

## Important Stage Three FDA Drug Trial Soon

Opportunity: **XORTX Therapeutics Inc.**

TSXV: XRTX NASDAQ: XRTX FSE: ANU

***Recent Buy Rating With Target Price of US\$14.00;  
Fast-Developing Therapy Drug To Fight Fatal Kidney Disease***

**Focus on Biotech - The Venture Letter™** has found a company we feel is **set to soar**. We are excited to introduce readers to **NASDAQ-listed XORTX Therapeutics Inc.** and the exciting drugs the company has developed for the treatment of progressive kidney disease.

**Autosomal dominant polycystic kidney disease (ADPKD)** is a genetic disorder **affecting 1 in 1000 people worldwide** and is associated with an increased risk of intracranial aneurysms. The average life expectancy of a patient with ADPKD ranges from 53 to 70 years, depending on the subtype. (Source: American Journal of Neuroradiology)

**XORTX Therapeutics Inc. is leading the charge** toward the most effective, life-prolonging treatment for all ADPKD patients.



The worldwide biotechnology market was valued at US\$1.55 trillion in 2023 and is projected to grow at a **compound annual growth rate (CAGR) of 13.96% from 2024 to 2030**. (Source: Grand View



Research) The global healthcare services market grew from **\$7,499.75 billion in 2022 to \$7,975.87 billion in 2023** at a compound annual growth rate (CAGR) of 6.3%. (Source: "Healthcare Services Global Market Report 2023" - Reportlinker.com)

And as stated by Allied Market Research on November 10th, 2023 "The chronic kidney disease treatment market size was valued at **\$32 billion in 2022**, and is estimated to reach **\$47.9 billion by 2032**, growing at a CAGR of 4% from 2023 to 2032."

# XORTX Therapeutics Inc.

## Proven Management Again Pursuing Maximum Shareholder Value

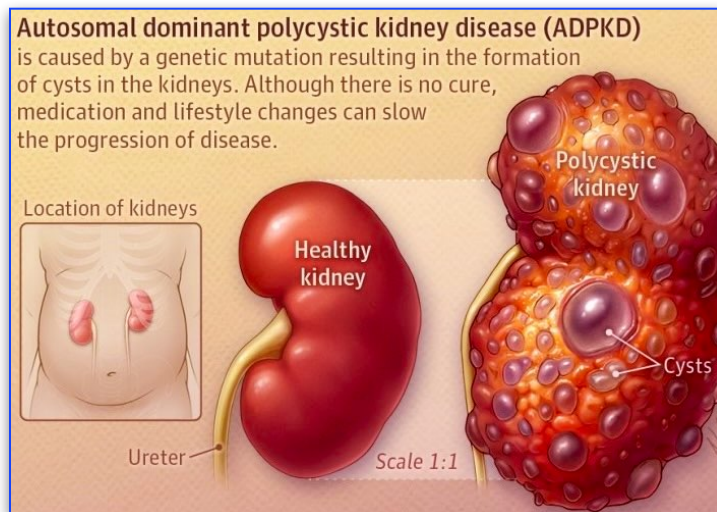
We were recently introduced to **XORTX Therapeutics Inc.**, listed on the NASDAQ Stock Exchange (**XRTX**), the TSX Venture Exchange (**XRTX**) and also on the Frankfurt Stock Exchange (**ANU**). We were surprised that such an advanced-stage developer of drug therapies for kidney disease and diabetes had such a unnecessarily low market capitalisation.

**XORTX Therapeutics Inc.** is a biotech pharmaceutical company with two clinically advanced products in development:

- 1) its lead, **XR<sub>x</sub>-008 program** for Autosomal Dominant Polycystic Kidney Disease (ADPKD);
- 2) its secondary **XR<sub>x</sub>-101 program** for acute kidney and other acute organ injury associated with Respiratory Viral infection;
- 3) In addition, its **XR<sub>x</sub>-225 program** 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.

**As you can see in the image at the top right of this page**, a very recent special report by Mr. James Molloy, the Managing Director, Biotechnology & Specialty Pharmaceuticals Equity Research Analyst with **Alliance Global Partners** of New York City agrees with our last sentence. On January 4th of this year his special report on **XORTX Therapeutics Inc.** gave XRTX a 'Buy' rating with a **price target of US\$14.00 per share**. Based on XRTX's January 23rd, 2024 closing price on the NASDAQ of US\$2.22, XRTX hitting a \$14.00 share price would mean a **return on investment (ROI) of approximately 630%** for smart investors interested in supporting XORTX now as shareholders.





**AllianceGlobalPartners**  
member FINRA, SIPC

January 4, 2024  
Biotechnology

---

<b>XORTX Therapeutics</b>	<b>Buy</b>
<b>James Molloy</b> (617) 283-5521, <a href="mailto:jmolloy@alliancegp.com">jmolloy@alliancegp.com</a>	
Sales & Trading 888-543-4448	
<hr/> <b>(NASDAQ: XRTX )</b> <hr/>	
Price	\$2.49
52 Week Range	(\$1.98 - \$11.16)
<b>Price Target</b>	<b>\$14.00</b>
Market Cap (mil)	\$5.00
Shares out (mil)	2.00
3-Mo Avg Vol	219,863
Cash per share	\$2.54
Total Debt (mil)	NA
Debt/Equity	NA

# XORTX Therapeutics Inc.

## - KEY POINTS TO CONSIDER -

- ✓ **Developing greatly needed, drug-based therapies for serious progressive kidney diseases with a high, unmet medical need**, including Autosomal Dominant Polycystic Kidney Disease (ADPKD), Diabetes Type-2 Nephropathy (T2DN) and Acute Kidney Injury (AKI).
- ✓ **Three patent families derived from its proprietary technology** with broad therapeutic claims.; patent protection until 2034.
- ✓ **US\$1.0 - 1.8 Billion per year revenue potential for XORTX in the US alone** to help an estimated 160,000 ADPKD patients. Clear focus on XRx-008 program for ADPKD for a **strong unmet medical need**; potential for early revenue in 2026/7 to replace Tolvaptan by Otsuka.
- ✓ Based on the percentage of US patients to US population, the **global number of ADPKD patients** in need of XORTX' proprietary ADPKD drug therapy could be **over 3.8 million** which gives XRTX Incredible Blue Sky potential.
- ✓ **Orphan Drug Designation granted by FDA**; path to accelerated approval has been confirmed.
- ✓ **Strong current cash position** of US\$5.2 Million vs. a market cap of US\$4.4 Million: runway for fourteen months; **extremely low shares outstanding**
- ✓ **Senior team led by CEO Allen Davidoff, Ph.D who was responsible for Oxypurinol development** in prior ventures; known builders of strong shareholder value:
  - ★ **Trillium Therapeutics** - bought for **US\$2.2 Billion** by Pfizer
  - ★ **Cynapsus Therapeutics** - acquired for **US\$624 Million**

XORTX is dedicated to developing medications to improve the quality of life and future health of patients with kidney disease. With over **160,000 people suffering from ADPKD each year** in the United States alone (Source: Vicente E. Torres March 2021 [AJKD](#)), and a relative percentage of ADPKD patients globally, the demand for desperately-needed, new drug therapies is great. **This deadly kidney disease has the largest market with a genetic origin, and it does not discriminate by race or sex.** ADPKD has a **50% chance of being passed from parent to child.** Sadly, a majority of patients require regular dialysis or even kidney transplantation by the time they reach their mid-50s.



## ADPKD Pain & Discomfort

Cysts put pressure on abdomen and imping of organs

**Liver cysts (40%)**

**10x increase in Neurologic Aneurisms**

**Increased Cardiovascular disease**

**Hypertension – High Blood Pressure**

**Kidney Stones**

**Declining Renal Function “GFR”**

- End Stage Renal Disease (ESRD)

## ADPKD – Only One Therapy Approved While Suboptimal Treatment Options Remain

The opportunity for XORTX Therapeutics to beat out the sole existing ADPKD drug therapy available for patients couldn’t be better.

Otsuka America Pharmaceutical, Inc.’s drug JYNARQUE® (Tolvaptan) was approved in 2018 for the treatment of ADPKD with a **major black box warning** – “for risk of serious liver injury”. The Annual Treatment Cost of Tolvaptan is approximately US\$156,000 per patient. **Otsuka reported 2022 sales of Tolvaptan of US\$962 million.** More than 7,000 ADPKD patients have been treated with Tolvaptan (Source: Alliance Global Partners Research)

DRUG	STATUS
<b>Tolvaptan</b> (oral vasopressin V2 antagonist) Otsuka Pharma	<b>FDA-APPROVED</b> Black Box Warning – Liver toxicity Extremely low usage du to tolerability
<b>Lixivaptan</b> (oral vasopressinV2 antagonist) Centessa Pharma	<b>ABANDONED</b> Phase III
<b>Bardoxolone</b> (oral Nrf2 activator) Reata Pharmaceuticals Inc.	<b>ABANDONED</b> Phase III
<b>GLPG2737</b> (a Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) inhibitor) Galapagos	<b>ABANDONED</b> Phase II
<b>XR<sub>x</sub>008</b> <small>XORTX THERAPEUTICS INC.</small> (xanthine oxidase inhibitor) XORTX Therapeutics Inc.	<b>IN DEVELOPMENT</b> Preparing to Enter Phase III

**NOTE: It has been estimated that 95% of ADPKD patients cannot tolerate Tolvaptan.** (Source: Wim Van Biesen, Jan 2019, **NDT**) Naturally, most anyone can clearly see the need for a Tolvaptan replacement, and XORTX Therapeutics’ 100% owned **XR<sub>x</sub>008 drug therapy** could be just that replacement. And an incredibly valuable replacement it could be, **especially to XRTX shareholders.**

## 2023 - XORTX Milestones Achieved

- ✓ Dosing of PK Bridging Clinical Trial – **Completed** - Topline Results released;
- ✓ Type D meeting with FDA – Accelerated Approval **Confirmed** (May 1, 2023);
- ✓ Orphan Drug Designation (ODD) – **Granted** (April 20, 2023);

	Preclinical	Phase I	Phase II	Phase III	Phase III
XRx-008 For Polycystic Kidney Disease		505(b)2 →			
XRx-101 AKI Associated with Respiratory Virus Infection		505(b)2 →			
XRx-225 For Diabetic Nephropathy	→				

## 2024 - Continued XORTX Progress Anticipated

- ☆ Initiation of XRX-OXY-201 – near term readout Interim H1 2025 / topline 2026
- ☆ Initiation of XRX-OXY-301 Registration Trial for XRx-008 in individuals with ADPKD (accelerated approval);
- ☆ European Medicines Agency – Orphan Drug Designation - 2024
- ☆ Potential significant global licensing deal with Big Pharma (non-dilutive financing)
- ☆ Novel Patent Filings *in preparation* – ADPKD discoveries; Dose ranging; New NCE Drug Candidates

2024 Q1		2024 Q2		2024 H2		
Clinical Trial Drug Supply <u>mfg</u>				Commercial Drug Supply & <u>Mfg</u>	→	
XRX-OXY-201 - FDA submission-		XRX-OXY-201 - Site initiation -		<b>XRX-OXY-201</b> - 1 <sup>st</sup> Patient		
		US FDA & EMA XRX-OXY-301 Protocol reviewed		XRX-OXY-301 – FDA submission	→	
XO expression Studies in ADPKD	T2DN (NCE) testing					
Ongoing - - - Global Licensing Discussions					→	

## Comparables: Trading Orphan Disease Companies

Company Name	Trading Symbol	Share Price	Market Capitalization
As of Jan 16, 2024			
Albireo Pharma	Nasdaq:ALBO	N/A	Acquired by Ibsen \$42/share
Apellis Pharma	Nasdaq:APLS	\$66.30	\$7,856,543,731
Arrowhead	Nasdaq:ARWR	\$35.09	\$4,319,649,198
Ascendis Pharma	Nasdaq:ASND	\$133.50	\$7,696,477,920
Avro Bio	Nasdaq:AVRO	\$1.34	\$59,729,027
Editas Medicine	Nasdaq:EDIT	\$8.83	\$721,178,588
Gain Therapeutics, Inc.	Nasdaq:GANX	\$3.63	\$59,127,665
Glokus Therapeutics	NYSE: GKOS	\$89.25	\$4,355,362,515
IMARA Inc.	Nasdaq:ELVN	\$11.90	\$490,422,427
Immunovant	Nasdaq:IMVT	\$42.25	\$6,111,965,275
Intelli Therapeutics	Nasdaq:NTLA	\$26.76	\$2,396,488,876
Kadmon Holdings Inc.	Nasdaq:KDMN	N/A	Acq'd by Sanofi \$9.50/share (\$1.9B)
Krystal Bio	Nasdaq:KRY5	\$126.95	\$3,580,792,237
Longboard Pharmaceuticals	Nasdaq:LBPH	\$23.00	\$778,479,850
Meiragtx Holdings	Nasdaq:MGTX	\$6.13	\$389,850,536
Morphic Holdings	Nasdaq:MORF	\$27.85	\$1,385,341,454
Nkarta	Nasdaq:NKTX	\$8.69	\$426,438,614
Passage BIO	Nasdaq:PASG	\$0.96	\$52,626,843
Pliant Therapeutics	Nasdaq:PLRX	\$17.61	\$1,054,768,068
Proper Therapeutics	Nasdaq:PRQR	\$2.50	\$202,876,000
Regenx Bio	Nasdaq:RGNX	\$15.27	\$671,757,402
Rocket Pharmaceuticals	Nasdaq:RCKT	\$28.52	\$2,571,331,584
Sangamo Therapeutics	Nasdaq:SGMO	\$0.47	\$82,172,975
Taysha Gene Therapies	Nasdaq:TSHA	\$1.53	\$286,048,947
Uniqure	Nasdaq:QURE	\$5.88	\$281,131,449
<b>XORTX Therapeutics</b>	<b>Nasdaq:XRTX</b>	<b>\$2.18</b>	<b>\$6,023,714</b>
<b>Average</b>		<b>\$28.60</b>	<b>\$1,909,857,704</b>
<b>Avg. &lt; \$1B Mkt</b>		<b>\$6.59</b>	<b>\$321,990,288</b>

**NOTE:** The table found on the last page shows XORTX Therapeutics Inc.'s market capitalisation is over **318x less than the average of other trading Orphan Drug designated companies**, and over **53x less** than the average of other trading Orphan Drug designated companies with a market capitalisation of less than US\$1 billion.

## Comparables: Peer Group to XORTX Therapeutics

Company Name	Trading Symbol	Share Price	Market Capitalization
As of Jan 16, 2024			
Ardelyx Inc.	Nasdaq:ARDX	\$8.78	\$2,038,168,944
Caladrius Biosciences	Nasdaq:CLBS		Merged with Cend Therapeutics for \$76 million valuation
Calliditas Therapeutics	Nasdaq:CALT	\$24.50	\$690,492,320
Cara Therapeutics	Nasdaq:CARA	\$0.54	\$29,206,780
Centessa Pharmaceuticals	Nasdaq:CNTA	\$7.30	\$712,694,127
Chinook Therapeutics	Nasdaq:KDNY		Acquired by Novartis for \$3.2 billion (\$40/share)
DiaMedica Therapeutics	Nasdaq:DMAC	\$2.85	\$108,168,069
Keros Therapeutics	Nasdaq:KROS	\$53.17	\$1,764,134,813
Kodiak Sciences	Nasdaq: KOD	\$3.31	\$173,683,309
Lexicon Pharmaceuticals	Nasdaq:LXRX	\$1.32	\$322,112,484
Miriam Pharmaceuticals	Nasdaq:MIRM	\$26.72	\$1,245,533,796
Reata Pharmaceuticals	Nasdaq:RETA		Acquired by Biogen for \$7.3 billion (\$172/share)
Regulus Therapeutics	Nasdaq:RGLS	\$1.26	\$25,581,664
<b>XORTX Therapeutics</b>	<b>Nasdaq:XRTX</b>	<b>\$2.18</b>	<b>\$6,023,714</b>
	<b>Average</b>	<b>\$11.99</b>	<b>\$646,890,911</b>
	<b>Avg. &lt; \$1B Mkt Cap</b>	<b>\$5.41</b>	<b>\$258,495,308</b>

**NOTE:** The table found on this page is **of greatest interest to us**. XORTX Therapeutics Inc.'s market capitalisation therein is over **100x less than the average of its peer group**, and over **43x less** than the average of peers with a market capitalisation of less than US\$1 billion.

**The Venture Letter™** feels XORTX Therapeutics Inc. is drastically undervalued at its current trading level and feel there is significant room for improvement in the company's market capitalisation.

## **XORTX Therapeutics' Management Team is second to none.**



### **Mr. Anthony Giovinazzo – Chairman of the Board**

Mr. Giovinazzo has 43 years of total work experience, is an internationally recognized expert in intellectual property, drug development and commercialization, including numerous licensing agreements, with more than 25 years' experience in Central Nervous System diseases. Co-inventor, Chief Executive Officer & Director of Cynapsus Therapeutics, led a NASDAQ-listed specialty pharmaceutical company that developed the first successful sublingual apomorphine thin film strip for Parkinson's disease and led a highly successful exit of Cynapsus by way of a 120% premium to market of an \$841 MM all cash M&A deal. Mr. Giovinazzo is currently Executive Chairman of Kalgene, and director of Titan Medical Inc.



### **Dr. Allen W. Davidoff, Ph.D., Chief Executive Officer**

Dr. Davidoff has 20 years of drug development experience and is the founder and CEO of XORTX. Allen has a broad range of clinical and regulatory experience and senior management experience in pharmaceutical R&D. Previously, Allen was co-founder, CSO at Stem Cell Therapeutics Corp. which merged with Trilium and thereafter was acquired by Pfizer. Prior to his role at Stem Cell, Allen was Senior Scientist/Head of Pharmacology at Cardiome Pharma Corp. Allen earned his PhD in Cardiovascular Physiology and Biophysics at University of Calgary.



### **Mr. Patrick Treanor – Newly-Appointed Board Member**

Mr. Treanor is a seasoned pharmaceutical industry executive. He is the current Chief Operating Officer of Pathalys Pharma, Inc., a private company focused on the development of advanced therapeutics to improve the management of late stage chronic kidney disease. He previously served as President, US for Vifor Pharma, an international pharmaceutical company focused on nephrology. Mr. Treanor began his career with large pharmaceutical organizations such as Johnson & Johnson and Abbott Laboratories over 25 years ago but found his niche building early-stage commercial organizations at companies such as Oscient Pharmaceuticals, AMAG Pharmaceuticals, Insulet Corporation and Relypsa Pharmaceuticals.



### **Dr. Taryn Boivin, Ph.D., Head Chemistry, Manufacturing & Controls (CMC)**

Dr. Boivin is a pharmaceutical veteran with >30 years of experience leading all aspects of CMC and related disciplines. Her experience includes multiple worldwide drug submissions, post approval support activities, and commercial supply chain operations. Early in her career, Taryn was among a key group of leaders who established the Glaxo Canada (later GSK) pharmaceutical development organization, and was a pivotal contributor to this world-class research, development, and manufacturing facility.





**Dr. Stephen Haworth, MD, Chief Medical Officer**

Dr. Haworth has >25 years of successful global drug development and senior leadership in both “start-up” and Fortune 500 pharmaceutical firms in both the US and Europe. Stephen has a broad clinical and regulatory experience that ranges from nephrology, cardiovascular, and infectious disease. He has extensive regulatory experience with FDA and EMA submissions, as well as licensing and M&A transactions. Stephen holds a MD from University College Hospital Medical School, University of London, having graduated with Honors.



**Dr. Stacy Evans, M.D., MBA Chief Business Officer (Consultant)**

Dr. Evans has >20 years of commercial development and business development experience, including 12 years at Pfizer where he was last responsible for leading transactions across all TAs. Stacy has been consulting at an executive level for small to mid-size private and public biopharma companies for the past 7 years including as part-time Chief Business Officer for Avillion, LLP, a Blackstone-backed late-stage financing and co-development company. Stacy holds a MD from McGill University and an Executive MBA from Columbia University.

## **A Powerhouse Team Building A Powerhouse Company**

As we have stated multiple times in multiple editions of The Venture Letter™, ***professional investors bet on people more than anything.*** XORTX Therapeutics Inc. has a management team, board of directors and top clinical advisory board fully capable of delivering short, medium and long-term growth/value to company shareholders.

## **Final Thoughts from The Venture Letter™**

**XORTX Therapeutics Inc. (NASDAQ: XRTX / TSXV: XRTX / FSE: ANU)** has the potential to be the next micro-cap, biotech stock that can deliver its shareholders a strong return on investment through its pursuits of valuable, new orphan disease drug therapies.

As well, **the company has only just commenced its 2024 market awareness campaign** to introduce interested, new retail and institutional investors to its stock. With a soon fast-growing investor audience in North America and Europe anticipated, XORTX Therapeutics Inc. should soon realize **maximized shareholder value** along with greater liquidity.

**The Venture Letter™** will be providing follow-up reports on XORTX in the weeks ahead as further news and updates are released from the company. We are excited to watch this advanced-stage biotech company as it advances in its drug therapy efforts and in its trading shares.

For more information on **XORTX Therapeutics**, we encourage you to contact the company via phone at +1 (403) 455-7727 or email at [info@xortx.com](mailto:info@xortx.com). Visit the company's corporate website at [www.xortx.com](http://www.xortx.com).

Good luck and good hunting.



**Legal Disclaimer/Disclosure:** This document is not and should not be construed as an offer to sell or the solicitation of an offer to purchase or subscribe for any investment. No information in this report should be construed as individualised investment advice. A licensed financial advisor should be consulted prior to making any investment decision. The Venture Letter makes no guarantee, representation or warranty and accepts no responsibility or liability as to its accuracy or completeness. Expressions of opinion are those of The Venture Letter only and are subject to change without notice. The Venture Letter assumes no warranty, liability or guarantee for the current relevance, correctness or completeness of any information provided within this report and will not be held liable for the consequence of reliance upon any opinion or statement contained herein or any omission. Furthermore, we assume no liability for any direct or indirect loss or damage or, in particular, for lost profit, which you may incur as a result of the use and existence of the information, provided within this report.

The Content contained on this page (including any facts, views, opinions, recommendations, description of, or references to, products or securities) made available by The Venture Letter is for information purposes only and is not tailored to the needs or circumstances of any particular person. Any mention of a particular security is merely a general discussion of the merits and risks associated there with and is not to be used or construed as an offer to sell, a solicitation of an offer to buy, or an endorsement, recommendation, or sponsorship of any entity or security by The Venture Letter. The Reader should apply his/her own judgment in making any use of any Content, including, without limitation, the use of any information contained therein as the basis for any conclusions. The Reader bears responsibility for his/her

own investment research and decisions. Before making any investment decision, it is strongly recommended that you seek outside advice from a qualified investment advisor. The Venture Letter does not provide or guarantee any financial, legal, tax, or accounting advice or advice regarding the suitability, profitability, or potential value of any particular investment, security, or information source.

The Venture Letter and/or its affiliates and/or their respective officers, directors or employees may from time to time acquire, hold or sell securities and/or commodities and/or commodity futures contracts in certain underlying companies mentioned in its reports and which may also be clients of The Venture Letter's affiliates. In such instances, The Venture Letter and/or its affiliates and/or their respective officers, directors or employees will use all reasonable efforts to avoid engaging in activities that would lead to conflicts of interest and The Venture Letter and/or its affiliates will use all reasonable efforts to comply with conflicts of interest disclosures and regulations to minimise the conflict.

The Venture Letter is a provider of research on publicly traded, emerging growth and/or resource focused companies. We are not a licensed broker-dealer and do not publish investment advice and remind readers that investing involves considerable risk. The Venture Letter encourages all readers to carefully review the securities commission filings of any issuers we cover and consult with an investment professional before making any investment decisions. The Venture Letter is a for-profit business and is often compensated for coverage of issuers we cover as well as other advisory work we perform.

**NOT AN INVESTMENT ADVISOR.** The Venture Letter is not registered or licensed by any governing body in any jurisdiction to give investing advice or provide investment recommendation. **ALWAYS DO YOUR OWN RESEARCH** and consult with a licensed investment professional before making an investment. This communication should not be used as a basis for making any investment.

**RISK OF INVESTING.** Investing is inherently risky. While a potential for rewards exists, by investing, you are putting yourself at risk. You must be aware of the risks and be willing to accept them in order to invest in any type of security. Don't trade with money you can't afford to lose. This is neither a solicitation nor an offer to Buy/Sell securities.

**RISK OF BIAS.** We often own shares in the companies we feature. For those reasons, please be aware that we are extremely biased with regard to the companies we write about and feature in our newsletter and on our website. As of the date of this Special Report, principals of The Venture Letter™ own no shares of **XORTX Therapeutics Inc.**

**The CEO of XORTX Therapeutics Inc., Mr. Allen W. Davidoff Ph.D. has reviewed and approved the information contained in this report.**