

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

December 26, 2018

David Platt Chairman BIOXYTRAN, INC 233 Needham Street Newton, MA 02464

> Re: BIOXYTRAN, INC Registration Statement on Form S-1 Filed November 30, 2018 File No. 333-228602

Dear Dr. Platt:

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.

Registration Statement on Form S-1

Cover Page

1. Your disclosure on the direct offering cover page that you "expect the public offering price to be \$1.00 per share" is inconsistent with your disclosure on page 45 that the shares will be sold at the fixed price of \$1.00 per share. Please revise your disclosure to clarify that you will offer and sell the securities for a fixed price for the duration of the offering. In addition, we note that your cover page of the selling stockholder prospectus states that the "[s]elling [s]tockholder may sell the shares of common stock described in the prospectus in a number of different ways and at varying prices." Please note that the OTC Pink marketplace is not an established public trading market into which the selling stockholder may offer and sell its shares of common stock at other than a fixed price. Given the absence of an existing trading market for your common stock, please disclose

- the fixed price (or range) at which the selling stockholders will sell the shares for the duration of the offering. Refer to Item 501(b)(3) of Regulation S-K.
- 2. We note your disclosure on the cover page that the estimates, statistics, industry data and projections of future performance of the industries in which you operate "are subject to a high degree of uncertainty." As you are responsible for the contents of the prospectus, please revise your disclosure to eliminate any suggestion that you lack a reasonable belief as to the accuracy of the market data in the filing.

Company Overview, page 1

3. Your statements on pages 2 and 50 that you will need to raise \$2,350,000 in this offering in order to have sufficient working capital to repay the Auctus Note and develop your business over the next 15 months appear to be inconsistent with your statements on pages 5 and 52 that you "anticipate that [y]our cash resources are sufficient to fund [y]our planned operations through the end of March, 2019, if [you] succeed in raising \$2,350,000 or more in this offering." In addition, your disclosure on pages 2 and 50 that if you raise \$1,350,000, you will be able to repay the Auctus Note and "develop [y]our business over the same 15-month period but funding at that level will delay the development of [y]our technology and business" appears to be inconsistent with your disclosure on pages 38 and 86 that you anticipate the need for approximately \$1,000,000 in additional funding to support the planned expansion of your operations for the next 12 months. Also, your disclosure regarding your cash resources on pages 4. 5, 51 and 52 appears to be inconsistent with your disclosure on pages 38 and 86 that you believe that you will be able to continue your business operations for the next 12 months without raising any additional capital. Please revise throughout for clarity and consistency.

Prospectus Summary, page 1

- 4. Please eliminate all statements throughout the prospectus that present your conclusions regarding the safety or efficacy of your product candidates, as these determinations are solely within the authority of the FDA and comparable regulatory bodies to make. We note, for example, your disclosure on page 1 that you believe that BXT-25 will be effective in preventing necrosis and that your technology, potentially, will offer effective treatments for anemia, cancer conditions and trauma.
- 5. Please disclose here and on page 49, if true, that you have yet to begin preclinical studies of your product candidates. In this regard, we note your disclosure on page 6 that you "plan to initiate pre-clinical studies of BXT-25."

The Offering, page 3

6. We note your disclosure on pages 3, 18, 46, 65 and 94 that indicates that you intend to have your shares quoted on the OTCQB. Please revise to disclose the eligibility requirements to have your shares quoted on the OTCQB and clarify that there is no

guarantee that your shares will be quoted on the OTCQB. In addition, disclose here and on page 49 the exercise date of the warrant, the number of shares outstanding after both the direct offering and the selling stockholder offering, in the aggregate, and, on page 49, disclose the termination date of the offering.

Risk Factors

Risks Related to Our Business

If serious adverse or unacceptable side effects are identified, page 8

7. We note your disclosure on pages 8 and 55 referencing compounds that showed early promise in early stage testing for treating diabetes and your statements on pages 9 and 56 that reference current diabetes treatments. However, in your prospectus summary, you state that you are focused on the development of drugs designed to address hypoxia in humans and that, "[w]hile [y]our initial focus is on hypoxia in the brain and wound healing, [you] believe that [y]our technology potentially will offer effective treatments for anemia, cancer conditions and trauma." Please revise to clarify how the treatment of diabetes is related to your business. Similarly, your disclosure on pages 35 and 82 that "[y]our strategy is to leverage considerable industry experience . . . to . . . identify . . . product candidates . . . that can fulfill unmet medical needs in the treatment of diabetes and inflammatory diseases" appears to be inconsistent with the description of your business in your prospectus summary. Please revise for clarity and consistency.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our products, page 15

8. We note your disclosure on page 15 that your "plans for the development of both BXT-25 and BXT-252 will be based in part upon the further development of technology developed by a company, Biopure Corporation, that suspended operations and filed for bankruptcy on July 16, 2009," and your disclosure that "[t]he Biopure technology is in the public domain." Please disclose in your prospectus summary sections on pages 1 and 49, if true, (i) that BXT-25 and BXT-252 are based upon technology developed by the Biopure Corporation, which filed for bankruptcy in 2009, and (ii) that this technology, including a biosimilar product to your product candidates, is in the public domain.

<u>Risks Relating to this Offering and Ownership of Our Common Stock</u> <u>Our Certificate of Incorporation permits "blank check" preferred stock, page 21</u>

9. Your disclosure on page 21 that you have 5,000,000 authorized shares of preferred stock is inconsistent with your disclosure on page 43 that you have 50,000,000 authorized shares of preferred stock. Please revise throughout your registration statement for consistency regarding the number of authorized shares of preferred stock.

Risks Related to the Note Financings

We may be required to issue significant amount of common stock, page 23

10. We note your disclosure on page 23 that you are currently authorized to issue 300,000,000 common shares and presently have 85,103,673 shares of common stock outstanding. Please tell us why you believe that you will be required to increase your authorized shares to provide sufficient authorized common stock for conversion of the note, and why you believe that the conversion of the Auctus Note could result in a change of control. In this regard, we note your disclosure on page 22, that you are obligated to issue approximately 25,500,000 common shares upon conversion of the note and your disclosure on page 2 that Auctus is limited to holding a total of 4.99% of your issued and outstanding shares of common stock.

Use of Proceeds, page 25

11. Please revise your Use of Proceeds section on page 25 to disclose a description of how you intend to use the proceeds received from the shares of common stock offered by the company and how you intend to raise additional funds if the proceeds from this offering are insufficient to cover the intended uses. Your discussion should show the amount of proceeds to be allocated for each purpose assuming different amounts of proceeds raised and the number of shares sold. To the extent that you intend to use the proceeds for the development of your product candidates, disclose an estimate of how far you expect to reach in the development process.

Directors, Executive Officers, Promoters and Control Persons, page 27

12. Please revise to briefly discuss, for each director, the specific experience, qualifications, attributes or skills that led to the conclusion that the person should serve as a director for your company, in light of your business and structure. Refer to Item 401(e)(1) of Regulation S-K. In addition, we note your disclosure on page 40 that your non-employee directors are entitled to receive 1,000 shares of common stock for each meeting they attend. Please revise pages 40 and 88 to include the director compensation disclosure required by Item 402(r) of Regulation S-K for the fiscal year ended December 31, 2017 or tell us why you believe it is unnecessary.

Description of Business

Overview, page 30

13. Your statement on page 31 that you believe that your approach is novel and will lead to the creation of safe drug alternitves for addressing hypoxic conditions in humans and your statement on page 36 that your lead product candidates are well-differentiated from other formulations appear to be inconsistent with your disclosure on page 15 that your "plans for the development of both BXT-25 and BXT-252 will be based in part upon the further development of technology developed by a company, Biopure Corporation, that suspended operations and filed for bankruptcy on July 16, 2009," and your disclosure that "[t]he Biopure technology is in the public domain." In addition, throughout your

disclosure you refer to biosimilar products and product candidates. Please revise your registration statement for clarity and consistency.

Hemoglobin and Complex Co-Polymer Science, page 31

- 14. Please disclose here and on page 79 whether you have received any indication from the FDA that you will receive a GRAS designation.
- 15. Throughout your prospectus you compare BXT-25 to other products, product candidates and treatments. For example, we note (i) your disclosure on page 31 that your BXT-25 co-polymer hemoglobin molecule will reach hypooxic tissues more effectively than RBC's, (ii) your comparison of BXT-25 to the biosimilar product produced by Biopure Corporation on page 31 and (iii) your disclosure on page 34 that you believe BXT-25 will benefit patients as well as or better than HBOT and do so with greater cost effectiveness. Please revise your disclosure throughout your registration statement to limit comparisons of your product to only those products, product candidates and treatments with which you have conducted a head-to-head clinical trial. Similarly, you state that because biosimilar products were approved or had certain characteristics, your product will also be approved and have certain characteristics. For example, we note your disclosure on pages 31 and 79 that because a biosimilar product had no adverse effects in humans that your product will also have no adverse effects in humans, and, on pages 35 and 83, you state that because the European Directorate for the Quality of Medicines Certification approved a biosimilar product that it will also approve your product. Revise these statements as they appear to be inappropriate given the stage of your product candidates.

Business Developments

BXT-25, page 34

16. Your disclosure on page 34 that you have yet to determine which indication to focus on in connection with BXT-25 and that you intend to conduct pre-clinical pilot trials to determine which indication to focus on, followed by more extensive preclinical trials as well as an IND for such indication so that you can begin patient enrollment in the first quarter of 2020 is inconsistent with your disclosure that you are in the process of planning BXT-25 pre-clinical studies, expect to file an IND application with the FDA in 2018 and will seek approval of BXT-25 for the treatment of early stages of stroke in an out-of-hospital setting. Please revise throughout your registration statement for clarity and consistency and disclose the estimated amount of funding necessary to accomplish each step in your current plans for attempting to obtain FDA approval of BXT-25 as well as certification from the European Directorate for the Quality of Medicines.

Market Opportunity, page 35

17. Please revise your statements on pages 36 and 84 that BXT-25 may be used when blood is not available and that it has a very broad range of potential applications beyond ischemic stroke or wound healing as this statement implies that your product candidate will receive

FDA approval, and, given the stage of development of BXT-25, this statement is inappropriate.

Certain Relationships and Related Transactions, page 39

18. Please revise to disclose here and on page 87 the terms of the loans from Mr. Platt and Mr. Soderquist as well as the interest rates. Please refer to Item 404 of Regulation S-K.

Employment Contracts, page 40

19. We note your disclosure on page 28 that your employment agreements with your executive officers include provisions related to payments received upon termination without cause. Please revise your disclosure on pages 40 and 87 to describe these provisions.

Corporate Governance, page 42

20. Your disclosure on page 42 that four of the members of your board of directors are independent is inconsistent with your earlier disclosure on page 42 that three of the members of your board of directors are independent. Please revise throughout your registration statement for consistency.

Selling Stockholder, page 92

21. Your disclosure that you are registering the shares underlying the Auctus Note and the Auctus warrant is inconsistent with your introductory paragraph to the selling stockholder table on page 92 that identifies both EMA and Auctus as selling stockholders and addresses the shares underlying the EMA Note. Please revise for clarity and consistency.

Exhibits and Financial Statement Schedules, page II-3

22. Exhibit 3.7 indicates that it includes your amended and restated bylaws. However, it includes a certificate of amendment to your articles of incorporation. Please file your amended and restated bylaws as an exhibit to your registration statement.

General

- 23. We note that you issued press releases on November 12, 2018, November 16, 2018 and December 17, 2018, all of which contain forward looking statements and one of which appears to be directed to investors. In this regard, we were unable to identify similar past press releases that you issued in the ordinary course of your business. Please provide us with your analysis as to how these press releases comport with the requirements of Section 5(c) of the Securities Act and the related offering communication rules under the Securities Act.
- 24. It appears the Auctus resale transaction may be an indirect primary offering by or on behalf of the registrant. In this regard, among other factors, we note the number of shares

being offered relative to the number of shares held by non-affiliates, the dilutive nature of the conversion and exercise terms of the note and the warrant, respectively, as well as the relatively short period for which Auctus has held the note and the warrant. Accordingly, please revise the terms of the of the Auctus resale transaction to provide that for the duration of the offering Auctus will offer and sell at a fixed price any shares of common stock it comes to hold via the full or partial conversion of the note or the exercise of the warrant. Please disclose this price in the prospectus. In addition, please identify Auctus as a statutory underwriter. If you continue to believe the Auctus resale transaction should not be characterized as an indirect primary offering, please provide us with your written legal analysis in support of this view. For guidance, please refer to Question 612.09 of the Securities Act Rules Compliance and Disclosure Interpretations, which are available on our website.

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 Rolf Sundwall, staff accountant, at 202-551-3105 or Sharon Blume, accounting branch chief, at 202-551-3474 if you have questions regarding comments on the financial statements and related matters. Please contact Sonia Bednarowski, staff attorney, at 202-551-3666 or Dietrich King, staff attorney, at 202-551-8071 with any other questions.

Sincerely,

Division of Corporation Finance Office of Healthcare & Insurance