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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 August 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: August 7, 2025

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

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**EXHIBIT INDEX**

99.1 News release dated August 7, 2025

## XORTX Provides Corporate Update and Planned Activities for 2025 / 2026

CALGARY, Alberta, Aug. 07, 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 provide a comprehensive update on its 2025 progress and strategic goals for 2026. The first half of 2025 has been marked by intense focus and significant advancement, solidifying a robust plan to accelerate the lead gout program towards a NDA filing, aiming to propel technology toward revenue generation and foster substantial shareholder value.

### Strategic Acceleration of the Gout Program: XRx-026 and XORLO™

In the first quarter of the year, XORTX pivoted to prioritize and accelerate its gout program, XRx-026, leveraging significant progress in formulation development and clinical validation of its proprietary XORLO™ formulation. XORLO™, an oral oxypurinol formulation, shows increased oral bioavailability, a key differentiator for improved patient outcomes.

XORTX is committed to developing a needed gout therapy for patients who are intolerant to existing treatments. The XRx-026 program is approximately 12 months from filing a NDA (New Drug Application) with the US Food and Drug Administration (the “FDA”) for XORLO™ marketing approval, targeting an estimated USD \$700 million per year market opportunity.<sup>1</sup>

### 2025 Achievements

This year, we have made significant strides in advancing our mission to deliver high-value therapies:

#### *Strategic Focus on XRx-026 Gout Program:*

- XRx-026 program advanced to address gout in patients who are intolerant to allopurinol, targeting a USD \$700 million per year market opportunity.
- Engaged with the FDA through a Type B meeting (held March 31, 2025) to clarify the regulatory path for a NDA via the 505(b)(2) pathway, with responses received on April 30, 2025, confirming key steps for XORLO™ approval.
- Conducted the XRX-OXY-101 pharmacokinetics clinical trial to support NDA preparation.

#### *Intellectual Property Advancements:*

- On December 19, 2024, we submitted a Patent Cooperation Treaty (PCT) application for international protection, leveraging clinical data linking aberrant purine metabolism to kidney disease progression.
- On April 28, 2025, the European Patent Office granted a patent, “Formulations of Xanthine Oxidase Inhibitors” for renal and related diseases, thus strengthening our portfolio for XORLO™ in gout and other conditions.

#### *Corporate Enhancements:*

- Strengthened our leadership with the appointment of Michael Bumby, a biotech/pharma veteran with over 20 years of experience, including 14 years at Eli Lilly, on December 19, 2024.
- Welcomed Abigail Jenkins to our Board of Directors on April 8, 2024, adding strategic expertise.
- Closed a USD \$925,000 non-brokered LIFE public offering on July 21, 2025, to support ongoing initiatives.

#### *Clinical and Manufacturing Progress:*

- Validated XORLO™ formulation and advanced our XRx-026 (gout) and XRx-008 (autosomal dominant polycystic kidney disease) programs.

### 2025/2026 Goals and Action Plan

Looking ahead, XORTX is focused on advancing XORLO™ within the XRx-026 program toward a NDA filing and market approval within approximately 12 months. Our key objectives include:

1. *Investigational New Drug (IND) Application:* □ We will prepare and submit an IND (Investigative New Drug) application to the FDA, incorporating novel formulation data, pharmacology, toxicology, and clinical results from the XRX-OXY-101 trial to support further clinical studies.
2. *XRX-OXY-102 Clinical Trial:* □ We plan to initiate a clinical trial in the second half of 2025 to study XORLO™ pharmacokinetics in fed and fasted states. This trial will provide critical data for population-based pharmacokinetic modeling and support future FDA and European Medicines Agency (“EMA”) submissions.
3. *Chemistry, Manufacturing, and Controls (CMC):* In parallel with items 1 and 2, we will produce clinical drug supplies under the IND, scale up commercial supplies, and conduct validation and stability testing for XORLO™, adhering to GMP standards to support our planned NDA filing.
4. *Commercialization Preparations:* □ To prepare for a potential 2026 NDA filing under the FDA’s 505(b)(2) pathway, we will conduct commercialization studies, including interviews with nephrologists, patients, and payers to analyze pricing, reimbursement, and branding strategies. Product launch planning, including brand name selection, will also commence.
5. *European Market Strategy:* We will engage with the EMA to define the regulatory path for XORLO™ approval in the European

Union, including necessary clinical studies and reimbursement conditions, with activities ongoing through 2025/2026.

To achieve these goals, XORTX will strategically pursue non-dilutive and dilutive funding, expanding discussions for partnerships with major pharmaceutical/biotech companies with global reach. Such partnerships are critical accelerants for commercialization. XORTX also plans to increase financial and healthcare conference participation to strengthen and expand its investor base. Items 2 through 5 are subject to available funding.

Dr. Allen Davidoff, CEO of XORTX stated, “We are confident that our strategic decisions and operational advancements in 2025 position the Company for a truly transformative 2026 and beyond. XORTX remains steadfast in its commitment to developing innovative therapies that make a meaningful difference for patients while delivering significant returns for shareholders. We thank shareholders for the continued support and look forward to sharing further updates as we progress toward these milestones.”

#### **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](http://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 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).

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<sup>1</sup> Inflation-adjusted Febuxostat peak sales