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

DIVISION OF
CORPORATION FINANCE

June 9, 2023

Sammy Farah, M.B.A., Ph.D.
President and Chief Executive Officer
Turnstone Biologics Corp.
9310 Athena Circle, Suite 300
La Jolla, California 92037

Re: Turnstone Biologics Corp.
Draft Registration Statement on Form S-1
Submitted May 15, 2023
CIK No. 0001764974

Dear Sammy Farah:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1, submitted May 15, 2023

Cover Page

1. We note that you have applied to list your common stock on the Nasdaq Global Market. Please revise the cover page of the prospectus as follows, and make conforming revisions where appropriate:
   - State, if true, that no assurance can be given that your listing application will be approved.
   - Disclose whether your offering is contingent upon final approval of your NASDAQ listing, and ensure this disclosure is consistent with your underwriting agreement. If your offering is not contingent on listing approval, include a risk factor describing the consequences of not being listed.

Prospectus Summary , page 1

2. We note that your auditors have issued a going concern opinion regarding your operations. Please revise your disclosure throughout the prospectus as follows:
   - Expand and balance your Summary disclosure by including discussion regarding your recurring net operating losses with the exception of the year ended December 31, 2021, the expectation of continuing operating losses and negative cash flows for the foreseeable future, the termination in 2021 and 2022 of the AbbVie and Takeda Agreements that appear to have previously been your sole sources of collaboration revenue, the need to raise additional capital to finance your future operations, and the auditor's going concern opinion.
   - Revise your summary risk factor on page 7 to disclose that if you cannot continue as a viable entity, your stockholders may lose some or all of their investment in your company.

3. Please revise your prospectus summary to define or explain briefly the following scientific terms:
   • potency and potent T cells
   • TIL quality, function, and persistence
   • clinically meaningful
   • tumor heterogeneity
   • PD-(L)1 treatments

   Also, we note that you use terms such as "deep and durable response," "progression-free survival," "objective response rate" and "complete response rate" throughout the prospectus when describing third party clinical trial results. Explain the meaning of these terms in relation to observed clinical trial endpoints and clarify, if true, that they do not indicate that the patient was cured of the condition.

Our Solution: Selected TILs, page 2

4. You state on page 2 and elsewhere throughout the prospectus that the company is developing next generation TIL therapies designed to drive "curative outcomes" across multiple solid tumors. If true, please revise to clarify that no TIL therapies have received FDA approval to date and that at present, no therapies in clinical development for the solid tumor indications that you are addressing are curative.

5. You state on page 2, 113 and 120 that your selective expansion process "results in a substantially higher absolute number and proportion of tumor-reactive T cells in the final product in comparison to the relatively infrequent tumor-reactive T cells that are routinely found in bulk TIL." Please revise to provide the basis for this statement, and quantify the number and proportion of tumor-reactive T cells in Selected TILs versus bulk TIL to the extent appropriate so that investors can compare against your target rate of >70% disclosed in the figure on page 3.

6. In the figure depicting advantages of Selected TILs over bulk TILs appearing on pages 3, 113, and 121, please remove or revise the reference to tumor-reactive T cells contributing to "efficacy." In the appropriate place(s), please provide a reference for your disclosure that the reported median of on-target tumor-reactive T cells in bulk TIL is <3%. Additionally, on pages 2 and 113, please revise your related narrative discussion to provide context for the statement that Selected TILs hold potential for "potent" targeted tumor killing as you have on page 121.

Supporting Clinical Evidence , page 3

7. You state on pages 3 and 122 that clinical studies in academic centers utilizing selection strategies to select for tumor-reactive T cells have "demonstrated positive outcomes in challenging solid tumors, where bulk TILs have had limited to no success." Please revise your discussion of the results of these and any other clinical trials or preclinical studies, whether conducted by you or third parties, to remove any conclusory statements regarding the trial results or their meaning and instead focus on the specific factual details of the studies, including quantitative information regarding the range of results observed and describe the results using objective data and/or terminology based on the trial endpoint(s).

Our Pipeline, page 4

8. We note that an investigator-sponsored clinical trial is ongoing with H. Lee Moffitt Cancer Center and Research Institute, Inc., investigating TIDAL-01 as a potential therapy in both cutaneous and non-cutaneous melanoma. Please expand your disclosure in the appropriate place(s) to clarify briefly the nature of the investigator-sponsored study, how one differs from a trial sponsored by your company, and your role/responsibility, if any, in the trial. Please also tell us your consideration of providing risk factor disclosure concerning the clinical trial risks associated with investigator-sponsored clinical trials.

Our History and Team, page 5

9. Please limit your Summary disclosure of specific investors to those identified in the Principal Shareholder table on page 194. Additionally, indicate that prospective investors should not rely on the named investors' investment decision, that these investors may have different investment strategies and risk tolerances. If true, disclose that the preferred stock offering(s) in which such investors purchased shares were conducted at a significant discount to the IPO price.

Our Strategy , page 5

10. We note your use of the term "high unmet medical need" here and elsewhere throughout the prospectus, as well as your statement that you are pursuing a clinical development strategy designed to "support an efficient path to registration." Such statements might imply that your products are eligible for fast track designation or priority review granted

by the FDA for products that treat certain serious unmet medical needs. If material, please expand this section to provide context for these references and briefly explain your development strategy for your TIL product candidates in the U.S. and abroad. In this regard, we note that you state on page 55 that you intend to seek approval for your candidates in both the U.S. and in "selected foreign jurisdictions," which should be identified to the extent known or reasonably anticipated.

Additionally, please revise pages 6 and 117 to explain how the design of your analytical characterization program will "minimize regulatory hurdles" or remove this reference.

11. We note that you have initiated two Phase 1 clinical trials for your lead product candidate, TIDAL-01, for the treatment of various cancers. On page 5, you state your belief that positive results from one or both of these clinical trials has the potential to support advancement of TIDAL-01 into registrational trials across multiple solid tumor types. Please define the term "registrational trials" and explain the basis for your belief. Your discussion should clarify the factors that will determine whether your TIDAL-01 trials become registrational and who will make such determination.

The Offering
Use of Proceeds, page 10

12. Please revise your Use Of Proceeds disclosure here and on page 86 to provide your best reasonable estimate regarding how far into development and/or the regulatory review process you expect each such program to reach using the allocated offering proceeds. If any material amounts of other funds are necessary to accomplish any specified purposes for proceeds from this offering, state the amounts and sources of other funds needed for each specified purpose. Refer to Instruction 3 to Item 504 of Regulation S-K.

Risk Factors
We may attempt to secure approval from the FDA or comparable foreign authorities..., page 38

13. We note your disclosure that you may seek accelerated approval for one or more of your product candidates.
    - Please revise your disclosure to clarify that because your candidates are in early development, there can be no assurance that the FDA would approve any form of application for expedited review for any of your product candidates.
    - Affirmatively state that the FDA’s accelerated approval pathways do not guarantee an accelerated review by the FDA. Further, explain that even if a product candidate could be granted a designation or qualify for expedited development, it does not increase the likelihood that the product candidate will receive approval.

Our principal stockholders and management own a significant percentage of our stock..., page 77

14. We note your disclosure regarding the significant concentration of ownership of the company. Please tell us whether you will be considered a "controlled company" within

the meaning of NASDAQ listing standards post-offering. If so, provide appropriate disclosure of your controlled company status on the prospectus cover page and revise this section and the Prospectus Summary, where appropriate, to indicate that you will be a "controlled company" and the implications of such status, including whether you plan to utilize any of the exemptions available to you. Also revise the Prospectus Summary to address the risks of being a shareholder in a controlled company, and include information regarding the controlling shareholder(s) and their ability to impact your company and its stated business strategies.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware..., page 80

15. Please revise the last paragraph of this risk factor to disclose that the exclusive forum provisions that will be contained in your amended and restated certificate of incorporation may result in increased costs to shareholders to bring a claim. Additionally, make conforming revisions to the Choice of Forum section beginning on page 201.

Components of Our Results of Operations
Revenue
Collaboration Revenue, page 98

16. Please revise to clarify that you do not anticipate recording any additional revenue under the AbbVie Biotechnology Ltd. agreement in the future due to the contract termination and provide similar disclosure relating to the termination of the Takeda agreement for which the second termination notice is effective on July 6, 2023. Clarify on page 101 the amount of the revenue recorded in 2022 and 2021 that related to the terminated agreements.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Components of Our Results of Operations
Collaboration Revenue, page 98

17. Please revise your disclosure in this section to briefly explain why the AbbVie Agreement terminated in 2021 and the Takeda Agreement will be terminated in its entirety as of July 2023. Additionally, please file the Takeda Agreement as an exhibit to your registration statement or tell us why you believe you are not required to do so. Refer to Item 601(b)(10) of Regulation S-K.

Results of Operations
Research and Development Expenses, page 101

18. Please disclose the costs incurred during each period presented for each of your key research and development projects/indications. In particular, clarify how much of the historical research and development expense related to the RIVAL-01 program under the Takeda agreement which was terminated. If you do not track your research and

development costs by project, please disclose this fact and explain why you are not able to provide this level of disclosure.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Estimates
Determination of the Fair Value of Common Stock, page 109

19. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the awards underlying your incentive units and the reasons for any differences between the recent valuations of your units leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation. Please discuss with the staff how to submit your response.

Business
Our Strategy, page 116

20. We note your disclosure that you are "leveraging deep and strategic relationships with a number of academic collaborators, including Moffitt" to support development of your Selected TIL therapies.
    - Please revise to quantify the number of academic collaborators with whom you have material relationships.
    - We note your disclosure on page 134 regarding your "ongoing collaboration with Dr. Simon Turcotte at the Centre Hospitalier de l'Universite de Montreal" and disclosure on page 137 stating that you are collaborating with "the NCI," an acronym which should be defined at first use on page 119. Please advise if there is a collaboration agreement in place with either institution or any others. If so, please describe the material terms of the collaboration agreements and file them as exhibits with your next amendment or tell us why you believe you are not required to do so. Refer to Item 601(b)(10) of Regulation S-K.

Overview of Current Cancer Immunotherapies and Limitations, page 118

21. Please revise the figure on page 119 to remove the statements that TIL therapy is the only cell therapy that "has shown clinical efficacy in multiple solid tumors" and has a "manageable safety profile."

Virus Combinations, page 124

22. You state that the potential of viral immunotherapy has been "demonstrated through subsequent clinical data achieved by the next generation of viral immunotherapies in development." Please revise to place this statement within the proper context by objectively summarizing any material results from such trials, or remove.

TIDAL-01, page 125

23. Please revise your descriptions of the preclinical and nonclincal trials conducted in support of your programs to disclose the number of tests conducted, the number of participants or samples in each test, and the range of results observed. Disclose whether selected sample patient results presented are representative of a broader sampled group, as applicable.

Strategic Alliance and Collaboration with Moffitt Cancer Center, page 129

24. You state that the company has entered into a first of its kind strategic alliance with Moffitt to leverage their expertise for "rapid advancement of TIDAL-01 into the clinic" and for access to "accelerated clinical site activation and patient recruitment." Please revise these and any similar disclosures throughout the prospectus to remove any implication that you will be successful in developing your product candidates, obtaining necessary regulatory approvals, or commercializing your product candidates in a rapid or accelerated manner, as such statements are speculative. Additionally, please explain how your agreement with Moffitt is the "first of its kind."

Clinical Evidence Supporting Viral Immunotherapy Combination, page 135

25. You state that the graph on page 136 presents comparative translational data for "multiple" colorectal cancer patients from a prior clinical trial. Please revise to state when such clinical trial was conducted and by whom, quantify the number of such patients enrolled in the trial, and disclose whether any serious adverse events were observed.

Myst Merger Agreement, page 139

26. Please revise this section and the Dilution section beginning on page 91 to disclose that if the company elects to pay any milestone consideration owed to the Myst Holders in shares of common stock rather than in cash, there will be further dilution to stockholders.

Intellectual Property
Additional Miscellaneous Virus IP, page 142

27. In relation to the Company's material patents, please revise your intellectual property disclosure in this section to clearly describe on a patent family basis the type of patent protection granted for each product or technology, whether such patent is owned or licensed, and the jurisdiction, including any foreign jurisdiction, of each material pending or issued patent.

Certain Relationships and Related Party Transactions
Public Offering Participation Rights , page 192

28. Please revise this section to quantify the percentage of the shares of common stock in this offering that PFM will have the right to purchase, and disclose whether the shares will be

offered as part of the public offering or in a separate private placement.

Principal Stockholders, page 194

29. Please revise the table on page 194 to identify the natural person(s) with voting and/or dispositive control over the shares held by F-Prime Capital and FACIT Inc.

Notes to the Financial Statements
7. Asset Acquisition, page F-28

30. Please clarify in the filing the accounting treatment for the Myst Merger. Address whether or not the acquisition is considered a business pursuant to ASC 805-10-55-4 through 55-9. If you conclude the acquisition was not a business combination, tell us your consideration of accounting for the contingent consideration under ASC 815, and if ASC 815 is not applicable, ASC 450. If you believe ASC 815 and ASC 450 are not applicable, please tell us your basis for accounting for the liability under ASC 480.

General

31. With reference to the following non-exhaustive list of illustrative examples, please remove or revise these and all other statements throughout the prospectus that state or imply that your product candidates are safe or effective, as these determinations are solely within the authority of the U.S. Food and Drug Administration and comparable regulatory bodies:
    - Clinical trials with standard bulk TILs have "shown clinical efficacy in limited solid tumor types while demonstrating a consistent and manageable safety profile" (pages 1, 112, 119) and "bulk TILs have already shown clinical efficacy" (pages 3, 114, and 123). In this regard, we note your disclosure on page 42 that TIL-based therapy is an emerging field and there are no approved TIL therapies.
    - Many viruses have inherent oncolytic activity that can be modulated to "enhance potency and safety" (pages 4 and 114).
    - TIL therapy is the only cell therapy that "has shown clinical efficacy in multiple solid tumors" and has a "manageable safety profile" (figure on page 119).
    - The company's goal is to develop TIL therapies that will "provide greater efficacy" in a broad range of solid tumor types and the company believes that the greater the population of delivered tumor-reactive T cells, the "higher the tumor killing and resulting therapeutic benefit" (page 120).
    - Prospective and translational clinical data in the TIL field supports the potential of the company's Selected TIL approach to provide "superior clinical benefit relative to bulk TILs" (pages 3 and 113) and the "potential superiority" of the company's Selected TIL approach (page 121).
    - Academic studies utilizing TIL selection strategies have yielded "promising outcomes" and "promising responses" (pages 122 and 123), and the company has observed "encouraging translational data" and "favorable tolerability" supporting its combination of Selected TILs with viral immunotherapies (page 135).

- Your Selected TIL process includes "potent anti-tumor activity, as observed in preclincial studies" (page 128).
- Nonclinical studies demonstrated that your TIDAL-01 process resulted in "anti-tumor activity" and "potent tumor-killing activity" (page 129).
- TIDAL-01 data are "anticipated to corroborate clinical safety and efficacy observations" (page 134).
- The company believes its combination strategy "could be particularly effective" in indications with highly suppressive TMEs (page 135).

32. Please file the following as exhibits pursuant to Item 601(b)(10) of Regulation S-K with your next amendment, or tell us why you believe they need not be filed. We may have additional comments once we have had an opportunity to review these agreements.
    - Any material supply contracts. In this regard, we note your disclosure on page 33 that you do not have supply contracts with "many of [your] suppliers."
    - Any material license agreements. In this regard, we note your disclsoure on page 64 that you are a party to existing license agreements pursuant to which you in-license key patent and patent applications, know-how, trade secrets and data rights for your product candidates.
    - Second Amended and Restated Investors' Rights Agreement between the company and the convertible preferred stockholders.

33. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Christine Torney at 202-551-3652 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Lauren Sprague Hamill at 303-844-1008 or Joshua Gorsky at 202-551-7836 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Ryan Sansom