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): August 14, 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 August 14, 2024, Turnstone Biologics Corp. (the "Company") issued a press release announcing financial results for the three and six months ended June 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 7.01 Regulation FD Disclosure.

On August 14, 2024, Turnstone Biologics Corp. (the "Company") issued a press release announcing initial data from its Phase 1 clinical trials evaluating TIDAL-01. A copy of the press release is being furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

On August 14, 2024, the Company updated its corporate presentation on the Company's website to provide updates for the data. A copy of such presentation will be available on the Company's investor relations website at https://ir.turnstonebio.com/. Any other information contained in, or that can be accessed through, the Company's website is not a part of this filing.

The information furnished in this Item 7.01 (including Exhibit 99.2) and the presentation materials shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or the Securities 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 August 14, 2024, titled "Turnstone Biologics Corp. Reports Second Quarter 2024 Financial Results and Provides Recent Business Highlights"
99.2	Press Release dated August 14, 2024, titled "Turnstone Biologics Corp. Reports Positive Initial Data from Phase 1 Trial of TIDAL-01 in Metastatic Colorectal Cancer"
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: August 14, 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 First Quarter 2024 Financial Results and Provides Recent Business Highlights

- *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, August 14, 2024 – 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 interim 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 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 treatment 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 I 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, 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 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, interim, 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

Turnstone Biologics Corp. Reports Positive Initial Data from Phase 1 Trial of TIDAL-01 in Metastatic Colorectal Cancer

- *Overall response rate ("ORR") of 25% and 50% disease control rate ("DCR") observed in first four evaluable patients treated with TIDAL-01 with advanced CRC*
- *Complete response achieved in heavily pre-treated late line patient with progression free survival extending beyond one year*
- *Favorable tolerability profile and demonstrated manufacturing success*
- *Product characterization and translational data support biological hypothesis for Selected TILs*

SAN DIEGO, August 14, 2024 – 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 positive initial data from its Phase 1 STARLING trial of TIDAL-01 in metastatic microsatelite stable colorectal cancer ("MSS mCRC").

Turnstone's Phase 1 STARLING trial is an ongoing multi-site, first-in-human, non-randomized, open label, single-dose study, and is evaluating the safety, tolerability, and clinical activity of TIDAL-01. The trial is currently enrolling patients with colorectal cancer, head and neck squamous cell carcinoma, and uveal melanoma. As of the cutoff date of July 15, 2024, key takeaways from the interim data include the following:

- **Clinical Responses:** Among the four evaluable MSS mCRC patients included in the study, Turnstone observed a 25% overall response rate ("ORR") and 50% disease control rate ("DCR"). One patient demonstrated deep and durable ongoing complete response (CR).
- **Durability of Response:** 50% of patients showed sustained clinical benefit, with notable progression free survival of over one year in the patient with ongoing complete response and 6 months for a patient with stable disease.
- **Translational Profile:**The TIDAL-01 process demonstrated the ability to generate high titer, polyclonal and multi-epitope tumor neoantigen-reactive T cells that expanded in the patient, persisted in the blood and correlated with an increase in CD8 T cell tumor infiltration.
- **Tolerability Profile:** TIDAL-01 was generally well-tolerated and safety events observed were consistent with known AEs associated with the lymphodepletion regimen, and IL-2 and pembrolizumab administration.
- **Manufacturing Rates:**The manufacturing success rate for TIDAL-01 in CRC for evaluable patients with sufficient starting material was 80% which is consistent with other early clinical-stage cell therapies. Additionally, the target dose of at least $1x10^9$ cells was exceeded in all manufactured CRC products.

"The encouraging initial clinical data from the Phase 1 STARLING trial supports the potential of TIDAL-01 to transform the treatment paradigm for patients with metastatic CRC and other solid tumors," said Sammy Farah, M.B.A., Ph.D., Turnstone's President and Chief Executive Officer. "The 25% ORR with a deep and durable response and 50% DCR that we have been able to achieve with TIDAL-01 compare favorably to the standard of care for this patient population, where current therapies report a 1-6% ORR and median progression free survival (mPFS) of 2.0-5.6 months. Further bolstered by a well-tolerated profile and demonstrated manufacturing consistency, these data provide a strong foundation for our continued development of TIDAL-01 in this high unmet need patient population. Overall, we are extremely pleased by this positive start to our clinical study."

"CRC is a leading cause of cancer related deaths in the United States," said Mike Burgess, MBChB, Ph.D., Turnstone's Interim Chief Medical Officer. "The early evidence of clinical benefit highlights TIDAL-01 as a potential therapeutically viable option in metastatic CRC, and we are delighted to report that the patient who experienced a complete response remains in remission and is well more than one year post treatment. Through our STARLING study we will continue to evaluate the benefits of TIDAL-01 in CRC and in other tumor types where there are limited or no treatment including uveal melanoma and head and neck cancer. We look forward to bringing forward pioneering innovative treatment options that drive clinical efficacy and address the most critical needs in oncology."

Additional information related to the interim data set can be found in Turnstone's Corporate Presentation on the Company's website at www.turnstonebio.com.

About TIDAL-01

TIDAL-01, Turnstone's lead Selected TIL therapy candidate, utilizes an unbiased identification and functional screening process to isolate and selectively expand the most comprehensive set of tumor-reactive TILs from the patient's tumor. For more effective tumor killing, the TIDAL-01 production process targets a product with a significantly higher proportion of functional and potent

tumor-reactive T cells compared to bulk TIL and is also designed to deliver at least 10^9 cells. TIDAL-01 is currently advancing in ongoing multi-site, first-in-human, non-randomized, open-label, single-dose study Phase 1 trials, which include the Company sponsored STARLING trials and the investigator sponsored trials with Moffitt Cancer Center. The Phase 1 studies are evaluating safety, biology, initial efficacy, and manufacturing feasibility of TIDAL-01 in patients with solid tumors where standard bulk TILs have historically not shown objective and/or durable responses in clinical trials.

About CRC

CRC is the third most commonly diagnosed cancer and ranks second in terms of mortality in the United States. In 2024 in the United States, it is estimated that there will be approximately 153,000 new CRC cases, and 53,000 deaths. Of these cases, approximately 85% of patients are characterized as microsatellite stable, or MSS, as opposed to the approximately 15% which are microsatellite instable, or MSI. Whereas the microsatellite instability-high, or MSI-H, phenotype confers good prognosis and greater response to immunotherapy in CRC, MSS tumors are generally considered 'cold' tumors and are less responsive to immunotherapies, with anti-PD-(L)1 therapy demonstrating nearly no effect. The five-year survival rate for all colorectal cancer in the United States is approximately 65% and drops below 20% if the cancer has metastasized. Treatment options for CRC include surgery, radiation therapy, chemotherapy, targeted therapy, and immunotherapy. Advanced MSS mCRC is typically treated with chemotherapy +/- combination with bevacizumab or anti-EGFR, but resistance to chemotherapy is inevitable. Targeted therapies are available, however, most MSS mCRC patients do not have actionable mutations. For patients lacking actionable mutations, or that fail targeted therapies, treatment efficacy outcomes after exhausting chemotherapy are poor (ORR = 1-6%; mPFS 2.0-5.6 months; mOS 6.4-10.8 months).

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