Turnstone Biologics Corp. Reports Second Quarter 2024 Financial Results and Provides Recent Business Highlights

August 14, 2024

- *Announced positive initial data from Phase 1 trial of TIDAL-01 in metastatic colorectal cancer including a complete response in one of the four patients reported*
- *Cash position expected to fund operations into 3Q 2025*

SAN DIEGO, Aug. 14, 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 second quarter ended June 30, 2024, and provided recent business highlights.

"We have continued to bolster our position by making advances across our pipeline and corporate operations in the second quarter of 2024. This includes the reporting of encouraging initial data from our Phase 1 trial of TIDAL-01 in patients with metastatic colorectal cancer," said Sammy Farah, M.B.A., Ph.D., Turnstone's President and Chief Executive Officer. "The clinical signals from these initial data, including a remarkable complete response in one of the first four patients, demonstrated deep and durable anti-tumor activity along with corresponding biological data, which support our fundamental hypothesis of enriching for tumor-reactive T cells in our Selected TIL therapies. As the competitive profile of TIDAL-01 strengthens with this initial clinical data, we are prioritizing development in solid tumor indications, including metastatic colorectal cancer, where we believe we can differentiate our TIL technology and provide the most benefit to patients."

Second Quarter 2024 and Recent Business Highlights

Reported positive initial data from STARLING Phase 1 trial of TIDAL-01 in colorectal cancer. In August, initial results were shared from the first 4 evaluable microsatellite stable metastatic colorectal cancer ("MSS mCRC") patients from the STARLING Phase 1 study of TIDAL-01. The data demonstrated a 25% overall response rate ("ORR") with durable clinical benefit and 50% disease control rate ("DCR") in a setting where patients are unresponsive to checkpoint inhibitors and have almost no treatment options. One patient had a complete response ("CR") and has been progression free for over one year, while a second patient had stable disease, with both results being notable in highly pre-treated advanced and late line MSS mCRC. As a point of comparison, the current standard of care for this patient population has resulted in an ORR of 1-6% and a median progression free survival (mPFS) of 2.0-5.6 months. There were also no new safety observations in the Phase 1 trial specific to TIDAL-01, and the Company demonstrated consistent manufacturing success. Turnstone is continuing to enroll multiple Phase 1 trials of TIDAL-01 and has focused its clinical development strategy in three high unmet medical need indications including colorectal cancer, head and neck cancer and uveal melanoma, and in doing so, have deprioritized cutaneous melanoma and breast cancer.

Senior Leadership Promotion and Transition. In July, Ines Verdon, M.D., was promoted to Senior Vice President of Clinical Development, having previously served as Vice President of Clinical Development since she joined Turnstone in 2022, bringing with her more than 20 years of academic and pharmaceutical industry experience. The role of David Stojdl, Ph.D., Senior Vice President of Research and Discovery, was expanded to oversee all research and translational science activities at the Company, with Stewart Abbot, Ph.D., departing from his role as Turnstone's Chief Scientific Officer. Dr Stojdl is a seasoned R&D leader with over 20 years of research and drug development experience in academia and industry, and is also a co-founder of Turnstone.

Second Quarter 2024 Financial Results

Cash, Cash Equivalents and Short-Term Investments: As of June 30, 2024, cash, cash equivalents and short-term investments were $62.4 million. The Company expects that the combined cash, cash equivalents and short-term investments will be sufficient to fund its operations into the third quarter of 2025.

Research and Development (R&D) Expenses: R&D expenses for the three months ended June 30, 2024, were $17.7 million, compared to $17.2 million for the same period in 2023. The increase was due primarily to an increase in manufacturing costs related to TIDAL-01 clinical trials.

General and Administrative (G&A) Expenses: G&A expenses for the three months ended June 30, 2024, were $4.3 million, compared to $4.7 million for the same period in 2023. The decrease was due primarily to a reduction in personnel costs.

Net Loss: Net loss for the three months ended June 30, 2024, was $21.3 million, compared to net loss of $21.5 million for the same period in 2023.

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, head and neck cancer, and uveal 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 TILs; the potential of TIDAL-01 as a treatment option for patients with colorectal cancer, head and neck cancer and uveal melanoma; the potential for TIDAL-01 to be superior to current standard of care, if approved; Turnstone's projected cash runway into the third 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, initial, 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 Annual Report on Form 10-K or Quarterly Report on Form 10-Q filed with the SEC 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.

Contact:

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ —	$ —	$ —	$ 19,306
Operating expenses:				
Research and development	17,730	17,193	33,520	32,861
General and administrative	4,327	4,659	9,228	8,691
Total operating expenses	22,057	21,852	42,748	41,552
Loss from operations	(22,057)	(21,852)	(42,748)	(22,246)
Other income, net	755	347	1,833	727
Net loss before income taxes	(21,302)	(21,505)	(40,915)	(21,519)
Benefit (provision) for income taxes	(2)	6	(18)	88
Net income (loss)	$ (21,304)	$ (21,499)	$ (40,933)	$ (21,431)
Other comprehensive income (loss)	10	59	(107)	180
Total comprehensive loss	$ (21,294)	$ (21,440)	$ (41,040)	$ (21,251)
Net loss attributable to common stockholders, basic and diluted	(21,304)	(21,518)	(40,933)	(21,470)
Weighted-average shares of common stock outstanding, basic and diluted	23,037,714	2,847,675	23,024,754	2,817,008
Net loss per share attributable to common stockholders, basic and diluted	$ (0.92)	$ (7.56)	$ (1.78)	$ (7.62)

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

	June 30, 2024 (unaudited)	December 31, 2023
Cash and cash equivalents and short term investments	$ 62,398	$ 94,777
Total assets	76,877	112,815
Total liabilities	17,141	14,148
Total stockholders' deficit	59,736	98,667