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Via EDGAR

June 12, 2023

U.S. Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F Street, N.E. Washington, D.C. 20549

Attention: Lauren Sprague Hamill

Joshua Gorsky Christine Torney Mary Mast

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

#### Ladies and Gentlemen:

On behalf of Turnstone Biologics Corp. (the "Company"), the following information is submitted in response to the comments received from the staff (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") by letter dated June 9, 2023 (the "Comment Letter") regarding the above-referenced draft Registration Statement on Form S-1, as confidentially submitted to the Commission on May 15, 2023. Concurrently with the submission of this response letter, the Company is filing its Registration Statement on Form S-1 (the "Registration Statement") with the Commission. In addition to addressing the comments raised by the Staff in the Comment Letter, the Company has included other revisions and updates to its disclosure in the Registration Statement.

For the convenience of the Staff, the numbering of the paragraphs below corresponds to the numbering of the respective comment in the Comment Letter, the text of which we have incorporated into this response letter for convenience in italicized type and which is followed by the Company's response. In the responses below, page number references are to the Registration Statement.

## <u>Draft Registration Statement on Form S-1 submitted on May 15, 2023</u>

# 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.



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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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on the cover page and pages 79, 219, and 230 of the Registration Statement.

#### Prospectus Summary, page 1

- 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.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 7, 8, 18 and 19 of the Registration Statement.

- 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 1, 2, 3, 4, 100, 101, 121, 123, 124, 131, 132, 133, 134, 145, and 146 of the Registration Statement and has removed references to "deep and durable response".

# 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.



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**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 2, 100, 122, and 130 of the Registration Statement.

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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 2, 122, and 130 of the Registration Statement.

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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 1, 2, 3, 121, 123, 129, 130, 133, and 136 of the Registration Statement, including to revise the figure to remove references to "efficacy".

#### 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).

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 3 and 124 of the Registration Statement.

# 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.



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**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 1, 5, 100, 101, 121, 125, 135, and 144 of the Registration Statement. In response to the Staff's comment, the Company also has further revised risk factor disclosure on pages 46 and 47 of the Registration Statement 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 6, 126, and 206 of the Registration Statement. The Company respectfully acknowledges the Staff's request to disclose if the preferred stock offerings in which investors purchased shares were conducted at a significant discount to the IPO price, however, the Company cannot at this time ascertain whether such investors purchased shares at a significant discount to the IPO price to which the Registration Statement relates until a *bona fide* price range for the IPO is determined. The *bona fide* price range remains subject to determination based on factors outside of the Company's control, including market conditions at the time of determination. The Company undertakes to revise its disclosure to address the Staff's comment in a subsequent amendment to the Registration Statement that includes the *bona fide* price range.

#### 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 6, 7, 59, 101, 125, 126, 127, 135, 136, 137, 144, and 145 of the Registration Statement. Because the Company is very early in its clinical development efforts, it is too preliminary at this time to discuss fast track designation or priority review that might be granted by the FDA and as a result, the Company has removed references to "high unmet medical need" and further has not added disclosure relating to fast track designation or priority review. Furthermore, the Company acknowledges the Staff's comment to explain the Company's development strategy for the Company's TIL product candidates in the U.S. and abroad, if material, and respectfully advises the Staff that the Company did not include such disclosure because it is not material to the Company's business at this time.



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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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 6, 126, 136, 139, and 143 of the Registration Statement, including to change references to "registrational trials" to "pivotal trials" and to define such term.

The Company acknowledges the Staff's comment and respectfully advises the Staff that while the FDA and European Medicines Agency ("EMA") generally rely on well designed and executed Phase 3 randomized controlled clinical trials that demonstrate positive safety and efficacy of a product candidate to support BLA or MAA approval, both the FDA and EMA acknowledge that there are situations where such clinical trials are not feasible operationally and ethically. Under these circumstances, evidence from early non-randomized clinical trials may be used to support approval when an investigational product candidate is observed to demonstrate substantial benefit over currently available therapies. As indicated in the FDA guidance titled "Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics", in "settings where there is no available therapy and where major tumor regressions can be presumed to be attributed to the tested [product candidate], the FDA has sometimes accepted ORR and response duration observed in single-arm clinical trials as substantial evidence supporting accelerated approval[s]." A similar concept also is included in the EMA Guideline on Clinical Trials in Small Populations.

There are numerous examples in oncology where approval of new therapies has been granted based on single-arm clinical trials. For example, four CAR-T cell therapies that have received approval have been approved based on single-arm clinical trials. The FDA and EMA approved Kymriah for relapsed or refractory acute lymphoblastic leukemia based on a single-arm Phase 2 clinical trial with 68 treated patients and for relapsed or refractory diffuse large B-cell lymphoma based on a single-arm Phase 2 clinical trial with 106 treated patients. The FDA and EMA also approved Yescarta for relapsed or refractory diffuse large B-cell lymphoma based on a single-arm Phase 2 clinical trial with 101 treated patients. Tecartus also was approved by the FDA and EMA on the basis of the single arm, open label ZUMA-2 trial, evaluating 74 enrolled subjects with relapsed or refractory mantle cell lymphoma for overall response rate. Bristol-Myers Squibb also announced on March 31, 2020 the submission of a BLA for its product candidate, bb2121, based on a single-arm Phase 2 clinical trial in patients with relapsed or refractory multiple myeloma. The FDA also approved Bristol Myers Squibb's Breyanzi for adults with relapsed or refractory diffuse large B-cell lymphoma, based on results of a pivotal Phase 1 clinical trial. Nonetheless, the Company has revised the disclosure to reflect that if there are positive results from the Phase 1 and upon discussions with the applicable regulatory authorities, the Company intends to evaluate advancing TIDAL-01 into pivotal trials.



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# <u>The Offering</u> <u>Use of Proceeds, page 10</u>

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.

**Response:** The Company respectfully acknowledges the Staff's comment and will respond to this comment in a subsequent amendment to the Registration Statement that includes the *bona fide* price range and proposed aggregate offering size for the offering.

#### 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.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 41 of the Registration Statement.

#### 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.

**Response:** The Company respectfully acknowledges the Staff's comment and advises the Staff that the Company will not be a "controlled company" under Nasdaq Listing Rule 5615(c) following the offering, as no individual, "group" (as defined under Nasdaq Listing Rule 5615(c)), or other company will hold more than 50% of the voting power for the election of the Company's directors following the offering.



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## 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.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 86 and 218 of the Registration Statement.

#### 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 15, 18, 102, 105, and 109 of the Registration Statement.

# <u>Management's Discussion and Analysis of Financial Condition and Results of Operations Components of Our Results of Operations Collaboration Revenue, page 98</u>

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.

**Response:** In response to the Staff's comment, the Company has revised the disclosures on page 105 of the Registration Statement, including to explain that each of the AbbVie Agreement and Takeda Agreement were terminated by the counterparty pursuant to their terms.

The Company acknowledges the Staff's comment and respectfully advises the Staff that it did not file the Takeda Agreement because it does not consider this agreement to be a material agreement pursuant to Item 601(b)(10) of Regulation S-K. However, the Company respectfully advises the Staff that it has added disclosure on page 105 of the Registration Statement to clarify that, as of March 31, 2023, the Company has ceased all work under the Takeda Agreement and the Company has concluded that there are no remaining estimated services to be performed by the Company pursuant to the Takeda Agreement. Additionally, the Company added disclosure on page 105 to the Registration Statement clarifying that the Company will not receive any additional revenue under the Takeda Agreement in the future.



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The Company notes that it has carefully considered the requirements of Item 601(b)(10) of Regulation S-K as they relate to such agreements. Item 601 of Regulation S-K sets forth the parameters as to whether an agreement is a "material contract" required to be filed as an exhibit to the Registration Statement. Item 601(b)(10)(i)(A) of Regulation S-K provides, in pertinent part, that a registrant must file "[e]very contract that is not made in the ordinary course of business that is material to the registrant and is to be performed in whole or in part at or after the filing of the registration statement or report" and, for newly reporting registrants, "every contract not made in the ordinary course of business that is material to the registrant and that was entered into not more than two years before the date on which such registrant . . . [f]irst files a registration statement or report."

The Company respectfully advises the Staff that the Takeda Agreement (i) was entered into more than two years before the date the Company filed its Registration Statement, (ii) is not material to the Company's business, and (iii) is not to be performed in whole or in part at or after the filing of the Company's Registration Statement. As disclosed in the Registration Statement, the Takeda Agreement was entered into in November 2019, and on June 13, 2022, Takeda provided six months' written notice to terminate the development program in accordance with its termination for convenience rights, with such termination being effective as of December 13, 2022, and on January 6, 2023, Takeda provided six months' written notice to terminate the remainder of the Takeda Agreement, with such termination being effective as of July 6, 2023. The Company has concluded that the Takeda Agreement is not material to its business because it did not drive primary value for the Company and was not related to TIDAL-01, the Company's only product candidate in clinical development, and the expenses associated with the Takeda Agreement were not material for the Company. The Takeda Agreement is not to be performed in whole or in part at or after the filing of the Company's Registration Statement because there are no remaining services to be performed by the Company under the Takeda Agreement and the Company will not receive any additional revenue thereunder.

#### 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.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 106 of the Registration Statement.

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

19. Once you have an estimated offering price or range, please explain to us how you determined



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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.

**Response:** The Company acknowledges the Staff's comment and undertakes that, once an estimated offering price or range is available, the Company will provide the Staff with the requested information.

#### **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.

**Response:** In response to the Staff's comment, the Company has revised the disclosures on pages 7, 127, and 130 of the Registration Statement.

Additionally, the Company respectfully advises the Staff that the Company is party to two separate collaboration agreements, one with the Centre Hospitalier de l'Universite de Montreal ("CHUM") and a second Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("NCI"). However, based on present facts and circumstances, the Company has concluded that neither of these agreements is material within the meaning of Item 610(b)(10) of Regulation S-K and are therefore not required to be filed as exhibits to the Registration Statement because they were entered into in the ordinary course of business of the Company and they do not fall into any of the specified categories set forth in (A) through (D) of Item 601(b)(10)(ii) of Regulation S-K.

Item 601(b)(10)(i) of Regulation S-K requires that every contract "not made in the ordinary course of business which is material to the registrant and is to be performed in whole or in part at or after the filing of the registration statement or report or was entered into not more than two years before such filing" is required to be filed as an exhibit. Item 601(b)(10)(ii) of Regulation S-K goes on to state that "[i]f the contract is such as ordinarily accompanies the kind of business conducted by the registrant and its subsidiaries, it will be deemed to have been made in the ordinary course of business and need not be filed unless it falls within one or more" specified categories contained in (A) through (D) of Item 601(b)(10)(ii) of Regulation S-K, "in which case it shall be filed except where immaterial in amount or significance." The Company advises the Staff that a strategic agreement intended to facilitate the advancement of research with governmental or educational institutions are of a type that normally accompany the Company's business. Moreover, the Company respectfully



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advises the Staff that with respect to both the collaboration agreement with CHUM and the CRADA with NCI, no licensing arrangement is currently included within the agreements, no specific future licensing agreement is mandated within the agreements and the funding amount is currently immaterial from a financial perspective to the Company.

For the foregoing reasons, the Company believes both the collaboration agreement with CHUM and the CRADA with NCI were entered into by the Company in the ordinary course of business, and the Company does not believe it is substantially dependent on either of these agreements. Accordingly, the Company does not believe it is required to file such agreements as exhibits to the Registration Statement under Item 601(b)(10) of Regulation S-K. Further, the Company has determined that these agreements do not fall into any of the specified categories requiring filing as an exhibit set forth in (A) through (D) of Item 601(b)(10)(ii) of Regulation S-K.

The Company also respectfully submits that, other than the agreements already disclosed and filed as exhibits to the Company's Registration Statement, the Company does not consider any individual agreement to be material to its business such that it would be required to describe the material terms of such agreement in the Registration Statement. The Company assures the Staff that it will continue to evaluate all agreements with its collaborators and, in the event the Company determines it has become substantially dependent on any such agreement, or determines that any such agreement is material to its business within the meaning of Item 601(b)(10) of Regulation S-K, the Company will file such agreement as an exhibit and/or describe the material terms of such agreement in subsequent filings with the Commission.

# 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."

Response: In response to the Staff's comment, the Company has revised the disclosure on page 129 of the Registration Statement.

#### 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.

Response: In response to the Staff's comment, the Company has removed the disclosure on page 134 of the Registration Statement.

## TIDAL-01, page 125

23. Please revise your descriptions of the preclinical and nonclinical 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.



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**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 139, 140, 141, 142, and 143 of the Registration Statement.

## 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."

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 126, 136, and 139 of the Registration Statement, including to remove references to "rapid" or "accelerated" when describing its clinical development activities and to remove the reference to "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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 147 and 148 of the Registration Statement.

## 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 82, 83, 99, and 152 of the Registration Statement.

# **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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 156, 157, and 158 of the Registration Statement. In addition, the Company updated the intellectual property disclosure on these pages to reflect the patents that are material to the Company's current programs and product candidates, including the addition of disclosure of its



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SKV patents on page 156 of the Registration Statement that are relevant to the Company's TIDAL-01 viral immunotherapy combination program. The Company also removed disclosure in the Registration Statement related to patents that are not material to the Company's business as they relate to programs the development of which the Company has discontinued.

## 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 207 and 208 of the Registration Statement. The Company also respectfully acknowledges the Staff's comment to add disclosure whether the shares will be offered as part of the public offering or in a separate private placement and will respond to this comment in a subsequent amendment to the Registration Statement once this information is available.

# 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 211 of the Registration Statement. The Company also respectfully advises the Staff that no one, in his or her individual capacity, possesses voting and/or investment control over the securities of owned by FACIT Inc., and that its board of directors, which currently includes John Morrison, Har Grover, Ken Newport, Shana Kelley, Ken Lawless, share voting and/or investment control over 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 119, F-16, F-30, F-54, and F-65 of the Registration Statement.

The Company accounted for the merger pursuant to the Agreement and Plan of Merger and Reorganization (the "*Myst Merger Agreement*") as an asset acquisition as substantially all of the value received was concentrated in a group of similar identifiable assets—the acquired in-process research and development of Myst Therapeutics, Inc. ("*Myst*"). As such, the Company concluded the



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acquired asset is not considered a business, consistent with the guidance in Accounting Standards Codification ("ASC") 805-10-55-5A.

The contingent consideration milestones under the Myst Merger Agreement are payable in cash or equity, at the election of the Company, therefore the Company considered if ASC 815, ASC 480, or ASC 450 was applicable.

The initial milestone, triggered upon the closing of an IPO, meets the definition of a derivative and does not meet the scope exceptions under ASC 815-10-15-59. As such, this milestone is accounted for separately at fair value and is remeasured each reporting period at fair value with changes in fair value reported in research and development expense.

The second and third milestones are triggered upon (a) the first acceptance by the U.S. Food and Drug Administration of an investigational new drug application (or IND) filed by, on behalf of or for the benefit of the Company, or the Company's sublicensees for a product developed by or on behalf of the Company or the Company's sublicensees that is claimed as a product or method of making or using the product by a pending or issued Myst patent claim existing at the time of such acceptance (the second milestone) and (b) upon the occurrence of the earlier of (i) the commencement of the first registration study for a product being developed by, on behalf of or for the benefit of the Company or the Company's sublicensees that is claimed as a product or a method of making or using the product by an issued Myst patent claim existing as of the time of such commencement or (ii) the issuance of a Myst patent claim that claims a product or method of making or using the product then being developed by, on behalf of or for the benefit of the Company or the Company's sublicensees, that is or was the subject of a registration study that has or had commenced (the third milestone). While each milestone meets the definition of a derivative, the scope exception in ASC 815-10-15-59(b) would apply to the second and third milestone. In assessing the scope exception, the payment relates to a nonfinancial asset (intellectual property) which is unique and the Company would not benefit under the arrangement from an increase in the fair value of the nonfinancial asset (i.e., they are not the recipient of the milestone payment).

Under ASC 480-10 certain obligations to issue a variable number of equity shares require liability classification. A financial instrument other than an outstanding share that embodies an obligation, is classified as an asset or a liability if the issuer must or may settle the obligation by issuing a variable number of its equity shares and the obligation's monetary value is based solely or predominantly on one of the following: (1) a fixed monetary amount, (2) variations in something other than the fair value of the issuer's equity shares, or (3) variations inversely related to changes in the fair value of the issuer's equity shares. The Company's assessment of whether the second and third milestones are is within the scope of ASC 480 considered whether the arrangement's monetary value, at inception, was based predominately on the exercise contingency (e.g., milestone trigger) or share price. For the second and third milestones under the Myst Merger Agreement, the Company concluded that the monetary value is based predominately on the exercise contingency as the milestone amount is fixed and can be settled in variable number of shares at the Company's election, and therefore classified the contingent milestones as a liability under ASC 480.

## <u>General</u>

- 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).



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- Your Selected TIL process includes "potent anti-tumor activity, as observed in preclinical 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).

**Response:** In response to the Staff's comment, the Company has conducted a detailed review and removed or revised statements throughout the Registration Statement that state or imply that the Company's product candidates are safe or effective.

- 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 disclosure 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.

**Response:** In response to the Staff's comment, the Company respectfully advises the Staff that it (i) has filed the Second Amended and Restated Investors' Rights Agreement between the Company and convertible preferred stockholders as Exhibit 4.2 within the Registration Statement; and (ii) has revised it disclosure on page 68 of the Registration Statement. For purposes of Item 601(b)(10) of Regulation S-K, the Company respectfully advises the Staff that there are no other material supply contracts or material license agreements that are required to be filed as exhibits to the Company's Registration Statement.

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.

**Response:** The Company acknowledges the Staff's comment and will provide to the Staff, on a supplemental basis under separate cover, copies of the written communications, as defined in Rule 405 under the Securities Act of 1933, as amended (the "*Securities Act*"), that the Company, or anyone authorized to do so on the Company's behalf, has presented or expects to present to potential investors in reliance on Section 5(d) of the Securities Act. These materials were only made available for viewing by potential investors during the Company's presentations, and no copies were retained by any potential investor. Pursuant to Rule 418 under the Securities Act, the copies supplementally provided shall not be deemed to be filed with, or a part of, or included in, the Registration Statement.



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To the extent the Company conducts additional meetings, it expects to use the same or similar materials, and the Company undertakes to provide the Staff with copies of any additional written communications that are presented to potential investors in the future by it or anyone authorized to do so on its behalf in reliance on Section 5(d) of the Securities Act, whether or not such potential investors retain copies of such communications.

\* \* \*

Please contact me at (212) 479-6474 with any questions or further comments regarding the Company's response to the Staff's comments.

Sincerely,

/s/ Divakar Gupta

Divakar Gupta

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