive data from the KarMMa-3 study and the planned KarMMa-9 study and continue to grow our manufacturing capabilities to support a potential peak sales opportunity of $2-3 billion in the U.S. With our recent financing and the growth of *Abecma,* we are in a strong position to continue to prudently advance our clinical and preclinical pipeline, driving towards delivering proof-of-concept data this year for our bbT369 and SC-DARIC33 programs and advancement of MUC and MAGE solid tumor programs to IND by the end of the year. I couldn't be more optimistic for what lies ahead in 2023 and the position we are in today, and that is thanks to the hard work of our employees, the patients and physicians who participate in our studies, and our shareholders who share in our mission to deliver more time to patients with cancer."

***Abecma* Commercial Summary**
Our partner, Bristol Myers Squibb (BMS), reported total U.S. *Abecma* (idecabtagene vicleucel; ide-cel) fourth quarter revenues of $94 million, which represents 25% growth over the prior quarter, and 40% growth over the fourth quarter of 2021, and full year revenues of $297 million, which is in line with our stated 2022 U.S. *Abecma* revenue guidance of $250-300 million, in each case such revenue is shared equally with BMS. Assuming continued strong demand for *Abecma* and achievement of planned increases in manufacturing capacity throughout the year, we anticipate topline 2023 U.S. revenues of $470-570 million.

Assuming continued increases in manufacturing capacity and growth in the addressable patient population based on an anticipated approval in 3L+ multiple myeloma, we expect *Abecma* to generate $200-300 million in operating income for 2seventy bio in the 2024-25 period.

We reported *Abecma*-related collaborative arrangement revenue of $8.7 million for the fourth quarter of 2022 and collaborative arrangement revenue net of share of collaboration loss of $3.1 million for the year.

Financial Guidance
At the end of February 2023, 2seventy bio raised approximately $117 million in net proceeds through a public equity offering. Based on our current operating plans, which includes these net proceeds and the ongoing commercialization of *Abecma,* we believe our current cash position will be sufficient to fund operations into 2026.

"The financial outlook for 2seventy continues to strengthen, and the recent equity financing puts us in a privileged position, with cash runway now into 2026," said Chip Baird, chief financial officer. "We expect the cash flow from the *Abecma* collaboration to grow significantly over the 2023-25 time period, which will continue to reduce our annual net cash spend and our need for future capital infusions. Our pipeline programs have the potential to deliver meaningful benefit for cancer patients and we will balance an entrepreneurial mindset with a disciplined approach to capital allocation."

RECENT HIGHLIGHTS
KARMMA-3 DATA IN NEJM - On February 10, 2023, 2seventy announced the publication of our KarMMa-3 data in the *New England Journal of Medicine.* The positive results of this pivotal Phase 3 showed at median follow up of 18.6 months, treatment with *Abecma* (n=254) demonstrated a clinically meaningful and statistically significant improvement in the primary endpoint of progression-free survival (PFS) compared with standard regimens (n=132), with a median PFS of 13.3 months (95% CI: 11.8-16.1) vs. 4.4 months (95% CI: 3.4-5.9), respectively (HR:0.49; p<0.0001). This represents a 51% reduction in risk of disease progression or death with *Abecma.* Based on results from KarMMa-3, *Abecma* is the first and only chimeric antigen receptor (CAR) T cell therapy to demonstrate superiority over standard regimens in triple-class exposed relapsed and refractory multiple myeloma in a randomized, controlled Phase 3 trial. 2seventy and BMS anticipate submitting an sBLA to the FDA in the first quarter of 2023 to seek approval in the third line setting.

REGENERON COLLABORATION AMENDMENT – In January, 2seventy bio announced an expanded translational collaboration with Regeneron to facilitate the acceleration of novel cell therapy-based combinations for solid tumors. The collaboration will leverage 2seventy bio's unique cell therapy engineering and early-stage development capabilities, including the newly built in-house clinical cell therapy manufacturing facility, with Regeneron's differentiated antibodies and bispecifics. To support this expanded clinical development plan Regeneron made an approximately $20 million equity investment in 2seventy bio at a 50% premium and has committed to another approximately $20 million in near-term pre-clinical and clinical milestones. The parties will continue sharing costs for these activities in a manner largely consistent with the existing agreement, with Regeneron covering 75% of certain preclinical costs necessary to study combinations and 100% of the costs for the arms of the clinical studies that include Regeneron agents through regulatory approval. For other programs, cost-sharing will follow the existing 50/50 cost sharing agreement.

BOARD APPOINTMENT – Earlier this month, 2seventy bio announced the appointment of Wei Lin, M.D. to the company's Board of Directors.

UPCOMING ANTICIPATED MILESTONES
ABECMA

- Initiation of KarMMa-9 study in patients with newly-diagnosed multiple myeloma by end of 2023
- Potential FDA approval of sBLA in 3L+ multiple myeloma by the end of 2023

PIPELINE

- 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 by the end of 2023
- Submission of an IND for MUC-16 program in ovarian cancer, being developed in partnership with Regeneron by end of 2023
- Led by JW Therapeutics, initiation of an investigator-initiated study in China of 2seventy bio's potency enhanced MAGE-A4 TCR program in solid tumors by end of 2023

FINANCIAL GUIDANCE

- Topline U.S. *Abecma* revenue of $470-570 million in 2023
- Net cash spend of $180-220 million in 2023
- Cash runway into 2026

SELECT FOURTH QUARTER AND FULL YEAR 2022 FINANCIAL RESULTS

- Our partner, BMS, reported total U.S. revenues of $94 million and $297 million for *Abecma* for the three and twelve months ended December 31, 2022, respectively. 2seventy bio and BMS share equally in all profits and losses related to development, manufacture, and commercialization of *Abecma* in the U.S. We reported collaborative arrangement revenue of $8.7 million for the three months ended December 31, 2022 and collaborative arrangement revenue net of share of collaboration loss of $3.1 million for the twelve months ended December 31, 2022.
- Total 2seventy bio revenues were $56.2 million for the three months ended December 31, 2022 compared to $16.0 million for the three months ended December 31, 2021. Total revenues were $91.5 million for the twelve months ended December 31, 2022 compared to $54.5 million for the twelve months ended December 31, 2021. The increase for both the three and twelve-month periods was primarily due to an increase in service revenue in the fourth quarter of 2022, driven by the release of deferred revenue relating to bb21217, the development of which was discontinued in 2022.
- Research and development expenses were $60.1 million for the three months ended December 31, 2022 compared to $57.2 million for the three months ended December 31, 2021. This increase was primarily driven by increased costs for manufacturing activities of suspension lentiviral vector for ide-cel and MAGE-A4 development, partially offset by a decrease in costs related to our share of research and development expenses under our collaboration with BMS. Research and development expenses were $248.7 million for the twelve months ended December 31, 2022, compared to $252.6 million for the twelve months ended December 31, 2021. This decrease was primarily driven by a decrease in costs related to our share of research and development expenses under our collaboration with BMS, partially offset by increases in costs for manufacturing activities of suspension lentiviral vector.
- Selling, general and administrative expenses were $18.7 million for the three months ended

December 31, 2022, compared to $24.5 million for the three months ended December 31, 2021. Selling, general and administrative expenses were $79.5 million for the twelve months ended December 31, 2022, compared to $93.5 million for the twelve months ended December 31, 2021. The decrease for both the three and twelve-month periods was primarily driven by decreased employee compensation expenses, reflective of efforts to streamline 2seventy bio's operating model and a decrease in IT and other facility-related costs due to a lower allocation of these costs to selling, general and administrative expense based on headcount and facility square footage.

- Net loss was $23.1 million for the three months ended December 31, 2022, compared to $61.0 million for the three months December 31, 2021. Net loss was $254.2 million for the twelve months ended December 31, 2022, compared to $292.2 million for the twelve months ended December 31, 2021.
- 2seventy bio ended 2022 with cash, cash equivalents and marketable securities of $267.7 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.

Follow 2seventy bio on social media: 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) 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, market opportunities and demand therefor; 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, 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 December 31,		For the twelve months ended December 31,	
	2022	2021	2022	2021
Revenue:				
Service revenue	$ 41,126	$ 3,836	$ 55,489	$ 21,381
Collaborative arrangement revenue	13,933	11,394	32,358	26,921
Royalty and other revenue	1,118	803	3,649	6,220

Total revenues	56,177	16,033	91,496	54,522
Operating expenses:				
Research and development	60,144	57,163	248,735	252,617
Cost of manufacturing for commercial collaboration	4,019	2,381	14,851	9,320
Selling, general and administrative	18,701	24,480	79,450	93,506
Share of collaboration loss	-	-	9,642	10,071
Cost of royalty and other revenue	474	405	1,726	2,517
Change in fair value of contingent consideration	51	(25)	232	439
Total operating expenses	83,389	84,404	354,636	368,470
Loss from operations	(27,212)	(68,371)	(263,140)	(313,948)
Interest income, net	1,491	88	2,932	88
Other (loss) income, net	2,578	7,309	6,055	21,647
Loss before income taxes	(23,143)	(60,974)	(254,153)	(292,213)
Income tax (expense) benefit	-	-	-	-
Net loss	$ (23,143)	$ (60,974)	$ (254,153)	$ (292,213)
Net loss per share - basic and diluted	$ (0.60)	$ (2.55)	$ (7.13)	$ (12.44)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	38,679	23,884	35,637	23,499

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

	As of December 31, 2022	As of December 31, 2021
Cash, cash equivalents and marketable securities	$ 267,684	$ 362,181
Total assets	656,665	759,675
Total liabilities	346,199	399,853
Total stockholders' equity	310,466	359,822

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