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

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ABECMA generated $72M U.S. commercial revenue in 2Q; continues to track toward upper end of $250-$300M revenue guidance for 2022

Results from prespecified interim analysis of KarMMa-3 trial shows ABECMA (idecabtagene vicleucel) significantly improves progression-free survival versus standard regimens in relapsed and refractory multiple myeloma

Ended quarter with $399M cash, cash equivalents, and marketable securities; revising 2022 net cash spend to $245-265M; maintaining cash runway into 2025

Conference call at 8:00 a.m. ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 10, 2022-- 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, 2022.

“As 2seventy continues our first year as a new company, we remain on a solid growth trajectory with ongoing progress commercially with ABECMA and across our pipeline,” said Nick Leschly, chief kairos officer. “We were extremely pleased to announce this morning that the prespecified interim analysis of our KarMMa-3 Phase 3 study of ABECMA met the primary endpoint of progression-free survival with a safety profile that was consistent with prior studies. We look forward to sharing these results with regulators with the goal of treating multiple myeloma patients in earlier lines. We will share additional data from the KarMMa-3 study, our plans for future investment in ABECMA, and pipeline and portfolio updates throughout 2H22 as we continue our mission to develop innovative, un-incremental treatments for people living with cancer.”

ABECMA Commercial Summary and Business Update

Bristol Myers Squibb (BMS) reported total U.S. ABECMA (idecabtagene vicleucel; ide-cel) second quarter revenues of $72 million, representing 29% growth over the prior quarter. We continue to experience strong commercial demand and remain on track to achieve the upper end of our stated 2022 U.S. ABECMA revenue guidance of $250-300M. Given the continued strong demand and our growing belief in the potential for ABECMA to play an important role in earlier lines, we are continuing to advance our manufacturing strategy to expand capacity across the supply chain.

We reported share of collaboration loss of $4.3 million for the second quarter, which includes our share of gross profit/loss less costs associated with the commercialization of ABECMA in the U.S. In 2022, the collaboration experienced increased ABECMA manufacturing costs driven primarily by higher than anticipated vector costs. This has resulted in higher charges to 2seventy as part of our 50% share of U.S. costs with BMS. BMS is actively working with the vector manufacturer to lower costs and increase manufacturing capacity and 2seventy is supporting BMS in this work. Vector supply remains on track to meet our commercial plan for 2022 and we are continuing to invest in increasing manufacturing capacity in the future.

Given the increase in ABECMA costs that are shared by BMS with 2seventy, we are increasing our net cash spend guidance for 2022 to $245-265 million. All other spend for the rest of our business continues to track in line with previous guidance. We continue to forecast cash runway into 2025 based on current operating plans. This runway is sufficient to achieve important milestones across our business.

RECENT HIGHLIGHTS

- **KARMMA-3 STUDY DELIVERS AT INTERIM: MET PRIMARY ENDPOINT** - 2seventy, in partnership with BMS announced this morning positive topline results from the KarMMa-3 Phase 3 Study of ABECMA in adults with relapsed and refractory multiple myeloma who have had two to four prior lines of therapy and are refractory to the last regimen. This makes ABECMA the first B-cell maturation antigen (BCMA)-directed CAR T cell therapy to demonstrate superiority versus standard regimens in a randomized controlled trial. The study met its primary endpoint of demonstrating a statistically significant improvement in progression-free survival. Treatment with ABECMA also showed an improvement in the key secondary endpoint of overall response rate compared to standard regimens. Follow-up for overall survival, a key secondary endpoint, remains ongoing. Safety results were consistent with the well-established and predictable profile demonstrated in the pivotal KarMMa trial. The companies expect to present additional data from this study at a medical meeting in the future and discuss these findings with health authorities.
- **ABECMA REAL-WORLD DATA AT ASCO –** In June 2022, the largest data set to date for ABECMA patients treated in the commercial setting was presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting by the Multiple Myeloma Cell Therapy

Consortium of academic institutions. The data presented were consistent with what was seen in the pivotal KarMMa study, reinforcing the efficacy and safety profile of ABECMA, even with 77% of the patients having comorbidities which would have rendered them too sick to participate in the KarMMa clinical trial.

- **ADDITIONAL ASCO PRESENTATIONS** – Additional updates from 2seventy bio's portfolio of oncology cell therapies were presented at the meeting, including a correlative analysis, in partnership with BMS, defining patient profiles associated with manufacturing and clinical success in patients treated with ide-cel, a trial in progress poster on CRC-403, a phase 1/2 study on bbT369 in patients with relapsed and/or refractory B-NHL, and a trial in progress poster on PLAT-08, a phase 1 study of SC-DARIC-33 in relapsed or refractory pediatric and young adult acute myeloid leukemia (AML), presented by Seattle Children's Therapeutics.

UPCOMING ANTICIPATED MILESTONES

- Anticipated $250-300 million total U.S. commercial revenue in 2022; profits and losses shared with BMS
- Increasing manufacturing capacity expected over 2022 and in the future
- KarMMa-2 study in high-risk multiple myeloma proof-of-concept data in 2022

SELECT SECOND QUARTER 2022 FINANCIAL RESULTS

- BMS reported total U.S. revenues of $72 million for ABECMA for the three months ended June 30, 2022. 2seventy bio and BMS 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 $4.3 million and $9.6 million for the three months and six months ended June 30, 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 2seventy revenues were $13.5 million for the three months ended June 30, 2022 compared to $7.3 million for the three months ended June 30, 2021. Total revenues were $21.9 million for the six months ended June 30, 2022 compared to $19.2 million for the six months ended June 30, 2021. The increase for the three- and six-month period was primarily driven by an increase in collaboration revenue during the second quarter of 2022, primarily attributable to an increase in collaboration-related activities with Regeneron.
- Research and development expenses were $68.4 million for the three months ended June 30, 2022 compared to $63.7 million for the three months ended June 30, 2021. Research and development expenses were $137.7 million for the six months ended June 30, 2022, compared to $141.3 for the six months ended June 30, 2021. The increase for the three-month period was primarily driven by an increase in material production costs and IT and other facility-related costs. The decrease for the six-month period was primarily driven by decreased collaboration research funding costs, which is primarily driven by a decrease in our share of research and development costs under our collaboration with BMS.
- Selling, general and administrative expenses were $17.3 million for the three months ended June 30, 2022, compared to $21.4 million for the three months ended June 30, 2021. Selling, general and administrative expenses were $41.1 million for the six months ended June 30, 2022, compared to $46.0 million for the six months ended June 30, 2021. The decrease for both the three- and six-month periods was primarily driven by decreased employee compensation expenses, reflective of efforts to streamline 2seventy's operating model and a decrease in IT and other facility-related costs.
- Net loss was $77.4 million for the three months ended June 30, 2022, compared to $84.0

million for the three months ended June 30, 2021. Net loss was $163.1 million for the six months ended June 30, 2022, compared to $171.2 million for the six months ended June 30, 2021.

- 2seventy bio ended the second quarter of 2022 with cash, cash equivalents and marketable securities of $398.6 million.

Conference Call Information

2seventy bio will host a conference call and live webcast today, August 10, at 8:00 a.m. ET to discuss 2Q 2022 financial results and recent business highlights. To access the conference call, please register at: https://register.vevent.com/register/BI3e6a40291152487788cdc808e17e6e59. 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/hmxheige. 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/. A replay will be archived on 2seventy bio's site 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 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 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 June 30,		For the six months ended June 30,	
	2022	2021	2022	2021
Revenue:				
Service revenue	$ 5,666	$ 5,314	$ 9,721	$ 11,232
Collaborative arrangement revenue	7,035	1,671	10,522	3,190
Royalty and other revenue	781	343	1,668	4,807
Total revenues	13,482	7,328	21,911	19,229
Operating expenses:				
Research and development	68,439	63,692	137,684	141,263
Selling, general and administrative	17,278	21,402	41,139	46,029
Share of collaboration loss	4,290	10,071	9,642	10,071
Cost of royalty and other revenue	364	87	875	1,791
Change in fair value of contingent consideration	83	47	131	416

Total operating expenses	90,454	95,299	189,471	199,570
Loss from operations	(76,972)	(87,971)	(167,560)	(180,341)
Interest income, net	213	-	328	-
Other (loss) income, net	(644)	3,929	4,118	9,103
Loss before income taxes	(77,403)	(84,042)	(163,114)	(171,238)
Income tax (expense) benefit	(17)	-	(17)	-
Net loss	$ (77,420)	$ (84,042)	$ (163,131)	$ (171,238)
Net loss per share - basic and diluted	$ (2.02)	$ (3.60)	$ (5.00)	$ (7.33)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	38,381	23,369	32,598	23,369

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

	As of June 30, 2022	As of December 31, 2021
Cash, cash equivalents and marketable securities	$ 398,566	$ 362,181
Total assets	787,406	759,675
Total liabilities	408,422	399,853
Total stockholders' equity	378,984	359,822

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