# 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 January 2024

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 [ X ]

#### 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

## XORTX Therapeutics Inc. (Registrant)

Date: January 3, 2024 By:

<u>/s/ Allen Davidoff</u> Allen Davidoff Chief Executive Officer Name: Title:

#### EXHIBIT INDEX

99.1 News release dated January 3, 2024

#### XORTX Submits a New Patent for the Treatment of Chronic Kidney Disease

CALGARY, Alberta, Jan. 03, 2024 (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, announces submission of a new patent for the treatment of chronic kidney disease ("CKD"). This patent is designed to protect new discoveries and strategies for the treatment of individuals with varied degrees of kidney function in the setting of CKD. Importantly, this patent entitled "Oral and Sublingual Formulations of Xanthine Oxidase Inhibitors and Methods of Treating Disease" outlines new formulations and methods for safer and more effective the use of xanthine oxidase inhibitors (XOI) in the setting of CKD in particular autosomal dominant polycystic kidney disease (ADPKD), diabetic nephropathy (DN), IgA nephropathy, lupus nephritis and focal segmental glomerulosclerosis.

The positive topline results from the XRX-OXY-101 bridging pharmacokinetic clinical study reported in Q1 2023 (the "Study") characterized the pharmacokinetics of the Company's proprietary formulation of oral oxypurinol, XORLO<sup>TM</sup>. Results from the Study showed that XORLO<sup>TM</sup> was well tolerated by the 88 subjects who received the drug. There were no safety concerns during the testing of drug across the various dosing regimens used. Overall results were positive and showed: i) a substantial increase in the bioavailability of oxypurinol with the XORLO<sup>TM</sup> formulation platform; (ii) a substantially increased dose proportionality compared to non-formulated oxypurinol; (iii) a multiple dosing regimen that achieved therapeutic target values. In simple terms, substantially increased early oral absorption of XORLO<sup>TM</sup>, and increased circulating concentrations of oxypurinol necessary to inhibit production of uric acid across the desired therapeutic range and thereby slow down the advancements of CKD. Each of these results will provide key data to facilitate precise dosing recommendations for upcoming registration trials in individuals with progressing kidney disease due to ADPKD as well as other causes of CKD.

Dr. Allen Davidoff, CEO of XORTX, commented, "The Bridging Pharmacokinetic Study reported this year provided a wealth of clinical data regarding the potential substantive benefit of the novel formulations of the xanthine inhibitor class of drugs. Analysis of this data set, the use of in silico based pharmacokinetic modeling of data from the XRX-OXY-101 clinical trial, and further innovation, resulted in a deeper understanding of how to address the challenges of dosing in progressing kidney disease. This patent application is intended to claim new opportunities to enhance how the xanthine oxidase inhibitor class of drugs may be dosed in the future. Importantly, how to further improve the safe and effective administration of this class of drugs, including oxypurinol."

#### About the XRx-008 program

Oxypurinol is a purine based XOI with important pharmacologic characteristics ideal for administration to individuals with ADPKD. Key pharmacologic attributes include:

1/ the ability to act in the circulation, kidney and cardiovascular tissue and inhibit the production of uric acid and so attenuate the mechanism of injury and accelerating effect of XO on progressing diseases.

2/ XORTX's proprietary formulation of oxypurinol, XORLO™, provides substantially increased absorption of oxypurinol. Metabolism of oxypurinol is minimal and it is eliminated by the kidneys unchanged. This approach provides an effective, well tolerated drug with an extensive clinical safety experience suggesting the Company's XRx-008 program has the capacity to provide superior XOI to slow the accelerating decline kidney function in patients ADPKD with coexistent hyperuricemia.

#### **About ADPKD**

ADPKD is a rare disease that affects more that 10 million individuals worldwide.<sup>1,2</sup> ADPKD is typically diagnosed based upon expansion of fluid-filled cysts in the kidneys. Over time, the increasing number and size of cysts can contribute to structural and functional changes to kidneys and is frequently accompanied by chronic pain which is a common problem for patients with ADPKD.<sup>3</sup> Expansion of cysts is thought to compress healthy functioning tissue surrounding the cysts and contribute to further loss of kidney function, fibrosis, impaired nutrient exchange and impaired kidney function, accompanied later by end-stage renal disease.<sup>1</sup> For individuals with progressing ADPKD, treatment recommendations include anti-hypertensive treatment, dietary restrictions, and, for a limited percentage of suitable patients, pharmacotherapy.<sup>4</sup> New, more broadly applicable therapies to effectively slow decline of kidney function in ADPKD are needed.

#### References:

- 1. Wiley C., Kamat S., Stelhorn R., Blais J., Analysis of nationwide date to determine the incidence and diagnosis of autosomal dominant polycystic kidney disease in the USA, Kidney Disease, 5(2): 107-117, 2019
- 2. Bergmann C., Guay-Woodford L.M., Harris P.C., Horie S., Peters D.J., Torres V.E., Polycystic Kidney Disease, Nat Rev Dis Primers. 4(1): 50, 2018
- 3. https://pkdcure.org/living-with-pkd/chronic-pain-management/
- 4. Gimpel C., Bermann C., Bockenhauer D., et al., International consensus statement of the diagnosis and management of autosomal dominant polycystic kidney disease in children and young people, Nat Rev Nephrol 15(11):713-726, 2019

#### **About XORTX Therapeutics Inc.**

XORTX is a pharmaceutical company with two clinically advanced products in development: 1) our lead, XRx-008 program for ADPKD; and 2) our secondary program in XRx-101 for acute kidney and other acute organ injury associated with Respiratory Viral infection. In addition, XRx-225 is a pre-clinical stage program for Type 2 Diabetic Nephropathy. XORTX is working to advance its clinical development stage 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 to improve the quality of life and future health of patients with kidney disease. 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 TSXV 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, including those relating to future sales of Shares under the ATM Offering, the offering price therefor and the use of proceeds thereof. 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. 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.