United States securities and exchange commission logo

January 14, 2023

Francisco Salva
President and Chief Executive Officer
Azitra Inc
21 Business Park Drive
Branford, CT 06405

Re: Azitra Inc
Draft Registration Statement on Form S-1
Submitted December 15, 2022
CIK No. 0001701478

Dear Francisco Salva:

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

Cover page

1. Please disclose on your cover page whether your offering is contingent upon the final approval of your listing. Please ensure the disclosure is consistent with your underwriting agreement.

Prospectus Summary
Our Company, page 1

2. Please revise to explain whether your microbial drug candidates will be delivered topically or by other delivery methods.

Pipeline Table, page 2

3. Please revise the table to include a column for Phase 3. Also, revise so that the "Preclinical" column is not wider than the Phase 1/2 column.
4. Please remove the Consumer Health Programs from the table or tell us your basis for including these programs in the table showing your pipeline of biotherapeutic products.
In this regard, it appears that Bayer holds the commercial rights to these programs and that you generate service revenues from the joint development agreement.

Further, it is
unclear whether the oleogel formulations generated from the
partnership are subject to the
drug/biologic regulatory process that is depicted in the pipeline
table.
5. Please revise to remove the "Discovery Programs" from the pipeline
table. In this regard,
we note that it appears premature to highlight them prominently in
this table given their
present development status. We further note that your Business
discussion does not appear
to provide disclosure concerning these programs.
Our Market Opportunity, page 4

6. With a view to disclosure, please explain to us the basis for your
disclosure that the global
sales opportunity is $250 million.
Summary Financial Data, page 10

7. Please revise to disclose the historical and pro forma net loss per
share information for all
periods presented.
Use of Proceeds, page 39

8. Please revise the disclosure in the first two bullet points to specify
how much of the
funding will be allocated toward each product candidate or program.
Also disclose how
far the proceeds will take you into the development process.
Capitalization, page 41

9. Please revise your total capitalization balance to include the
convertible notes payable.
Dilution, page 42

10. Please revise to start your dilution disclosures with historical net
tangible book value and
per share information.
Management's Discussion and Analysis of Financial Condition and Results of
Operations
Research and Development, page 46

11. Considering research and development to be your main operation, please
address the
following related comments:

Please revise to disclose the nature of the components of your
research and
development expenses. In that regard, we note that you report
grants earned as a
negative research and development expense as disclosed on page
F-9, and that you
may also expense legal and filing expenses incurred related to
the rejected patent as
disclosed on page F-7.
Please tell us, and revise as necessary, how your accounting
for legal work in
connection with patent applications or litigation, and the sale
or licensing of patents
as research and development expenses is in accordance with ASC
730-10-55-2i.
Please disclose whether you track your research and development
expenses by
program and/or by product candidates, and if so, provide a
disaggregated
disclosure for that. If not, disclose that fact and the reason
you do not track them
separately, and also consider providing a disaggregated
disclosure such as by nature
of costs. Please also separately disclose the amount of grant
revenue recognized if
significant.
Please revise to provide any known trends or uncertainties

disclosures. e.g. total
expected costs, or any expectations to increase, related to your expected future
research and development expenses. Refer to Item 303(b)(2)(ii) of Regulation S-K.

Liquidity and Financial Condition, page 47

12. Revise to expand your liquidity disclosures to include a discussion that analyzes material
cash requirements from known contractual and other obligations, including specification
of the type of obligation and the relevant time period for the related cash requirements, as
required by Item 303(b)(1) of Regulation S-K. In that regard, we note you disclosed
certain lease obligations as well as obligations under license agreements.

ATR-12 for the treatment of Netherton syndrome, page 58

13. With reference to your disclosure at the top of page 63 concerning ATR-04, please
provide similar disclosure concerning your 1b/2a trials for ATR-12.

Preclinical data for ATR-12, page 59

14. Please expand your disclosure to include quantitative data supporting your claims
that several in vivo and ex vivo experiments collectively support the potential efficacy of
ATR-12 as a disease modifying therapy for patients with Netherton syndrome.

Preclinical data of ATR-04, page 61

15. Please revise to include narrative disclosure explaining the results depicted in the table so
it is clear how the results support the claims made in this section.

Our Business Strategies, page 64

16. Please revise your disclosure to provide information about the nature and terms of your
partnerships with Yale University and Jackson Laboratory for Genomic Medicine.

Preclinical data for ATR-01, page 64

17. Please expand your disclosure to include quantitative data supporting your claims of
improvement in the evaluations conducted on human skin explants and in mouse models.

Exclusive License Agreement with Fred Hutchison Cancer Center, page 68

18. Please revise to indicate which of your product candidates and programs are subject to the
license agreement.

Clinical Trials, page 70

19. We note your disclosure indicating that you intend to submit INDs for two Phase 1b/2a
trials. Please revise this section to provide a brief overview of Phase 1b/2a trials,
including, as applicable, why Phase 1a might not be required and whether additional
Phase 2 trials are typically required prior or in addition to Phase 3 trials. Discuss, as
applicable, the benefits and risks of combining phases.

Financial Statements for the Fiscal Year Ended December 31, 2021

Note 8. Stockholders' Equity - Preferred Stock, page F-14

20. Here you disclose that for all of your convertible preferred stock, dividends accumulate
from the original date of their issuance, are cumulative and are payable upon declaration
of the Board of Directors or liquidation of the Company. Please tell us how you have
considered the impact of these cumulative dividends to your basic and dilutive EPS
calculation. Refer to ASC 260-10-45-11.

Exhibits

21. Please file your agreements with Bayer and FHCC as exhibits or provide us analyses explaining why they should not be filed pursuant to Regulation S-K, Item 601.

You may contact Li Xiao at 202-551-4391 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Cindy Polynice at 202-551-8707 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

FirstName LastNameFrancisco Salva

Division of Corporation Finance

Comapany NameAzitra Inc

Office of Life Sciences

cc: Daniel K. Donahue, Esq.