
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of March 2023

Commission File Number: 001-40858

XORTX Therapeutics Inc.

3710 – 33rd Street NW, Calgary, Alberta, T2L 2M1

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F Form 40-F

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XORTX Therapeutics Inc.
(Registrant)

Date: March 14, 2023

By: /s/ Allen Davidoff
Name: Allen Davidoff
Title: Chief Executive Officer

EXHIBIT INDEX

99.1 [News Release dated March 14, 2023](#)

XORTX Announces Type D Meeting with FDA to be held May 1, 2023

• Type D Meeting Requested to Accelerate XRx-008 Clinical Program •

CALGARY, Alberta, March 14, 2023 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("XORTX" or the "Company") (NASDAQ: XRTX | TSXV: XRTX | Frankfurt: ANU), a late-stage clinical pharmaceutical company focused on developing innovative therapies to treat progressive kidney disease, is pleased to announce submission of a Type D meeting request to the US Food and Drug Administration ("FDA") and a response setting the date for a virtual meeting on May 1, 2023.

Accompanying the Type D meeting request was a revised clinical trial protocol for XRX-OXY-301, a data update from the XRX-OXY-101 bridging pharmacokinetic clinical trial as well as a description of future clinical development program plans for XORLO™, XORTX's proprietary oxypurinol formulation, for the treatment of autosomal dominant polycystic kidney disease ("ADPKD"). Prior discussions with the FDA and existing agency guidance permits accelerated approval for specified validated endpoints such as total kidney volume in ADPKD. **Submission of this revised clinical trial protocol, XRX-OXY-301, provides the opportunity for XORTX's XRx-008 program to achieve earlier completion of our planned registration trial and importantly accelerate FDA marketing approval.**

Dr. Allen Davidoff, CEO of XORTX stated, "XORTX is pleased to advance this discussion with the FDA regarding the path to accelerated approval for XORLO™ to treat individuals with a diagnosis of ADPKD. This discussion will explore FDA guidance regarding accelerated approval in the context of the conduct of the XRX-OXY-301 clinical trial as well as the optimal data needed for accelerated marketing approval."

XRX-OXY-301 is designed to characterize the beneficial effect of xanthine oxidase inhibition using XORLO™ on the rate of expansion of total kidney volume.

About XRX-OXY-301

The XRX-OXY-301 clinical trial is planned as a Phase 3, Multi-Centre, Double-Blind, Placebo Controlled, Randomized Withdrawal Design Study to Evaluate the Efficacy and Safety of a Novel Oxypurinol Formulation in Patients with Progressing Stage 2-4 ADPKD and Coexistent Hyperuricemia. This clinical trial will provide data to support a future "Accelerated Approval" new drug application ("NDA") submissions to the FDA and European Medicines Agency ("EMA"). This clinical trial is planned to start in the second half of 2023 and will enroll individuals with stage 2, 3 or 4 ADPKD accompanied by chronically high uric acid. The objective of this clinical trial is to evaluate the ability of XORLO™ to slow the expansion of total kidney volume over a 12-month treatment period. Following is a link to the FDA's Table of Surrogate Endpoints for Drug Approval or License - FDA Surrogate Endpoints for Drug Approval of License.

About XORTX Therapeutics Inc.

XORTX is a pharmaceutical company with two clinically advanced products in development: 1) our lead, XRx-008 program for ADPKD; and 2) our secondary program in XRx-101 for acute kidney and other acute organ injury associated with Coronavirus / COVID-19 infection. In addition, XRx-225 is a pre-clinical stage program for Type 2 Diabetic Nephropathy. XORTX is working to advance its clinical development stage products that target aberrant purine metabolism and xanthine oxidase to decrease or inhibit production of uric acid. At XORTX, we are dedicated to developing medications to improve the quality of life and future health of patients. Additional information on XORTX is available at www.xortx.com.

For more information, please contact:

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Neither the TSX Venture Exchange nor Nasdaq has approved or disapproved the contents of this news release. No stock exchange, securities commission or other regulatory authority has approved or disapproved the information contained herein.

Forward Looking Statements

This press release contains express or implied forward-looking statements pursuant to U.S. Federal securities laws. These forward-looking statements and their implications are based on the current expectations of the management of XORTX only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as otherwise required by law, XORTX undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. More detailed information about the risks and uncertainties affecting XORTX is contained under the heading "Risk Factors" in XORTX's Registration Statement on Form F-1 filed with the SEC, which is available on the SEC's website, www.sec.gov (including any documents forming a part thereof or incorporated by reference therein), as well as in our reports, public disclosure documents and other filings with the securities commissions and other regulatory bodies in

Canada, which are available on www.sedar.com.