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 September 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: September 3, 2025

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

EXHIBIT INDEX

99.1	News release dated September 3, 2025

EXHIBIT 99.1

XORTX Initiates IND Preparation for XORLO™ in Gout Program

Engagement with Allucent supports NDA pathway and advancement of late-stage gout program

CALGARY, Alberta, Sept. 03, 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, today announced the initiation of Investigational New Drug ("IND") preparation for its lead program, XRx-026, focused on the treatment of gout. In support of this milestone, XORTX has engaged Allucent, a global contract research organization specializing in regulatory and clinical development.

Preparation of the IND will include a comprehensive review of non-clinical, pharmacologic, toxicological, and regulatory progress, and will incorporate the clinical development plan and protocol for a pharmacologic characterization study of XORLO™, the Company's proprietary formulation of oxypurinol, in fed and fasted states. XORTX anticipates submission of the IND in the second half of 2025.

The submission of the IND follows the Type B meeting that was held in April 2025 with the U.S. Food and Drug Administration (the "FDA"), where the FDA provided guidance on the path toward a New Drug Application ("NDA") for XORLO™. The FDA outlined four critical requirements prior to NDA submission:

1. Filing of an IND;
2. Preparation of clinical and commercial drug supply with supporting stability data;
3. A pharmacologic study characterizing absorption of XORLO™ in fasted versus fed individuals; and
4. Compilation of data from steps 2 and 3 above, then submission of the NDA.

"The initiation of IND preparation marks a pivotal step toward regulatory submission and ultimately bringing XORLO™ to individuals with gout," stated Dr. Allen Davidoff, Chief Executive Officer of XORTX, who added, "Partnering with Allucent ensures we have the depth of regulatory expertise needed to deliver a high-quality submission and advance this important program with rigor and speed."

Dr. Stephen Haworth, Chief Medical Officer of XORTX, added, "Gout continues to impose a substantial burden on patients worldwide, and the limitations of current therapies leave many individuals undertreated. We believe that XORLO™ has the potential to provide a differentiated option for those who cannot tolerate or do not respond adequately to existing xanthine oxidase inhibitors."

Issuance of Shares under ATM Offering

In other news, the Company confirms the issuance of 73,871 common shares at US$1.54 (CAD $2.21) per share for gross proceeds of USD $113,547.11 (CAD $163,178.55) and net proceeds of USD $109,665.93 (CAD $157,600.91) during the quarter ended March 31, 2025 under the at-the-market offering (the "ATM Offering") announced November 30, 2023. The ATM Offering is being made in the United States pursuant to a registration statement on Form F-3 (File No. 333-269429) filed under the Securities Act of 1933, as amended (the "**Securities Act**"), with the Securities and Exchange Commission (the "**SEC**") and declared effective on February 3, 2023 (the "**Registration Statement**"), and the related Prospectus dated February 3, 2023 (the "**Base Prospectus**") and the Prospectus Supplement dated November 29, 2023 ("**Prospectus Supplement**", together with Base Prospectus, the "**Prospectus**") filed with the Commission.

About Hyperuricemia and Gout

In the United States, approximately 44 million individuals have uric acid levels above the normal range, with 9.2 million individuals living with gout[1]. Gout is associated with severe pain, reduced quality of life[2], decreased physical function[3], increased healthcare costs[4], and lost economic productivity[5]. It is also strongly associated with metabolic syndrome[5], myocardial infarction[6,7], type 2 diabetes mellitus[8], chronic kidney disease[9], and premature mortality[6,10,11]. Importantly, the global prevalence of gout is increasing, with cases expected to double over the next 25 years.

About the XRx-026 Program and XORLO™

The XRx-026 program is developing XORLO™, a proprietary formulation of oxypurinol, to treat individuals with gout. Oral xanthine oxidase inhibitors (XOIs) are the current standard of care, but limitations remain: approximately 3 to 5% of patients cannot tolerate allopurinol, and febuxostat, while once achieving >US$450 million in annual sales, now carries a boxed warning for cardiovascular risk. XORLO™ is designed to address this unmet need by providing an alternative therapeutic option with a differentiated safety and efficacy profile. Advancement of XRx-026 through NDA filing is a strategic priority for XORTX.

References

1. Chen-Xu M, et al. Prevalence of Gout and Hyperuricemia in the US. *Arthritis Rheumatol.* 2019;71(6):991–999.
2. Singh JA. Quality of life and quality of care for patients with gout. *Curr Rheumatol Rep.* 2009;11(2):154–60.
3. Burke BT, et al. Physical Function, Hyperuricemia, and Gout in Older Adults. *Arthritis Care Res.* 2015;67(12):1730–8.
4. Rai SK, et al. The economic burden of gout: a systematic review. *Semin Arthritis Rheum.* 2015;45(1):75–80.
5. Choi HK, et al. Prevalence of the metabolic syndrome in individuals with hyperuricemia. *Am J Med.* 2007;120(5):442–7.
6. Choi HK, Curhan G. Independent impact of gout on mortality and risk for coronary heart disease. *Circulation.* 2007;116(8):894–900.
7. Liu S-C, et al. Gout and Risk of Myocardial Infarction: A Systematic Review. *PLoS ONE.* 2015;10(7):e0134088.

8. Choi HK, et al. Gout and the risk of type 2 diabetes among men with high cardiovascular risk profile. *Rheumatology.* 2008;47(10):1567–70.
9. Roughley MJ, et al. Gout and risk of chronic kidney disease and nephrolithiasis: meta-analysis. *Arthritis Res Ther.* 2015;17(1).
10. Kuo C-F, et al. Gout: an independent risk factor for all-cause and cardiovascular mortality. *Rheumatology.* 2010;49(1):141–6.
11. Fisher MC, et al. Premature mortality gap in gout: a general population-based study. *Ann Rheum Dis.* 2017;76(7):1289–94.

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.