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 2026

Commission File Number: 001-40858

XORTX Therapeutics Inc.

3710 – 33rd Street NW, Calgary, Alberta, Canada 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 [ ]

EXHIBIT INDEX

Exhibit	Description
99.1	News release dated September 18, 2026.

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.

Date: September 18, 2026

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

EXHIBIT 99.1

XORTX Announces Planned FDA IND Submission for XRx-026 Gout Program Using XORLO™, Targeting USD$700M+ U.S. Gout Market Opportunity

Investigational New Drug application planned for submission to the U.S. FDA in the fourth quarter of 2026, advancing the Company's regulatory path toward NDA filing for gout program XRx-026

CALGARY, Alberta, Sept. 18, 2026 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("**XORTX**" or the "**Company**") (NASDAQ: XRTX), a late-stage clinical pharmaceutical company focused on developing innovative therapies to treat gout and progressive kidney disease, outlines its anticipated Investigational New Drug application ("**IND**") submission to the U.S. Food and Drug Administration (the "**FDA**") for the XRx-026 gout program. XORTX's drug development plan is to seek FDA marketing approval for XRx-026 and provide patients with a new therapeutic option. The key steps the Company anticipates will be necessary to file a marketing application with the FDA include meetings with the agency, a two-part clinical study to characterize the pharmacokinetics and efficacy of the XORLO™ formulation of oxypurinol, and manufacture of a commercial supply of XORLO™ for the first year of marketing.

Recent drug development team activities include preparation of a new IND for submission to the FDA in the fourth quarter of 2026. The application describes the Company's clinical development plan and its intention to file a New Drug Application ("**NDA**") with the FDA following completion of the planned two-part XRX-OXY-102 clinical trial, which is being advanced based on positive and supportive prior clinical trial results and discussions with the FDA. The focus of the XRX-OXY-102 clinical trial is to characterize key information needed by the FDA in its evaluation of a future NDA filing by XORTX for marketing approval.

If the XRX-OXY-102 clinical trial is successfully completed, the Company anticipates requesting a pre-NDA meeting with the FDA and preparing an NDA submission, in parallel with pre-commercialization activities. Subject to the availability of sufficient funding and the timely completion of the XRX-OXY-102 clinical trial, XORTX is targeting an NDA submission in approximately one year. Based on prior peak net sales for febuxostat, XORTX estimates the XRx-026 program addresses an estimated US$700M market opportunity per annum.

"Our planned IND submission to the FDA next quarter is a defining step for the XRx-026 program," stated Allen Davidoff, Co-Chief Executive Officer of XORTX, who added, "It reflects the strength of our prior clinical results and moves us closer to potentially offering gout patients a differentiated treatment option."

This planned submission is one part of XORTX's broader regulatory strategy for XRx-026, and the Company looks forward to providing further updates on its international development plans.

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 increase 70% over the next 25 years*.

About the XRx-026 Program and XORLO™

The XRx-026 program is developing XORLO™, the Company's proprietary formulation of oxypurinol, to treat individuals with gout. Oral xanthine oxidase inhibitors (XOIs) are the current standard of care, but limitations remain: approximately 3–5% 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 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, and the recently acquired VB4-P5 program, which is currently at the pre-IND stage of development and targets both rare and prevalent forms of kidney disease. 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.

For more information, please contact:

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

Mika Grasso, Co-CEO
mgrasso@xortx.com
+1 949 244 6011

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, as well as "forward-looking information" within the meaning of applicable Canadian securities laws. Forward-looking statements may be identified by the use of words such as "anticipate," "believe," "expect," "estimate," "plan," "intend," "will," "designed to," "positions," and similar expressions, and include all statements that are not statements of historical fact. These forward-looking statements include, but are not limited to, statements regarding the timing and content of the Company's planned IND submission to the FDA for the XRx-026 program; the design, initiation, conduct, and completion of the planned XRX-OXY-102 clinical trial; the timing of a pre-NDA meeting and the preparation and submission of an NDA, including the Company's target of submitting an NDA in approximately one year; the manufacture of commercial supply of XORLO™; the Company's estimate of the size of the U.S. market opportunity for XRx-026; the Company's international development plans; and the advancement of the Company's XRx-026 program, its other development programs, and its strategy.

Forward-looking statements are based on the Company's current expectations and assumptions and are subject to known and unknown risks, uncertainties, and other factors that could cause actual results, performance, or achievements to differ materially from those expressed or implied by such statements. Such risks and uncertainties include, among others: the Company's need for, and ability to obtain, additional capital to fund its development programs and operations; the risk that the Company's IND submission is delayed or, once submitted, is placed on clinical hold or otherwise not permitted to proceed by the FDA; the Company's ability to initiate, conduct, and complete the planned XRX-OXY-102 clinical trial on the timelines currently anticipated, or at all, and the risk that the results of that trial are not positive or do not support an NDA submission; the risk that the FDA does not agree with the Company's proposed clinical development plan or regulatory pathway, or requires additional studies or data; the Company's reliance on third-party contract research organizations and contract manufacturers; the risk that the Company's estimates of market size, which are based on third-party data and the historical sales of other products, prove to be inaccurate; competition from existing and future therapies for gout; the Company's ability to advance, and obtain regulatory approval for, the XRx-026 program and its other product candidates on the timelines currently anticipated, or at all; the evolving regulatory environment applicable to the Company's business in the United States and Canada; and the Company's ability to attract and retain qualified personnel.

For a more detailed discussion of these and other risks and uncertainties, investors should review the disclosures contained under the heading "Risk Factors" in the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2025, and in the Company's subsequent Reports of Foreign Private Issuer on Form 6-K, each as filed with or furnished to the SEC and available at www.sec.gov, as well as in the Company's continuous disclosure documents filed with the Canadian securities regulatory authorities and available at www.sedarplus.ca.

The forward-looking statements in this press release speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise. Readers are cautioned not to place undue reliance on these forward-looking statements.

_____

* https://pubmed.ncbi.nlm.nih.gov/38996590/