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 May 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 [X] 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: May 4, 2023

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

EXHIBIT INDEX

99.1	News Release dated May 4, 2023

EXHIBIT 99.1

FDA Confirms Eligibility of XORLO™ for Accelerated Approval

XORTX Expands Options for Accelerated Approval

CALGARY, Alberta, May 04, 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 completion of a positive and constructive Type D meeting with the U.S. Food and Drug Administration ("FDA") which resulted in the identification of additional clinical endpoints potentially available for accelerated approval and further understanding of the FDA expectations for the accelerated approval of XORLO™ for the treatment of autosomal dominant polycystic kidney disease ("ADPKD").

The FDA Type D meeting was conducted to discuss with the agency the details of the accelerated approval process, a clinical trial protocol for the XRX-OXY-301 study, and proposed future clinical development program plans for XORLO™, XORTX's proprietary oxypurinol formulation, for the treatment of ADPKD. The overall outcomes of the meeting included:

1/ Increased clarity regarding accelerated approval endpoints that would qualify for a new drug application ("NDA"), leading to marketing approval of XORLO™ for ADPKD.

2/ Phase 3 clinical trial parameters such as duration of treatment period required, follow up periods for subjects recruited into the trial and preferred statistical analysis methods, including the optimal information needed by the FDA in their decision-making process.

3/ With this information in hand, XORTX will now choose its primary clinical endpoint(s) and development strategy based on ongoing discussions with prospective partners for the asset.

4/ XORTX also intends to initiate and pursue a Special Protocol Assessment (SPA) with the FDA for the XRX-OXY-301 program to further de-risk the development program for XORLO™ for the treatment of ADPKD.

Dr. Allen Davidoff, CEO of XORTX, stated, "As a result of this Type D meeting with the FDA, the Company is in a much better position to advance and communicate the path to accelerated approval. We now have the optimal information needed to conduct the XRX-OXY-301 phase 3 clinical trial of XORLO™ to treat individuals diagnosed with ADPKD. The combination of Orphan Drug Designation granted April 21st and information from this Type D meeting signifies key data for the phase 3 registration trial and for ongoing partnering discussions."

About XORLO™

XORLO™ is the working name of XORTX' proprietary formulation of oxypurinol under development for the treatment of individuals with progressing ADPKD. This and related formulations are covered under granted US and European formulation patents. Recent completion of a "bridging" Pharmacokinetics – XRX-OXY-101, characterized key pharmacokinetics features of this novel formulation, such as bioavailability, food effects, dose proportionality and steady state PK parameters.

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 future "Accelerated Approval" NDA submissions to the FDA and European Medicines Agency ("EMA"). The XRX-OXY-301 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 the clinical trial will be to evaluate the ability of XORLO™ to slow the expansion of total kidney volume and/or slow glomerular filtration rate decline over a 12-month treatment period. For more information regarding the FDA's Table of Surrogate Endpoints for Drug Approval or License, please visit: www.fda.gov/drugs/development-resources/table-surrogate-endpoints-were-basis-drug-approval-or-licensure

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.

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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.