

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

Mail Stop 3030

March 23, 2017

Amir Avniel Chief Executive Officer AIT Therapeutics, Inc. 2 Ilan Ramon, Science Park Ness Ziona, 7403635 Israel

**Re:** AIT Therapeutics, Inc.

**Registration Statement on Form S-1** 

Filed February 27, 2017 File No. 333-216287

Dear Mr. Avniel:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

#### **Prospectus**

1. We note that you have included your financial statements after your outside back cover page of the prospectus and Part II information. Please revise to include your financial statements in the prospectus, as required by Item 11 of Form S-1.

## Prospectus Cover

2. There does not appear to be an existing established trading market for your securities. Accordingly, please revise your disclosure here and throughout your prospectus to include the fixed price at which the selling shareholders will sell their shares until such time as they are quoted on the OTC Bulletin Board, OTCQX, OTCQB or a national securities exchange, at which time they may be sold at prevailing market prices or in privately negotiated transactions, if applicable.

- 3. It appears that you qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act. If so, please disclose that fact in your filing.
- 4. 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, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

## Business Overview, page 4

- 5. Safety and efficacy are terms of art used in describing FDA clearances and approvals. Considering your disclosure regarding lack of FDA approval for you products, please refrain from describing your products with terms like "safely" and/or your test results as evaluating "efficacy." Instead, throughout your disclosure, please limit your conclusions about performance of your products and results of studies to your belief and the actual results of your studies. Similarly, please limit your conclusions regarding the lack of "efficacy" of treatments using products other than yours, like your disclosure on page 4, to specifically identify the market need not currently being met that you believe your product will address if your product is approved by the FDA.
- 6. If the NTM indication you are developing is limited only to NTM Abscessus in children with CF, as indicated by your disclosure on page 13, please revise each disclosure referring to this indication to clearly define its scope and the limited market opportunity presented.

# Competition, page 5

7. Please clarify the uncertainty that Novoteris "may" be eligible for orphan drug exclusivity if the FDA approves its product candidate.

## The Offering, page 7

8. Please revise to describe in clear, understandable terms the registration delay payments referenced here. Also note your disclosure obligations pursuant to Item 404 of Regulation S-K.

# It is highly likely . . ., page 9

9. Please discuss in this risk factor the impact the going concern opinion issued by your auditor may have on your ability to raise needed capital. For example, could it make accessing capital more difficult or costly?

# We are heavily dependent on the Aeronox system..., page 14

10. Please revise to clarify why you are dependent on the system only for trials "outside the United States."

## We will be seeking Fast Track review by the FDA..., page 19

11. Please specify the indications you mention on page 4 for which you will seek Fast Track review.

## If we fail to comply with our obligations . . ., page 32

12. Please disclose the "several milestones" referenced in your disclosure and how the dates of those milestones compare with your time line on page 68. In this regard, we note that Exhibit 10.11 currently omits Exhibit B. Please file a complete version of Exhibit 10.11.

# We will incur significant increased costs as a result..., page 37

13. Please clarify your statement in the last paragraph of this risk factor that "[u]pon completion of this offering, [y]our securities will be quoted on the OTCQB." It is unclear why you are certain your securities will be quoted on the OTCQB and when this offering will be "completed."

## Use of Proceeds, page 53

14. Please revise this section to disclose the amount of proceeds you will obtain in the event warrant holders exercise their warrants and describe how you plan to use those proceeds.

## Capitalization, page 55

- 15. Please revise the table to present total capitalization equal to the sum of total debt and stockholders' deficit. Also, remove the label "audited" from the header to the table and add formatting to clarify that cash and cash equivalents are not included in total capitalization.
- 16. As a related matter, please revise the presentation to show the impact of the reverse merger recapitalization and to show the pro forma impact of the subsequent changes in capitalization described in Note 14 to your financial statements and elsewhere in your filing.

# Research and Development Expenses, page 56

17. Your disclosure here about your intent to "initiate clinical activity" appears inconsistent with your disclosures regarding clinical trials you have already conducted outside the United States. Please revise or advise.

## Comparison of the year ended December 31, 2016 . . ., page 59

18. Given your disclosures that you have never submitted applications to the FDA and have conducted clinical trials only outside the United States, please clarify the reference here to "preparation for FDA regulatory submission." Please also clarify the reasons expenses related to device development efforts decreased over the periods presented, in light of your disclosure on page 66 that you are in the process of designing an improved version of the delivery system.

# Taxes on Income, page 61

19. To assist readers of your filing, please expand your disclosure to briefly explain the reference to the cost plus method.

# Liquidity and Capital Resources, page 61

20. We note that your cash and cash equivalents significantly decreased in fiscal year 2016 compared to fiscal year 2015. Please identify and separately describe your internal and external sources of liquidity, such as the lines of credit mentioned on page F-16 and loans from related parties discussed on page F-28, and discuss how you plan to fund your operations, including your future clinical trials, development of your delivery system and short and long-term liabilities. This also includes the significant changes in debt and equity disclosed in Note 14 to your financial statements and elsewhere in your filing on your liquidity and capital resources and your ability to continue as a going concern. Please also file as exhibits the agreements for the lines of credit and related-party loans mentioned on pages F-16 and F-28.

#### Business Overview, page 64

21. Please revise to describe clearly and consistently the regulatory status of your product candidates and product development efforts to date. As one example, you refer on page 10 to the early development stage of your products and that you have never submitted marketing applications to the FDA. However, on page 36, you indicate that you have received orphan drug designation.

# AITT Technology, page 66

- 22. Please limit your disclosure to your belief regarding your delivery system's advantages over other NO formulation delivery systems given that your delivery system has not been approved by any regulatory agency.
- 23. Please revise to clarify the development status of the delivery system for which you intend to seek FDA approval. It is unclear from your disclosure what you mean by you are "in the process of designing an improved version as compared to the model used" in clinical trials to date.
- 24. Your disclosure here refers to your "novel delivery system," referred to as NOxSysBSTM, and indicates this system is not yet developed and you have not yet contracted with a third party to manufacture this system for you. However, on page 73, you state that you currently rely on third-party contract manufacturers for the production of this system. Additionally, on page 14, you refer to being dependent on "our Aeronox system," which is manufactured for you by a third party. Please revise to clarify the references to these systems, your dependence on third parties, and regulatory status of each system. Ensure you revisions describe the nature of your arrangements with third parties who produce the system for you, geographical limitations on use of the systems they produce for you and file any material agreements as exhibits.

# Nitric Oxide and Infection, page 66

25. Please tell us whether you commissioned any of the studies you cite. See Rule 436 of Regulation C.

## Our Clinical Results to Date, page 69

26. Throughout your disclosure on pages 69-72 where you discuss your clinical results, please revise so that an investor without scientific training can understand the purpose of the studies and the significance of your findings. As one example only, it is unclear from your disclosure why you tested met hemoglobin levels and the significance and effect of increased levels of met hemoglobin. Also clarify the meaning of significant scientific or technical terms the first time they are used to ensure the reader understands the disclosure. We note as examples only the terms "2 log reduction" on page 70, "systemic inflammation" or "CRP levels" on pages 70-71 and "LOS>24 hours" on page 71.

# Security Ownership of Certain Beneficial Owners and Management, page 84

27. Please revise to clarify the references in the first paragraph to "Minimum Offering and Maximum Offering amounts." Please also reconcile the number of shares underlying warrants included in this table and the table on page 86 for Messrs. Grossman and Lisi

- and the number of shares underlying options held by Ms. Vizman, as disclosed in note 8 and on page 93.
- 28. Note 11 refers to 12,730 RSUs and 12,730 options, but only 12,730 is included in the table. Please revise to clarify why the number in the table is not 25,460.

## Selling Stockholders, page 85

29. We note the disclosure that you calculated beneficial ownership in accordance with the rules and regulations of the SEC. Please revise to clarify which of these rules or regulations led you to determine that Mr. Bentsur beneficially owned a negative number of securities after this offering, as disclosed on page 86.

## Management, page 88

30. We note that your Web site indicates Professors David Greenberg and Asher Tal are part of your management team. Please revise to include the information required by Items 401, 402, 403 and 404 of Regulation S-K to the extent applicable.

# Employment or Service Agreements . . ., page 94

31. Please revise to clarify the reference on page 97 to "this Current Report on Form 8-K."

## Certain Relationships and Related Transactions, page 97

32. We note your disclosure on pages 57 and 60-62 regarding "loans from related parties." We also note the related-party transactions referenced on pages F-28 and F-29. Please provide the information required by Item 404 of Regulation S-K with regard to these transactions or advise.

## Director Independence, page 97

33. Please revise to clarify how you determined that only Messrs. Avniel and Av-Gay are not independent, given your disclosure on page 93 listing Mr. Bentsur in the Summary Compensation Table under the heading "Executive Compensation" and with the title "Executive Chairman."

## Description of Securities, page 98

- 34. Please revise this section to provide all information required by Item 202(c) of Regulation S-K with regard to the warrants issued in the "Israeli Private Placement."
- 35. Please revise to discuss Section VII of Exhibit 3.1 and any material risks that provision presents.

# Item 16. Exhibits, page II-3

36. Please revise the list of exhibits to reflect the changes in the amended Form 8-K filed on March 15, 2017. Please also indicate what exhibits are subject to a pending confidential treatment request.

## Audited Financial Statements as of December 31, 2016 and 2015, page F-1

37. Please revise to retroactively reflect the changes in capitalization arising from the reverse merger recapitalization on the reissued financial statements included in the Form S-1. Refer to SAB Topic 4-C.

# Note 14, Subsequent Events, page F-31

38. We note that subsequent to December 31, 2016 you amended your certification of incorporation, declared a dividend and repurchased shares. Tell us why those matters should not be described in the subsequent events footnote pursuant to ASC 855-10.

#### Exhibit 5.1

39. The assumption in (ii) in the second paragraph on page 2 does not appear appropriate. It is also unclear why such assumption is necessary given your limitation in the next paragraph. Please revise.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Andri Carpenter at (202) 551-3645 or Gary Todd, Senior Accountant, at (202) 551-3605 if you have questions regarding comments on the financial statements and related matters. Please contact Heather Percival at (202) 551-3498 or Geoff Kruczek, Special Counsel, at (202) 551-3641 with any other questions.

Sincerely,

/s/ Geoff Kruczek for

Amanda Ravitz
Assistant Director
Office of Electronics and Machinery

cc: Robert L. Grossman, Esq. Drew M. Altman, Esq.