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March 20, 2023

#### **VIA EDGAR**

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

Re: Azitra Inc.

Registration Statement on Form S-1 Filed February 21, 2023

File No. 333-269876

#### Ladies and Gentlemen:

This letter is submitted on behalf of Azitra Inc, a Delaware corporation (the "<u>Company</u>"), in response to the comments of the staff of the Division of Corporation Finance (the "<u>Staff</u>") of the U.S. Securities and Exchange Commission (the "<u>Commission</u>") with respect to the Company's Registration Statement on Form S-1 filed with the Commission on February 21, 2023 (the "Registration Statement"), as set forth in your letter dated March 10, 2023 addressed to Mr. Francisco Salva, Chief Executive Officer of the Company (the "<u>Comment Letter</u>").

The headings and numbered paragraphs of this letter correspond to the same contained in the Comment Letter, and to facilitate your review, the text of the Comment Letter has been reproduced herein, followed by the Company's response to each comment. Unless otherwise indicated, page references in the descriptions of the Staff's comments refer to the Registration Statement, and page references in the Company's responses refer to prospectus made part of the Amendment No. 1 to the Registration Statement filed concurrently herewith.

#### Form S-1 filed February 21, 2023

# Our Company, page 1

1. We note your revised disclosure in response to prior comment 2. Please revise the first sentence in this section to avoid any implication that your therapies presently "can be applied topically to treat diseases of the skin."

# Response to Comment No. 1:

We have revised the first sentence on page 1 and the first sentence on page 51.

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#### Our Strategy, page 2

2. We note your revised disclosure on page 54 in response to prior comment 18. Please revise your Summary disclosure on page 2 to explain that the technology you license from the Fred Hutchison Cancer Center is not incorporated into any of your current product candidates.

#### Response to Comment No. 2:

The requested disclosure has been provided in the third paragraph on page 2.

# Pipeline Table, page 2

3. We refer to prior comment 4 and note your revised pipeline table on page 2 and its inclusion in the new cover graphics. Please revise both pipeline presentations to clarify the status of the Consumer Health Programs and the commercialization rights to the products under development. In this regard, it is unclear what the arrow depicts in this section. In addition it is not clear from your presentation what the Bayer symbol represents.

# Response to Comment No. 3:

We have revised the pipeline table on the inside front cover page, page 2 and page 52.

# Our Market Opportunities, page 4

4. We note your response to prior comment 6. With reference to your disclosure on page 56, please revise the disclosure on page 4 to clarify that the market opportunity is an estimate of the market in the mid-2030s. With reference to your disclosure on page 66-67, tell us whether the \$250 million estimate takes into account that the US composition of matter patent covering recombinant bacteria for treating abnormal skin conditions expires in 2035.

# Response to Comment No. 4:

The requested revision has been made to the first paragraph on page 4. Concerning the US composition of matter patent expiring in 2035, please be supplementally advised that the Company believes that its ATR-12 product candidate is protected by a second patent that expires in 2039 and the Company is optimistic that pending patent applications will result in additional covered claims that would expire between 2035 and 2039. The Company reasonably believes that it could obtain FDA approval for ATR-12 within four to six years. As a result, the Company should enjoy meaningful patent protection for up to ten to 12 years from the commencement of commercial sales.

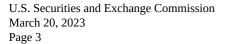
Furthermore, Netherton syndrome has been recognized as an orphan drug indication by the FDA. This represents an additional protection aside from our patents. Orphan drug status offers seven years of sales exclusivity without generic competition for the approved orphan designation.

# Our Business Strategies, page 52

5. We note your revised disclosures in response to prior comment 16. Please revise the disclosure concerning the clinical trial agreement with Yale to explain the status of the observational trial. Discuss material financial arrangements concerning the agreement.

#### Response to Comment No. 5:

The requested disclosure has been provided on page 52.



#### Bayer Joint Development Agreement, page 64

6. Please revise to disclose the term and termination provisions of the Joint Development Agreement and restore the disclosure concerning the option period. Discuss the planned timeline for conducting the in vitro and ex vivo characterization work and any other additional work that is required before there would be delivery of the results of the JDA development activities to Bayer. With reference to prior comment 21, please revise to clarify that no commercial license has been negotiated and this will only occur after Bayer has reviewed the data.

#### Response to Comment No. 6:

The requested disclosure has been provided in the fourth paragraph on page 64.

# Preclinical Data for ATR-01, page 64

7. We note your response to our comment 17; however, please further expand your disclosure to include narrative disclosure to explain graphs B, C and D regarding the mouse models.

# Response to Comment No. 7:

Please see the revisions to page 64.

# General

8. Please remove the graphic highlighting the peak sales figure. In this regard, we note that you have not commenced clinical trials and your disclosure on page 56 indicates that the estimate is based on multiple assumptions and is an estimate for the market in the mid- 2030s. For additional guidance, please refer to Compliance Disclosure Interpretations, Securities Act Forms, Question 101.03.

# Response to Comment No. 8:

The Company has removed the graphic.

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We thank the Staff for its review and consideration of the Company's Registration Statement and the foregoing responses to the Staff's comments. If the Staff needs any additional information or has any questions regarding the foregoing responses, please do not hesitate to contact the undersigned at (949) 732-6557 or by email at <a href="mailto:DonahueD@gtlaw.com">DonahueD@gtlaw.com</a>.

Sincerely,

/s/ Daniel Donahue

Daniel K. Donahue, Esq.

cc: Francisco Salva, Chief Executive Officer, Azitra Inc