

Daniel K. Donahue
Tel 949.732.6500
Fax 949.732.6501
donahued@gtlaw.com

February 20, 2023

VIA EDGAR

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

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

Ladies and Gentlemen:

On behalf of our client, Azitra Inc, a Delaware corporation (the "**Company**"), we are responding to the comment letter issued by the staff of the Commission (the "**Staff**") to Francisco Salva, President and Chief Executive Officer of the Company, dated January 14, 2023 on the above-referenced draft Registration Statement on Form S-1. Concurrent with the filing of this letter, the Company is publicly filing with the Commission its Registration Statement on Form S-1 ("**Registration Statement**").

The Registration Statement has been prepared in response to Staff's comment letter dated January 14, 2023, the text of which we have incorporated into this response letter for your convenience.

Staff Comment and Company Response

Draft Registration Statement on Form S-1

Cover Page

- 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.***

Response: The requested disclosure has been provided on the cover page. The form of underwriting agreement to be filed by amendment to the Registration Statement will contain a representation and warranty from the Company. To further insure consistency, the final version of the underwriting agreement that will be filed by the Company with a Current Report on Form 8-K will include the exchange listing approval as a condition to the underwriter's obligations to purchase the shares in the initial public offering.

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.***

Response: All of the Company's current product candidates are intended to be delivered topically. Appropriate disclosure has been provided in the third paragraph on page 1 and elsewhere throughout the prospectus as appropriate.

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.***

Response: The requested revisions have been made on page 2.

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.***

Response: The Company respectfully submits that it is meaningful to include the product candidates being developed under the Bayer JDA in the pipeline table. As noted in the fourth full paragraph on page 64, these products are the proprietary property of the Company. Pursuant to the Bayer JDA, Bayer is funding the development of the products and, in return, has an option to exclusively license the products, however at this time they are the property of the Company and will remain so until such time, if ever, as Bayer exercises its option in accordance with the JDA and enters into a commercial license with the Company. The Company has revised the table and the disclosure in the third full paragraph on page 2 and the fourth full paragraph on page 64 to clarify that the product candidates are being developed as consumer products and will not be expected to require a FDA New Drug Application or Biologics License Application to be approved.

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.***

Response: The Company has removed the “Discovery Programs” from the pipeline table as requested.

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.***

Response: According to several studies, the average prevalence of Netherton Syndrome is 1 in 100,000, or approximately 3,300 people in the U.S. At an estimated cost of treatment of \$170,000 per year, which the Company believes to be reasonable for an ultra-orphan drug such as ATR-12, the Company estimates peak U.S. sales to be \$100 million. With the global population estimated to be over 24 times the US population, the \$250 million projection is considered by the Company to be conservative. Please see page 56 of the prospectus.

Summary Financial Data, page 10

7. ***Please revise to disclose the historical and pro forma net loss per share information for all periods presented.***

Response: The Company has provided the requested disclosure related to historical periods; however, in order to provide the pro forma net loss per share at this time, the Company would need the estimated offering price to compute the incremental common shares resulting from the conversion of the convertible notes and preferred shares.

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.***

Response: The Company has provided the requested disclosure on page 39.

Capitalization, page 41

9. ***Please revise your total capitalization balance to include the convertible notes payable.***

Response: The Company has revised the capitalization balance on page 41 as requested.

Dilution, page 42

10. Please revise to start your dilution disclosures with historical net tangible book value and per share information.

Response: The Company respectfully submits that the addition of the historical net tangible book value per share may cause confusion and, in any event, would be irrelevant to investors. At the close of this offering, approximately \$5.4 million of debt represented by convertible notes will convert to common stock along with all of the outstanding shares of convertible preferred stock. These conversions alone (and without giving effect to this offering) will cause the Company's net tangible book deficit at December 31, 2022 to increase from approximately a negative \$2.57 million to approximately a positive \$4.0 million, and the number of outstanding common shares will increase from 147,041 to approximately 2 million (both share figures pre-split). As of December 31, 2022, the historical net tangible book deficit per share (pre-split) is approximately (\$17.45), however the pro forma historical net tangible book value per share (pre-split) as of December 31, 2022 and after taking into account the conversion of the convertible promissory notes and convertible preferred stock, would be approximately \$2.02 per share. These tangible book value per share numbers will be proportionately reduced by way of the forward split the Company intends to effect prior to this offering, however the range of variance between the two numbers will remain, and the historical net tangible book value per share amount (post-split) will be far less dilutive than the pro forma historical net tangible book value per share (post-split).

In conclusion, we believe that the historical net tangible book value per share adds a layer of complexity to the dilution discussion that is unnecessary and not helpful in that it presents a distorted view of the Company's net tangible book value at the time of the offering. We are aware of several definitive IPO prospectuses that were subject to similar facts and presented the dilution discussion in the manner provided by the Company.

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.

Response: The Company has provided the requested disclosure in the first paragraph on page 46. As discussed below, the Company does not record legal expenses as part of research and development.

- 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.

Response: The Company does not record legal expenses in connection with patent applications or litigation, and the sale or licensing of patents, as research and development expenses. In accordance with ASC 730-10-55-2i, the Company excludes all legal expenses from research and development expense. The Company capitalizes all legal expense in connection with patent applications and the licensing of patents as intangible assets. Amortization associated with these patent costs is recorded as part of general and administrative expense.

- 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.

Response: As an early-stage private company, the Company does not allocate its human resources involved in research and development to any specific drug candidate but plans to do so in the future. The Company does allocate certain research and development costs among its product candidates, and is able to generally assess the changes in research and development expenses between the reported periods, however given that the related human resources costs are by far the greatest component of research and development expenses, the Company does not believe it is meaningful to provide a break-down of only a portion of the research and development expenses. The Company will comply with the staff's request in future filings.

- 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.

Response: The Company has added disclosure concerning its known trends in the third paragraph on page 46.

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.**

Response: The payment obligations under the Company's license agreements are contingent in nature and not fixed obligations. The Company has added disclosure concerning its operating lease obligations in the third paragraph on page 47.

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.**

Response: The Company has provided the requested disclosure in the last paragraph on page 58.

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.**

Response: The Company has provided the requested disclosure on pages 57 and 58.

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.**

Response: The Company has provided the requested disclosure on pages 61 through 64.

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.**

Response: The Company has provided the requested disclosure in the fourth paragraph on page 52.

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.***

Response: The Company has provided the requested disclosure on page 64.

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.***

Response: The requested disclosure has been provided in the fourth paragraph on page 68.

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.***

Response: The requested disclosure has been provided in the third full paragraph on page 71.

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.***

Response: The Company acknowledges this comment and notes in accordance with ASC 260-10-46-11, income available to common shareholders should be reduced by dividends accumulated for the period on cumulative preferred stock (whether or not earned).

In quantifying this error, the Company notes the total dividends on Series A, A-1, and B in the aggregate requiring this disclosure for the following periods would be as follows:

	Year-ended December 31, 2020	Year-ended December 31, 2021	Nine-months ended September 30, 2021	Nine-months ended September 30, 2022
Dividends earned at 8% per annum	\$ 1,824,530.44	\$ 2,768,983.71	\$ 2,076,737.78	\$ 2,076,737.78
Original net loss available to common shareholders	\$ (6,811,147.00)	\$ (8,939,675.00)	\$ (7,031,350.00)	\$ (6,633,781.00)
Recalculated net loss available to common shareholders	\$ (8,635,677.44)	\$ (11,708,658.71)	\$ (9,108,087.78)	\$ (8,710,518.78)
Percentage of increase in net loss available to common shareholders	-27%	-31%	-30%	-31%
EPS initially presented	\$ (46.67)	\$ (60.69)	\$ (48.15)	\$ (44.63)
EPS as recalculated	\$ (59.17)	\$ (79.49)	\$ (62.37)	\$ (58.60)

Management has reviewed the magnitude of the error in accordance with SEC Staff Accounting Bulletin 99, Materiality (“SAB 99”) and Staff Accounting Bulletin 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements (“SAB 108”) to determine whether the error is material or immaterial. This analysis is outlined below, and as will be demonstrated, management has concluded this error is immaterial and thus proposes to revise these financial statements, including the interim financial information, on future filings (for comparative purposes).

SAB 99/SAB 108 Analysis

SAB 99 and SAB 108 provide the Issuer relevant guidance in applying materiality thresholds to the preparation of financial statements filed with the SEC. This guidance is also considered by the Issuer to be a relevant factor in relation to its judgment about whether the misstatements contained in prior-period consolidated financial statements were material, so as to require a restatement pursuant to ASC 250-10, Accounting Changes and Error Corrections and pursuant to SEC regulations.

The omission or misstatement of an item in a financial report is material if, in the light of surrounding circumstances, the magnitude of the item is such that it is probable that the judgment of a reasonable person relying upon the report would have been changed or influenced by the inclusion or correction of the item.

This formulation in the accounting literature is, in substance, identical to the formulation used by the courts in interpreting the federal securities laws. The Supreme Court has held that a fact is material if there is - a substantial likelihood that the fact would have been viewed by the reasonable investor as having significantly altered the “total mix” of information made available.

Under the governing principles, an assessment of materiality requires that one views the facts in the context of the “surrounding circumstances,” as the accounting literature puts it, or the “total mix” of information, in the words of the Supreme Court. In the context of a misstatement of a financial statement item, while the “total mix” includes the size in must consider both “quantitative” and “qualitative” factors in assessing an item’s materiality. Court decisions, commission rules and enforcement actions, and accounting and auditing literature have all considered “qualitative” factors in various contexts.

When errors in previously-issued financial statements are identified, they must be assessed to determine whether the affected financial statements are materially misstated. Materiality analyses require significant professional judgment. The materiality analysis must consider all relevant qualitative and quantitative factors (including company/industry-specific factors). The materiality evaluation requires significant professional judgment and should consider all relevant qualitative and quantitative factors.

In a December 2008 speech, an Associate Chief Accountant in the SEC's Office of the Chief Accountant clarified the SEC staff's view of how SAB 108 should be applied to previously-issued financial statements. He indicated that if the effect of a correction would not materially affect the previously issued financial statements, those financial statements may still be relied upon, and the correction may be made in future filings. Expanding upon this, if one is correcting financial statements that are not materially misstated, the errors should be corrected by revising the previously issued financial statements the next time they are filed.

In evaluating this error which consists of the omission of additional deductions from income available to common shareholders, which would result in incremental net losses in the ranges documented above to common shareholders increasing approximately from ranges from 20% to 31%, the Company noted the following:

- The magnitude of the restatement is not such that it is probable that the judgment of a reasonable person relying upon the report would have been changed by the correction of this item. The Company evaluated the qualitative factors that must also be taken into consideration as to what is probable that the judgment of a reasonable person relying upon the report would have been changed or influenced by the correction of this particular item. For that to occur, a hypothetical user would have to believe these incremental losses available to common shareholders would drive a different decision than those initially disclosed to common shareholders. The Company cannot think of such a user of the financial statements that would consider this a significant change in the mix of information available.
- The Company determined that the restatement would not affect the Company's Consolidated Balance Sheets, Consolidated Statements of Cash Flows nor Net Loss. A reasonable user of the financial statements for a pre-revenue biotech is more likely to be focusing on operations of the entity, liquidity or operating cash flow then below net income adjustments related to the form of capital structure.
- The existence of the dividends was known to the user of the financial statements and such items were disclosed in the notes accompanying the financial statements.
- The preferred shares shall automatically convert into common shares upon an IPO.

As noted above, the only effect of this error is an increase in the net loss available to common shareholders which increases the net loss per share in the ranges previously disclosed. Although these numbers may appear quantitatively large in isolation, they are not considered material to a reasonable investor for the qualitative reasons discussed above. Accordingly, based on these facts and the analysis above, the Company has determined that the impact of these adjustments is not material to the previously issued annual and interim unaudited consolidated financial statements using the guidance of SAB 99 and SAB 108 and therefore will address the adjustments via footnote disclosures within our filing of the S-1/A for the same periods as discussed above.

Finally, the Company notes that the income to common stockholders for the year ended December 31, 2022 has been calculated and presented in accordance with 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.***

Response: The Company acknowledges the Staff's comments and advises the Staff that the Company analyzes each of its agreements for materiality when it enters into the agreement and periodically thereafter. The Company respectfully advises the Staff that it does not believe that either its Joint Development Agreement, or Bayer JDA, with Bayer or exclusive license agreement with Fred Hutch, or Fred Hutch license agreement, is a material contract under Item 601(b)(10) of Regulation S-K. The Company's consideration of Item 601(b)(10) of Regulation S-K is summarized below.

Item 601(b)(10)(i) of Regulation S-K defines a "material contract" as a contract made outside of the ordinary course of business which is material to the registrant. Item 601(b)(10)(ii) of Regulation S-K states that "If 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 [of the three exceptions to 601(b)(10)(ii) of Regulation S-K], in which case it shall be filed except where immaterial in amount or significance."

With regard to the Bayer JDA, the agreement relates to the parties' joint development of certain strains selected from the Company's proprietary microbial library and Bayer's option to acquire an exclusive royalty bearing license for up to six strains subject to development activities under the JDA. The work under the Bayer JDA is in complete alignment with the business conducted by the Company. Only once the JDA research activities are complete and Bayer has reviewed the data, will a commercial license be negotiated. No terms of such license have yet been formally discussed. Further, the Company, like all biotechnology companies, routinely in-licenses and out-license proprietary technologies, therapies and drugs. Consequently, the Company respectfully submits that the Bayer JDA is the type of agreement that ordinarily accompanies its business.

With regard to the Fred Hutch license agreement, it is an in-licensing of certain technology useful in the discovery, development and commercialization of engineered microbial therapies and microbial-derived peptides and proteins for skin diseases. Because the Fred Hutch license agreement is a license of intellectual property rights useful in the discovery, development and commercialization of engineered microbial therapies and microbial-derived peptides and proteins for skin diseases, and the Company's business principally relates to the treatment and prevention of serious skin diseases, the Company believes that the Fred Hutch license agreement is also the type of agreement that ordinarily accompanies its business.

The Company further submits that neither the Bayer JDA nor Fred Hutch license agreement fall within any of the exceptions set forth in Item 601(b)(10)(ii) of Regulation S-K. The Company believes that the Bayer JDA clearly does not fall within either of the three exceptions to Item 601(b)(10)(ii) of Regulation S-K. The only exception to Item 601(b)(10)(ii) of Regulation S-K that might relate to the Fred Hutch license agreement is Item 601(b)(10)(ii)(B) of Regulation S-K which states clarifies that if an agreement is such as ordinarily accompanies the kind of business conducted by the registrant, it will be deemed to be made in the ordinary course of business, and therefore not required to be filed, unless the agreement is, among other things, one "upon which the registrant's business is substantially dependent" or constitutes "any franchise or license or other agreement to use a patent, formula, trade secret, process or trade name upon which registrant's business depends to a material extent." The Company respectfully submits that while the Fred Hutch license is useful to the Company's business and provides the Company with certain advantages the Company is neither "substantially dependent" on the Fred Hutch license agreement nor dependent on such agreement to a material extent. The Company's first three programs, ATR-12, ATR-04 and ATR-01 were all developed without the Fred Hutch technology. The Fred Hutch license grants the Company rights to the SyMPL technology platform, which makes human-made DNA invisible to the bacteria's defenses. This feature may be an important part of the Company's future product candidates. However, the SyMPL technology platform is not the only mechanism or technology available that can enable genetically engineered materials to overcome or evade the bacterial defenses. The Company has proven that it can resource alternative means of genetic engineering and that the Fred Hutch license agreement does not constitute an agreement upon which the Company's business is substantially dependent or depends on to a material extent.

For the foregoing reasons, the Company believes that neither Bayer JDA nor Fred Hutch license agreement are required to be filed as a material agreement under Item 601(b)(10) of Regulation S-K. The Company advises the Staff that it will continue to evaluate in future periods whether the Bayer JDA or the Fred Hutch license agreement satisfies the definition of a "material contract" under Item 601(b)(10) of Regulation S-K.

The Company has endeavored to fully respond to the Staff's comments set forth in its letter dated January 14, 2023. Thank you in advance for your review. Please contact the undersigned with any questions or comments at (949) 732-6557.

Very truly yours,

/s/ Daniel K. Donahue

Daniel K. Donahue

cc: Azitra Inc

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