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**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 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  Form 40-F

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**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 19, 2025

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

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**EXHIBIT INDEX**

99.1 Press Release dated March 19,  
2025

## XORTX Announces Update for Discussion with the FDA

### • Type B Meeting Discussion to Accelerate XRx-026 for Gout to NDA •

CALGARY, Alberta, March 19, 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 progressive kidney disease and gout, is pleased to provide an update regarding communications with the US Food and Drug Administration (the "FDA"). At the request of the FDA a type B meeting package will be provided by the Company during the next week, and accompanying FDA communications are expected by April 26, 2025. The Company has prepared a broad Type B meeting review at the request of the FDA, including review of chemistry, manufacturing, pharmacology, toxicology and clinical evidence regarding the Company's XRx-026 program for the treatment of gout. Drug Development of XORLO™, the Company's proprietary drug formulation of oxypurinol, has advanced substantially to a state where a Type B meeting and discussion with the FDA to confirm the developmental state of each element of the program is warranted. The purpose of this meeting will be to review the XRx-026 program and its readiness for submission of a New Drug Application ("NDA") to gain marketing approval for XORLO™ in the US using the FDA 505(b)2 development pathway. The Company believes that a Type B meeting will facilitate a broader discussion toward market approval.

Dr. Allen Davidoff, CEO of XORTX commented, "We look forward to FDA feedback the last week in April and advancing the XRx-026 program, thereafter. Many key elements of the XRx-026 program have advanced sufficiently to warrant this robust program review with the FDA to define any additional information needed to complete this marketing approval. We believe that the XRx-026 program provides a much needed therapeutic option for individuals with gout and that advancing with the XRx-026 program will transform XORTX to a revenue positive state."

The Company will provide further updates following communications with the FDA when additional information is available.

### About Hyperuricemia and Gout

In the US it is estimated that approximately 44 million individuals have circulating uric acid above the normal range<sup>(1)</sup>. 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)<sup>(1)</sup>. 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<sup>(2)</sup>, decreased physical function<sup>(2,3)</sup>, increased healthcare costs<sup>(4)</sup>, and lost economic productivity<sup>(5)</sup>. Furthermore, gout is strongly associated with the metabolic syndrome<sup>(5)</sup>, and may contribute to myocardial infarction<sup>(6,7)</sup>, type 2 diabetes mellitus<sup>(8)</sup>, chronic kidney disease<sup>(9)</sup>, and premature mortality<sup>(6,10,11)</sup>.

### 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 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. *Arthritis Rheumatol*. 2019; 71(6):991-999. [PubMed: 31002533]
- (2) Singh JA. Quality of life and quality of care for patients with gout. *Curr Rheumatol Rep*. 2009; 4(11):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(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; 45(1):75-80. [PubMed: 25912932]
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- (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 XR<sub>x</sub>-026 program for the treatment of gout; 2) XR<sub>x</sub>-008 program for ADPKD; and 3) XR<sub>x</sub>-101 for acute kidney and other acute organ injury associated with respiratory virus infections. In addition, the Company is developing XR<sub>x</sub>-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](http://www.xortx.com).

For more information, please contact:

Allen Davidoff, CEO  
[adavidoff@xortx.com](mailto:adavidoff@xortx.com) or +1 403 455 7727

Nick Rigopulos, Director of Communications  
[nick@alpineequityadv.com](mailto:nick@alpineequityadv.com) or +1 617 901 0785

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#### **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](http://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](http://www.sedarplus.ca).