UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 12, 2024

Turnstone Biologics Corp.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41747**	**83-2909368**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
9310 Athena Circle, Suite 300 La Jolla, California		**92037**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (347) 897-5988

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock ($0.001 par value)	TSBX	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 12, 2024, Turnstone Biologics Corp. (the "Company") issued a press release announcing financial results for the three and nine months ended September 30, 2024 and other business highlights. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 2.02 in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 12, 2024, titled "Turnstone Biologics Corp. Reports Third Quarter 2024 Financial Results and Provides Recent Business Highlights"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TURNSTONE BIOLOGICS CORP.

Date: November 12, 2024

By: /s/ Sammy Farah

Sammy Farah, M.B.A., Ph.D.
President and Chief Executive Officer and Director

Exhibit 99.1

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

Portfolio Prioritization and Corporate Restructuring Extends Cash Runway into 2Q 2026

SAN DIEGO, November 12, 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 third quarter ended September 30, 2024, and provided recent business highlights.

"Earlier this quarter, we announced a corporate restructuring and the decision to focus resources on our Phase 1 program, TIDAL-01, which we believe puts us on the path to significant value creation. Importantly, our extended cash runway into the second quarter of 2026 enables us to achieve potential key clinical milestones and we remain steadfast in advancing our differentiated approach to TIL therapy for cancer patients with high unmet need," said Sammy Farah, M.B.A., Ph.D., Turnstone's President and Chief Executive Officer. "Recently, we reported initial clinical data from our STARLING trial which showcased durable anti-tumor activity in a heavily pre-treated late-line microsatellite stable colorectal cancer patient population, including the achievement of a complete response. The patient remains in remission with progression-free survival extending beyond one year. Our encouraging initial clinical data, combined with results that continue to emerge from within the field in support of selection-based approaches, strengthen the competitive profile of our next-generation selected TIL technology and its potential to treat solid tumors. We look forward to sharing our next clinical update in 1H 2025."

Third Quarter 2024 and Recent Business Highlights

Presented at the 2024 Society for Immunotherapy of Cancer (SITC) Annual Meeting – Tumor Infiltrating Lymphocytes (TIL) Symposium, supporting ongoing clinical efforts. On November 6, 2024, Turnstone delivered a presentation titled "TIDAL-01: Enriching for a More Potent TIL Population with Selected TIL therapy" at the SITC TIL Symposium in Houston, TX. The presentation showcased Turnstone's initial clinical data from its Phase 1 TIDAL-01 program, including the achievement of a complete response in a third-line microsatellite stable metastatic colorectal cancer ("MSS mCRC") patient. Additionally, two posters were presented at the SITC Annual Meeting with preclinical data that demonstrated the practicality of selecting and expanding tumor-reactive TIL as a potential treatment option for patients with solid tumors.

Reported positive initial data from the STARLING Phase 1 Trial of TIDAL-01 in MSS mCRC. In August, initial results were shared from the first 4 evaluable MSS mCRC patients from the STARLING Phase 1 study of TIDAL-01. The trial yielded a 25% overall response rate ("ORR") with durable clinical benefit and 50% disease control rate ("DCR") in a heavily pre-treated, advanced disease, third-line 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 which is notable in this patient population, while another patient had stable disease ("SD") for 6 months. As a point of comparison, the current standard of care treatment for this patient population has resulted in an ORR of 1-6% and a median progression-free survival ("mPFS") of 2-5.6 months. There were also no new safety observations specific to Turnstone's Selected TILs.

Completed strategic restructuring and portfolio review to extend cash runway. In October, Turnstone announced the streamlining of its operations to optimize its portfolio and strengthen its financial position to focus on achieving clinical milestones. Key initiatives include:

- **Pipeline strategy and prioritization**: Following a comprehensive evaluation of the business, Turnstone has decided to sharpen its focus on development of the TIDAL-01 program.
- **Organizational restructuring**: The Company executed a 60% workforce reduction to prioritize the development of its core Selected TIL program and extend its cash runway.

- **Financial strategy**: Turnstone expects its cash runway to support operations and clinical development through the second quarter of 2026.
- **Talent strategy**: As part of Turnstone's updated corporate strategy, Ines Verdon, M.D., Senior Vice President of Clinical Development, is assuming leadership of all clinical activities. Michael Fitch, Ph.D., has been promoted to Senior Vice President of Manufacturing and will oversee all manufacturing and technical operations activities. Wendy Worcester, CPA, is assuming the responsibility of the Finance function as the Principal Financial and Accounting Officer. Saryah Azmat has been promoted to Chief Operating Officer.

Third Quarter 2024 Financial Results

Cash, cash equivalents and short-term investments: As of September 30, 2024, cash, cash equivalents and short-term investments were $45.3 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 2026.

Research and development (R&D) expenses: R&D expenses for the three months ended September 30, 2024, were $14.4 million, compared to $14.2 million for the same period in 2023. The increase was due primarily to an increase in manufacturing, clinical, and regulatory costs related to TIDAL-01 clinical trials.

General and administrative (G&A) expenses: G&A expenses for the three months ended September 30, 2024, were $3.9 million, compared to $4.8 million for the same period in 2023. The decrease was due primarily to reductions in personnel costs, professional service costs, and other general and administrative costs.

Net loss: Net loss for the three months ended September 30, 2024, was $17.0 million, compared to net loss of $17.3 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 lead clinical program, TIDAL-01, is currently being evaluated in multiple Phase 1 studies in patients with colorectal cancer, head and neck cancer, and uveal melanoma. 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 therapeutic potential for TIDAL-01 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; the potential for TIDAL-01 to be superior to current standard of care, if approved; statements related to the results of the workforce reduction and leadership changes; expectations regarding any cost savings resulting from the workforce reduction; Turnstone's projected cash runway into the second quarter of 2026; 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; impediments to the Company's ability to execute the workforce reduction as currently contemplated, the Company's ability to achieve projected cost savings in connection with the workforce reduction, unintended consequences from the workforce reduction that impact the Company's business; 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 Reports on Form 10-Q filed with the SEC and other documents Turnstone has filed, or will file, with the SEC. 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:

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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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration revenue	$ —	$ —	$ —	$ 19,306
Operating expenses:				
Research and development	14,424	14,172	47,944	47,033
General and administrative	3,944	4,758	13,172	13,449
Total operating expenses	18,368	18,930	61,116	60,482
Loss from operations	(18,368)	(18,930)	(61,116)	(41,176)
Other income, net	520	1,578	2,353	2,305
Net loss before income taxes	(17,848)	(17,352)	(58,763)	(38,871)
Benefit for income taxes	816	33	798	121
Net loss	$ (17,032)	$ (17,319)	$ (57,965)	$ (38,750)
Other comprehensive income (loss)	30	(8)	(77)	172
Total comprehensive loss	$ (17,002)	$ (17,327)	$ (58,042)	$ (38,578)
Net loss attributable to common stockholders, basic and diluted	(17,032)	(17,319)	(57,965)	(38,789)
Weighted-average shares of common stock outstanding, basic and diluted	23,037,714	17,397,845	23,029,106	7,730,694
Net loss per share attributable to common stockholders, basic and diluted	$ (0.74)	$ (1.00)	$ (2.52)	$ (5.02)

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

	September 30, 2024 (unaudited)	December 31, 2023
Cash and cash equivalents and short term investments	$ 45,284	$ 94,777
Total assets	58,484	112,815
Total liabilities	14,843	14,148
Total stockholders' deficit	43,641	98,667