Prospectus Supplement No. 4 (to Prospectus dated August 7, 2023)



#### 555,555 Common Shares Issuable Upon Exercise of Warrants

# XORTX THERAPEUTICS INC.

This Prospectus Supplement No. 4 (this "**Prospectus Supplement**") amends and supplements the Prospectus dated August 7, 2023 (the "**Prospectus**") of XORTX Therapeutics Inc. (the "**Company**"), which forms a part of our Registration Statement on Form F-1 (Registration No. 333-267328). This Prospectus Supplement is being filed to amend and supplement the information included or incorporated by reference in the Prospectus with the information contained in this Prospectus Supplement. The Prospectus and this Prospectus Supplement relate to the offer by us of 555,555 common shares issuable upon exercise of 555,555 common share purchase warrants (the "**Warrants**"). The Warrants have an exercise price of \$5.00 and expire five years from the original date of issuance (October 7, 2027).

This Prospectus Supplement should be read in conjunction with the Prospectus, as it has been further supplemented, which is to be delivered with this Prospectus Supplement. This Prospectus Supplement updates and supplements the information in the Prospectus. If there is any inconsistency between the information in the Prospectus and this Prospectus Supplement, you should rely on the information in this Prospectus Supplement.

Our common shares are currently traded under the symbol "XRTX" on the TSX Venture Exchange (the **TSXV**") and on the Nasdaq Capital Market ("Nasdaq"). On June 12, 2024, the last reported sale price of our common shares on the TSXV was CAD\$2.99 per common share and on the Nasdaq was \$2.12 per common share.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 10 of the Prospectus and under similar headings in any further amendments or supplements to the Prospectus before you decide whether to invest in our securities.

Neither the Securities and Exchange Commission, Canadian securities commission nor any domestic or international securities body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is June 13, 2024.

# 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 November 2023

Commission File Number: 001-40858

**XORTX** Therapeutics Inc.

3710 - 33<sup>rd</sup> 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  $\boxtimes$  Form 40-F  $\square$ 

# 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: November 15, 2023 By: /s/ Allen Davidoff

Name: Allen Davidoff
Title: Chief Executive Officer

CEO Certificate

<u>99.1</u>

CFO Certificate

Exhibit 99.1



CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS As at and for the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

# XORTX THERAPEUTICS INC.

**Condensed Interim Consolidated Statements of Financial Position** (Unaudited - expressed in U.S. Dollars)

Note	September 30, 2023	Restated	Restated
Note	2023	(NIata 2)	
		(Note 2)	(Note 2)
	\$	\$	\$
5	5,069,233	10.434.196	14,869,861
_			40,654
6	88,927	379,620	1,002,215
	5,226,401	10,895,568	15,912,730
7	1,200,000	1,185,946	1,267,065
8	171,521	199,834	202,125
9	42,225	92,678	
	6 640 147	12 374 026	17,381,920
	0,040,147	12,5/4,020	17,301,720
10.13	525 245	1 445 213	552,948
11	28,512	66,090	-
	553,757	1,511,303	552,948
12(g)	-	3,854,403	3,626,375
	7 8 9	68,241 6 88,927  5,226,401  7 1,200,000 8 171,521 9 42,225  6,640,147  10,13 525,245 11 28,512	68,241 81,752 88,927 379,620  5,226,401 10,895,568  7 1,200,000 1,185,946 8 171,521 199,834 9 42,225 92,678  6,640,147 12,374,026  10,13 525,245 1,445,213 11 28,512 66,090  553,757 1,511,303

Lease obligation	11	-	11,509	-
Total Liabilities		553,757	5,377,215	4,179,323
Shareholders' Equity				
Share capital	12	17,056,535	16,524,354	16,088,677
Share-based payments, warrant reserve and other	12	9,611,845	6,197,158	4,991,594
Obligation to issue shares	8(c)	24,746	24,746	24,746
Accumulated other comprehensive (loss) income		(52,605)	(52,605)	75,540
Accumulated deficit		(20,554,131)	(15,696,842)	(7,977,960)
Total Shareholders' Equity		6,086,390	6,996,811	13,202,597
Total Liabilities and Shareholders' Equity		6,640,147	12,374,026	17,381,920

/s/ "Allen Davidoff" /s/ "Paul Van Damme"

Director Director

The accompanying notes are an integral part of these condensed interim consolidated financial statements.

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# XORTX THERAPEUTICS INC.

Condensed Interim Consolidated Statements of Comprehensive Loss For the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

		Thre	e months ended September 30 2022 Restated	Nine	e months ended September 30 2022 Restated
	Note	2023	(Note 2)	2023	(Note 2)
-	11000	\$	\$		\$
Expenses				·	·
Research and development	13	569,713	1,472,856	2,284,583	4,858,614
Wages and benefits	13	118,566	132,559	419,900	444,176
Consulting	13	130,467	111,563	357,051	222,101
Directors' fees	13	46,469	45,495	133,911	80,495
Investor relations		236,934	100,706	640,556	746,232
Professional fees	13	102,617	56,244	457,900	361,637
General and administrative		90,140	117,236	281,938	360,598
Public company costs		45,822	25,105	140,554	89,533
Travel		14,267	84	138,416	11,497
Amortization of property and equipment	8	18,329	18,308	54,763	24,264
Amortization of intangible assets	9	(1,862)	3,749	60,571	11,325
Share-based payments	12(f),13	21,850	19,268	92,169	420,258
Loss before other items		(1,393,312)	(2,103,173)	(5,062,312)	(7,630,730)
Fair value adjustment on derivative warrant liability	12(g)	-	362,688	-	1,816,335
Foreign exchange (loss)/gain		(3,668)	507,859	1,295	624,823
Interest income		63,614	35,460	203,728	49,873
Net loss for the period		(1,333,366)	(1,197,166)	(4,857,289)	(5,139,699)
		( ) / /	()))	( )== = )	(=) == )=== )
Other comprehensive loss:					
Items that may be subsequently reclassified to profit or loss:					
Currency translation differences		-	(511,862)	-	(671,495)
Total other comprehensive loss for the period		-	(511,862)	-	(671,495)
Total comprehensive loss for the period		(1,333,366)	(1,709,028)	(4,857,289)	(5,811,194)
Basic and diluted loss per common share		(0.67)	(0.83)	(2.45)	(3.56)
Weighted average number of common shares outstanding					
Basic and diluted		1,998,848	1,443,293	1,975,972	1,443,293

The accompanying notes are an integral part of these condensed interim consolidated financial statements.

		Number of			Obligation		Accumulated other	
		common	Share		to issue	Accumulated	comprehensive	
	Note	shares	capital	Reserves	shares	Deficit	(loss) income	Total
			\$	\$	\$	\$	\$	\$
Balance, December 31, 2021 (Restated Note 2)		1,443,293	16,088,677	4,991,594	24,746	(7,977,960)	75,540	13,202,597
Share-based payments	12(f)	-	-	420,258	-	<b>=</b>	-	420,258
Comprehensive loss for the period		-	-	-	-	(5,139,699)	(671,495)	(5,811,194)
D 1								
Balance, September 30, 2022 (Restated Note 2)		1,443,293	16,088,677	5,411,852	24,746	(13,117,659)	(595,955)	7,811,661
(restated Note 2)		1,443,273	10,000,077	3,411,032	24,740	(13,117,037)	(373,733)	7,011,001
Shares issued pursuant to public offering	12(b)	155,555	359,868	-	-	-	-	359,868
Pre-funded warrants issued	12(b)	-	-	925,015	-	-		925,015
Share issuance costs	12(b)	-	(88,959)	(42,687)	-	-	-	(131,646)
Pre-funded warrants exercised	12(b)	71,223	164,768	(164,704)	-	-	-	64
Share-based payments	12(f)	-	-	67,682	-	-	-	67,682
Comprehensive income (loss) for the period		-	-	-	-	(2,579,183)	543,350	(2,035,833)
Balance, December 31, 2022								
(Restated Note 2)		1,670,071	16,524,354	6,197,158	24,746	(15,696,842)	(52,605)	6,996,811
(		-,0,0,0,0	,	0,227,9220	_ 1,1 10	(-2,0,0,0,0)	(=2,000)	0,270,000
Reclassification of derivative warrant								
liability	12(g)	-	-	3,854,403	-	-	-	3,854,403
Pre-funded warrants exercised	12(b)	328,777	532,181	(531,885)	-	-	-	296
Share-based payments	12(f)	-	-	92,169	-	-	-	92,169
Comprehensive loss for the period		-	-	-	-	(4,857,289)	-	(4,857,289)
Balance, September 30, 2023		1,998,848	17,056,535	9,611,845	24,746	(20,554,131)	(52,605)	6,086,390
Dalance, September 30, 2023		1,770,040	17,030,333	7,011,043	24,740	(20,334,131)	(32,003)	0,000,370

The shares outstanding presented have been adjusted to reflect the effect of the 9:1 share consolidation that took place on November 10, 2023. Common shares, options, warrants and per share amounts have been adjusted for the 9:1 share consolidation unless otherwise noted.

The accompanying notes are an integral part of these condensed interim consolidated financial statements.

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# **XORTX THERAPEUTICS INC.**

Condensed Interim Consolidated Statements of Cash Flows For the nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

	Nine months ende	
	2023	Restated (Note 2)
	\$	\$
Cash provided by (used in):		
Operating activities		
Net loss for the period	(4,857,289)	(5,139,699)
Items not affecting cash:		
Amortization	115,334	35,589
Fair value adjustment on derivative warrant liability	· -	(1,816,335
Share-based payments	92,169	420,258
Unrealized foreign exchange gain	(16,778)	(565,198)
Changes in non-cash operating assets and liabilities:		
Accounts receivable	13,511	(22,490)
Prepaid expenses	290,693	937,057
Accounts payable and accrued liabilities	(922,738)	801,038
	(5,285,098)	(5,349,780)
Investing activities		
Acquisition of intangible assets	(32,258)	(14,614
Acquisition of equipment	(4,310)	(14,272)
	(36,568)	(28,886
Financing activities		
Pre-funded warrants and warrants exercised	296	-
Payment of lease obligation	(49,087)	(18,423)
Deferred share issuance costs		(448,554
	(48,791)	(466,977)

Effect of foreign exchange gain (loss) on cash	5,494	(152,248)
Decrease in cash	(5,364,963)	(5,997,891)
	· · · · · · · · · · · · · · · · · · ·	· · · · ·
Cash, beginning of period	10,434,196	14,869,861
Cash, end of period	5,069,233	8,871,970
Supplemental Cash Flow and Non-Cash Investing Activities Disclosure		
Recognition of right-of-use asset	-	114,588

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

# 1. Nature of operations

XORTX Therapeutics Inc. (the "Company" or "XORTX") was incorporated under the laws of Alberta, Canada on August 24, 2012.

XORTX is a public company listed on the TSX Venture Exchange (the "TSXV") and on the Nasdaq Stock Market ("Nasdaq") under the symbol "XRTX". The Company's operations and mailing address is 3710 – 33<sup>rd</sup> Street NW, Calgary, Alberta, Canada T2L 2M1 and its registered address is located at 550 Burrard Street, Suite 2900, Vancouver, British Columbia, V6C 0A3.

XORTX is a late stage clinical pharmaceutical company focused on developing innovative therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism in orphan disease indications such as autosomal dominant polycystic kidney disease, as well as more prevalent type 2 diabetic nephropathy, and fatty liver disease. The Company's current focus is on developing products to slow and/or reverse the progression of kidney disease in patients at risk of end stage kidney failure.

The Company is subject to a number of risks associated with the successful development of new products and their marketing and the conduct of its clinical studies and their results. The Company will have to finance its research and development activities and its clinical studies. To achieve the objectives in its business plan, the Company plans to raise the necessary capital and to generate revenues. Although there is no certainty, management is of the opinion that additional funding for future projects and operations can be raised as needed. The products developed by the Company will require approval from the U.S. Food and Drug Administration and equivalent organizations in other countries before their sale can be authorized. If the Company is unsuccessful in obtaining adequate financing in the future, research activities will be postponed until market conditions improve.

#### 2. Basis of preparation

#### Statement of Compliance

These condensed interim consolidated financial statements have been prepared in accordance with International Accounting Standard 34 (IAS 34), Interim Financial Reporting as issued by the International Accounting Standards Board ("IASB") and interpretations of the IFRS Interpretations Committee ("IFRIC"). Accordingly, certain disclosures included in the annual financial statements prepared in accordance with International Financial Reporting Standards ("IFRS") have been condensed or omitted. These unaudited condensed interim consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements for the year ended December 31, 2022.

# **Basis of Measurement and Presentation**

These condensed interim consolidated financial statements have been prepared using the historical cost convention except for financial instruments which have been measured at fair value as explained in the notes to these condensed interim consolidated financial statements. These condensed interim consolidated financial statements were prepared on an accrual basis except for cash flow information.

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# **XORTX THERAPEUTICS INC.**

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

#### 2. Basis of preparation (continued)

# **Basis of Measurement and Presentation (continued)**

In the opinion of management, all adjustments (including normal recurring accruals) considered necessary for a fair presentation have been included. The accounting policies have been applied consistently to all periods presented in these condensed interim consolidated financial statements.

These condensed interim consolidated financial statements incorporate the financial statements of the Company and its 100% owned subsidiary, XORTX Pharma Corp. The accounts of the Company's subsidiary are prepared for the same reporting period as the parent company, using consistent accounting policies. Inter-company transactions, balances and unrealized gains or losses on transactions are eliminated.

These condensed interim consolidated financial statements were approved for issue by the Board of Directors on November 14, 2023.

# Change in functional and presentation currency

Determination of functional currency may involve certain judgments to determine the primary economic environment, and management reconsiders the functional currency of the Company and its subsidiary if there is a change in events and conditions which determine the primary economic environment. The Company had determined that the functional currency of the Company's Canadian operations has changed from Canadian dollars ("CAD") to United States dollars ("USD") as the primary economic environment for the Company changed due to changing sources of recent and expected future sources of financing. The change in functional currency from CAD to USD is accounted for prospectively from January 1, 2023.

Concurrent with the change in functional currency, the Company has also changed its presentation currency from CAD to USD. This change in presentation currency is to better reflect the Company's business activities, following the increased presence in the U.S. and to be consistent with peer companies in the industry. Under IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors, the change in presentation currency represents a voluntary change in accounting policy and is applied retrospectively. The comparative consolidated statements of comprehensive loss and consolidated statements of cash flows for each period have been translated into the presentation currency using the average exchange rate prevailing during each period. All assets, liabilities and equity transactions have been translated using the exchange rate prevailing on the consolidated statements of financial position dates.

Prior period comparable information has been restated to reflect the change in presentation currency. All revenues and expenses were translated into USD at the average exchange rate for each quarter, with no adjustments to the measurement of or accounting for previously reported results. The exchange rates used to reflect the change in presentation currency were as follows:

CAD – USD exchange rate	Q1-22	Q2-22	Q3-22	Q4-22	Q4-21
Closing rate	0.8003	0.7760	0.7296	0.7383	0.7888
Average rate	0.7898	0.7834	0.7662	0.7366	0.7936

Foreign currency transactions are translated into the functional currency using exchange rates in effect at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated using the exchange rate in effect at the measurement date. Non-monetary assets and liabilities denominated in foreign currencies are translated using the historical exchange rate or the exchange rate in effect at the measurement date for items recognized at fair value through profit and loss. Gains and losses arising from foreign exchange are included in profit and loss.

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022

(Unaudited - expressed in U.S. Dollars)

#### 2. Basis of preparation (continued)

Change in functional and presentation currency (continued)

Consolidated Statements of Financial Position

·	Decemb	31, 2022	January 1, 2			1, 2022	
	As reported,	As reported,			As reported,		Restated,
	CAD		USD		CAD		USD
Total current assets	\$ 14,750,412	\$	10,895,568	\$	20,173,339	\$	15,912,730
Total assets	\$ 16,752,929	\$	12,374,026	\$	22,035,902	\$	17,381,920
Total current liabilities	\$ 2,050,262	\$	1,511,303	\$	700,999	\$	552,948
Total liabilities	\$ 7,286,499	\$	5,377,215	\$	5,298,331	\$	4,179,323
Total shareholders' equity	\$ 9,466,430	\$	6,996,811	\$	16,737,571	\$	13,202,597

Condensed Interim Consolidated Statements of Comprehensive Loss

	Three months ended			Nine mo	nth	s ended	
	Septemb	er 30, 2022	September 30, 2022				
	As reported, Restated,		As reported,		Restated,		
	CAD	USD		CAD		USD	
Loss before other items	\$ (2,744,942)	\$ (2,103,173)	\$	(9,771,049)	\$	(7,630,730)	
Net loss	\$ (1,562,474)	\$ (1,197,166)	\$	(6,567,100)	\$	(5,139,699)	
Net loss and comprehensive Loss	\$ (1,562,474)	\$ (1,709,028)	\$	(6,567,100)	\$	(5,811,194)	
Basic and diluted loss per common share	\$ (1.08)	\$ (0.83)	\$	(4.55)	\$	(3.56)	

Condensed Interim Consolidated Statements of Cash Flows

	Nine months ended September 30, 2022				
		As reported, CAD		Restated, USD	
Cash used in operating activities	\$ S	(6,811,510)	\$	(5,349,780)	
Cash used in investing activities	\$ S	(38,336)	\$	(28,886)	
Cash used in financing activities	\$ S	(643,567)	\$	(466,977)	
Effect of foreign exchange on cash	\$ S	802,216	\$	(152,248)	
Net decrease in cash	\$ S	(6,691,197)	\$	(5,997,891)	
Cash beginning of period	\$ S	18,851,244	\$	14,869,861	
Cash end of period	\$ S	12,160,047	\$	8,871,970	

# 3. Accounting policies

These condensed interim consolidated financial statements have been prepared on a basis consistent with the significant accounting policies disclosed in the annual financial statements for the year ended December 31, 2022. Accordingly, they should be read in conjunction with the annual consolidated financial statements for the year ended December 31, 2022.

(Unaudited - expressed in U.S. Dollars)

# 4. Critical accounting judgments and estimates

The preparation of condensed interim consolidated financial statements requires management to make judgments and estimates that affect the amounts reported in the condensed interim consolidated financial statements and notes. By their nature, these judgments and estimates are subject to change and the effect on the condensed interim consolidated financial statements of changes in such judgments and estimates in future periods could be material. These judgments and estimates are based on historical experience, current and future economic conditions, and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Actual results could differ from these judgments and estimates.

Revisions to accounting estimates are recognized in the period in which the estimate is revised and may affect both the period of revision and future periods. Information about critical accounting judgments in applying accounting policies that have the most significant risk of causing material adjustment to the carrying amounts of assets and liabilities recognized in the condensed interim consolidated financial statements within the next financial year are discussed below:

#### Share-based payment transactions

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them.

#### Classification of contract payments

In concluding that contract payments are a non-current asset, management considered when future regulatory and clinical trial programs are anticipated to be completed. Management assessed that the future regulatory and clinical trial programs would not be completed within 12 months from period end and therefore reclassified contract payments as a non-current asset.

#### Impairment of intangible assets

Patents (obtained and pending) and licenses are reviewed for impairment at each financial reporting date. If, in the judgment of management, future economic benefits will not flow to the Company, then the Company will assess the recoverable value of the asset. If the carrying value is greater than the recoverable value, the asset will be impaired to the recoverable value.

#### **Determination of functional currency**

In concluding that the U.S. dollar is the functional currency of the Company and its subsidiary, management considered the currency that mainly influences the cost of providing goods and services in the primary economic environment in which each entity operates, or if there has been a change in events or conditions that determined the primary economic environment.

#### Treatment of research and development costs

Costs to develop products are capitalized to the extent that the criteria for recognition as intangible assets in IAS 38 Intangible Assets are met. Those criteria require that the product is technically and economically feasible, the Company has the intention and ability to use the asset, and how the asset will generate future benefits. Management assessed the capitalization of development costs based on the attributes of the development project, perceived user needs, industry trends and expected future economic conditions. Management considers these factors in aggregate and applies significant judgment to determine whether the product is feasible. The Company has not capitalized any development costs as at September 30, 2023.

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022

(Unaudited - expressed in U.S. Dollars)

# 4. Critical accounting judgments and estimates (continued)

#### Leases

Value of right-of-use assets and lease obligations require judgement in determining lease terms such as extension options, determining whether a lease contract contains an identified asset to which the Company has the right to use substantially all of the economic benefits from the use of that asset and the incremental borrowing rate applied. The Company estimates the incremental borrowing rate based on the lease term, collateral assumptions and the economic environment in which the lease is denominated. Renewal options are only included if management is reasonably certain that the option will be renewed.

# Classification of pre-funded warrants

Management applied judgment when determining the appropriate classification of pre-funded warrants included in unit offerings. Management considered the characteristics of derivative instruments and concluded that the pre-funded warrants should be classified as an equity instrument.

#### 5. Cash

The Company's cash equivalents consist of cash held and interest-bearing deposits with the Company's bank and brokerage accounts. The current annual interest rate earned on these deposits is 5.15% (December 31, 2022 - 3.90%).

	September 30, 2023	December 31, 2022	January 1, 2022
	\$	\$	\$
Cash	344,229	3,823,217	14,869,861
Interest-bearing deposits	4,725,004	6,610,979	-
	5,069,233	10,434,196	14,869,861

#### 6. Prepaid expenses

The Company's prepaid expenses relate to the following:

	September 30, 2023	December 31 2022	January 1, 2022
	\$	\$	\$
Research and development	-	-	563,768
Insurance	1,590	238,365	348,167
Investor relations conferences and services	70,576	66,305	49,715
Consulting	-	12,305	39,440
Administrative services and other	16,761	62,645	1,125
	88,927	379,620	1,002,215

#### 7. Contract payments

During the year ended December 31, 2020, the Company entered into an agreement with Prevail InfoWorks Inc. As part of the agreement, the Company paid \$1,200,000 through the issuance of units in the private placement that closed February 28, 2020, to be applied to future regulatory and clinical trial programs. The 108,590 units issued were measured by reference to their fair value on the issuance date, which is equal to CAD \$14.76 per unit.

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

#### 8. Intangible assets

Cost	Total
	\$
Balance, December 31, 2021	287,905
Additions	26,005
Foreign currency translation adjustment	(19,159)
Balance, December 31, 2022	294,751
Additions	32,258
Balance, September 30, 2023	327,009
Accumulated amortization	Total
Accumulated amoi dzadon	\$
Balance, December 31, 2021	85,780
Amortization	17,077
Foreign currency translation adjustment	(7,940)
Balance, December 31, 2022	94,917
Amortization	60,571
Balance, September 30, 2023	155,488
Carrying values	Total
	\$
At January 1, 2022	202,125
At December 31, 2022	199,834
At September 30, 2023	171,521

The Company has licensed intellectual property from various third parties. The intangible assets relate solely to licensed intellectual property and there are no other classes of intangible assets. The intangible assets are as described below:

- a) The Company has licensed from a third party (the "Licensor"), under patent rights purchase agreement dated July 9, 2013 and amended April 15, 2014, certain patents relating to allopurinol for the treatment of hypertension. The Company paid a total of \$40,000 to the Licensor per the terms of the agreement.
  - The Company will also pay the Licensor royalties on the cumulative net revenues from the sale or sublicense of the product covered under the patent license until the later of (i) the expiration of the last patent right covering the product; and (ii) the expiration of ten years from the date of the first commercial sales of a product. As of September 30, 2023, no royalties have been paid.
- b) In December 2012, the Company entered into an agreement to license certain intellectual property relating to the use of all uric acid lowering agents to improve the treatment of metabolic syndrome. Under this patent rights purchase agreement, between the Company and Dr. Richard Johnson and Dr. Takahiko Nakagawa (the "Vendors"), the Company will pay the Vendors a royalty based on the cumulative net revenues from the sale or sublicense of the product covered under the licensed intellectual property until the later of (i) the expiration of the last patent right covering the product; and (ii) the expiration of 10 years from the date of the first commercial sales of a product.

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

# 8. Intangible assets (continued)

c) Pursuant to a license agreement dated October 9, 2012, as amended on June 23, 2014, between the Company and the University of Florida Research Foundation, Inc. ("UFRF"), the Company acquired the exclusive license to a patent that claims the use of any uric acid lowering agent to treat insulin resistance. The Company has paid or is obligated to pay UFRF the following:

- i) An annual license fee of \$1,000;
- ii) Reimburse UFRF for United States and/or foreign costs associated with the maintenance of the licensed patents;
- The issuance to UFRF of 180,397 shares of common stock of the Company (160,783 have been issued to UFRF as at September 30, 2023 and December 31, 2022. Remaining shares to be issued are included in obligation to issue shares (\$24,746));
- iv) Milestone payments of \$500,000 upon receipt of FDA approval to market licensed product in the United States of America and \$100,000 upon receipt of regulatory approval to market each licensed product in each of other jurisdictions;
- v) Royalty payments of up to 1.5% of net sales of products covered by the license until the later of (i) the expiration of any patent claims; or (ii) 10 years from the date of the first commercial sale of any covered product in each country. Following commencement of commercial sales, the Company will be subject to certain annual minimum royalty payments that will increase annually to a maximum of \$100,000 per year. As at September 30, 2023, no royalties have been paid; and
- vi) UFRF is entitled to receive a royalty of 5% of amounts received from any sub-licensee that are not based directly on product sales, excluding payments received for research and development or purchases of the Company's securities at not less than fair market value.

UFRF may terminate the agreement if the Company fails to meet the above specified milestones.

# 9. Property and equipment

	Right-of-		
Cost	use asset	Equipment	Total
	\$	\$	\$
Balance, December 31, 2021	-	-	-
Additions	114,588	19,696	134,284
Foreign currency translation adjustment	-	(663)	(663)
Balance, December 31, 2022	114,588	19,033	133,621
Additions	-	4,310	4,310
Balance, September 30, 2023	114,588	23,343	137,931

	Right-of-		
Accumulated amortization	use asset	Equipment	Total
	\$	\$	\$
Balance, December 31, 2021	-	-	-
Amortization	38,195	2,874	41,069
Foreign currency translation adjustment	-	(126)	(126)
Balance, December 31, 2022	38,195	2,748	40,943
Amortization	49,110	5,653	54,763
Balance, September 30, 2023	87,305	8,401	95,706

	Right-of-		
Carrying values	use asset	Equipment	Total
	\$	\$	\$
At December 31, 2022	76,393	16,285	92,678
At September 30, 2023	27,283	14,942	42,225

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

# 9. Property and equipment (continued)

The Company entered into an office lease during the year ended December 31, 2022 for which a right-of-use asset was recognized (Note 11).

# 10. Accounts payable and accrued liabilities

	September 30,	December 31	January 1
	2023	2022	2022
	\$	\$	\$
Trade payables	394,032	1,293,807	323,961
Accrued liabilities	131,213	151,406	228,987
Total	525,245	1,445,213	552,948

# 11. Lease obligation

The Company has entered into an office lease expiring in 2024, with an imputed interest rate of 8% per annum. A reconciliation of the outstanding lease obligation as at September 30, 2023 is as follows:

	\$
Balance, December 31, 2021	-
Additions	114,588
Lease payments	(36,989)
Balance, December 31, 2022	77,599
Lease payments	(49,087)
Balance, September 30, 2023	28,512

The following is a schedule of the Company's future minimum lease payments related to the office lease obligation:

	\$	\$
2023	17,442	69,769
2024	11,628	11,628
Total minimum lease payments	29,070	81,397
Less: imputed interest	(558)	(3,798)
Total present value of minimum lease payments	28,512	77,599
Less: current portion	(28,512)	(66,090)
Non-current portion	-	(11,509)

# 12. Share capital and reserves

#### a) Authorized and issued

Unlimited common shares - 1,998,848 issued at September 30, 2023 (December 31, 2022 - 1,670,071).

The shares outstanding presented have been adjusted to reflect the effect of the 9:1 share consolidation that took place on November 10, 2023. Common shares, options and warrants and per share amounts have been adjusted for the 9:1 share consolidation unless otherwise noted.

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

# 12. Share capital and reserves (continued)

#### b) Issuances

# Nine months ended September 30, 2023:

On January 19, 2023, the Company issued 328,777 common shares for the exercise of Pre-Funded Warrants at \$0.0009 per share in the amount of \$296. An amount of \$531,885 was transferred from reserves to share capital as a result.

#### Year ended December 31, 2022:

On October 7, 2022, the Company closed a public offering of: (i) 155,555 common share units ("Common Share Units") at a price of \$9.00 per Common Share Unit, with each Common Share Unit consisting of one common share and one warrant ("Warrant") to purchase one common share; and (ii) 400,000 pre-funded warrant units ("Pre-Funded Units") at a price of \$8.9991 per Pre-Funded Unit, with each Pre-Funded Unit consisting of one pre-funded warrant ("Pre-Funded Warrant") to purchase one common share and one Warrant to purchase one common share. Aggregate gross proceeds amounted to \$4,999,640. The Pre-Funded Warrants have an exercise price of \$0.0009 per share, and will terminate once exercised in full. The Warrants are exercisable at an exercise price of \$10.98 per share expiring five years from the date of issuance.

The proceeds were allocated \$3,714,757 to the derivative warrant liability (Note 12(g)) and the residual amounts of \$359,868 and \$925,015 were allocated to common shares and pre-funded warrants respectively.

In connection with the public offering, the Company incurred issuance costs of \$1,067,153 and issued 27,777 underwriters warrants with a fair value of \$185,738. The costs were allocated between common shares and derivative warrant liability in proportion to their initial carrying amounts with \$317,301 recorded as a reduction of equity and \$917,357 recorded as transaction costs on derivative warrant liability and pre-funded warrants.

On December 29, 2022, the Company issued 71,223 common shares for the exercise of Pre-Funded Warrants at \$0.0009 per share in the amount of \$64. An amount of \$164,704 was transferred from reserves to share capital as a result.

# **Diluted Weighted Average Number of Shares Outstanding**

	Three months ended		Nine months ended	
	September 30,	September 30,	September 30,	September 30,
	2023	2022	2023	2022
Basic weighted average shares outstanding	1,998,848	1,443,293	1,975,972	1,443,293
Effect of outstanding securities	-	-	-	-
Diluted weighted average shares outstanding	1,998,848	1,443,293	1,975,972	1,443,293

During the three and nine month periods ended September 30, 2023 and 2022, the Company had a net loss, as such, the diluted loss per share calculation excludes any potential conversion of options and warrants that would decrease loss per share.

#### 12. Share capital and reserves (continued)

# c) Common Share Purchase Warrants

A summary of the changes in warrants for the nine month period ended September 30, 2023 and the year ended December 31, 2022 is presented below:

	Number of Warrants	Weighted Average Exercise price	
Balance, December 31, 2021	569,655	\$	33.12
Granted – October 7, 2022	555,555		10.98
Balance, September 30, 2023 and December 31, 2022	1,125,210	\$	22.23

At September 30, 2023, the weighted average contractual remaining life of the unexercised warrants was 3.41 years (December 31, 2022 - 4.15 years).

The following table summarizes information on warrants outstanding at September 30, 2023:

	Number		Remaining
Exercise Price	Outstanding	Expiry date	Contractual Life
CAD\$42.26	198,333	February 9, 2026	2.36 years
\$42.93	270,211	October 15, 2026	3.04 years
\$10.53	101,111	October 15, 2026	3.04 years
\$10.98	555,555	October 7, 2027	4.02 years
Total	1,125,210		3.41 years

# d) Pre-Funded Warrants

A summary of the changes in Pre-Funded Warrants for the nine month period ended September 30, 2023 and the year ended December 31, 2022 is presented below:

	Number of Warrants	Weighted Average Exercise price
Balance, December 31, 2021	-	-
Granted – October 7, 2022	400,000	\$ 0.0009
Exercised	(71,223)	\$ 0.0009
Balance, December 31, 2022	328,777	\$ 0.0009
Exercised	(328,777)	\$ 0.0009
Balance, September 30, 2023	-	-

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022

(Unaudited - expressed in U.S. Dollars)

# 12. Share capital and reserves (continued)

# e) Finders' and Underwriters Warrants

A summary of the changes in finders' and underwriters warrants for the nine month period ended September 30, 2023 and the year ended December 31, 2022 is presented below:

	Number of Warrants	A	eighted verage cise price
Balance, December 31, 2021	22,521	\$	39.60
Granted – October 7, 2022	27,777	-	10.98
Balance, September 30, 2023 and December 31, 2022	50,298	\$	23.85

At September 30, 2023, the weighted average contractual remaining life of the unexercised finders' and underwriters warrant was 3.50 years (December 31, 2022 - 4.25 years).

The following table summarizes information on finders' and underwriters warrants outstanding at September 30, 2023:

	Number		Remaining
Exercise Price	Outstanding	Expiry date	Contractual Life
CAD\$42.30	6,377	February 9, 2026	2.36 years
\$42.93	16,144	October 15, 2026	3.04 years
\$10.98	27,777	October 7, 2027	4.02 years

Total 50,298 3.50 years

The fair value of the underwriters warrants issued on October 7, 2022 was estimated at \$185,738 on the date of grant using the Black-Scholes option pricing model with the following assumptions: expected life of 5.0 years; expected volatility of 100%; risk free rate of 3.66%; and expected dividend yield of 0%.

The risk-free interest rate is the yield on zero-coupon Canadian Treasury Bills of a term consistent with the assumed option life. The expected life of the option is the average expected period to exercise.

Volatility is based on available historical volatility of the Company's share price, excluding specific time frames in which volatility was affected by specific transactions that are not considered to be indicative of the Company's expected share price volatility. The Company has not declared dividends in the past.

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022

(Unaudited - expressed in U.S. Dollars)

#### 12. Share capital and reserves (continued)

#### f) Stock Options

The Company has an incentive Stock Option Plan (the "Plan") for directors, officers, employees and consultants, under which the Company may issue stock options to purchase common shares of the Company provided that the amount of incentive stock options which may be granted and outstanding under the Plan at any time shall not exceed 10% of the then issued and outstanding common shares of the Company.

The fair value of stock options granted was estimated on the date of grant using the Black-Scholes model with the following data and assumptions:

	2022
Dividend yield	Nil
Annualized volatility	100%
Risk-free interest rate	1.44%-3.32%
Expected life	5 years

The risk-free interest rate is the yield on zero-coupon Canadian Treasury Bills of a term consistent with the assumed option life. The expected life of the option is the average expected period to exercise.

Volatility is based on available historical volatility of the Company's share price, excluding specific time frames in which volatility was affected by specific transactions that are not considered to be indicative of the Company's expected share price volatility. The Company has not declared dividends in the past.

Share-based payment expense recognized during the three and nine months ended September 30, 2023 amounted to \$21,850 and \$92,169 (2022 - \$19,268 and \$420,258) and related to vesting of options issued in prior years.

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

#### 12. Share capital and reserves (continued)

# f) Stock Options (continued)

A summary of the changes in stock options for the nine month period ended September 30, 2023 and the year ended December 31, 2022 is presented below:

		Weighted
	Number of Options	Average Exercise price (CAD)
Balance, December 31, 2021	67,329	\$ 27.90
Granted – January 12, 2022	14,162	22.86
Granted – June 6, 2022	43,866	14.40
Granted – November 25, 2022	7,776	12,42
Expired	(4,896)	28.71
Balance, December 31, 2022	128,237	\$ 27.90
Expired	(14,566)	48.60
Balance, September 30, 2023	113,671	\$ 18.27
Vested and exercisable, September 30, 2023	95,004	\$ 18.54

The weighted average contractual remaining life of the unexercised options was 3.04 years (December 31, 2022 - 3.43 years).

The following table summarizes information on stock options outstanding at September 30, 2023:

Exercise	Number	Number		Remaining
Price (CAD)	Outstanding	Exercisable	Expiry Date	Contractual Life

\$52.83	2,366 <sup>(1)</sup>	2,366	November 5, 2023	0.10 years
\$14.76	18,927	18,927	June 23, 2025	1.73 years
\$25.38	1,419	1,419	August 27, 2025	1.91 years
\$29.61	6,624	6,624	January 11, 2026	2.28 years
\$16.92	2,366	2,366	May 12, 2026	2.62 years
\$15.84	2,366	2,366	June 16, 2026	2.71 years
\$21.69	6,353 <sup>(1)</sup>	4,588	July 14, 2026	2.79 years
\$22.86	9,607	9,607	December 21, 2026	3.23 years
\$22.86	12,701 <sup>(1)</sup>	7,058	January 12, 2027	3.29 years
\$14.40	43,866	37,723	June 6, 2027	3.68 years
\$12.42	7,076 <sup>(1)</sup>	1,966	November 25, 2027	4.16 years
	113,671	95,014		

<sup>(1) 6,271</sup> options were cancelled or expired unexercised subsequent to September 30, 2023.

#### g) Derivative warrant liability

During the years ended December 31, 2022 and 2021, the Company issued warrants which were recorded as derivative financial liabilities as the exercise price was denominated in a currency other than the functional currency of the Company and therefore may be settled other than by the exchange of a fixed amount of cash. These warrants are revalued at each reporting period and any gain or loss is recorded in profit or loss.

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

#### 12. Share capital and reserves (continued)

# g) Derivative warrant liability (continued)

The fair value of the warrants issued during the year ended December 31, 2022 was estimated at \$3,714,757 on the date of grant using the Black-Scholes option pricing model with the following assumptions: share price on date of grant of \$9.09; exercise price of the warrant of \$10.98; expected life of 5.0 years; expected volatility of 100%; risk free rate of 3.66%; and expected dividend yield of 0%.

During the period ended September 30, 2023, with the change in functional currency of the Company to USD, the exercise price of these warrants is now denominated in the functional currency of the Company and therefore these warrants no longer meet the definition of a derivative warrant liability and instead meet the definition of equity instruments. Accordingly, all warrants recorded as derivative financial liabilities on January 1, 2023, the date of the change in functional currency, were reclassified to equity instruments at their estimated fair value as of that date.

## The balance of the derivative warrant liabilities (level 3) is as follows:

Balance at December 31, 2021	\$ 3,626,375
Warrants issued October 7, 2022	3,714,757
Fair value adjustment	(3,486,729)
Balance at December 31, 2022	\$ 3,854,403
Reclassified to reserves	(3,854,403)
Ralance at Sentember 30, 2023	

Significant weighted average assumptions used in determining the fair value of the derivative warrant liabilities at December 31, 2022 are as follows:

	De	cember 31,
		2022
Share price	\$	7.29
Risk-free interest rate		3.55%
Dividend yield		0%
Expected volatility		100%
Remaining term (in years)		3.8-4.8

The fair value is classified as level 3 as expected volatility is determined using historical volatility and is therefore not an observable input.

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022 (Unaudited - expressed in U.S. Dollars)

#### 13. Related party transactions

All related party transactions were measured at the amount of consideration established and agreed to by the related parties. All amounts due from/payable to related parties are unsecured, non-interest bearing and have no fixed terms of repayment.

During the three and nine months ended September 30, 2023 and 2022, the Company incurred the following transactions with related parties:

- a) Wages and benefits and professional fees were paid or accrued to Allen Davidoff, the Chief Executive Officer ("CEO"), Amar Keshri, former Chief Financial Officer ("CFO"), and David MacDonald, former Chief Technology Officer ("CTO") in the amount of \$80,250 and \$324,597 (2022 \$112,595 and \$404,811).
- b) Fees were paid or accrued to 1282803 Ontario Inc., a company owned by James Fairbairn, the Chief Financial Officer ("CFO") of the Company in the amount of \$38,325 and \$38,325 (2022 \$nil and \$nil)
- c) Research and development fees were paid or accrued to Haworth Biopharmaceutical, a company owned by Stephen Haworth, the Chief Medical Officer ("CMO") of the Company in the amount of \$56,250 and \$165,479 (2022 \$57,164 and \$169,724).
- d) Consulting fees were paid or accrued to Stacy Evans, the Chief Business Officer ("CBO") of the Company in the amount of \$75,000 and \$225,000 (2022 \$nil and \$nil).
- e) Directors' fees were paid or accrued to the directors of the Company in the amount of \$45,278 and \$136,862 (2022 \$48,238 and \$84,087). The amount includes director fees payment of \$34,064 and \$100,148 for the three and nine months ended September 30, 2023 (2022 \$35,486 and \$40,682) to Anthony Giovinazzo, Chairman of the Company.
- f) As at September 30, 2023, \$8,876 (December 31, 2022 \$14,914) was payable to directors of the Company, \$nil (December 31, 2022 \$28,846) was accrued to the CEO of the Company, for CEO services, \$nil (December 31, 2022 \$10,904) was accrued to the former CFO of the Company, for CFO services, \$14,313 (December 31, 2022 \$nil) was accrued to the CFO of the Company, for CFO services, \$18,750 (December 31, 2022 \$49,998) was payable and accrued to the CMO of the Company, for consulting services, and \$25,000 (December 31, 2022 \$24,999) was payable and accrued to the CBO of the Company, for consulting services. The balances are unsecured, non-interest bearing, and have no fixed terms of repayment.
- g) Management and directors' compensation transactions for the three and nine months ended September 30, 2023 and 2022 are summarized as follows:

	Management Compensation	Directors' fees	Share- based payments	Total
	\$	\$	\$	\$
Three months ended September 30, 2022				
Directors and officers	169,759	48,238	36,332	254,329
Three months ended September 30, 2023				
Directors and officers	249,825	45,278	11,874	306,977

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# XORTX THERAPEUTICS INC.

Notes to the Condensed Interim Consolidated Financial Statements For the three and nine months ended September 30, 2023 and 2022

(Unaudited - expressed in U.S. Dollars)

# 13. Related party transactions (continued)

	Management Compensation	Directors' fees	Share- based payments	Total
	\$	\$	\$	\$
Nine months ended September 30, 2022 Directors and officers	574,732	84,087	372,331	1,031,150
Nine months ended September 30, 2023 Directors and officers	753,401	136,862	55,820	946,083

# 14. Financial instruments and risk management

The Company's financial instruments consist of cash and cash equivalents, accounts payable and accrued liabilities, lease obligation and derivative warrant liability. Cash and cash equivalents are classified as a financial asset at FVTPL, accounts payable and accrued liabilities and lease obligation are classified as financial liabilities at amortized cost and warrant liability is classified as a financial liability at FVTPL.

The fair values of these financial instruments approximate their carrying values at September 30, 2023, due to their short-term nature.

The Company thoroughly examines the various financial instruments and risks to which it is exposed and assesses the impact and likelihood of those risks. These risks include foreign currency risk, interest rate risk, market risk, credit risk, and liquidity risk. Where material, these risks are reviewed and monitored by the Board of Directors

There have been no changes in any risk management policies since December 31, 2022.

# 15. Capital management

The Company defines capital that it manages as shareholders' equity. The Company manages its capital structure in order to have funds available to support its research and development and sustain the future development of the business. When managing capital, the Company's objective is to ensure the entity continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders. Management adjusts the capital structure as necessary in order to support its activities.

Since inception, the Company's objective in managing capital is to ensure sufficient liquidity to finance its research and development activities, general and administrative expenses, expenses associated with intellectual property protection and its overall capital expenditures. There were no changes during the nine months ended September 30, 2023. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

(Unaudited - expressed in U.S. Dollars)

#### 16. Commitments

The Company has long-term arrangements with commitments that are not recognized as liabilities as at September 30, 2023 and December 31, 2022 are as follows:

#### a) Employment Agreements

	September 30, 2023	December 31, 2022
	\$	\$
Management services – officers	321,000	441,7541

<sup>&</sup>lt;sup>1</sup> The former CFO of the Company had a termination clause whereby he was entitled to the equivalent of 12 times his then current monthly salary which as of December 31, 2022, equated to an annual salary of CAD \$192,000.

The President, CEO and a director of the Company has a long-term employment agreement with the Company. The agreement has a termination clause whereby he is entitled to the equivalent of 12 times his then current monthly salary which, as of September 30, 2023 and December 31, 2022, equated to an annual salary of \$321,000 and \$300,000.

## b) Payments

In the normal course of business, the Company has committed to payments totaling \$310,000 (December 31, 2022 - \$1,994,232) for activities related to its clinical trial, manufacturing, collaboration programs and other regular business activities which are expected to occur over the next two years.

#### 17. Segmented information

The Company operates in one reportable operating segment, being the development and commercialization of therapies to treat progressive kidney disease. As the operations comprise a single reporting segment, amounts disclosed also represent segment amounts. All long-term assets of the Company are located in Canada.

#### 18. Events after the reporting period

On October 27, 2023, the shareholders of the Company approved a consolidation of the common shares on a basis of 1 post-Consolidation common shares for 9 preconsolidation common shares (the "Consolidation"). The share consolidation was completed on November 10, 2023.

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Exhibit 99.2

#### XORTX THERAPEUTICS INC.

Management Discussion and Analysis
For the nine months ended September 30, 2023

This management discussion and analysis of financial position and results of operations (\*MD&A") is prepared as at November 14, 2023 and should be read in conjunction with the unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2023 and 2022 of XORTX Therapeutics Inc. (the "Company" or "XORTX"), together with the audited financial statements of the Company for the years ended December 31, 2022 and 2021, as well as the accompanying MD&A for the period then ended (the "Annual MD&A").

All dollar figures in this MD&A are expressed in US dollars unless stated otherwise.

The referenced unaudited condensed interim consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (**\*\*IFRS\*\***), including International Accounting Standard 34, Interim Financial Reporting, as issued by the International Accounting Standards Board (**\*\*IASB\*\***) and Interpretations of the IFRS Interpretations Committee (**\*\*IFRIC\*\***). All dollar amounts included therein and in the following MD&A are expressed in United States dollars except where noted.

The Company's critical accounting estimates, significant accounting policies and risk factors as disclosed in the Annual MD&A have remained substantially unchanged and are still applicable to the Company unless otherwise indicated. The Company changed its functional and presentation currency as detailed in the notes to the condensed interim consolidated financial statements.

In this discussion, unless the context requires otherwise, references to "we" or "our" are references to XORTX Therapeutics Inc.

# CORPORATE INFORMATION

XORTX was incorporated under the laws of Alberta, Canada on August 24, 2012, under the name ReVasCor Inc. and continued under the Canada Business Corporations Act on February 27, 2013, under the name of XORTX Pharma Corp. Upon completion of a reverse take-over transaction on January 10, 2018, with APAC Resources Inc., a company incorporated under the laws of British Columbia, the Company changed its name to "XORTX Therapeutics Inc." and XORTX Pharma Corp. became a wholly-owned subsidiary. The Company's operations and mailing address is 3710 – 33 rd Street NW, Calgary, Alberta, Canada T2L 2M1 and its registered address is located at 550 Burrard Street, Suite 2900, Vancouver, British Columbia, V6C 0A3. The Company's shares trade on the TSX Venture Exchange ("TSXV"), on the Nasdaq Stock Exchange ("Nasdaq") under the symbol "XRTX", and on the Börse Frankfurt under the symbol "ANU".

# FORWARD LOOKING STATEMENTS

This MD&A contains certain statements, other than statements of historical fact that are forward-looking statements, which reflect the current view of the Company with respect to future events including corporate developments, financial performance and general economic conditions which may affect the Company.

All statements other than statements of historical fact contained in this MD&A, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:



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- · 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;
- our ability to obtain and maintain regulatory approval of "XORLOM", XORTX's proprietary formulation of oxypurinol for use in the Company's XRx-008 program to treat ADPKD, and any other product candidates we may develop, and the labeling under any approval we may obtain;
- regulatory approvals and other regulatory developments in the United States and other countries;
- 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;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- · the successful development of our sales and marketing capabilities;
- the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available; and
- the loss of key scientific or management personnel.

XORTX relies on certain key expectations and assumptions in making the forecasts, projections, predictions or estimations set out in forward-looking information. These factors and assumptions are based on information available at the time that the forward-looking information is provided. These include, but are not limited to, expectations and assumptions concerning:

- the availability of capital on acceptable terms to fund planned expenditures;
- prevailing regulatory, tax and environmental laws and regulations; and
- the ability to secure necessary personnel, equipment and services.

Undue reliance should not be placed on forward-looking information because a number of risks and factors may cause actual results to differ materially from those set out in such forward-looking information. These include:

- the availability of capital on acceptable terms;
- · incorrect assessments of the value of acquisitions, licenses and development programs;
- · technical, manufacturing and processing problems;
- · actions by governmental authorities, including increases in taxes;
- fluctuations in foreign exchange, currency, or interest rates and stock market volatility;
- failure to realize the anticipated benefits from licenses or acquisitions;
- the other factors specifically identified as risk factors in this MD&A; and
- potential labour unrest.

Readers are cautioned that the foregoing list of factors should not be construed as exhaustive. Further information relating to risks is included in this MD&A under Risks Related to the Business.

Except as may be required by applicable law or stock exchange regulation, XORTX undertakes no obligation to update publicly or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events. Accordingly, readers should not place undue reliance on forward-looking statements. If XORTX does update one or more forward-looking statements, no inference should be drawn that additional updates will be made with respect to those or other forward-looking statements. Additional information relating to the Company is available by accessing the SEDAR website at www.sedarplus.ca.



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# BUSINESS OVERVIEW

XORTX is a late-stage clinical pharmaceutical company, focused on developing innovative and potentially commercializing innovative therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism in orphan (rare) disease indications such as autosomal dominant polycystic kidney disease ("ADPKD") and larger, more prevalent type 2 diabetic nephropathy ("T2DN") as well as acute kidney injury ("AKI") associated with respiratory virus infection.

Our focus is on developing three unique therapeutic products to:

- 1/ slow or reverse the progression of chronic kidney disease in patients at risk of end stage kidney failure;
- 2/ address the immediate need of individuals facing AKI associated with respiratory virus infection; and
- 3/ identify other opportunities where our existing and new intellectual property can be leveraged to address health issues.

We believe that our technology is underpinned by well-established research and insights into the underlying biology of aberrant purine metabolism, chronically high serum uric acid and its health consequences. Our aim is to advance novel proprietary formulations of oxypurinol, a uric acid lowering agent that works by effectively inhibiting xanthine oxidase. We are developing product candidates that include new or existing drugs that can be adapted to address different disease indications where aberrant purine metabolism and/or elevated uric acid is a common denominator, including polycystic kidney disease, pre-diabetes, insulin resistance, metabolic syndrome, diabetes, diabetic nephropathy, and infection. We are focused on building a pipeline of assets to address the unmet medical needs for patients with a variety of serious or life-threatening diseases using our

innovative formulation of oxypurinol, and our proprietary pipeline-in-a-product strategy supported by our intellectual property, established exclusive manufacturing agreements, and proposed clinical trials with experienced clinicians,

Our three unique product development programs are:

- · XRx-008, a program for the treatment of ADPKD;
- · XRx-101, a program to treat AKI associated with respiratory virus infection, AKI and associated health consequences; and
- · XRx- 225, a program for the treatment of T2DN.

At XORTX, we aim to redefine the treatment of kidney diseases by developing medications to improve the quality of life of patients with life threatening diseases by modulating aberrant purine and uric acid metabolism, including lowering elevated uric acid as a therapy.

# **Our Proprietary Therapeutic Platforms**

Our expertise and understanding of the pathological effects of aberrant purine metabolism combined with our understanding of uric acid lowering agent structure and function, has enabled the development of our proprietary therapeutic platforms. These are a complementary suite of therapeutic formulations and new chemical entities designed to provide unique solutions for acute and chronic disease. Our therapeutic platforms can be used alone, or in combination, with synergistic activity to develop a multifunctional tailored approach to a variety of indications that can address disease in multiple body systems through management of chronic or acute hyperuricemia, immune modulation, and metabolic disease. We continue to leverage these therapeutic platforms to expand our pipeline of novel and next generation drug-based product candidates that we believe could represent significant improvements to the standard of care in multiple acute and chronic cardiovascular diseases and specifically kidney disease.

We believe our in-house drug design and formulation capabilities confer a competitive advantage to our therapeutic platforms and are ultimately reflected in our programs. Some of these key advantages are:



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# **Highly Modular and Customizable**

Our platforms can be combined in multiple ways and this synergy can be applied to address acute, intermittent or chronic disease progression. For example, our XRx-101 program for AKI associated with coronavirus is designed to produce rapid suppression of hyperuricemia then maintain purine metabolism at a low level during viral infection and target management of acute organ injury. Our XRx-008 program is designed for longer term stable chronic oral dosing of xanthine oxidase inhibitors ("XOI"). We believe that the capabilities of our formulation technology allow us to manage the unique challenges of cardiovascular and renal disease by modulating purine metabolism, inflammatory and oxidative state.

#### Fit-for-purpose

Our platforms can also be utilized to engineer new chemical entities and formulations of those agents that have enhanced properties For example, our XRx-225 product candidate program, some of the intellectual property for which we license from third parties, represents a potential new class of xanthine oxidase inhibitor(s) with a targeted design to enhance anti-inflammatory activity. The capability of tailoring the potential therapeutic benefit of this class of new agents permits us to identify targets and disease that we wish to exploit and then, through formulation design, optimize those small molecules and proprietary formulations to maximize potentially clinically meaningful therapeutic effect.

# Readily Scalable and Transferable

Our in-house small molecule and formulations design expertise is positioned to create a steady succession of drug product candidates that are scalable, efficient to manufacture (by us or a partner or contract manufacturing organization) and produce large scale and high purity active pharmaceutical drug product. We believe this will provide a competitive advantage, new intellectual property and opportunity to provide first-in-class products that target unmet medical needs and clinically meaningful quality of life.

Our team's expertise in uric acid lowering agents, specifically in the development and use of xanthine oxidase inhibitors, has enabled the development of our therapeutic product candidates to treat the symptoms of, and potentially delay the progression of ADPKD, AKI associated with respiratory virus infection, and T2DN. We note that there is no guarantee that the United States Food and Drug Administration ("FDA") will approve our proposed uric acid lowering agent product candidates for the treatment of kidney disease or the health consequences of diabetes.

# **Product Candidate Pipeline**

Our lead product candidates are XRx-008, XRx-101, and XRx-225. The XRx-008 program has reported topline results for the XRX-OXY-101 Bridging Pharmacokinetic Study of XORLO<sup>TM</sup> (the "XRX-OXY-101 PK Clinical Trial") in advance of initiating Phase 3 registration clinical trial testing, the last stage of clinical development before application for FDA approval. Recent FDA discussions confirmed that a single clinical trial with a one year treatment period would be sufficient to make this program eligible for accelerated approval once the benefit of XORLTM on decreasing the rate of decline of glomerular filtration rate was demonstrated. Our recently reported study XRX-OXY-101 supports both the XRx-008 and XRx-101 programs. Future late-stage clinical studies targeting attenuation or reversal of AKI in hospitalized individuals with respiratory virus infection are planned. XRx-225 is a non-clinical stage program advancing new chemical entities toward the clinical development stage.

# Products

The Company's most advanced development program, XRx-008, is a late clinical stage program focused on demonstrating the potential of our novel product candidate for ADPKD. XRx-008 is the development name given to XORTX's therapeutics program and associated proprietary oral formulation of oxypurinol, XORLO<sup>TM</sup>. XORLO<sup>TM</sup> has shown increased oral bioavailability compared to a control formulation and demonstrates the potential for an expanded use across a broad therapeutic range. XORTX is also developing a drug product combination therapy that includes both intravenous and oral anti-hyperuricemic therapy, XRx-101, for use in treating patients with AKI associated with respiratory virus infection and/or associated co-morbidities including sepsis.



XORTX is currently evaluating novel XOI candidates for the XRx-225 program to potentially treat T2DN as well as developing new chemical entities to address other orphan and large market unmet medical need.

#### **Patents**

XORTX is the exclusive licensee of two U.S. granted patents with claims to the use of all uric acid lowering agents to treat insulin resistance or diabetic nephropathy, and two U.S. patent applications with similar claims for the treatment of metabolic syndrome, diabetes, and fatty liver disease. Counterparts for some of these patent applications have also been submitted in Europe. In both the US and Europe, XORTX owns composition of matter patent applications for unique proprietary formulations of xanthine oxidase inhibitors – U.S. and European patents have been granted. XORTX has also submitted two patent applications to cover the use of uric acid lowering agents for the treatment of the health consequences of respiratory virus infection.

#### **OUR STRATEGY**

The Company's goal is to apply our interdisciplinary expertise and pipeline-in-a-product strategy to further identify, develop and commercialize novel treatments in orphan indications, with an initial focus on renal and significant unmet medical needs.

Our ability to implement our business strategy is subject to numerous risks. These risks include, among others (see "Risks Related to the Business"):

- · we have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future;
- we will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to alter, delay, scale back, or cease our product development programs or operations;
- we have not generated any revenue to date and may never be profitable;
- we have a limited number of product candidates, all of which are still in preclinical or clinical development, and we may fail to obtain regulatory approval or experience significant delays in doing so;
- our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approved, require them to be taken off the market, require them to include contraindications, warnings and precautions, limitations of use, or otherwise limit their sales;
- we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements, and the denial or delay of any such approval would delay commercialization of our product candidates, if approved, and adversely impact our potential to generate revenue, our business and our results of operations;
- security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation;
- our existing strategic partnerships are important to our business, and future strategic partnerships may also be important to us; if we are unable to maintain any of these strategic partnerships, or if these strategic partnerships are not successful, we may not realize the anticipated benefits of our strategic partnerships and our business could be adversely affected:
- we rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates;
- our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties;
- our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged;



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- · if we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed; and
- if we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

# **Funding Requirements**

The Company has not generated any revenue from product sales to date and does not expect to do so until such time as XORTX obtains regulatory approval for and commercializes one or more of our product candidates. As the Company is currently in clinical and preclinical stages of development, it will be some time before we expect to achieve this, and it is uncertain that we ever will. We expect that we will continue to increase our operating expenses in connection with ongoing clinical trials and preclinical activities and the development of product candidates in our pipeline. We also expect to continue our strategic partnerships and we continue to seek additional collaboration opportunities. Further, we expect to continue our efforts to pursue additional grants and refundable tax credits from the Canadian government in order to further our research and development. Although it is difficult to predict our funding requirements, based upon our current operating plan, the Company anticipates that our existing cash and cash equivalents as of September 30, 2023, combined with the net proceeds of future financings, will enable us to advance the clinical development of XRx-008 and XRx-101 product candidates. XORTX may also be eligible to receive certain research, development, and commercial milestone payments in the future. However, because successful development of our product candidates and the achievement of milestones by our strategic partners is uncertain, we are unable to estimate the actual funds we will require to complete the research, development, and commercialization of product candidates.

# RECENT DEVELOPMENTS

# **Regulatory Advancements**

On January 3, 2023, the Company announced the submission of a PCT patent application seeking international patent protection for the patent entitled "Compositions and Methods for Diagnosis, Treatment and Prevention of Kidney Disease".

On February 1, 2023, the Company announced the submission of an Orphan Drug Designation ("ODD") Request to the FDA for the XRx-008 program and specifically for XORLO<sup>TM</sup> for the treatment of ADPKD.

On April 21, 2023, the Company announced the grant of Orphan Drug Designation for oxypurinol – "orphan drug designation request of oxypurinol is granted for treatment of autosomal dominant polycystic kidney disease".

On March 14, 2023, the Company announced the submission of a Type D meeting request to the FDA and a response setting the date for a virtual meeting on May 1, 2023. A Type D meeting provides an opportunity to discuss with FDA a narrow set of issues on a shorter timeline than with other meeting types. Additionally, a revised clinical trial protocol for XRX-OXY-301, a data update from the XRX-OXY-101 PK Clinical Trial as well as a description of future clinical development program plans for XORLO TM for

the treatment of ADPKD were submitted. We believe our prior discussions with the FDA and existing agency guidance will permit application for accelerated approval based on specified validated endpoints such as total kidney volume in ADPKD. We believe submission of this revised clinical trial protocol, XRX-OXY-301 will provide the opportunity for XORTX's XRx-008 program to potentially achieve earlier completion of our planned registration trial and importantly to potentially accelerate our application to FDA for marketing approval.

On May 4, 2023, the Company announced completion of a positive and constructive Type D meeting with the FDA which resulted in the identification of additional clinical endpoints potentially available for accelerated approval and further understanding of the FDA expectations for the accelerated approval of XORLO<sup>TM</sup> for the treatment of ADPKD. The FDA Type D meeting was conducted to discuss with the agency the details of the accelerated approval process, a clinical trial protocol for the XRX-OXY-201 study, and proposed future clinical development program plans for XORLO<sup>TM</sup>, XORTX's proprietary oxypurinol formulation, for the treatment of ADPKD. The overall outcomes of the meeting included: (1) increased clarity regarding accelerated approval endpoints that would qualify for a new drug application ("NDA"), leading to marketing approval of XORLO<sup>TM</sup> for ADPKD; (2) Phase 3 clinical trial parameters such as duration of treatment period required, follow up periods for subjects recruited into the trial and preferred statistical analysis methods, including the optimal information needed by the FDA in their decision-making process; (3) With this information in hand, XORTX will now choose its primary clinical endpoint(s) and development strategy based on ongoing discussions with prospective partners for the asset; and (4) XORTX also continues to assess the value of initiating and pursuing a SPA with the FDA for the XRx-008 clinical program and to further de-risk the development program for XORLO TM for the treatment of ADPKD.



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On August 29, 2023, the Company announced that it had submitted an ODD application for XORLO<sup>TM</sup> to the EMA. The "orphan-drug designation request is for the use of XORTX's patented unique proprietary formulation of oxypurinol – XORLO<sup>TM</sup> – for the treatment of ADPKD. The EMA's COMP (Committee for Orphan Medicinal Products) office, will review this initial application package and provide feedback and a decision, which is expected in December of this year. The EMA ODD submission follows on receipt of ODD status granted by the FDA in April 2023. Benefits of EMA ODD designation include reduced fees for protocol assistance, market authorization applications and annual fees for authorized medicines; automatic access to centralized procedure for EMA marketing authorization, access to research grants, a simplified approval process and 10 years of market exclusivity.

#### **Change in Functional and Presentation Currency**

Determination of functional currency may involve certain judgments to determine the primary economic environment, and management reconsiders the functional currency of the Company and its subsidiary if there is a change in events and conditions which determine the primary economic environment. The Company had determined that the functional currency of our Canadian operations has changed from Canadian dollars ("CAD") to United States dollars ("USD") as the primary economic environment for the Company changed due to changing sources of recent and expected future sources of financing. The change in functional currency from CAD to USD is accounted for prospectively from January 1, 2023.

Concurrent with the change in functional currency, the Company has also changed its presentation currency from CAD to USD. This change in presentation currency is to better reflect our business activities, following the increased presence in the U.S. and to be consistent with peer companies in the industry. Under IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors, the change in presentation currency represents a voluntary change in accounting policy and is applied retrospectively. The comparative consolidated statements of comprehensive loss and consolidated statements of cash flows for each period have been translated into the presentation currency using the average exchange rate prevailing during each period. All assets, liabilities and equity transactions have been translated using the exchange rate prevailing on the consolidated statements of financial position dates.

Prior period comparable information has been restated to reflect the change in presentation currency. All revenues and expenses were translated into USD at the average exchange rate for each quarter, with no adjustments to the measurement of or accounting for previously reported results. The exchange rates used to reflect the change in presentation currency were as follows:

CAD – USD exchange rate	Q1-22	Q2-22	Q3-22	Q4-22	Q4-21
Closing rate	0.8003	0.7760	0.7296	0.7383	0.7888
Average rate	0.7898	0.7834	0.7662	0.7366	0.7936

Foreign currency transactions are translated into the functional currency using exchange rates in effect at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated using the exchange rate in effect at the measurement date. Non-monetary assets and liabilities denominated in foreign currencies are translated using the historical exchange rate or the exchange rate in effect at the measurement date for items recognized at fair value through profit and loss. Gains and losses arising from foreign exchange are included in profit and loss.



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# **Nasdaq Compliance**

On November 25, 2022, the Company announced that it received notification from Nasdaq Listing Qualifications Department that it was not in compliance with the minimum bid price requirement set forth in Nasdaq Rule 5550(a)(2) since the closing bid price for the Company's common shares listed on Nasdaq was below US\$1.00 for 30 consecutive business days. Nasdaq Rule 5550(a)(2) requires the shares to maintain a minimum bid price of US\$1.00 per share, and Nasdaq Rule 5810(c)(3)(A) provides that failure to meet such a requirement exists when the bid price of the shares is below US\$1.00 for a period of 30 consecutive business days. It was noted that these notifications do not impact the Company's listing on Nasdaq at this time. In accordance with Listing Rule 5810(c)(3)(A), the Company had a period of 180 calendar days from the date of notification to regain compliance with the minimum bid price requirement, during which time the shares would continue to trade on the Nasdaq Capital Market. If at any time before the 180 calendar day period, the bid price of the shares closed at or above US\$1.00 per share for a minimum of 10 consecutive business days, Nasdaq had the discretion to provide written notification that the Company has achieved compliance with the minimum bid price requirement and consider such deficiency matters closed. At the juncture of the 180 day period, the Company had not cured the minimum bid price requirement and the Company made an application to extend the compliance period for a further 180 days. On May 23, 2023, Nasdaq granted the Company's request for a 180-day extension to regain compliance with the minimum bid price requirement. The Company has until November 20, 2023 to meet the requirement. The Company believes that the Share Consolidation will bring the Company back into compliance.

#### **Changes in Officers and Directors**

On June 28, 2023, the Company announced that Jacqueline Le Saux decided to not stand for re-election from the Board of Directors and it announced that James Fairbairn was appointed Interim Chief Financial Officer.

On August 4, 2023, the Company announced the appointment of James Fairbairn as Chief Financial Officer to replace Amar Keshri who left the Company's employ effective July 31, 2023.

#### **Share Consolidation**

On October 3, 2023, the Company mailed proxy circular documents for a special meeting of shareholders to consider a consolidation of the Company's issued and outstanding shares up to nine pre-consolidation shares to comply with continued listing requirements for Nasdaq. On October 25, 2023, the Company announced the rescheduling of the Meeting to October 27, 2023 (the "Special Meeting"). At the Special Meeting, the Company received shareholder approval for the Share Consolidation. On November 10, 2023 the Share Consolidation was effected resulting in consolidated shares outstanding on that date of 1,998,848.

#### FUTURE PLANS AND OUTLOOK

XORTX intends to grow its business by developing three programs focused on kidney disease.

For the balance of 2023, XORTX will continue its focus of advancing XORLO<sup>TM</sup> for the XRx-008 program for ADPKD into a Phase 2/3 clinical trial program, ODD in the EU, initiation of special protocol assessment ("SPA") discussions with the FDA and initiation of commercialization activities, if approved, for XORLO<sup>TM</sup> as well as advancing research in other kidney disease applications. To achieve these objectives, XORTX's action plan includes:

1. Under the XRx-008 program, initiate the Phase 3 clinical trial named -"XRX-OXY-201", to support an application for "Accelerated Approval" of XORLO<sup>TM</sup> for individuals with ADPKD. The XRX-OXY-201 Clinical Trial is a Phase 2/3, Multi-Centre, Double-Blind, Placebo Controlled, Randomized Withdrawal Design Study to Evaluate the Efficacy and Safety of a Novel Oxypurinol Formulation in Patients with Progressing Stage 3-4 ADPKD and Coexistent Hyperuricemia. The XRX-OXY-201 Clinical Trial will provide data for future "Accelerated Approval" NDA submissions to the FDA and MAA to the EMA. The XRX-OXY-201 Clinical Trial is planned to start in the first half of 2024 and will enroll individuals with stage 2, 3 or 4 ADPKD and presenting with chronically high uric acid. The objective of the XRX-OXY-201 Clinical Trial is to evaluate the ability of XORLO<sup>TM</sup> to slow rate of decline of glomerular filtration rate and/or the expansion of total kidney volume over a 12-month treatment period. An estimated 120 patients will be enrolled.



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- 2. Under the XRx-008 program, prepare and communicate with the FDA and EMA regarding a second phase clinical trial named "XRX-OXY-301", a Full Registration trial in ADPKD. The XRX-OXY-302 Clinical Trial is a Phase 3, Multi-Centre, Double-Blind, Placebo Controlled, Randomized Withdrawal Design Study to Evaluate the Efficacy and Safety of a Novel Oxypurinol Formulation in Patients with Progressing Stage 2-4 ADPKD and Coexistent Hyperuricemia with progressing stage 2, 3, or 4 kidney disease. The objective of the XRX-OXY-301 Clinical Trial is to evaluate the safety and effectiveness of XORLO<sup>TM</sup> for the XRx-008 program over a 24-month treatment period and importantly to obtain "full FDA marketing approval". The aim of the XRX-OXY-301 Clinical Trial is to characterize the ability of XORLO<sup>TM</sup> to potentially decrease the rate of decline of glomerular filtration rate. An estimated 300 patients will be enrolled. The XRX-OXY-301 Clinical Trial is planned to start in the second half of 2024, and may be subject to SPA review by FDA.
- 3. **Ongoing CMC Work.** In parallel with the XRX-OXY-201 and XRX-OXY-301 Clinical Trials, XORTX will focus on scale-up, validation and stability testing of clinical drug product supplies of XORLO<sup>TM</sup> under the Company's granted IND, as well as building, validating and characterization of stability of future clinical and commercial supplies. All development will be performed according to current GMP methodology. This work will be ongoing throughout 2024.
- 4. **Activities Related to Potential Commercial Launch.** In preparation for a possible "Accelerated Approval" NDA filing in 2026 in the US for XORLOTM for XRx-008, XORTX will conduct commercialization studies to support in-depth analysis of pricing and/or reimbursement, as well as evaluate product brand name selection and prepare related filings, and conduct other launch preparation activities. This work will be ongoing from 2023 to 2026.
- 5. **Activities Related to European Registration.** XORTX will continue to work with and seek out guidance from the EMA to facilitate the path to potential approval of XORLO<sup>TM</sup> in the EU, including required clinical studies and reimbursement conditions. This work will be ongoing from 2023 through 2026, and will include a future request for orphan drug status. In addition, XORTX is preparing an information dossier to support an orphan drug designation from the EMA.

XORLO<sup>TM</sup> is the working name of XORTX's unique proprietary formulation of oxypurinol being developed for the XRx-008 drug development program for testing in the XRX-OXY-201 and XRX-OXY-301 clinical trials.

To achieve the above goals, XORTX will continue to pursue non-dilutive and dilutive funding and expand discussions to partner with major pharma / biotech companies with a global reach. XORTX will also increase financial and healthcare conference participation to further strengthen and expand its investor base.



The following table sets forth unaudited quarterly results prepared by management for the eight previous quarters to September 30, 2023:

(unaudited)	2023 Q3	2023 Q2	2023 Q1	2022 Q4
Amortization of intangible and capital assets	16,467	32,020	66,847	21,542
Foreign exchange loss (gain)	3,668	3,494	(8,457)	194,541
Consulting	130,467	195,744	30,840	18,293
Directors' fees	46,469	43,204	44,238	42,077
General and administrative	90,140	90,299	101,499	88,226
Interest income	(63,614)	(73,312)	(66,802)	(53,716)
Investor relations	236,934	223,334	180,288	182,192
Professional fees	102,617	214,425	140,858	92,434
Public company costs	45,822	47,371	47,361	31,280
Research and development	569,713	667,913	1,046,957	1,903,204
Share based payments (1)	21,850	30,769	39,550	70,896
Travel	14,267	68,765	55,384	11,041
Wages and benefits	118,566	147,862	153,472	200,890
Transaction costs on derivative warrant liability	-	-	-	926,456
Gain on derivative warrant liability	-	-	-	(1,579,802)
Total loss	(1,333,366)	(1,691,888)	(1,832,035)	(2,149,554)
Loss per share	(0.67)	(0.85)	(0.95)	(1.34)

(unaudited)	2022 Q3	2022 Q2	2022 Q1	2021 Q4
Amortization of intangible assets	22,057	9,756	3,776	3,761
Foreign exchange loss (gain)	(507,859)	(272,869)	155,905	(275,154)
Consulting	111,563	(120,069)	230,607	292,570
Directors' fees	45,495	23,153	11,847	18,015
General and administrative	117,236	123,467	119,895	115,875
Interest (income)/expense	(35,460)	(11,764)	(2,649)	1,325
Investor relations	100,706	407,138	238,388	106,773
Professional fees	56,244	221,038	84,355	56,541
Public company costs	25,105	37,903	26,525	117,839
Research and development	1,472,856	1,458,077	1,927,681	342,000
Share based payments (1)	19,268	332,912	68,078	113,878
Travel	84	11,413	-	190
Wages and benefits	132,559	146,786	164,831	109,261
Transaction costs on derivative warrant liability	-	-	-	1,220,516
Gain on derivative warrant liability	(362,688)	(1,128,101)	(325,546)	(9,440,572)
Total (loss) income	(1,197,166)	(1,238,840)	(2,703,693)	7,217,182
(Loss) earnings per share	(0.83)	(0.86)	(1.87)	5.14

#### Notes:

#### Three months ended September 30, 2023

The Company incurred a loss of \$1,333,366 (\$0.67 per share) for the three months ended September 30, 2023, compared to a loss of \$1,197,166 (\$0.83 per share) in the three months ended September 30, 2022.

Variances within the loss items are as follows:

Foreign Exchange loss -\$3,668 (2022 – gain of \$507,859) – Foreign exchange loss \$3,668 for the three months ended September 30, 2023 as compared to a gain of \$507,589 in the prior year quarter primarily due to an unrealized translation loss on the CAD dollar denominated cash balance in the current quarter as compared to unrealized translation gain on the U.S. dollar denominated cash balance in the previous year quarter.

Consulting - \$130,467 (2022 - \$111,563) - Consulting expenses increased during the three months ended September 30, 2023 as more consultants were engaged during the current quarter due to an increase in Company activity with respect to corporate development.



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General and administrative - \$90,140 (2022 - \$117,236) - General and administrative expenses decreased slightly mainly due to lower directors and officer insurance premium.

*Investor relations* - \$236,934 (2022 - \$100,706) – Investor relations expense increased during the three months ended September 30, 2023 as the Company entered into various engagements to provide information to investors.

**Professional fees** - \$102,617 (2022 - \$56,244). Professional fees, which consists mainly of accounting, audit and legal fees, increased due to the Company's increased corporate activity in relation to various registration statements with SEC and other compliance requirements for TSXV.

**Public company costs** - \$45,822 (2022 - \$25,105) – Public company costs increased during the three months ended September 30, 2023 primarily due to the various filing fees paid to maintain compliance with the SEC/Nasdaq.

**Research and development** - \$569,713 (2022 - \$1,472,856) – Research and development expenses decreased in the three months ended September 30, 2023, compared to the same period last year as detailed in the following table (future expenditures will depend upon financial resources available):

The table below presents combined research and development costs for XRx-008, XRx-101, and XRx-225 as the Company's projects are presently run concurrently and in combination.

<sup>(1)</sup> Share based payments relate to the vesting of options over the period.

	Q3 2023	Q3 2022	Change \$	Change %
Clinical trials expense <sup>1</sup>	275,066	514,271	(239,205)	(47%)
Manufacturing and related process expenses <sup>2</sup>	96,209	355,759	(259,550)	(73%)
Intellectual property expenses <sup>3</sup>	27,342	15,743	11,599	74%
Translational science expenses <sup>4</sup>	81,363	299,833	(218,470)	(73%)
External consultants' expenses <sup>5</sup>	89,733	287,250	(197,517)	(69%)
Total Research and development	\$ 569,713	\$ 1,472,856 \$	(903,143)	(61%)
Notes				

- (1) Clinical trials expenses include those costs associated with our clinical trial program which primarily included expenses related to the XRx-008 and XRx-101 projects. Included in clinical trials expenses are regulatory and consulting activities, contract research organization expenses, data management expenses, and other costs associated with our clinical trial program. In Q3 2023, clinical trials expense decreased mainly as the bridging pharmacokinetics study was mostly completed at the end of 2022 as compared to the comparative period when the XRX-OXY-101 PK Clinical Trial was starting as a new expense.
- (2) Manufacturing and related process expenses includes third party direct manufacturing costs, quality control testing and packaging costs. In Q3 2023, manufacturing costs primarily related to the Company's oxypurinol quality control and stability related costs as compared to previous year quarter which includes manufacturing costs primarily related to oxypurinol drug substance, stability and formulation development as the Company began to start preparing for the upcoming Pharmacokinetics study.
- (3) Intellectual property expenses include legal and filing fees associated with our patent portfolio. No significant change in intellectual property expenses in Q3 2023 as compared to O3 2022
- (4) Translational science expenses include various research studies conducted to expand our intellectual knowledge base related to oxypurinol and our proprietary formulations of oxypurinol, pharmacokinetic testing, non-clinical bioavailability studies, pharmacology and toxicology testing and identify potential licensing opportunities. The translational science expense in Q3 2023 related to new sponsored research at the University of Denver, Colorado as compared to Q3 2022 relates to animal studies.
- (5) External consultants' expenses include third party consultants engaged in the activities of research and development, including chemistry, manufacturing, drug product development, regulatory, non-clinical and clinical study execution. The decrease in external consultants' expenses in Q3 2023 as compared to Q3 2022 was attributed to decreased activity associated with completion of the XRX-OXY-101 PK Clinical Trial versus the previous year quarter the activities were attributed to the initiation of the Company's bridging study and thereafter a single registration trial associated to the XRx-008 program in individuals.

Travel - \$14,267 (2022 - \$84) - Travel increased during the three months ended September 30, 2023, as compared with the 2022 period due to the CEO attended several conferences following the easing of COVID restrictions.



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Wages and benefits - \$118,566 (2022 - \$132,559) - The wages and benefits expense decreased in the three months ended September 30, 2023, due to the departure of the Company's former CFO.

Gain on derivative warrant liability - \$\sin \text{iii} (2022 - \$\\$362,688) -During the period ended September 30, 2023, with the change in functional currency of the Company to USD, the exercise price of these warrants is now denominated in the functional currency of the Company and therefore these warrants no longer meet the definition of a derivative warrant liability and instead meet the definition of equity instruments. Accordingly, all warrants recorded as derivative financial liabilities on January 1, 2023, the date of the change in functional currency, were reclassified to equity instruments at their fair values as of that date.

# Nine months ended September 30, 2023

The Company incurred a loss of \$4,857,289 (\$0.27 per share) for the nine months ended September 30, 2023, compared to a loss of \$5,139,699 (\$0.40 per share) in the nine months ended September 30, 2022.

Variances within the loss items are as follows:

Foreign Exchange gain - \$1,295 (2022 - \$624,823) - Foreign exchange gain \$1,295 for the nine months ended September 30, 2023 as compared to a gain of \$624,823 in the prior year period primarily due to an unrealized translation gain on the CAD dollar denominated cash balance as compared to the unrealized translation gain on the U.S. dollar denominated cash balance in the nine months ended September 30, 2022.

Consulting - \$357,051 (2022 - \$222,101) - Consulting expenses increased during the nine months ended September 30, 2023, as more consultants were engaged during the current quarter due to an increase in Company activity with respect to corporate development.

Directors' fees - \$133,911 (2022 - \$80,495) - Directors' fees expenses increased during the nine months ended September 30, 2023, due to an increase in director fees related to the non-executive Chairman and increased director and committee meetings.

General and administrative - \$281,938 (2022 - \$360,598) - General and administrative expenses decreased due to lower directors and officer insurance premiums.

Investor relations - \$640,556 (2022 - \$746,232) - Investor relations expense decreased during the nine months ended September 30, 2023, due to a decrease in Company's activity with respect to dissemination of information and outreach initiatives.

Professional fees - \$457,900 (2022 - \$361,637). Professional fees, which consists mainly of accounting, audit and legal fees, increased during the nine months ended September 30, 2023, as compared with the 2022 period, mainly due to the Company's increased corporate activity in relation to various registration statements with SEC and other compliance requirements for TSXV.

Public company costs - \$140,554 (2022 - \$89,533) - Public company costs increased during the nine months ended September 30, 2023, primarily due to the various filing fees paid to maintain compliance with the SEC/Nasdaq.

Research and development - \$2,284,583 (2022 - \$4,858,614) - Research and development expenses decreased in the nine months ended September 30, 2023, compared to the same period last year as detailed in the following table.



The table below presents combined research and development costs for XRx-008, XRx-101, and XRx-225 as the Company's projects are presently run concurrently and in combination.

	2023	2022	Change \$	Change %
Clinical trials expense <sup>1</sup>	1,051,632	1,933,129	(881,497)	(46%)
Manufacturing and related process expenses <sup>2</sup>	412,108	1,348,402	(936,294)	(69%)
Intellectual property expenses <sup>3</sup>	29,367	21,062	8,305	39%
Translational science expenses <sup>4</sup>	219,729	690,994	(471,265)	(68%)
External consultants' expenses <sup>5</sup>	571,747	865,027	(293,280)	(34%)
Total Research and development	\$ 2,284,583	\$ 4,858,614	\$ (2,574,031)	(53%)

#### Notes:

- (1) Clinical trials expenses include those costs associated with our clinical trial program which primarily included expenses related to the XRx-008 and XRx-101 projects. Included in clinical trials expenses are regulatory and consulting activities, contract research organization expenses, data management expenses, and other costs associated with our clinical trial program. YTD Q3 2023 clinical trials expense decreased mainly as the bridging pharmacokinetics study was mostly completed at the end of 2022 as compared to the comparative period when the XRX-OXY-101 PK Clinical Trial was starting as a new expense.
- (2) Manufacturing and related process expenses includes third party direct manufacturing costs, quality control testing and packaging costs. YTD Q3 2023 manufacturing costs primarily related to the Company's oxypurinol quality control and stability related costs as compared to previous year quarter which includes manufacturing costs primarily related to oxypurinol drug substance, stability and formulation development as the Company began to start preparing for the upcoming Pharmacokinetics study.
- (3) Intellectual property expenses include legal and filing fees associated with our patent portfolio. No significant change in intellectual property expenses in YTD Q3 2023 as compared to YTD Q3 2022.
- (4) Translational science expenses include various research studies conducted to expand our intellectual knowledge base related to oxypurinol and our proprietary formulations of oxypurinol, pharmacokinetic testing, non-clinical bioavailability studies, pharmacology and toxicology testing and identify potential licensing opportunities. The translational science expense incurred YDT Q3 2023 related to new sponsored research at the University of Denver, Colorado as compared to YTD Q3 2022 relates to animal studies.
- (5) External consultants' expenses include third party consultants engaged in the activities of research and development, including chemistry, manufacturing, drug product development, regulatory, non-clinical and clinical study execution. The decrease in external consultants' expenses YTD Q3 2023 as compared to YTD Q3 2022 was attributed to decreased activity associated with completion of the XRX-OXY-101 PK Clinical Trial versus the activities were attributed to the initiation of the Company's bridging study and thereafter a single registration trial associated to the XRx-008 program in individuals in the prior year period.

Travel - \$138,416 (2022 - \$11,497) – Travel increased during the nine months ended September 30, 2023, as compared with the 2022 period due to the CEO attended several conferences following the easing of COVID restrictions.

Wages and benefits - \$419,900 (2022 - \$444,176) – The wages and benefits expense decreased in the nine months ended September 30, 2023, due to the departure of the Company's former CFO.

Gain on derivative warrant liability - \$nil (2022 - \$1,816,335) — During the period ended September 30, 2023, with the change in functional currency of the Company to USD, the exercise price of these warrants is now denominated in the functional currency of the Company and therefore these warrants no longer meet the definition of a derivative warrant liability and instead meet the definition of equity instruments. Accordingly, all warrants recorded as derivative financial liabilities on January 1, 2023, the date of the change in functional currency, were reclassified to equity instruments at their fair values as of that date.

# Comparison of cash flows for the nine months ended September 30, 2023 and 2022

The Company realized a net cash outflow of \$5,364,963 for the nine months ended September 30, 2023, compared to a cash outflow of \$5,997,891 for the nine months ended September 30, 2022. The variances in the cash flow for the nine months ended September 30, 2023, compared to September 30, 2022 were as follows:

*Operating activities* – Cash used in operating activities for the nine months ended September 30, 2023, was \$5,285,098 (2022 - \$5,349,780). The cash used in operating activities is broadly consistent from the prior period.



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Investing activities — Cash used in investing activities for the nine months ended September 30, 2023, was \$36,569 (2022 - \$28,886). The cash used related to the acquisition of intangible assets and equipment during the period.

Financing activities – Cash used in financing activities in the nine months ended September 30, 2023, was \$48,791 (2022 - \$466,977). The cash used was mostly related to the payment of lease obligations. The prior period was higher due to deferred transaction costs of \$448,554.

# LIQUIDITY AND CAPITAL RESOURCES

As at September 30, 2023, the Company had a cash balance of \$5,069,233 and working capital of \$4,672,644 as compared to a cash balance of \$10,434,196 and working capital of \$9,384,265 as at December 31, 2022. During the year ended December 31, 2022, the Company closed a public offering that consisted of 155,555 common share units and 400,000 pre-funded warrant units with each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one common share and one Warrant to purchase one common

share at a public offering price of \$8.9991 per Pre-Funded Unit, for aggregate gross proceeds of \$4,999,640.

Although there is no certainty, management is of the opinion that additional funding for its projects and operations can be raised as needed. The Company is subject to a number of risks associated with the successful development of new products and their marketing and the conduct of its clinical studies and their results. The Company will have to finance its research and development activities and its clinical studies. To achieve the objectives in its business plan, the Company plans to raise the necessary capital and to generate revenues. It is anticipated that the products developed by the Company will require approval from the FDA and equivalent organizations in other countries before their sale can be authorized. If the Company is unsuccessful in obtaining adequate financing in the future, corporate initiatives may be affected or postponed.

#### **USE OF FINANCING PROCEEDS**

On October 7, 2022, the Company closed an underwritten public offering of: (i) 155,555 Common Share Units, with each Common Share Unit consisting of one common share, no par value, and one Warrant to purchase one common share at a public offering price of \$9.00 per Common Share Unit, and (ii) 400,000 Pre-Funded Units and together with the Common Share Units, the Units, with each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one common share and one Warrant to purchase one common share at a public offering price of \$8.991 per Pre-Funded Unit, for aggregate gross proceeds of \$5 million, prior to deducting underwriting discounts and other offering expenses and excluding any exercise of the underwriters' option to purchase any additional securities as described herein (the "Offering"). The common shares and Warrants contained in the Pre-Funded Units were immediately expensed units and the Pre-Funded Units were immediately expensed for five years from the date of issuance. The Warrants have an initial exercise price of \$10.98 per share, are immediately exercisable, and will terminate once exercised in full. On December 29, 2022 and January 19, 2023, 71,223 and 328,777, Pre-Funded Warrants, respectively were exercised leaving a balance of Nil outstanding as at the date of this MD&A.

The proceeds that the Company has used have been for funding operations and general corporate purposes, which has included further research and development and manufacture of active pharmaceutical ingredients and drug product to support clinical trials. The Company intends to continue to use the remaining net proceeds of the offering, together with existing cash, for funding operations and general corporate purposes, which may include further research and development, clinical trials, manufacture of active pharmaceutical ingredients and drug product to support clinical trials and intends to use the proceeds in approximately the following proportions: XRx-008: 90%; XRx-101: 5%; XRx-225: 5%.



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#### **COMMITMENTS**

The Company has long-term arrangements with commitments that are not recognized as liabilities as at September 30, 2023 and December 31, 2022 are as follows:

#### **Employment Agreements**

	September 30, 2023	December 31, 2022
	\$	\$
Management services – officers	321,000	441,7541

#### Note:

(1) The former CFO of the Company had a termination clause whereby he was entitled to the equivalent of 12 times his then current monthly salary which as of December 31, 2022, equated to an annual salary of CAD \$192,000.

The President, CEO and a director of the Company has a long-term employment agreement with the Company. The agreement has a termination clause whereby he is entitled to the equivalent of 12 times his then current monthly salary which, as of September 30, 2023 and December 31, 2022, equated to an annual salary of \$321,000 and \$300,000 respectively.

# **Payments**

In the normal course of business, the Company has committed to payments totaling \$310,000 (2022 \$1,994,232) for activities related to its clinical trials, manufacturing, collaboration programs and other regular business activities which are expected to occur over the next two years.

#### OFF BALANCE SHEET ARRANGEMENTS

The Company has no off-balance sheet arrangements.

# TRANSACTIONS WITH RELATED PARTIES

All related party transactions were measured at the amount of consideration established and agreed to by the related parties. All amounts due from/payable to related parties are unsecured, non-interest bearing and have no fixed terms of repayment.

During the three and nine months ended September 30, 2023 and 2022, the Company incurred the following transactions with related parties:

- a) Wages and benefits and professional fees were paid or accrued to Allen Davidoff, the Chief Executive Officer ("CEO"), Amar Keshri, former Chief Financial Officer ("CFO"), and David MacDonald, former Chief Technology Officer ("CTO") in the amount of \$80,250 and \$324,597 (2022 \$112,595 and \$404,811).
- b) Fees were paid or accrued to 1282803 Ontario Inc., a company owned by James Fairbairn, the Chief Financial Officer ("CFO") of the Company in the amount of \$38,325 and \$38,325 (2022 \$nil and \$nil)
- c) Research and development fees were paid or accrued to Haworth Biopharmaceutical, a company owned by Stephen Haworth, the Chief Medical Officer ("CMO") of the Company in the amount of \$56,250 and \$165,479 (2022 \$57,164 and \$169,724).
- d) Consulting fees were paid or accrued to Stacy Evans, the Chief Business Officer ("CBO") of the Company in the amount of \$75,000 and \$225,000 (2022 \$nil and \$nil).
- e) Directors' fees were paid or accrued to the directors of the Company in the amount of \$45,278 and \$136,862 (2022 \$48,238 and \$84,087). The amount includes director fees payment of \$34,064 and \$100,148 for the three and nine months ended September 30, 2023 (2022 \$35,486 and \$40,682) to Anthony Giovinazzo, Chairman of the Company.



- f) As at September 30, 2023, \$8,876 (December 31, 2022 \$14,914) was payable to directors of the Company, \$\text{snil}\$ (December 31, 2022 \$28,846) was accrued to the CEO of the Company, for CEO services, \$\text{\$\text{snil}}\$ (December 31, 2022 \$10,904) was accrued to the former CFO of the Company, for CFO services, \$14,313 (December 31, 2022 \$\text{snil})\$ was accrued to the CFO of the Company, for CFO services, \$18,750 (December 31, 2022 \$49,998) was payable and accrued to the CMO of the Company, for consulting services, and \$25,000 (December 31, 2022 \$24,999) was payable and accrued to the CBO of the Company, for consulting services. The balances are unsecured, non-interest bearing, and have no fixed terms of repayment.
- g) Management and directors' compensation transactions for the three and nine months ended September 30, 2023 and 2022 are summarized as follows:

	Management Compensation	Directors' fees	Share-based payments	Total
	\$	\$	\$	\$
Three months ended September 30, 2022				
Directors and officers	169,759	48,238	36,332	254,329
Three months ended September 30, 2023				
Directors and officers	249,825	45,278	11,874	306,977
	Management	D:	Ch h J	
	Management Compensation	Directors' fees	Share-based payments	Total
	\$	\$	\$	\$
Nine months ended September 30, 2022				
Directors and officers	574,732	84,087	372,331	1,031,150
Nine months ended September 30, 2023				
Directors and officers	753,401	136,862	55,820	946,083

#### FINANCIAL AND CAPITAL RISK MANAGEMENT

The Company's financial instruments consist of cash and cash equivalents, accounts payable and accrued liabilities, lease obligation, derivative warrant liability and warrants. Cash and cash equivalents are classified as financial assets at FVTPL, accounts payable and accrued liabilities and lease obligations are classified as financial liabilities at amortized cost and warrant liability is classified as a financial liability at FVTPL.

The fair values of these financial instruments approximate their carrying values at September 30, 2023, due to their short-term nature.

The Company thoroughly examines the various financial instruments and risks to which it is exposed and assesses the impact and likelihood of those risks. These risks include foreign currency risk, interest rate risk, market risk, credit risk, and liquidity risk. Where material, these risks are reviewed and monitored by the Board of Directors.

There have been no changes in any risk management policies since December 31, 2022.



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#### **Capital Management**

The Company defines capital that it manages as shareholders' equity. The Company manages its capital structure in order to have funds available to support its research and development and sustain the future development of the business. When managing capital, the Company's objective is to ensure the entity continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders. Management adjusts the capital structure as necessary in order to support its activities.

The Company includes the following items in its managed capital as at the following periods:

	September 30	December 31
Equity is comprised of:	2023	2022
	\$	\$
Share capital	17,056,535	16,524,354
Share-based payments, warrant reserve and other	9,611,845	6,197,158
Obligation to issue shares	24,746	24,746
Accumulated other comprehensive loss	(52,605)	(52,605)
Deficit	(20,554,131)	(15,696,842)

Since inception, the Company's objective in managing capital is to ensure sufficient liquidity to finance its research and development activities, general and administrative expenses, expenses associated with intellectual property protection and its overall capital expenditures. There were no changes during the nine months ended September 30, 2023. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

#### **OUTSTANDING SHARE DATA**

The Company has an unlimited number of unauthorized common shares without par value.

Type of Security	Common shares
As of November 14, 2023	(number)
Issued and outstanding	1,998,848
Stock options	95,922
Share purchase warrants	1,175,508
Fully diluted shares outstanding	3,270,278

#### RISKS RELATED TO THE BUSINESS

An investment in the Company is speculative and involves a high degree of risk. Accordingly, prospective investors should carefully consider the specific risk factors set out below, in addition to the other information contained in this MD&A, before making any decision to invest in the Company. The Directors consider the following risks and other factors to be the most significant for potential investors in the Company, but the risks listed do not necessarily comprise all those associated with an investment in the Company and are not set out in any particular order of priority. Additional risks and uncertainties not currently known to the Directors may also have an adverse effect on the Company's business. If any of the following risks actually occur, the Company's business, financial condition, capital resources, results or future operations could be materially adversely affected. In such a case, the price of the common shares could decline, and investors may lose all or part of their investment.

For additional discussion on XORTX's risks, refer to the "Risk Factors" section of the Company's Annual Information Form ("AIF") for the year ended December 31, 2022, and the "Forward Looking Statements" section of this MD&A.



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#### Speculative Nature of Investment Risk

An investment in the common shares of the Company carries a high degree of risk and should be considered as a speculative investment by purchasers. The Company has limited cash reserves, a limited operating history, has not paid dividends, and is unlikely to pay dividends in the immediate or near future. The Company is in the development stage. Operations are not yet sufficiently established such that the Company can mitigate the risks associated with planned activities.

# **Limited Operating History**

The Company has no present prospect of generating revenue from the sale of products. The Company is therefore subject to many of the risks common to early-stage enterprises, including under-capitalization, cash shortages, limitations with respect to personnel, financial, and other resources and lack of revenues. There is no assurance that the Company will be successful in achieving a return on shareholders' investment and the likelihood of success must be considered in light of the early stage of operations.

# Negative Cash Flow for the Foreseeable Future

The Company has a no history of earnings or cash flow from operations. The Company does not expect to generate material revenue or achieve self-sustaining operations for several years, if at all. To the extent that the Company has negative cash flow in future periods, the Company may need to allocate a portion of its cash reserves to fund such negative cash flow.

# Reliance on Management

The success of the Company is dependent upon the ability, expertise, judgment, discretion and good faith of its management. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on the Company's business, operating results or financial condition.

# Clinical trials for potential drug candidates will be expensive and time consuming, and their outcomes uncertain.

Before the Company can obtain regulatory approval for the commercial sale of any drug candidate or attract major pharmaceutical companies with which to collaborate, it will be required to complete extensive clinical trials to demonstrate safety and efficacy. Clinical trials are expensive and are difficult to design and implement. The clinical trial process is also time-consuming and can often be subject to unexpected delays. The timing and completion of clinical trials may be subject to significant delays relating to various causes, including but not limited to: inability to manufacture or obtain sufficient quantities of materials for use in clinical trials; delays arising from collaborative partnerships; delays in obtaining regulatory approvals to commence a study, or government intervention to suspend or terminate a study; delays, suspensions or termination of clinical trials by the applicable institutional review board or independent ethics board responsible for overseeing the study to protect research subjects; delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites; slow rates of patient recruitment and enrollment; uncertain dosing issues; inability or unwillingness of medical investigators to follow clinical protocols; variability in the number and types of subjects available for each study and resulting difficulties in identifying and enrolling subjects who meet trial eligibility criteria; scheduling conflicts; difficulty in maintaining contact with subjects after treatment, resulting in incomplete data; unforeseen safety issues or side effects; lack of efficacy during clinical trials; reliance on clinical research organizations to efficiently and properly conduct clinical trials in accord with contracted arrangements and regulatory, or other regulatory delays.



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# Risks Related to Food and Drug Administration (FDA) Approval

In the United States, the FDA regulates the approval of therapeutics and the FDA notification and approval process requires substantial time, effort and financial resources, and the Company cannot be certain that any approvals for its products will be granted on a timely basis, if at all. Foreign jurisdictions have similar government regulatory bodies and requirements that the Company must meet prior to selling products in those jurisdictions.

The Company must be considered in light of the risks, expenses, shifts, changes and difficulties frequently encountered with companies whose businesses are regulated by various federal, state and local governments. The health care, wellness, workers' compensation and similar companies are subject to a variety of regulatory requirements and the

regulatory environment is ever changing particularly with recent legislation, the full impact of which is not yet understood as regulations have not been issued. Failure to follow applicable regulatory requirements will have a materially negative impact on the business of the Company. Furthermore, future changes in legislation cannot be predicted and could irreparably harm the business of the Company.

# **Intellectual Property Rights**

The Company could be adversely affected if it does not adequately protect its intellectual property rights. The Company regards its marks, rights, and trade secrets and other intellectual property rights as critical to its success. To protect its investments and the Company's rights in these various intellectual properties, it may rely on a combination of patents, trademark and copyright law, trade secret protection and confidentiality agreements and other contractual arrangements with its employees, clients, strategic partners, acquisition targets and others to protect proprietary rights. There can be no assurance that the steps taken by the Company to protect proprietary rights will be adequate or that third parties will not infringe or misappropriate the Company's copyrights, trademarks and similar proprietary rights, or that the Company will be able to detect unauthorized use and take appropriate steps to enforce rights. In addition, although the Company believes that its proprietary rights do not infringe on the intellectual property rights of others, there can be no assurance that other parties will not assert infringement claims against the Company. Such claims, even if not meritorious, could result in the expenditure of significant financial and managerial resources.

The Company will rely on trade secrets to protect technology where it does not believe patent protection is appropriate or obtainable. Trade secrets are difficult to protect. While commercially reasonable efforts to protect trade secrets will be used, strategic partners, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose information to competitors.

If the Company is not able to defend patents or trade secrets, then it will not be able to exclude competitors from developing or marketing competing products, and the Company may not generate enough revenue from product sales to justify the cost of development of products and to achieve or maintain profitability.

# The results of preclinical studies or initial clinical trials are not necessarily predictive of future favorable results.

Preclinical tests and initial clinical trials are primarily designed to test safety and to understand the side effects of drug candidates and to explore efficacy at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Favorable results in early trials may not be repeated in later ones.

# **Difficulty to Forecast**

The Company must rely largely on its own market research to forecast sales as detailed forecasts are not generally obtainable from other sources at this early stage of the industry. A failure in the demand for its products to materialize as a result of competition, technological change or other factors could have a material adverse effect on the business, results of operations and financial condition of the Company.



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#### Litigation

The Company may become party to litigation from time to time in the ordinary course of business which could adversely affect its business. Should any litigation in which the Company becomes involved be determined against the Company such a decision could adversely affect the Company's ability to continue operating and the market price for the Company's common shares. Even if the Company is involved in litigation and wins, litigation can redirect significant Company resources.

Commercial success of the Company will depend in part on not infringing upon the patents and proprietary rights of other parties and enforcing its own patents and proprietary rights against others. The research and development programs will be in highly competitive fields in which numerous third parties have issued patents and pending patent applications with claims closely related to the subject matter of the Company's programs. The Company is not currently aware of any litigation or other proceedings or claims by third parties that its technologies or methods infringe on their intellectual property.

While it is the practice of the Company to undertake pre-filing searches and analyses of developing technologies, it cannot guarantee that it has identified every patent or patent application that may be relevant to the research, development, or commercialization of its products. Moreover, it cannot assure that third parties will not assert valid, erroneous, or frivolous patent infringement claims.

# Uninsurable Risks

The business of the Company may not be insurable or the insurance may not be purchased due to high cost. Should such liabilities arise, they could reduce or eliminate any future profitability and result in increasing costs and a decline in the value of the Company.

# The market price of the Company's common shares may be subject to wide price fluctuations.

The market price of the Company's common shares may be subject to wide fluctuations in response to many factors, including variations in the operating results of the Company and its subsidiary, divergence in financial results from analysts' expectations, changes in earnings estimates by stock market analysts, changes in the business prospects for the Company and its subsidiary, general economic conditions, legislative changes, and other events and factors outside of the Company's control. In addition, stock markets have from time-to-time experienced extreme price and volume fluctuations, which, as well as general economic and political conditions, could adversely affect the market price for the Company's common shares.

#### Dividends

The Company has no earnings or dividend record and does not anticipate paying any dividends on the common shares in the foreseeable future.

# Dilution

The financial risk of the Company's future activities will be borne to a significant degree by purchasers of the common shares. If the Company issues common shares from its treasury for financing purposes, control of the Company may change and purchasers may suffer additional dilution.

# Rapid Technological Change

The business of the Company is subject to rapid technological changes. Failure to keep up with such changes may adversely affect the business of the Company is subject to the risks of companies operating in the medical and healthcare business. The market in which the Company competes is characterized by rapidly changing

technology, evolving industry standards, frequent new service and product announcements, introductions and enhancements and changing customer demands. As a result, an investment in the stocks of the Company is highly speculative and is only suitable for investors who recognize the high risks involved and can afford a total loss of investment.



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#### Risks Associated with Acquisitions

If appropriate opportunities present themselves, the Company may acquire businesses, technologies, services or products that the Company believes are strategic. The Company currently has no understandings, commitments or agreements with respect to any other material acquisition and no other material acquisition is currently being pursued. There can be no assurance that the Company will be able to identify, negotiate or finance future acquisitions successfully, or to integrate such acquisitions with its current business. The process of integrating an acquired business, technology, service or product into the Company may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of the Company's business. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to goodwill and other intangible assets, which could materially adversely affect the Company's business, results of operations and financial condition. Any such future acquisitions of other businesses, technologies, services or products might require the Company to obtain additional equity or debt financing, which might not be available on terms favorable to the Company, or at all, and such financing, if available, might be dilutive.

#### **Economic Environment**

The Company's operations could be affected by the economic context should the unemployment level, interest rates or inflation reach levels that influence consumer trends and consequently, impact the Company's future sales and profitability.

#### Global Economy Risk

The ongoing economic problems and downturn of global capital markets has generally made the raising of capital by equity or debt financing more difficult. Access to financing has been negatively impacted by the ongoing global economic risks. As such, the Company is subject to liquidity risks in meeting its development and future operating cost requirements in instances where cash positions are unable to be maintained or appropriate financing is unavailable. These factors may impact the Company's ability to raise equity or obtain loans and other credit facilities in the future and on terms favorable to the Company. If uncertain market conditions persist, the Company's ability to raise capital could be jeopardized, which could have an adverse impact on the Company's operations and the trading price of the Company's Shares on the stock exchange.

#### **International Conflict**

International conflict and other geopolitical tensions and events, including war, military action, terrorism, trade disputes and international responses thereto have historically led to, and may in the future lead to, uncertainty or volatility in financial markets and supply chains. Russia's invasion of Ukraine in early 2022 has led to sanctions being levied against Russia by the international community and may result in additional sanctions or other international action, any of which may have a destabilizing effect on supply chain disruptions which may adversely affect the Company's business, financial condition and results of operations. The extent and duration of the current Russia-Ukraine conflict and related international action cannot be accurately predicted at this time and the effects of such conflict may magnify the impact of the other risks identified in this document, including those relating to global financial conditions. The situation is rapidly changing and unforeseeable impacts, including on our shareholders and counterparties on which we rely and transact, may materialize and may have an adverse effect on the Company's business, results of operations and financial condition.



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#### Going-Concern Risk

The Company's future operations are dependent upon the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that the Company will be successful in completing an equity or debt financing or in achieving profitability.

# Financial Risk Exposures

The Company may have financial risk exposure to varying degrees relating to the currency of each of the countries where it operates. The level of the financial risk exposure related to currency and exchange rate fluctuations will depend on the Company's ability to hedge such risk or use another protection mechanism.

# Attracting and keeping senior management and key scientific personnel

The success of the Company depends on the continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel and to develop and maintain important relationships with leading academic institutions, companies, and thought leaders. Allen Davidoff, the Company's CEO, exercises significant control over the day-to-day affairs of the Company. The Company depends on Dr. Davidoff to engage with third parties and contractors to operate the business.

#### SEGMENT REPORTING

We view our operations and manage our business in one segment, which is the development and commercialization of biopharmaceuticals, initially focused on the treatment of progressive kidney disease.

## TREND INFORMATION

Other than as disclosed elsewhere we are not aware of any trends, uncertainties, demands, commitments, or events that are reasonably likely to have a material effect on our net revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause reported financial information not necessarily to be indicative of future operating results or financial condition.

#### MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL STATEMENTS

The Company's management is responsible for the presentation and preparation of the financial statements and the MD&A. The MD&A have been prepared in accordance with the requirements of securities regulators, including National Instrument 51-102 of the Canadian Securities Administrators.

The financial statements and information in the MD&A necessarily include amounts based on informed judgments and estimates of the expected effects of current events and transactions with appropriate consideration to materiality. In addition, in preparing the financial information, we must interpret the requirements described above, make determinations as to the relevancy of information included, and make estimates and assumptions that affect reported information. The MD&A also includes information regarding the impact of current transactions and events, sources of liquidity and capital resources, operating trends, risks and uncertainties. Actual results in the future may differ materially from our present assessment of this information because future events and circumstances may not occur as anticipated.

#### DISCLOSURE CONTROLS AND PROCEDURES

Disclosure controls and procedures are designed to provide reasonable assurance that material information required to be disclosed in the prescribed filings and reports filed with the Canadian securities regulatory authorities is recorded, processed, summarized and reported on a timely basis. Controls are also designed to provide reasonable assurance that information required to be disclosed is assimilated and communicated to senior management in a timely manner so that appropriate decisions can be made regarding public disclosure. The Company's CEO and CFO have evaluated the effectiveness of the Company's disclosure controls and procedures and concluded that they provide reasonable assurance that material information relating to the Company was made known to them and reported as required.



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Exhibit 99.3

# FORM 52-109F2 CERTIFICATION OF INTERIM FILINGS FULL CERTIFICATE

I, Allen Davidoff, Chief Executive Officer of XORTX Therapeutics Inc., certify the following:

- 1. *Review:* I have reviewed the interim financial report and interim MD&A (together, the "interim filings") of XORTX Therapeutics Inc. (the "issuer") for the interim period ended September 30, 2023.
- 2. **No misrepresentations:** Based on my knowledge, having exercised reasonable diligence, the interim filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, with respect to the period covered by the interim filings.
- 3. *Fair presentation:* Based on my knowledge, having exercised reasonable diligence, the interim financial report together with the other financial information included in the interim filings fairly present in all material respects the financial condition, financial performance and cash flows of the issuer, as of the date of and for the periods presented in the interim filings.
- 4. **Responsibility:** The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as those terms are defined in *National Instrument 52-109 Certification of Disclosure in Issuers' Annual and Interim Filings*, for the issuer.
- 5. **Design:** Subject to the limitations, if any, described in paragraphs 5.2 and 5.3, the issuer's other certifying officer(s) and I have, as at the end of the period covered by the interim filings:
  - (a) designed DC&P, or caused it to be designed under our supervision, to provide reasonable assurance that:
    - (i) material information relating to the issuer is made known to us by others, particularly during the period in which the interim filings are being prepared;
    - (ii) information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and
  - (b) designed ICFR, or caused it to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP.
- 5.1 Control framework: The control framework the issuer's other certifying officer(s) and I used to design the issuer's ICFR is COSO Financial Controls Framework.
- 5.2 ICFR material weakness relating to design: N/A
- 5.3 Limitation on scope of design: N/A
- 6. **Reporting changes in ICFR:** The issuer has disclosed in its interim MD&A any change in the issuer's ICFR that occurred during the period beginning on July 1, 2023 and ended on September 30, 2023 that has materially affected, or is reasonably likely to materially affect, the issuer's ICFR.

Date: November 14, 2023

/s/ Allen Davidoff

Allen Davidoff
Chief Executive Officer

# FORM 52-109F2 CERTIFICATION OF INTERIM FILINGS FULL CERTIFICATE

I, James Fairbairn, Chief Financial Officer of XORTX Therapeutics Inc., certify the following:

- 1. *Review:* I have reviewed the interim financial report and interim MD&A (together, the "interim filings") of XORTX Therapeutics Inc. (the "issuer") for the interim period ended September 30, 2023.
- 2. No misrepresentations: Based on my knowledge, having exercised reasonable diligence, the interim filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, with respect to the period covered by the interim filings.
- 3. *Fair presentation:* Based on my knowledge, having exercised reasonable diligence, the interim financial report together with the other financial information included in the interim filings fairly present in all material respects the financial condition, financial performance and cash flows of the issuer, as of the date of and for the periods presented in the interim filings.
- 4. **Responsibility:** The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as those terms are defined in *National Instrument 52-109 Certification of Disclosure in Issuers' Annual and Interim Filings*, for the issuer
- 5. **Design:** Subject to the limitations, if any, described in paragraphs 5.2 and 5.3, the issuer's other certifying officer(s) and I have, as at the end of the period covered by the interim filings:
  - (a) designed DC&P, or caused it to be designed under our supervision, to provide reasonable assurance that:
    - (i) material information relating to the issuer is made known to us by others, particularly during the period in which the interim filings are being prepared; and
    - (ii) information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and
  - (b) designed ICFR, or caused it to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP.
- 5.1 Control framework: The control framework the issuer's other certifying officer(s) and I used to design the issuer's ICFR is COSO Financial Controls Framework.
- 5.2 ICFR material weakness relating to design: N/A
- 5.3 Limitation on scope of design: N/A
- 6. **Reporting changes in ICFR:** The issuer has disclosed in its interim MD&A any change in the issuer's ICFR that occurred during the period beginning on July 1, 2023 and ended on September 30, 2023 that has materially affected, or is reasonably likely to materially affect, the issuer's ICFR.

Date: November 14, 2023

/s/ James Fairbairn

James Fairbairn
Chief Financial Officer