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 April 2025

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: April 30, 2025

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

EXHIBIT INDEX

99.1	News release dated April 30, 2025

EXHIBIT 99.1

XORTX Provides Update on FDA Type B Meeting Request

• XORTX will focus on key steps
to advance a NDA filing for Gout indication •

CALGARY, Alberta, April 30, 2025 (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 gout and progressive kidney disease, is pleased to announce it has received responses from the US Food and Drug Administration (the "FDA") and clarified key steps for a new drug application ("NDA") for the Company's novel proprietary formulation of oxypurinol for the treatment of gout. The Type B meeting conducted by the FDA, included review of chemistry, manufacturing, pharmacology, toxicology and clinical evidence to support the Company's XRx-026 program for the treatment of gout. Responses from the FDA substantially confirmed and clarified the remaining key steps necessary prior to filing a NDA to gain marketing approval for XORLO™ in the US using the FDA 505(b)2 development pathway.

With this FDA guidance, XORTX will now advance the following key steps to support the NDA application and its submission for the XRx-026 program for gout.

i) Finalize meeting minutes with the FDA regarding the agency and XORTX's responses;
ii) Prepare and file an Investigative New Drug ("IND") application for the XRx-026 program;
iii) Characterize pharmacokinetics of the commercial tablet formulation of XORLO™ in absence and in the presence of food;
iv) Manufacture, validate commercial supplies of drug accompanied by stability data in parallel with the NDA preparation; and
v) Prepare and file a NDA for marketing approval of XORLO™.

Dr. Allen Davidoff, CEO of XORTX commented, "The clarity gained during this review of supporting data with the FDA will permit the further advancement of the XRx-026 program and will facilitate the timely completion of key steps necessary for filing the NDA. The Company believes that the gout NDA may be filed in the H1 2026. We continue to prioritize our XRx-026 program and advance this much needed therapeutic option for individuals with gout."

The Company will provide further updates following final communications with the FDA once meeting minutes are finalized and available.

About Hyperuricemia and Gout

In the US it is estimated that approximately 44 million individuals have circulating uric acid above the normal range[(1)]. The prevalence of gout was 3.9% or 9.2 million individuals. Mean serum urate levels were 6.0 mg/dL among men and 4.8 mg/dL among women, with hyperuricemia prevalences of 20.2% and 20.0%, respectively. The prevalence of ULT use among patients with gout was 33% during 2007 to 2014 and remained stable over time (P for trend >0.05)[(1)]. Gout is an inflammatory arthritis that is triggered by the crystallization of monosodium urate inside the joints and is preceded by hyperuricemia. Gout flares lead to substantial morbidity by causing severe pain, reduced quality of life[(2)], decreased physical function[(2,3)], increased healthcare costs[(4)], and lost economic productivity[(5)]. Furthermore, gout is strongly associated with the metabolic syndrome[(5)], and may contribute to myocardial infarction[(6,7)], type 2 diabetes mellitus[(8)], chronic kidney disease[(9)], and premature mortality[(6,10,11)].

About the XRx-026 Program and XORLO™

The XRx-026 program is developing XORLO™, a proprietary formulation of oxypurinol to treat individuals suffering from gout. At present, oral xanthine oxidase inhibitors ("XOIs") are the preferred therapeutic option used to inhibit the production of uric acid and decrease chronically high uric acid in the circulation. Allopurinol is the most commonly prescribed XOI, with approximately 3.3 million prescriptions written per year in North America, however 3 to 5% of patients cannot tolerate Allopurinol. An alternative XOI, Febuxostat, was launched in the US in 2009 with the hope of treating individuals with gout, however while Febuxostat achieved peak sales greater than US$450 million[1] after its launch, a Black Box warning due to its associated risk of sudden cardiovascular death resulted in a decline in its use. XORLO™ can address this unmet medical need and accelerating advancement of the XRx-026 program through an NDA filing is now a priority for XORTX.

About Type B Meetings with the FDA

Type B meetings for each potential application (e.g., investigational new drug application (IND), NDA, biologics license application (BLA)) or combination of closely related products developed by the same sponsor or applicant (e.g., same active ingredient but different dosage forms being developed concurrently). Typically, it may be appropriate to conduct more than one of some of the Type B meetings for concurrent development of a product for unrelated claims.

References:

(1) Chen-Xu M_Prevalence of Gout and Hyperuricemia in the US_ArthritisRheumatol_71-6_991-999_2019_nihms-1002533
(2) Singh JA. Quality of life and quality of care for patients with gout. Curr Rheumatol Rep. 2009 4;11(2):154–60. [PubMed: 19296889]
(3) Burke BT, Köttgen A, Law A, Windham BG, Segev D, Baer AN, et al. Physical Function, Hyperuricemia, and Gout in Older Adults. Arthritis Care Res. 2015 12;67(12):1730–8.
(4) Rai SK, Burns LC, De Vera MA, Haji A, Giustini D, Choi HK. The economic burden of gout: A systematic review. Semin Arthritis Rheum. 2015 8;45(1):75–80. [PubMed: 25912932]

(5) Choi HK, Ford ES. Prevalence of the metabolic syndrome in individuals with hyperuricemia. Am J Med. 2007 5;120(5):442–7. [PubMed: 17466656]
(6) Choi HK, Curhan G. Independent impact of gout on mortality and risk for coronary heart disease. Circulation. 2007 8 21;116(8):894–900. [PubMed: 17698728]
(7) Liu S-C, Xia L, Zhang J, Lu X-H, Hu D-K, Zhang H-T, et al. Gout and Risk of Myocardial Infarction: A Systematic Review and Meta-Analysis of Cohort Studies. Pizzi C, editor. PLOS ONE. 2015 7 31;10(7):e0134088. [PubMed: 26230580]
(8) Choi HK, De Vera MA, Krishnan E. Gout and the risk of type 2 diabetes among men with a high cardiovascular risk profile. Rheumatology. 2008 8 13;47(10):1567–70. [PubMed: 18710901]
(9) Roughley MJ, Belcher J, Mallen CD, Roddy E. Gout and risk of chronic kidney disease and nephrolithiasis: meta-analysis of observational studies. Arthritis Res Ther. 2015 12;17(1).
(10) Kuo C-F, See L-C, Luo S-F, Ko Y-S, Lin Y-S, Hwang J-S, et al. Gout: an independent risk factor for all-cause and cardiovascular mortality. Rheumatology. 2010 1;49(1):141–6. [PubMed: 19933595]
(11) Fisher MC, Rai SK, Lu N, Zhang Y, Choi HK. The unclosing premature mortality gap in gout: a general population-based study. Ann Rheum Dis. 2017 7;76(7):1289–94. [PubMed: 28122760]

About XORTX Therapeutics Inc.

XORTX is a pharmaceutical company with three clinically advanced products in development: 1) our lead program XRx-026 program for the treatment of gout; 2) XRx-008 program for ADPKD; and 3) XRx-101 for acute kidney and other acute organ injury associated with respiratory virus infections. In addition, the Company is developing XRx-225, a pre-clinical stage program for Type 2 diabetic nephropathy. XORTX is working to advance 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 that improve the quality of life and health of individuals with gout and other important diseases. Additional information on XORTX is available at www.xortx.com.

For more information, please contact:

Allen Davidoff, CEO
adavidoff@xortx.com or +1 403 455 7727

Nick Rigopulos, Director of Communications
nick@alpineequityadv.com or +1 617 901 0785

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 applicable securities laws. These forward-looking statements include, but are not limited to, the Company's beliefs, plans, goals, objectives, expectations, assumptions, estimates, intentions, future performance, other statements that are not historical facts and statements identified by words such as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates" or words of similar meaning. 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. Such risks, uncertainties, and other factors include, but are not limited to, our ability to obtain additional financing; the accuracy of our estimates regarding expenses, future revenues and capital requirements; the success and timing of our preclinical studies and clinical trials; the performance of third-party manufacturers and contract research organizations; our plans to develop and commercialize our product candidates; our plans to advance research in other kidney disease applications; and, our ability to obtain and maintain intellectual property protection for our product candidates. Except as otherwise required by applicable law and stock exchange rules, 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 Annual Report on Form 20-F 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.sedarplus.ca.

---

[1] Source: Takeda Pharmaceutical Company 2018 Annual Report.