Turnstone Biologics Corp. Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Recent Business Highlights

March 21, 2024

Lead program, TIDAL-01, advancing in Phase 1 trials with initial clinical data expected in mid-2024

Promising preclinical data highlighting Turnstone's novel Selected TIL programs for solid tumors presented at SITC 2023

Further strengthened Scientific Advisory Board with appointment of internationally recognized cancer immunotherapy expert, Dr. Jeffrey S. Weber

SAN DIEGO, March 21, 2024 (GLOBE NEWSWIRE) -- **Turnstone Biologics Corp. ("Turnstone" or the "Company") (Nasdaq: TSBX)**, a clinical-stage biotechnology company developing a differentiated approach to treat and cure patients with solid tumors by pioneering selected tumor-infiltrating lymphocyte (Selected TIL) therapy, today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided recent business highlights.

"2023 marked a transformative year for Turnstone Biologics in which we transitioned into a publicly traded company and continued to advance our pipeline through clinical development. We are encouraged by the increasing momentum in the TIL landscape that paves the way for next-generation approaches like our Selected TIL therapy, which is designed to create a TIL product with a significantly greater population of potent tumor-reactive T cells, which we believe is the key to extending their therapeutic potential to high unmet medical needs in solid tumors beyond melanoma," said Sammy Farah, M.B.A., Ph.D., Turnstone's President and Chief Executive Officer. "In 2024, we look forward to generating clinical data that potentially highlights the differentiation of our platform and supports further development of our lead asset, TIDAL-01, which is currently being evaluated in Phase 1 studies in patients with colorectal cancer, head and neck squamous cell carcinoma, breast cancer, uveal melanoma, and cutaneous melanoma. We remain on-track to share initial clinical data for TIDAL-01 in mid-2024 and we believe we are well-positioned for another year of meaningful progress for our organization."

Fourth Quarter and Recent Business Highlights

Advancing TIDAL-01 in Multiple Phase 1 Clinical Trials and Expanding of Targeted Solid Tumor Indications. TIDAL-01 employs an unbiased identification and functional screening process to isolate and selectively expand the greatest breadth of tumor-reactive TILs from the patient's tumor. Turnstone believes TIDAL-01 can expand the utility of TIL therapy to solid tumor types where first-generation TILs have not to date shown objective responses in clinical trials and is pursuing several indications with critical unmet need, potentially enabling meaningful therapeutic differentiation. Recently, Turnstone expanded their trials to evaluate additional solid tumor types in addition to the existing indications of breast cancer and uveal melanoma. The multi-site STARLING trial protocol has been amended to cover head and neck squamous cell carcinoma (HNSCC), and the H. Lee Moffitt Cancer Center and Research Institute sponsored trial has been expanded to include colorectal cancer (CRC) and HNSCC. Turnstone expects to provide an initial clinical update across these trials in mid-2024.

Preclinical Data Presentations at the 2023 Society for Immunotherapy of Cancer (SITC) Annual Meeting Support Ongoing Clinical and Preclinical Efforts. In November 2023, Turnstone presented preclinical data on its Selected TIL therapies, including the demonstration of the feasibility of selecting and expanding tumor-reactive TIL as further evidence for the potential of TIDAL-01 as a treatment option for patients with colorectal and gastric cancers. Turnstone also presented on its next Selected TIL program from its development pipeline, TIDAL-02, which seeks to utilize a novel direct selection method, genetically engineered to rapidly select for the greatest breadth of tumor-reactive T cells.

Strengthened Company's Scientific Advisory Board. In October 2023, Turnstone appointed Jeffrey S. Weber, M.D., Ph.D., to its Scientific Advisory Board. Dr. Weber, a world-renowned thought leader with extensive experience in innovative immunotherapies for solid tumors, currently serves as Deputy Director of the Perlmutter Cancer Center and Co-Director of the Melanoma Research Program at the New York University-Langone Cancer Center.

Fourth Quarter 2023 Financial Results

Cash, Cash Equivalents and Short-Term Investments: As of December 31, 2023, cash, cash equivalents and short-term investments were $94.8 million. The Company expects that the combined cash, cash equivalents and short-term investments will be sufficient to fund its operations into the second quarter of 2025.

Research and Development (R&D) Expenses: R&D expenses for the three months ended December 31, 2023, were $13.6 million, compared to $20.2 million for the same period in 2022. The decrease was due primarily to decreases in pre-clinical and regulatory costs, personnel-related costs, and manufacturing expenses due to the termination of the discovery, collaboration and license agreement entered into on November 7, 2019, with Takeda Oncology for certain viral immunotherapy candidates offset by an increase due to ramp up of TIDAL-01 activities.

General and Administrative (G&A) Expenses: G&A expenses for the three months ended December 31, 2023, were $4.4 million, compared to $4.4 million for the same period in 2022.

Net Loss: Net loss for the three months ended December 31, 2023, was $16.5 million, compared to net loss of $13.7 million for the same period in 2022.

Full Year 2023 Financial Results

Cash, Cash Equivalents and Short-Term Investments: For the full year ended December 31, 2023, cash, cash equivalents and short-term investments were $94.8 million.

Research and Development (R&D) Expenses: R&D expenses for the full year ended December 31, 2023, were $60.5 million, compared to $86.7 million for the prior year period. The decrease was due primarily to decreases in pre-clinical and regulatory and manufacturing expenses due to the termination of the discovery, collaboration and license agreement entered into on November 7, 2019, with Takeda Oncology for certain viral immunotherapy candidates offset by an increase in personnel-related costs and costs due to ramp up of TIDAL-01 activities.

General and Administrative (G&A) Expenses: G&A expenses for the full year ended December 31, 2023, were $17.8 million, compared to $18.2 million for the prior year period. We anticipate that G&A expenses will remain stable as we support public company operations.

Net Loss: Net loss for the full year ended December 31, 2023, was $55.2 million, compared to net loss of $30.8 million for the prior year period.

About Turnstone

Turnstone Biologics is a clinical-stage biotechnology company developing a differentiated approach to treat and cure patients with solid tumors by pioneering selected tumor-infiltrating lymphocyte (Selected TIL) therapy. Turnstone's next-generation TIL therapy is based upon the identification, selection and expansion of the most potent tumor-reactive T cells, known as Selected TILs, and is designed to overcome the limitations of first-generation bulk TIL that have demonstrated objective responses only in limited tumor types. Turnstone's most advanced program, TIDAL-01, is currently being evaluated in multiple Phase 1 studies in patients with colorectal cancer, breast cancer, head and neck cancer, uveal melanoma, and cutaneous melanoma. The Company is also actively advancing its preclinical pipeline programs including TIDAL-02, its next Selected TIL program, and its TIDAL-01 and viral immunotherapy combination program. For additional information about Turnstone, please visit www.turnstonebio.com, and follow us on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, statements regarding: the potential for TIDAL-01 and other pipeline programs to achieve objective responses in solid tumors; the potential for Turnstone's Selected TILs to efficiently select and expand tumor-reactive TIL to and to effectively apply current TIL therapies across a wider range of solid tumors; the potential of TIDAL-01 as a treatment option for patients with colorectal and gastric cancer; Turnstone's projected cash runway into the second quarter of 2025; and Turnstone's strategies and objectives. All statements, other than statements of historical fact, contained in this press release, including statements regarding future events, future financial performance, business strategy and plans, and objectives for future operations, are forward-looking statements and can be identifies by terminology such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will" or "would," or the negative of these terms or other comparable terminology. These statements are based on the current plans, objectives, estimates, expectations and intentions, beliefs and assumptions of our management team, and on information currently available to such management team and are not guarantees of future performance and inherently involve numerous risks and uncertainties, many of which are beyond Turnstone's control. We undertake no obligation to update or revise publicly any of the forward-looking statements after the date hereof to conform the statements to actual results or changed expectations except as required by law. The reader is cautioned not to place undue reliance on forward-looking statements. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, but are not limited to, risks and uncertainties related to: macroeconomic conditions and the effects of global health concerns, such as global pandemics; Turnstone's ability to initiate and execute clinical trials on the anticipated timelines, if at all; the potential for results from clinical trials to differ from preclinical, early clinical, preliminary or expected results; the significant uncertainty associated with Turnstone's product candidates ever receiving any regulatory approvals; Turnstone's ability to obtain, maintain or protect intellectual property rights related to its product candidates; the sufficiency of Turnstone's capital resources and need for additional capital to achieve its goals; and other risks, including those described under the heading "Risk Factors" in Turnstone's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed with the SEC on November 13, 2023 and other documents Turnstone has filed, or will file, with the SEC, including the Annual Report on Form 10-K for the year ended December 31, 2023. This press release discusses product candidates that are under clinical study and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these product candidates for the uses for which they are being studied.

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Turnstone Biologics, Corp.
Condensed Consolidated Statement of Operations and Comprehensive Income (Loss)(unaudited)
(In thousands, except share and per share data)

	Three Months ended December 31,		Twelve Months ended December 31,	
	2023	2022	2023	2022
Collaboration revenue	$ -	$ 10,447	$ 19,306	$ 73,300
Operating expenses				
Research and development	13,458	20,214	60,491	86,703
General and administrative	4,398	4,353	17,847	18,223
Total operating expenses	17,856	24,567	78,338	104,926
Loss from operations	(17,856)	(14,120)	(59,032)	(31,626)
Other income, net	1,241	468	3,546	933

Net loss before income taxes	(16,615)	(13,652)	(55,486)	(30,693)
Benefit (provision) for income taxes	165	(15)	286	(141)
Net loss	$ (16,450)	$ (13,667)	$ (55,200)	$ (30,834)
Other comprehensive income (loss)	122	72	294	(168)
Total comprehensive income (loss)	$ (16,328)	$ (13,595)	$ (54,906)	$ (31,002)
Net loss attributable to common stockholder, basic and diluted	(16,773)	(13,688)	(55,239)	(31,024)
Weighted-average shares of common stock outstanding, basic and diluted	22,934,594	2,484,569	11,562,910	2,484,569
Net loss per share attributable to common stockholders, basic and diluted	$ (0.73)	$ (5.51)	$ (4.78)	$ (12.49)

Turnstone Biologics, Corp.
Condensed Consolidated Balance Sheet (unaudited)
(amount in thousands)

	December 31, 2023	December 31, 2022
Cash and cash equivalents and short-term investments	$ 94,777	$ 82,061
Total assets	112,815	114,938
Total liabilities	14,148	44,461
Total redeemable convertible preferred stock	-	171,944
Total stockholders' deficit	98,667	(101,467)