



Turnstone Biologics Corp. Reports Third Quarter 2023 Financial Results and Provides Recent Business Highlights

November 10, 2023 2:50 AM EST

– Promising preclinical data showcasing Turnstone’s novel Selected TIL programs for solid tumors presented at SITC 2023 –

– Lead program, TIDAL-01, advancing and on track in two Phase 1 trials with initial clinical data expected mid-2024 –

– Upsized IPO extends runway into Q2 2025 and supports advancement of pipeline through key milestones –

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

SAN DIEGO, Nov. 09, 2023 (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 quarter ended September 30, 2023, and provided recent business highlights.

“We continue to make progress advancing our pipeline of Selected TIL therapies and we believe we are well-capitalized to deliver on value-creating milestones. At SITC, we presented encouraging preclinical data that demonstrated our ability to successfully identify, select and expand the most potent tumor-reactive T cells, a lack thereof we believe to be a fundamental barrier in the field to the effective application of current TIL therapies across a wider range of solid tumors. We remain focused on execution and are on track to report initial clinical data in several solid tumor indications for TIDAL-01 in mid-2024,” said Sammy Farah, M.B.A., Ph.D., Turnstone’s President and Chief Executive Officer. “I would also like to take this opportunity to convey sincere gratitude for the support of staff at clinical sites, physicians, patients and their loved ones, and our talented employees whose tireless efforts enable Turnstone’s mission.”

Third Quarter 2023 and Recent Business Highlights

- **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 colorectal and gastric cancer patients. Turnstone also presented a next-generation strategy from its development pipeline showcasing a 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.
- **Completed Upsized Initial Public Offering.** In July 2023, Turnstone priced its initial public offering (IPO) at \$12.00 per share. In connection with the offering, the Company issued 7,318,275 common shares and received gross proceeds of approximately \$88.0 million before deducting underwriting discounts and commissions and other offering expenses.

Anticipated Milestones Over the Next 12 Months

- **Initial Clinical Data for TIDAL-01.** Turnstone’s lead Selected TIL program, TIDAL-01, is currently being evaluated in two Phase 1 clinical trials, including STARLING, a multi-site trial for the treatment of breast cancer, colorectal cancer and uveal melanoma, and an investigator-sponsored trial with H. Lee Moffitt Cancer Center and Research Institute in both cutaneous and non-cutaneous melanomas. Turnstone expects to provide an initial clinical update across

these two trials in mid-2024.

Third Quarter 2023 Financial Results

- **Cash, Cash Equivalents and Short-Term Investments:** As of September 30, 2023, cash, cash equivalents and short-term investments were \$109.1 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 September 30, 2023, were \$14.2 million, compared to \$21.3 million for the same period in 2022. The decrease was due primarily to decreases in 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 September 30, 2023, were \$4.8 million, compared to \$5.2 million for the same period in 2022. The decrease was due primarily to a decrease in compensation due to the streamlining of operations.
- **Net Loss:** Net loss for the three months ended September 30, 2023, was \$17.3 million, compared to net loss of \$16.2 million for the third quarter of 2022.

Upcoming Events

- Dr. Sammy Farah, Turnstone's President and Chief Executive Officer, will participate in a fireside chat at the Piper Sandler 35th Annual Healthcare Conference on Thursday, November 30, 2023, at 1:00 pm ET / 10:00 am PT.

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 novel TIL therapy is based upon the identification, selection and expansion of the most potent tumor-reactive T cells, known as Selected TIL, 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 two Phase 1 studies in patients with melanoma, breast cancer and colorectal cancer, and 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; and the potential of TIDAL-01 as a treatment option for colorectal and gastric cancer patients; . 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 identified 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 lingering effects of the COVID-19 pandemic; 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 June 30, 2023, filed with the SEC on September 1, 2023 and other documents Turnstone has filed, or will file, with the SEC, including the Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

Contact

Ahmed Anezi
Investor Relations
Turnstone Biologics
(347) 897-5988
ahmed.anezi@turnstonebio.com

Condensed Consolidated Balance Sheet (unaudited) (In thousands)

	September 30, 2023	December 31, 2022
Cash and cash equivalents and short-term investments	\$ 109,105	\$ 82,061
Total assets	131,312	114,938
Total liabilities	17,413	44,461
Total redeemable convertible preferred stock	-	171,944
Total stockholders' deficit	113,899	(101,467)

Condensed Consolidated Statement of Operations and Comprehensive Income (Loss) (unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	\$ -	\$ 10,220	\$ 19,306	\$ 62,853
Operating expenses				
Research and development	14,172	21,251	47,033	66,489
General and administrative	4,758	5,240	13,449	13,870
Total operating expenses	18,930	26,491	60,482	80,359
Income (loss) from operations	(18,930)	(16,271)	(41,176)	(17,506)
Other income (expense), net	1,578	200	2,305	465
Net income before income taxes	17,352	(16,071)	(38,871)	(17,041)
Benefit (provision) for income taxes	33	(80)	121	(126)
Net income (loss)	\$ (17,319)	\$ (16,151)	\$ (38,750)	\$ (17,167)
Other comprehensive income (loss)	(8)	(65)	172	(240)
Total comprehensive income (loss)	\$ (17,327)	\$ (16,216)	\$ (38,578)	\$ (17,407)
Net income (loss) attributable to common stockholder, basic and diluted	(17,319)	(16,208)	(38,789)	(17,338)
Weighted-average number of shares used in computing net earnings (loss) per share				
Basic and diluted	17,397,845	2,633,588	7,730,694	2,424,107
Net income (loss) per share attributable to common stockholders				
Basic and diluted	\$ (1.00)	\$ (6.15)	\$ (5.02)	\$ (7.15)