



DIVISION OF
CORPORATION FINANCE

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

June 25, 2021

Allen Davidoff
President and Chief Executive Officer
XORTX Therapeutics Inc.
Suite 4000, 421 – 7th Avenue SW
Calgary, Alberta
Canada T2P 4K9

Re: XORTX Therapeutics Inc.
Draft Registration Statement on Form F-1
Submitted May 26, 2021
CIK No. 0001729214

Dear Mr. Davidoff:

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 F-1

Cover Page

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.
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.

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.

Our Proprietary Therapeutic Platforms, page 2

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

Prospectus Summary
Overview, page 2

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.
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.
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.

Our Strategy, page 3

10. Please revise your statements here and throughout that you will rapidly and efficiently advance XR_x-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 XR_x-008.

Product Candidate Pipeline, page 3

11. We note your statement here and in Business that XR_x-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.

Risk Factors, page 3

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.

Implications of Being an Emerging Growth Company, page 5

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.

Implications off Being an Emerging Growth Company, page 5

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.

Risk Factors

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

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.

Market, Industry and Other Data, page 60

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.

Use of Proceeds, page 61

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.

Capitalization, page 62

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.

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

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.

Business, page 72

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.

Product Candidate Pipeline, page 73

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

Anticipated clinical development of XRx-008, page 77

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.
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.
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.

Anticipated clinical development of XRx-101, page 78

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.

XRx-225, page 78

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.).

Strategic Partnerships and Collaborations, page 79

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.

Competition, page 81

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."

Certain Relationships and Related Party Transactions, page 112

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.

Independent Auditors' Report, page F-2

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

Allen Davidoff
XORTX Therapeutics Inc.
June 25, 2021
Page 7

2415.12 and .13.

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.

Financial Statements

Note 5. Deposits, page F-13

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.

Note 7. Intangible Assets, page F-14

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.

You may contact Jeanne Bennett at (202) 551-3606 or Mary Mast at (202) 551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Campbell at (202) 551-4224 or Joe McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Anthony W. Epps