

CONFIDENTIAL

July 20, 2021

CONFIDENTIAL SUBMISSION VIA EDGAR

Division of Corporation Finance
Office of Life Sciences
Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549
Attn: Jeanne Bennett, Mary Mast, Alan Campbell, and Joe McCann

**Re: Responses to the Securities and Exchange Commission
Staff Comments dated June 25, 2021 regarding
XORTX Therapeutics Inc.
Draft Registration Statement on Form F-1
Submitted May 26, 2021
CIK No. 0001729214**

Dear Sirs and Madams:

This letter responds to the written comments from the staff (the "Staff") of the Securities and Exchange Commission (the "SEC") set forth in the June 25, 2021 letter regarding the above-referenced confidential Draft Registration Statement on Form F-1 (the "Registration Statement") of XORTX Therapeutics Inc. (the "Company", "we," "our," or "us") confidentially submitted on May 26, 2021. For your convenience, the Staff's comments are included below and we have numbered our responses accordingly. Simultaneously with the transmission of this letter, the Company is confidentially submitting via EDGAR an amendment ("Amendment No. 1") to the Registration Statement, responding to the Staff's comments and including certain other revisions and updates.

Page numbers in the text of the Company's responses correspond to page numbers in Amendment No. 1. Please note that capitalized terms used but not otherwise defined in this letter have the meanings ascribed to such terms in Amendment No. 1.

Our responses are as follows:

[Draft Registration Statement on Form F-1](#)

[Cover Page](#)

Staff Comment No. 1.

Please clarify whether your reference to “Public Warrants” in the first paragraph of the prospectus cover page is a reference to the Common Share Purchase Warrants being offered or to different warrants.

Company’s Response:

In response to the Staff’s comment, we have changed the reference from “Public Warrants” to “Common Share Purchase Warrant” on the prospectus cover page.

Staff Comment No. 2.

We note your statement that you intend to offer shares at an “assumed public offering price” which is based on the last reported price of your common shares on the Canadian Securities Exchange. Please revise your disclosure to explain how you will use the trading price on the Canadian Securities Exchange to determine the offering price of both your common shares and Common Share Purchase Warrants. Please refer to the instructions to Item 501(b)(3) of Regulation S-K which require bona fide pricing information for offerings by companies not subject to the reporting requirements of Section 13(a) or 15(d) of the Exchange Act.

Company’s Response:

In response to the Staff’s comment, the Company plans to use an assumed offering price and an assumed exercise price for the Common Share Purchase Warrants for illustrative purposes only. However, the actual public offering price per common share, Pre-Funded Warrant and corresponding Common Share Purchase Warrant and Pre-funded Unit, as the case may be, will not be determined by any particular formula or the market price of the Company’s common shares on the Canadian Securities Exchange but will rather be determined through negotiations between the Company and the underwriter at the time of pricing and may be at a greater than the current market price. Therefore, the assumed public offering prices used throughout the prospectus may not be indicative of the final offering price. We have included disclosure on the cover page to clearly state that the assumed price is for illustrative purposes only and that the final offering price will be determined through negotiations between the Company and the underwriter at the time of pricing.

Staff Comment No. 3.

Please revise your description of the compensation to be paid to A.G.P. to include a discussion of the compensation warrant discussed on page 137.

Company’s Response:

In response to the Staff’s comment, we have added a description of the underwriter’s warrants on the cover page.

[Our Proprietary Therapeutic Platforms, page 2](#)

Staff Comment No. 4.

Please revise your disclosure here and in Business to explain the difference between your “proprietary therapeutic platforms” and your product candidates. Also, balance your discussion in this section and in Business to clarify, if true, that your product candidates and therapeutic platforms are still in preclinical and clinical development, the process of product development is inherently uncertain and any potential advantages of your product candidates are speculative. Please also explain to us the basis for your statement that your platforms can be used alone, or in combination, with synergistic activity to develop an approach to a variety of diseases.

Company’s Response:

In response to the Staff’s comment, we have revised the disclosures in both the Prospectus Summary and Business sections to clarify the XORTX product pipeline and XORTX’s current product candidates and removed references to the proprietary therapeutic platform. We also clarified the disclosures to include that the process of product development is inherently uncertain and any potential advantages of our product candidates are speculative. We removed references to synergistic activity. The registration statement was revised at pages 2, 3, 12, 75 and 79 to address this comment.

Staff Comment No. 5.

Please provide us with the basis for your statement that your “platforms can be combined in multiple ways and this synergy can be applied to address acute, intermittent or chronic disease progression.” In that regard, we note that you have yet to develop any product candidates that have advanced to a Phase 3 clinical trial or received a marketing approval.

Company’s Response:

In response to the Staff’s comment, we have revised the disclosure at pages 3 and 76 to clarify that the pipeline is based upon the use of oxypurinol formulations with additional ingredients, other uric acid lowering agents, and/or modified with other functional groups to address acute, intermittent or chronic disease progression such as ADPKD, AKI due to COVID-19 infection, and T2DN.

Staff Comment No. 6.

Please remove your statement here and in Business that you will have the opportunity to provide “first-in-class” products.

Company’s Response:

In response to the Staff’s comment, we have revised the disclosures in both the Prospectus Summary and Business sections to remove the references to “first-in-class” products. The registration statement was revised at pages 4 and 75³ to address this comment.

Prospectus Summary

Overview, page 2

Staff Comment No. 7.

Please revise the Prospectus Summary, where appropriate, to briefly explain the current regulatory status of oxypurinol and the difference between oxypurinol and allopurinol. Please also provide a brief discussion of how your product candidates differ from oxypurinol.

Company’s Response:

In response to the Staff’s comment, we have revised the disclosure to explain the current regulatory status of oxypurinol and the difference between oxypurinol and allopurinol, and have also briefly explained how the XORTX product candidates are based upon oxypurinol. The registration statement was revised at pages 2, 3, 75 and 79 to address this comment.

Staff Comment No. 8.

We note your statements here and throughout the Prospectus Summary, MD&A and Business that you are focusing on treating “orphan” indications. Please refrain from stating that you are targeting orphan indications unless you have obtained orphan drug designation.

Company’s Response:

In response to the Staff’s comment, we have revised the disclosure at pages 2, 4, 24, 67, 75, 77 and 85 to remove references to treating orphan indications.

Staff Comment No. 9.

We note your statement that you “combine the power of oxypurinol with innovative therapeutic products existing drugs that can be adapted for different disease indications where elevated uric acid is a common denominator.” Please revise here and in Business to explain what is meant by this sentence and whether you have actually combined oxypurinol with other existing drugs to create new product candidates.

We further note your statement that you intend to treat a variety of serious or life-threatening diseases. Please revise your disclosure here and throughout to clarify, if true, that you have not developed any product candidates to treat diseases beyond ADPKD, T2DN and AKI due to coronavirus infection.

Company's Response:

In response to the Staff's comment, we have revised the disclosure to clarify that at least one product candidate combines oxypurinol with an existing drug, and the other two product candidates are based upon oxypurinol. We have also revised the disclosure to specify that the XORTX product candidates are designed. The registration statement was revised at pages 3, 9 and 75 to address this comment.

[Our Strategy, page 3](#)

Staff Comment No. 10.

Please revise your statements here and throughout that you will rapidly and efficiently advance XRx-008 through Phase 3 clinical development and regulatory approval. You may state, if true, that you plan to submit an NDA to the FDA following the conclusion of your Phase 3 clinical trial of XRx-008.

Company's Response:

In response to the Staff's comment, we have revised the language on pages 4 and 77 of the registration statement to clarify that we plan to submit an NDA to the FDA following the conclusion of our Phase 3 clinical trial of XRx-008.

[Product Candidate Pipeline, page 3](#)

Staff Comment No. 11.

We note your statement here and in Business that XRx-008 is in preparations for a Phase 3 trial, the last stage before FDA approval. Please revise to disclose whether you have an active IND for this trial and to clarify that there is no guarantee that the results from this trial will be positive or that the FDA will view the results from this trial to be sufficient for a marketing approval.

Company's Response:

In response to the Staff's comment, we have revised the language on pages 4, 76 and 81 of the registration statement to clarify that we have filed a Pre-IND submission and plan to pursuing an active IND status for a Phase 3 trial for XRx-008. We have also added a disclosure that there is no guarantee that the results from this trial will be positive or that the FDA will view the results from this trial to be sufficient for a marketing approval.

Risk Factors, page 3

Staff Comment No. 12.

Please revise to highlight the risk factor discussed on page 54 concerning your belief that were a PFIC during fiscal 2020 and potential adverse tax consequences to stockholders.

Company's Response:

In response to the Staff's comment, we have added an additional bullet to the prospectus summary on page 5 of the registration statement highlighting the risk relating to our PFIC status and potential adverse tax consequences to stockholder if it is determined that we are a PFIC.

Implications of Being an Emerging Growth Company, page 5

Staff Comment No. 13.

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.

Company's Response:

The Company undertakes that if any written communication as defined in Rule 405 under the Securities Act of 1933, as amended (the "Securities Act"), is presented to potential investors in reliance on Section 5(d) of the Securities Act by the Company or anyone authorized to do so on its behalf, the Company will provide the Staff with a copy of the written communication on a confidential, supplemental basis.

Implications of Being an Emerging Growth Company, page 5

Staff Comment No. 14.

We note the discussion that you qualify as an “emerging growth company” as defined in the JOBS Act. Please revise to disclose in the filing, including MD&A, whether you intend to take advantage of the extended transition period allowed for emerging growth companies for complying with new or revised accounting guidance as allowed by Section 107 of the JOBS Act and Section 7(a)(2)(B) of the Securities Act of 1933.

Company’s Response:

In response to the Staff’s comment, we have added language on page 74 of the registration statement disclosing that we intend to take advantage of certain reporting and other exemptions until we are no longer an emerging growth company.

Risk Factors

Our commercial success depends significantly on our ability to operate without infringing the patents.... page 35

Staff Comment No. 15.

We note your statement that you are aware of third party patents and patent applications “containing claims.” Please revise your disclosure to clarify if these claims are directed towards your product candidates or technology.

Company’s Response:

In response to the Staff’s comment, we have revised the disclosure on page 36.

Market, Industry and Other Data, page 60

Staff Comment No. 16.

Your statements that you have not independently verified any third party information may imply an inappropriate disclaimer of responsibility with respect to this information. Please either delete these statements or specifically state that you are responsible for such information.

Company’s Response:

In response to the Staff’s comment, we have revised the disclosure at page 62 to delete the statement “We have not independently verified any third party information.”

Use of Proceeds, page 61

Staff Comment No. 17.

Please revise this section to provide more specificity regarding the use of proceeds from the offering including the approximate amount of funds you plan to allocate toward each of your three lead product candidates. If the proceeds will not be sufficient to fund all of the proposed purposes, disclose the priority of such purposes as well as the amount and sources of other funds needed.

Company's Response:

In response to the Staff's comment, we have revised the disclosure on page 63 to state the approximate amount of funds we plan to allocate to each of our three lead product candidates, and that XRx-008 is the highest priority program.

Capitalization, page 62

Staff Comment No. 18.

We note that you include your statement of financial condition from page F-4 in the Capitalization section. Revise to only include capitalization and indebtedness. If you present cash, place a double line below the cash line.

Company's Response:

In response to the Staff's comment, we have revised the capitalization table on page 64 to include only capitalization and indebtedness.

Management's Discussion and Analysis of Financial Condition and Results of Operations Research and Development Expense, page 68

Staff Comment No. 19.

We note the increase in your research and development expenses and from page 73 that you have multiple products in varying stages of development. Please revise to provide more detail for your research and development expenses for each period presented including, but not limited to, by product candidate as well as by the nature of the expenses. To the extent that you do not track expenses by product candidate, please disclose as such.

Company's Response:

In response to the Staff's comment, we have revised the disclosure at pages 69, 72, and 73 to state that we currently do not track expenses by product candidate.

Business, page 72

Staff Comment No. 20.

Please revise your Business section, where appropriate, to discuss the results of the clinical trials of your product candidates. In your revisions, please disclose who conducted the trial, the phase of the trial, the primary and secondary endpoints and whether the trial achieved these endpoints, metrics utilized, the number and nature of any drug-related adverse events and the duration of the trial.

Company's Response:

In response to the Staff's comment, we have revised the disclosure at pages 75, 81, 82 and 84 to reflect the status of the planned clinical trials for XORTX's product candidates.

Product Candidate Pipeline, page 73

Staff Comment No. 21.

Your pipeline chart indicates that XRx-225 has completed preclinical studies. However, your disclosure on page 79 appears to indicate that XRx-225 still needs to complete preclinical studies before advancing to Phase 1 clinical testing. Please revise your pipeline chart to shorten the arrow for XRx-225 to reflect its current development status or advise.

Company's Response:

In response to the Staff's comment, we have revised the pipeline chart on page 77 to reflect that XRx-225 has not yet completed preclinical studies.

Anticipated clinical development of XRx-008, page 77

Staff Comment No. 22.

We note your statement that oxypurinol has not been approved for marketing anywhere in the world, though it has previously received FDA review under an NDA filing. Please revise to discuss the circumstances of this FDA filing, including who made the filing and, if known, why the FDA did not approve the product candidate under review.

Company's Response:

In response to the Staff's comment, we have revised the disclosure at page 79 and 81 to provide the circumstances of the FDA's review of oxypurinol on behalf of third-party Cardiome Pharam Corp. In 2003, Cardiome filed an NDA for the orphan indication of "allopurinol intolerant gout". In 2005, after FDA review, Cardiome announced that it had received an "approvable letter" for oxypurinol for "allopurinol intolerant gout".

Staff Comment No. 23.

We note your statement that if XRx-008 is approved, it would fit well in combination with other pulmonary and cardiovascular products. Please revise to provide the basis for this statement and to clarify whether XRx-008 has been clinically evaluated in combination with other product candidates.

Company's Response:

In response to the Staff's comment, we have revised the disclosure at page 81 to clarify that we believe that XRx-008 could fit well in combination with other product candidates.

Staff Comment No. 24.

We note your statements that you are preparing for a bridging pharmacokinetic study and a Phase 3 clinical trial of XRx-008. Please revise to disclose for each trial who will conduct the trial, the primary and secondary endpoints, metrics utilized and the planned duration of the trial.

Company's Response:

In response to the Staff's comment, details of the planned bridging pharmacokinetic study for XRx-008 have been added to page 81 of the disclosure.

Anticipated clinical development of XRx-101, page 78

Staff Comment No. 25.

We note your statement that you expect to conduct a Phase 3 pivotal clinical trial of XRx-101 to evaluate whether it can attenuate acute tissue injuries in the setting of COVID-19 infection. Please revise to disclose who will conduct the trial, the primary and secondary endpoints, metrics utilized and the planned duration of the trial.

Company's Response:

In response to the Staff's comment, we have revised the disclosure at page 83 to include details of the Phase 3 clinical trial.

XRx-225, page 78

Staff Comment No. 26.

Please revise your disclosure to provide the source for your claim that T2DN is forecast to double in the next decades and provide more precision regarding the time period over which T2DN is anticipated to double (e.g. next 10 years, 20 years, etc.).

Company's Response:

In response to the Staff's comment, we have revised the disclosure at page 83 to include details of the statistics regarding T2DN.

Staff Comment No. 27.

Your disclosure on page 44 indicates that you license technology from the University of Florida, the University of Washington and Dr. Richard Johnson. Please revise this subsection of your Business section to disclose the material terms of these license agreements, as well as any other license agreements that are material to your business, including:

- **the technology or product candidates subject to the agreement;**
- **each parties' rights and obligations under the agreement;**
- **quantify all payment made to date;**
- **disclose separately the aggregate amount of all potential development, regulatory and commercial milestone payments;**
- **disclose any milestones that you are required to achieve pursuant to the agreements;**
- **disclose the amount of option fees for additional targets;**
- **quantify the royalty rate, or a range no greater than 10 percentage points per tier;**
- **disclose when royalty provisions expire, if the expiration is based on a number of years following commercialization, disclose the number of years;**
- **disclose the expiration date; and**
- **describe any termination provisions.**

Please also revise your Prospectus Summary to briefly explain which of your products and technology are subject to license agreements. Finally, please file these agreements as exhibits to your registration statement.

Company's Response:

In response to the Staff's comment, we have added descriptions of the license agreements on page 86 of the registration statement. We have removed the description of the license agreement with the University of Washington, as it has expired or been abandoned and is no longer material to the Company's business. We are currently reviewing the license agreements, and will provide them to the Staff separately.

Competition, page 81

Staff Comment No. 28.

Please remove your statement that XRX-008 is a “potent oral uric acid lowering agent that does not require hospital administration and has a much superior safety profile” to Jynarque. Given the current stage of development of this product candidate, it appears to be premature to make this claim.

Similarly, please remove your statements that “XRX-101 will be a more effective and better therapy...because it will be both potent and safe” and that “XRX-225 will be a more effective and better therapy because it has been shown to be a powerful and safe uric acid lowering agent.”

Company’s Response:

In response to the Staff’s comment, we have revised the disclosure at pages 84 and 87 to remove these statements.

Certain Relationships and Related Party Transactions, page 112

Staff Comment No. 29.

Please revise your disclosure to provide more specificity regarding the clinical trials that are being supported by Prevail including the services that Prevail is providing, the product candidates being evaluated and the timing of the clinical trials.

Company’s Response:

In response to the Staff’s comment, we have revised the disclosure at page 117 to provide more detail regarding the services that Prevail is providing.

Independent Auditors' Report, page F-2

Staff Comment No. 30.

We note that the audit report references Canadian generally accepted auditing standards and does not conform to the format required by PCAOB AS 3101. Please revise to include financial statements that are audited in accordance with the standards of the Public Company Accounting Oversight Board and a report of your independent registered public accounting firm that fully complies with the guidance in PCAOB AS 3101.06 through .10 and Article 2 of Regulation S-X. Refer to PCAOB Release No. 2017-001.

Company's Response:

We acknowledge the Staff's comment and confirm that we have revised the draft audit report accordingly.

Staff Comment No. 31.

We reference the disclosure in Note 2 that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). Please have the auditors revise their report to opine on the financial statements prepared in accordance with IFRS as issued by the IASB. Refer to 17(c) of Form 20-F.

We acknowledge the Staff's comment and confirm that we have revised the draft audit report accordingly.

Staff Comment No. 32.

Please revise such that the title of your financial statements is consistent with the exact title included in the auditors' report.

Company's Response:

We acknowledge the Staff's comment and confirm that we have revised the draft audit report accordingly.

Staff Comment No. 33.

Please have your auditors revise the section "Material Uncertainty Related to Going Concern" to reference substantial doubt and comply with the guidance in PCAOB AS 2415.12 and .13.

Company's Response:

We acknowledge the Staff's comment and confirm that we have revised the draft audit report accordingly.

Staff Comment No. 34.

The audit report does not present the signature of the audit firm, or state the date since which they have served as the Company's auditors. Please revise for these issues in accordance with Rule 2-02 of Regulation S-X and AS 3101.

Company's Response:

We acknowledge the Staff's comment and confirm that we have revised the draft audit report accordingly.

Financial Statements

Note 5. Deposits, page F-13

Staff Comment No. 35.

Revise to disclose your accounting treatment for deposits paid in connection with the agreements discussed in the Note, including your accounting and valuation of the shares issued for the deposit in connection with the private placement. Cite the accounting literature used that supports your accounting treatment.

Company's Response:

We acknowledge the Staff's comment but confirm that no changes have been made to the current filing, as the consolidated financial statements have already been publicly published.

Per the Company's significant accounting policy related to share-based payment transactions listed in Note 3 to the consolidated financial statements, "share-based payments to non-employees are measured at the fair value of the goods or services received or the fair value of the equity instruments issued as calculated using the Black-Scholes option pricing model."

The significant accounting policy is consistent with IFRS 2.10 which states:

For equity-settled share-based payment transactions, the entity shall measure the goods or services received, and the corresponding increase in equity, directly, at the fair value of the goods or services received, unless that fair value cannot be estimated reliably. If the entity cannot estimate reliably the fair value of the goods or services received, the entity shall measure their value, and the corresponding increase in equity, indirectly, by reference to the fair value of the equity instruments granted.

The Company determined that it could not reliably estimate the fair value of the services to be provided under the Master Service and Technology Agreement with Prevail Partners LLC. Therefore, the deposit and corresponding units issued were measured by reference to the fair value of the units issued. As the units were issued concurrently with a private placement whereby units were issued at \$0.14 per unit this was considered the fair value of the units. Therefore 11,473,714 units issued to Prevail were fair valued at \$1,606,320.

Therefore, the Company has recorded the value of the deposit and units issued in accordance with its own significant accounting policies which are consistent with IFRS 2. Although it is not explicitly stated in Note 5 it is possible the reader could infer that the deposit and units were valued with respect to the fair value of the units issued in the private placement.

As the consolidated financial statements have already been made publicly available, we plan that the note disclosure be revised in all future filings to more clearly disclose the accounting treatment related to the deposit.

Note 7. Intangible Assets, page F-14

Staff Comment No. 36.

Please revise to clarify that your intangible assets relate solely to licensed intellectual property. Confirm there are no other individual intangible assets that are material to your financial statements. Refer to paragraphs 118-123 of IAS 38.

Company's Response:

We acknowledge the Staff's comment but confirm that no changes have been made to the current filing, as the consolidated financial statements have already been publicly published.

The first sentence in Note 7 states that the Company has licensed intellectual property from various third parties. Licensed intellectual property is the Company's only class of intangible assets and therefore have been grouped together in accordance with IAS 38-118 and IAS 38-119.

As the consolidated financial statements have already been made publicly available, we plan that the note disclosure be revised in all future filings to explicitly state that the intangible assets relate solely to licensed intellectual property and that there are no other individual intangible assets that are material to the financial statements.

Thank you for your review of the filing. If you should have any questions regarding the response letter, please do not hesitate to contact the undersigned at (403) 607-2621, or Anthony W. Epps of Dorsey & Whitney LLP, our outside legal counsel at (303) 352-1109.

Sincerely,

XORTX Therapeutics Inc.

Allen Davidoff

President and Chief Executive Officer

cc: Anthony W. Epps, Dorsey & Whitney LLP
