## **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): March 5, 2024

## **Turnstone Biologics Corp.** (Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-41747 (Commission File Number

83-2909368 (IRS Employer

9310 Athena Circle, Suite 300 La Jolla, California 92037 (Address of principal executive offices)

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<br>Symbol(s) | Name of each exchange<br>on which registered |
|---|----------------------|--|
| Common Stock, \$0.001 par value per share | TSBX                 | Nasdaq Global Market                         |

Indicate by check mark whether the registrant is an emerging growth company as defined in 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.  $\Box$ 

#### Item 7.01 Regulation FD Disclosure.

On March 5, 2024, Turnstone Biologics Corp. ("Turnstone" or the "Company") made available an updated corporate presentation that the Company will use to present at the TD Cowen 44th Annual Global Health Care Conference on March 6, 2024, which can be found on the Company's website. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference into this Item 7.01.

The information provided in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, 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        | Corporate Presentation (March 2024)   |  |
| 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.

#### ACELYRIN, INC.

By: /s/ Sammy Farah Sammy Farah, M.B.A., Ph.D. President and Chief Executive Officer and Director

Dated: March 5, 2024



## **Corporate Presentation**

March 2024

Nasdaq: TSBX

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## Disclaimers

This presentation and any accompanying oral commentary have been prepared by Turnstone Biologics Corp. ("Turnstone") for informational purposes only and not for any other purpose. All statements contained in this presentation and the accompanying oral commentary, other than statements of historical facts, are forward-looking statements, including: statements about our expectations regarding the potential benefits, activity, effectiveness, and safety of our Selected tumor-infiltrating lymphocyte (TIL) product candidates and programs; our expectations with regard to the design and results of our research and development programs, preclinical studies, and clinical trials, including the timing and availability of data from such trials; our preclinical, clinical, and regulatory development plans for our Selected TIL product candidates and programs, including the timing or likelihood of regulatory filings and approvals for our Selected TIL product candidates; our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements; our ability to improve process to improve manufacturing processes; and our business strategy. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, timing of results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks and uncertainties include those factors discussed in the Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") on November 13, 2023, under the heading "Risk Factors," and other documents Turntone has filed, or will file, with the SEC. These filings, when available, are available on the investor relations section of our website at inturnstonebio.com and on the SEC's website at www.sec.gov.

New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially and adversely from those anticipated or implied in the forward-looking statements. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements. Actual results or events could as of the date of this presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. Except as required by law, none of Turnstone, its affiliates or any of their respective employees, directors, officers, contractors, advisors, members, successors, representations or agents makes any representation or warranty as to the accuracy or completeness of any information contained in this presentation and shall have no liability for any representations (expressed or implied) contained in, or for any omissions from, this presentation.

This presentation contains trademarks, service marks, trade names and copyrights of Turnstone and other companies which are the property of their respective owners.

This presentation 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.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

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## **OUR MISSION**

Profoundly transform the treatment paradigm for patients with a broad range of solid tumors with next-generation TIL therapies that overcome the limitations of current treatment options



## Solid Tumors Represent a Serious Unmet Medical Need

Approximately 90% of all new cancers per year are solid tumors

#### In the U.S. Each Year

#### **1.6M**

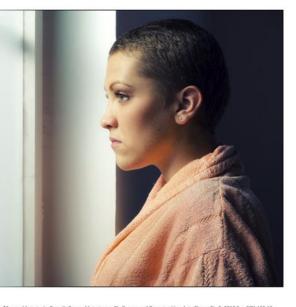
new cancer patients1

**500K** deaths with low

90%+ mortality in long-term survival<sup>1</sup> metastatic disease<sup>2</sup>

#### **New Therapeutic Options Urgently Needed**

Checkpoint inhibitors only benefit a fraction of cancer patients<sup>3</sup> Targeted and other cell therapies have shown only limited success One FDA approved TIL therapy and only in advanced melanoma<sup>4</sup>



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Mational Cancer Institute's Surveillance, Epidemiology, and End Results (SEER), accessed March 2024; <sup>2</sup>Cancer Metastasis: Guan X. Cancer Metastases: Challenges and Opportunities. Acta Pharm Sin B. 2015 Sep;5(5):402-18. Haslam A, Prasad V. Estimation of the Percentage of US Patients With Cancer Who Are Eligible for and Respond to Checkpoint Inhibitor Immunotherapy Drugs. JAMA Netw Open. 2019 May 3;2(5):e192535. 4United Stated Food and Drug Association (US FDA) approval granted on 02/16/2024; <u>News release</u> TURNSTONE Non-Confidential

## **Turnstone is Tackling Solid Tumors of Greatest Need**

Our focus is on colorectal cancer, head and neck cancer, uveal melanoma and breast cancer

#### Indication Spotlight: Colorectal Cancer (CRC)



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Marerican Cancer Society. Cancer Facts & Figures 2024; <sup>1</sup>CA: A Cancer Journal for Clinicians – Colorectal Cancer Statistics, 2023 – DOI: 10.3322/caoc.21772; <sup>1</sup>Notional Cancer Institute's Surveillance, Epidemiology, and End Results (SEER), accessed March 2024

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## **Turnstone is Pioneering Advancements in Selected TIL Therapy**

Next-generation therapy designed to treat and cure solid tumors



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## **Turnstone Executive Team**

Proven experience across all areas and stages of drug development



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## **Turnstone External Network**

Supported by prominent scientific and corporate advisors and collaborators

## Key Collaborators







Steven A. Rosenberg, MD, PhD Chief of Surgery Branch National Cancer Institute

#### Simon Turcotte, MD, MSc Associate Professor of Surgery

Associate Professor of Surgery; Lead of Adoptive T Cell Cancer Immunotherapy Program, University of Montreal Hospital Research Centre (CRCHUM)

### **Distinguished Advisors**

Malcolm Brenner, MD, PhD Professor, Center for Cell and Gene Therapy Baylor College of Medicine

> Adrian Hill, PhD Director, The Jenner Institute University of Oxford

Robert Seder, MD Chief, Cellular Immunology Section Vaccine Research Center National Institutes of Health



Founder and Advisor Tempest Therapeutics Alan Melcher, PhD Team Leader

Translational Immunology

The Institute of Cancer Research

Eric Tran, PhD

ACT Laboratory Lead

Providence Cancer Institute

Tassos Gianakakos, MBA Former CEO MyoKardia

Thomas Dubensky Jr., PhD



Bernard Fox, PhD Chief, Laboratory of Molecular and Tumor Immunology Providence Cancer Institute



Providence Cancer Institute Nicholas Restifo, MD

Special Volunteer National Institutes of Health

Jeffrey S. Weber, MD, PhD Deputy Director, PCC; Co-Director, Melanoma Research Program NYU-Langone Cancer Center

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## Turnstone Pipeline

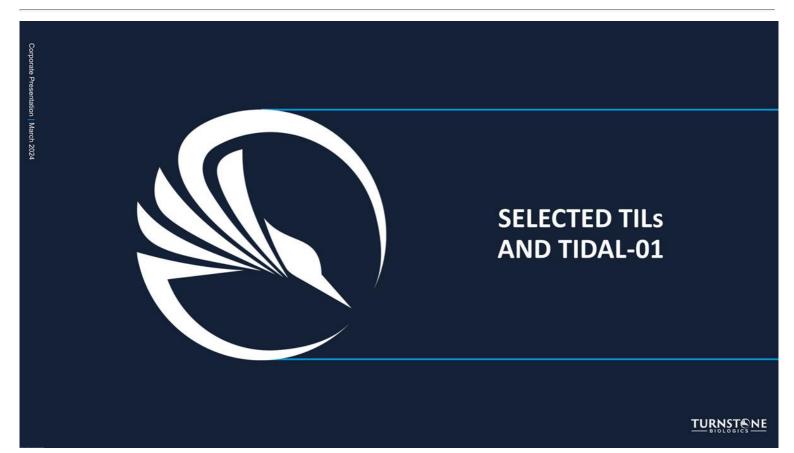
Opportunity to address broad set of solid tumor patient populations

|          | Program  | Product Overview   | Key Indications  | Preclinical       | Phase 1 | Phase 2 | Phase 3 | Next Anticipated<br>Milestone |
|----------|----------|--|--|-------------------|---------|---------|---------|-------------------------------|
|          | TIDAL-01 | Tumor-reactive Selected TILs   | Breast cancer,<br>Colorectal cancer,<br>Head and neck cancer,<br>Uveal melanoma          |                   | -®      |         |         | Initial clinical data         |
| ed TILs  |          | Tumor-reactive Selected TILS   | Colorectal cancer,<br>Head and neck cancer,<br>Cutaneous and non-<br>cutaneous melanomas | Moffitt Collabora | tion*   |         |         | in mid-2024                   |
| Selected |          | Combination with<br>viral immunotherapy                                      | Solid tumors   | -                 |         |         |         | IND submission                |
|          | TIDAL-02 | Selected TILs with next-gen<br>manufacturing and TIL<br>quality enhancements | Solid tumors   | <u>_</u>          |         |         |         | IND submission                |

\*Investigator sponsored trials at Moffitt Cancer Center

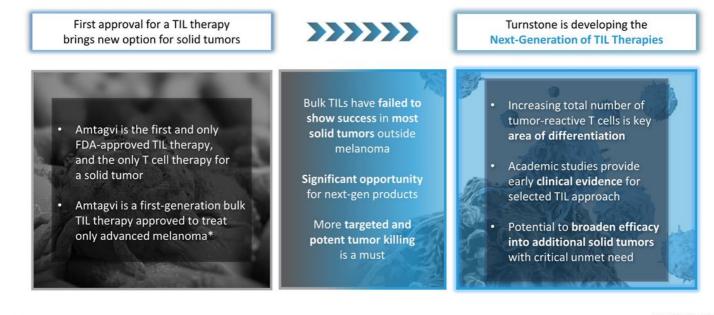
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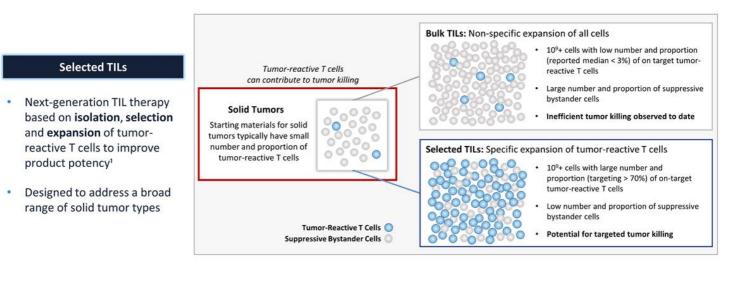
## **Expanding the Frontiers of TIL Therapy**

Building upon first-to-market TIL therapy to deliver differentiated product with unique market opportunity



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## Selected TILs Have Potential for More Targeted Tumor Killing



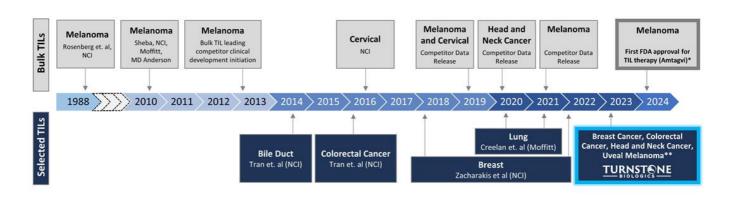
\* We define potency as the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result

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## Selected TILs Are Based on Advances from Academia

Early academics working on first-generation TILs led to development of a leading Bulk TIL company's current process ⇒ Success to date has been limited to melanoma



Recent academic data in next-generation TILs has provided early clinical evidence for next-generation selected TIL approach  $\Rightarrow$  Objective responses extended to other major solid tumor types

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## **Clinical Validation of Selected TILs**

#### Historical data from the NCI demonstrates limited evidence of benefit of Bulk TILs in epithelial malignancies

|           | Tumor Type   |     | Response   | Source                                  |  |
|-----------|--|-----|------------|---|--|
| Bulk TILs | Various Solid Tumors (including Colorectal,<br>Bile Duct, Pancreas, Breast, Gastric) | 50+ | No success | NCI – Rosenberg AACR 2020 / NCT01585428 |  |

#### Early academic selection strategies: deployed at the NCI have demonstrated clinical POC

|               | Tumor Type                     | N  | Response    | Source   |
|---------------|--------------------------------|----|-------------|--|
|               | Bile Duct (Cholangiocarcinoma) | 1  | 1 PR        | NCI - Tran et al; Science 2014 Science                       |
| Academic      | Colorectal Cancer              | 1  | 1 PR        | NCI - Tran et al; NEJM 2016                                  |
| Selected TILs | Non-Small Cell Lung Cancer     | 7* | 2 CRs, 1PR  | Moffitt - Creelan et al; Nature Medicine 2021 nature         |
|               | Breast Cancer                  | 6† | 1 CR, 2 PRs | NCI - Zacharakis et al; JCO 2022 Journal of Cinical Oncology |

\*7 patients received TIL product with confirmed tumor-specific reactivity out of 13 patients who were evaluable for clinical response

t6 patients enrolled on adoptive cell transfer protocol of enriched neoantigen-specific TIL out of 28 patients who contained TIL that recognized at least one immunogenic somatic mutation

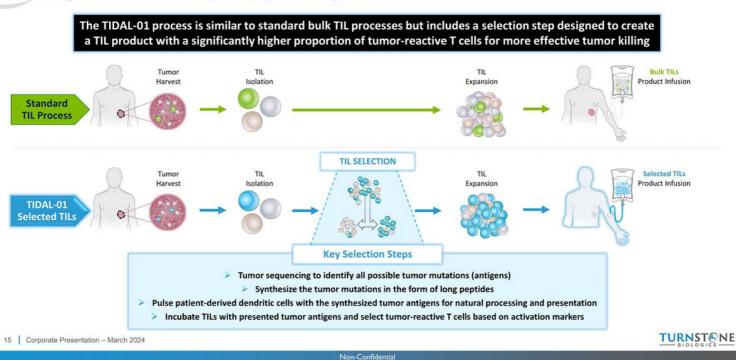
<sup>1</sup> Early academic selection and enrichment strategies typically utilized fragment-based selection and expansion approaches. Following harvest and dissection of the tumor, small numbers of tumor fragments were placed into separate multi-well tissue culture dishes and cultured with the tumor or manufactured antigens. TIL populations that were activated by exposure to tumor antigens in culture would then be identified based on cytokine expression and/or T cell activation marker expression, and only those activated TIL populations would be expanded for use in the final product

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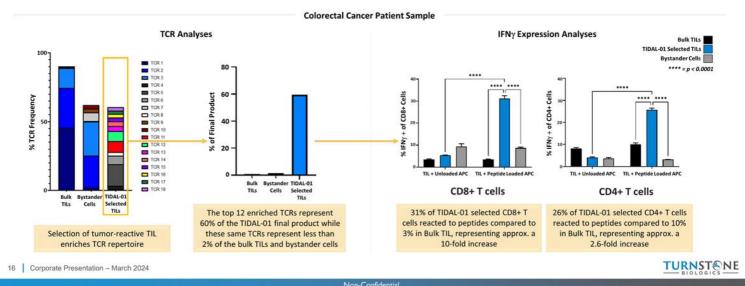
**TIDAL-01** Process

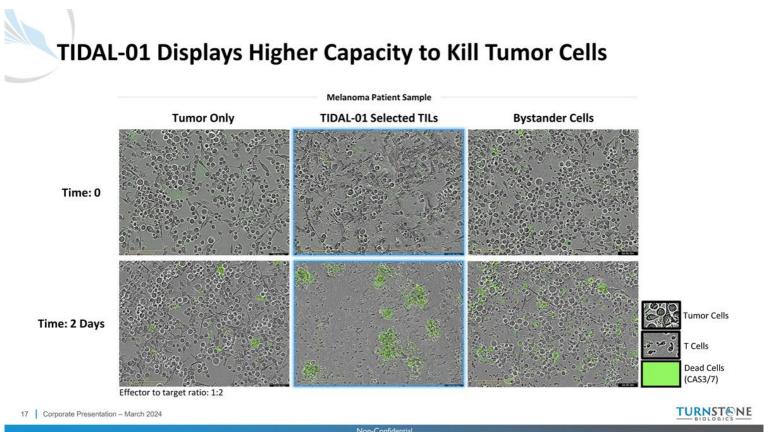
Designed to select a more potent population of T cells



## TIDAL-01 Designed to Select for Tumor-Reactive T Cells that are Typically Only Found in Very Low Levels in Bulk TILs

- TIDAL-01 product consists of diverse set of T cells with confirmed tumor-reactivity (TCRs)
- Selected tumor-reactive T cells are typically found in only very low frequencies in Bulk TILs
- These TCRs within Selected TILs deliver higher frequency of immunostimulatory cytokine expression in CD4+ and CD8+ T cells vs. Bulk TILs







## **TIDAL-01** Phase 1 Clinical Trials in Advanced Solid Tumors

#### Objective

Demonstrate the safety, biology, initial efficacy and manufacturing feasibility of TIDAL-01 in a Phase 1, first-in-human, non-randomized, open-label, single-dose study in patients with advanced solid tumors

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#### Structure



Turnstone sponsored trial (STARLING) enrolling across 10+ clinical sites

- Colorectal cancer (CRC)
- Head and neck cancer (HNSCC)
- Uveal melanoma
- Breast cancer

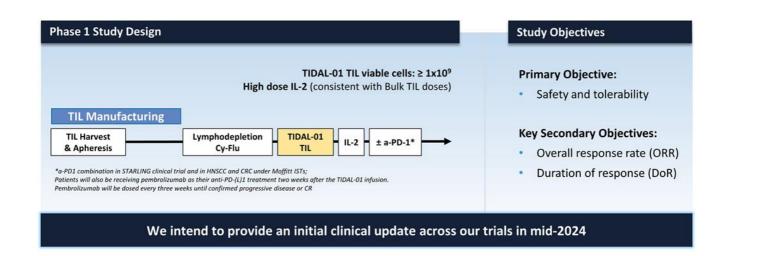
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Two investigator sponsored trials (ISTs) in collaboration with Moffitt Cancer Center

- Colorectal cancer (CRC)
- Head and neck cancer (HNSCC)
- Uveal melanoma
- Cutaneous melanoma

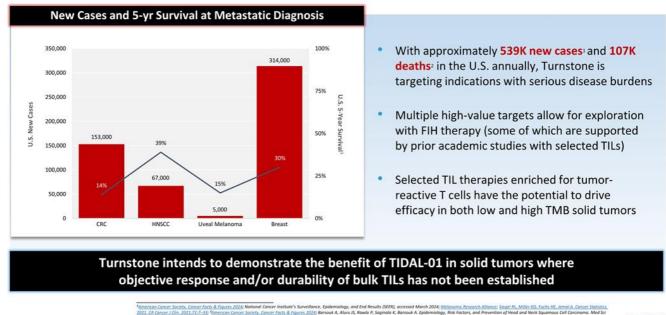
# TIDAL-01 Phase 1 Study is Actively Enrolling Patients



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## TIDAL-01 Phase 1 Indication Focus on Multiple Solid Tumors with Critical Unmet Need



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DOI: Of Genery Cen. 2021;712–33; American Cover Socy: Genery Forty Environment Fuery SOCIA Bandward, Nucl. S, Raviol P, Soginalo K, Bandward K, Ban

## **Indication Spotlight: Colorectal Cancer**

#### Metastatic CRC patients have very limited treatment options

- 1<sup>st</sup> and 2<sup>nd</sup> line options mainly limited to chemotherapy (FOLFIRI / FOLFOX) with or without targeted agent combinations (bevacizumab and/or anti-EGFR)<sup>1</sup>
- 3<sup>rd</sup> line treatment options are mostly targeted therapies with applicability limited to a small percentage of patients with specific mutations (i.e. BRAF-V600E, HER2)<sup>1</sup>
- No approved immunotherapies for MSS-CRC<sup>2</sup> which comprise 85% of all CRC cases<sup>3</sup>

Treatments options for metastatic CRC are characterized by poor objective responses and low durability

2<sup>nd</sup> and 3<sup>rd</sup> line agent ORRs range from 2-38% with supporting OS ranging from 7.4 – 14.5 months<sup>1</sup>

#### Unmet need remains high and market size is significant

Large patient numbers create significant market opportunity for Turnstone in 2<sup>nd</sup> and 3<sup>rd</sup> line metastatic CRC

#### Our Phase 1 study is enrolling across all subtypes of 2<sup>nd</sup> and 3<sup>rd</sup> line CRC

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NCCN Guidelines Version 4.2023: <u>BRAFTOW</u> Prescribing Information; <u>Erbitus</u> Prescribing Information; <u>Dalichi Sankyo</u> Press Release Aug 2023 (Enhertu BTD); <u>ICO</u> 40, 119-119(2022) (DESTINY-CRC01), <u>Ann Sura Oncol</u>. 2008 Sep;15(9):2388 94; <u>Cancer Med</u>, 2020 Feb; 19(3): 1044–1057; <u>Onco Tarzets</u>: There, 2020 Dec 8: 13:12601-12613; <u>Curres</u>, 2020 3an; <u>15(1)</u>: e33736. <u>Clin Adv Hematol Oncol</u>. 2018 Nov; <u>16(11)</u>: 735–745; <u>Front Oncol</u>. 2022; <u>12</u>: 888181; <u>ICO Precis Oncol</u>. 2023 Jam; <u>79:2200179</u>; <u>Cancers</u> (Basel). 2023 Feb; <u>15(4)</u>: 1023; <u>Cancers</u>; <u>Basel</u>). 2023 Apr; <u>15(8)</u>: 2288; <u>11 Nivo Pius (pi Shows Benefit in mCR</u>; <u>"Point Farber Cancer Institutes</u>" Press <u>Non-Confidential</u>

# Manufacturing Highlights

| <u>(</u> )       | Internal Capabilities |                                | Fully operational TIL therapy process and analytical development at our San Diego facility  |
|------------------|-----------------------|--------------------------------|---|
|                  |                       | ernal cGMP<br>ers for TIDAL-01 | Moffitt Cell Therapy Facility to support investigator sponsored trials and Charles River Laboratories to support the STARLING trial |
| eas of Future Gr | owth                  |                                |   |
|                  |                       |                                | ing the overall manufacturing time towards our target of 4 weeks<br>all steps will be implemented prior to start of pivotal trials  |
| In-House Mar     | nufacturing:          |                                | ng and intend to develop a fully integrated commercial<br>supply chain once clinical success of TIDAL-01 is demonstrated            |
|                  |                       |                                | supply chain once clinical success of TIDAL-01 is demonstrated  |

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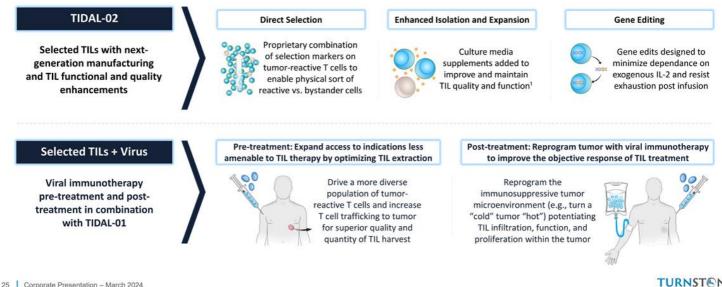
tt = Moffitt Cancer Cen

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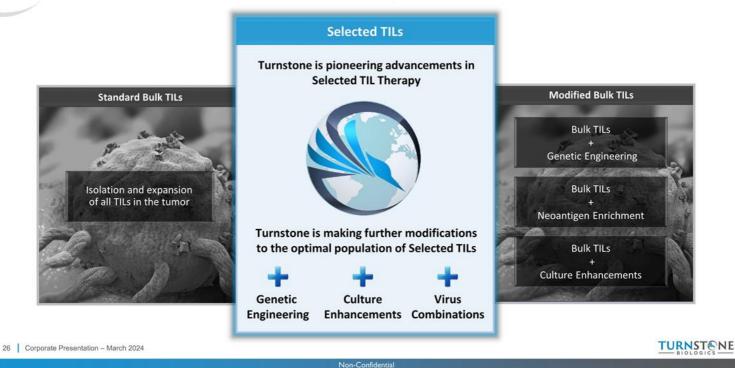
## **Emerging Pipeline with Significant Upside Potential**

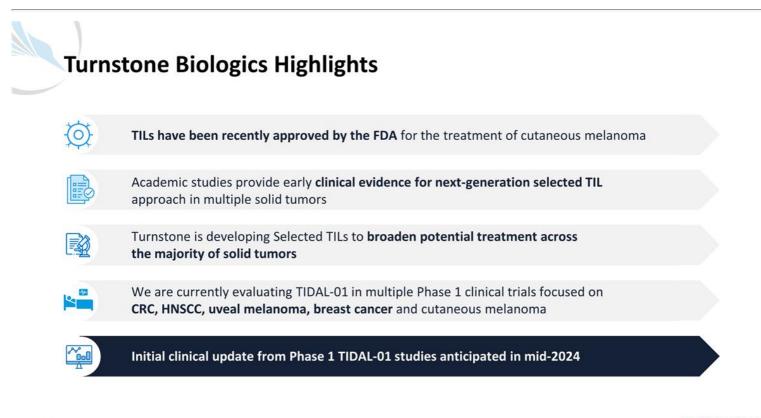
Turnstone is building a TIL pipeline to further broaden objective responses and treat patients in earlier lines of therapy



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# Turnstone Competitive Positioning





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