## **XORTX THERAPEUTICS INC.**

# Management Discussion and Analysis For the nine months ended September 30, 2024

This management discussion and analysis of financial position and results of operations ("MD&A") is prepared as at November 14, 2024 and should be read in conjunction with the unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2024 and 2023 of XORTX Therapeutics Inc. (the "Company" or "XORTX"), together with the audited financial statements of the Company for the years ended December 31, 2023 and 2022, as well as the accompanying MD&A for the period then ended (the "Annual MD&A").

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.

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 – 33rd 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:

- our ability to obtain additional financing;
- the accuracy of our estimates regarding expenses, costs associated with clinical trials, regulatory and commercial activities, 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 "XORLO<sup>TM</sup>", 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 <a href="https://www.sedarplus.ca">www.sedarplus.ca</a>.

### **BUSINESS OVERVIEW**

XORTX is a late-stage clinical pharmaceutical company, focused on developing 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:

## **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 respiratory virus infection is designed to produce rapid suppression of hyperuricemia and 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 product candidates include XRx-008, XRx-101, and XRx-225. Our lead program, XRx-008, 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. Discussions with the FDA have 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 XORLO<sup>TM</sup> on decreasing the rate of decline of glomerular filtration rate was demonstrated. Our 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 lead and 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 uric acid lowering therapy combined with an oral anti-hyperuricemic xanthine oxidase inhibitor, XRx-101, for use in treating patients with AKI associated with respiratory virus infection and/or associated co-morbidities including sepsis.

XORLO™ 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.

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. Recently, XORTX filed a third provisional patent application covering formulations and methods of dosing xanthine oxidase inhibitors in individuals with kidney disease.

#### **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 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 incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future;
- 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;
- 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, 2024, combined with the net proceeds of future financings, will enable us to advance the clinical development of XRx-008 and XRx-101 product candidates. The XRx-008 will receive 98% of funding, subject to available funds. The XRx-101 and XRx-225 programs will not be advanced until sufficient funding is available. Approximately 2% of funding is anticipated for intellectual property development. 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

## **Financing Activities**

On October 18, 2024, the Company closed its registered direct offering and concurrent private placement for the purchase and sale of: (i) 320,000 common share units ("Common Share Units") at a price of \$1.85 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) 490,810 pre-funded warrant units ("Pre-Funded Units") at a price of \$1.8499 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 \$1,500,000. The Pre-Funded Warrants have an exercise price of \$0.0001 per share, and will terminate once exercised in full. The Warrants are exercisable at an exercise price of \$2.18 are immediately exercisable and expire five years from issuance. The company intends to use the net proceeds from the offering for working capital and general corporate purposes.

On February 15 and March 4, 2024, the Company closed two tranches of a non-brokered offering of 899,717 common share units at a price of CAD \$3 per common share unit for aggregate gross proceeds of CAD \$2,699,151. Each common share unit consisted of one common share and one warrant to purchase one common share at CAD \$4.50 per common share for a period of two years. The warrants were immediately exercisable, and may be exercised for two years from the date of issuance, provided, however that, if, the common shares on the TSXV trade at greater than CAD \$6.00 for 10 or more consecutive trading days, the warrants will be accelerated and the warrants will expire on the 30<sup>th</sup> business day following notice. In connection with the non-brokered offering, the Company paid finder's fees of CAD \$132,551, representing a 5% finder's fee on certain subscriptions to qualified finders.

During the nine months ended September 30, 2024, the Company announced it had received TSXV approval to amend the terms of an aggregate of 1,125,210 outstanding common share purchase warrants as follows:

 198,333 of the warrants issued pursuant to the private placement that closed on February 9, 2021 and which had an original exercise price of CAD \$42.26 per share (CAD \$0.40 per share, adjusted to reflect the 2021 and 2023 Share Consolidations), the TSXV has approved an amended exercise price of \$5.00.



- 371,322 of the warrants issued pursuant to the prospectus offering that closed on October 15, 2021 and which had an original exercise price of \$42.93 per share (\$4.77 per share, adjusted to reflect the 2023 Share Consolidation), the TSXV has approved an amended exercise price of \$5.00.
- 555,555 of the warrants issued pursuant to the prospectus offering that closed on October 7, 2022 and which had an original exercise price of \$10.98 per share (\$1.22 per share, adjusted to reflect the 2023 Share Consolidation), the TSXV has approved an amended exercise price of \$5.00.

If the volume weighted average price for the Company's common shares on TSXV is greater than \$6.50 (approximately CAD \$8.7562) per common share for a period of ten (10) consecutive trading days, then the Company may give notice to the Holders of the Warrant by way of a news release (the "Notice") notifying such Holder that the warrants must be exercised within thirty (30) calendar days from the date of delivery of such Notice, otherwise the warrants will expire at 4:30 p.m. (Calgary time) on the 30<sup>th</sup> day after the date of delivery of the Notice (the "Forced Conversion Right"). Notwithstanding anything herein to the contrary, the Forced Conversion Right shall only be available to the Company on or after such time in which such forced exercise of the warrants will result in the issuance of free trading shares to the Holder.

## **Regulatory Advancements**

On January 3, 2024, the Company announced the submission of a new patent for the treatment of chronic kidney disease ("**CKD**"). This patent is designed to protect new discoveries and strategies for the treatment of individuals with varied degrees of kidney function in the setting of CKD.

## **Changes in Officers and Directors**

On March 27, 2024, the Company announced Dr. Ronald Perrone has joined the Company's Clinical Advisory Board.

On April 8, 2024, the Company announced the appointment of Ms. Abigail Jenkins to the Board of Directors.

#### **FUTURE PLANS AND OUTLOOK**

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

Recent independent peer-reviewed research that reported that genetic factors are linked to the over-expression of xanthine oxidase ("XO") and play a role in several diseases, including kidney disease, have provided the Company with the opportunity to develop diagnostics that identify specific genetic factors. These diagnostic tools alongside the Company's expertise at developing unique formulations of uric acid lowering agents and XO inhibitors will permit XORTX to tailor treatments to subpopulations of individuals that have common susceptibility or similar response to a particular drug. The Company will begin evaluating individuals as early as our planned registration clinical trial in patients with ADPKD providing XORTX with an opportunity to better understand the role these genetic factors play in progressive kidney disease.

For the balance of 2024, XORTX will continue to focus on advancing XORLO<sup>™</sup> for the XRx-008 program for ADPKD into a Phase 2/3 "registration" clinical trial program – XRX-OXY-201, ODD in the EU, discussion with the US FDA regarding the XRX-OXY-301 clinical trial and possible initiation of special protocol assessment ("**SPA**") discussions with the FDA and initiation of commercialization activities, if approved, for XORLO<sup>™</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 Pivotal Registration clinical trial named "XRX-OXY-201", to support an application for "Accelerated Approval" of XORLO™ for individuals with ADPKD. The XRX-OXY-201 Clinical Trial is a Phase 2b/3a, 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. Subject to available financing, the XRX-OXY-201 Clinical Trial is planned to start in the first half of 2025 and enroll individuals with stage 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 150 patients will be enrolled with 120 patients completing the study. (Estimated cost - \$5 million to \$30 million.)

- 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-301 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 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. Subject to available financing, the XRX-OXY-301 Clinical Trial will not be scheduled or budgeted until XRX-OXY-201 is well underway, 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™ 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 to 2027. (Estimated cost of Clinical and Commercial drug supply \$5 million to \$15 million.)
- 4. **Activities Related to Potential Commercial Launch.** In preparation for a possible "Accelerated Approval" NDA filing in 2027 for XORLO™ 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 2024 to 2027. (Estimated cost \$500,000 and \$3 million.)
- 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™ in the EU, including required clinical studies and reimbursement conditions. This work will be ongoing from 2024 through 2027 and will include continued pursuit of orphan drug status. In addition, XORTX is updating an information dossier to support an orphan drug designation from the EMA. (Estimated cost \$500,000 and \$3 million.)

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.



#### SUMMARY OF QUARTERLY RESULTS

The following table sets forth unaudited quarterly results prepared by management for the eight previous quarters to September 30, 2024:

(unaudited)	2024 Q3	2024 Q2	2024 Q1	2023 Q4
Research and development	34,741	67,683	73,643	134,132
Consulting, wages and benefits	213,340	360,617	224,721	260,607
Directors' fees	40,144	46,371	39,161	45,495
Investor relations	236,603	502,265	439,405	278,934
Professional fees	195,527	274,635	120,210	56,363
General and administrative	81,765	92,258	74,920	93,567
Public company costs	30,823	56,053	29,683	29,630
Travel	-	16,728	1,607	31,771
Amortization of property and equipment	19,560	26,885	20,246	18,299
Amortization of intangible assets	6,389	6,164	11,886	6,061
Share based payments (1)	15,857	44,031	53,134	28,815
Loss/(gain) on derivative warrant liability	(244,000)	(1,645,548)	1,724,792	(3,641,403)
Foreign exchange (gain) loss	(14,715)	17,744	12,644	8,320
Interest income	(29,023)	(35,952)	(31,602)	(49,815)
Transaction costs on derivative warrant liability	-	-	224,486	-
Total (loss) income	(587,011)	170,066	(3,018,936)	2,699,224
(Loss) income per share	(0.20)	0.06	(1.24)	1.38

(unaudited)	2023 Q3	2023 Q2	2023 Q1	2022 Q4
Research and development	569,713	667,913	1,046,957	1,903,204
Consulting, wages and benefits	249,033	343,606	184,312	219,183
Directors' fees	46,469	43,204	44,238	42,077
Investor relations	236,934	223,334	180,288	182,192
Professional fees	102,617	214,425	140,858	92,434
General and administrative	90,140	90,299	101,499	88,226
Public company costs	45,822	47,371	47,361	31,280
Travel	14,267	68,765	55,384	11,041
Amortization of property and equipment	18,329	18,328	18,105	16,836
Amortization of intangible assets	(1,862)	13,692	48,742	5,721
Share based payments (1)	21,850	30,769	39,550	
Gain on derivative warrant liability	-	-	-	(1,579,802)
Foreign exchange (gain) loss	3,668	3,494		626,369
Interest income	(63,614)	(73,312)	(66,802)	(53,716)
Transaction costs on derivative warrant liability	-	-	-	926,456
Total loss	(1,333,366)	(1,691,888)	(1,832,035)	(2,579,183)
Loss per share	(0.67)	(0.85)	(0.95)	(1.62)

#### Notes:

(1) Share based payments relate to the vesting of options over the period.

## Three months ended September 30, 2024

The Company has a net loss of \$587,011 (\$0.20 per share) for the three months ended September 30, 2024, compared to a loss of \$1,333,366 (\$0.67 per share) in the three months ended September 30, 2023.

Variances within the loss items are as follows:

**Consulting, wages and benefits** - \$213,340 (2023 - \$249,033) — Consulting expenses decreased during the three months ended September 30, 2024, as less consultants were engaged during the current quarter due to a decrease in Company activity with respect to corporate development.



**Professional fees** - \$195,527 (2023 - \$102,617). Professional fees, which consists mainly of accounting, audit and legal fees, increased during the three months ended September 30, 2024 as compared with the 2023 period, due to the Company's increased corporate activity.

**Research and development** - \$34,741 (2023 - \$569,713) — Research and development expenses decreased in the three months ended September 30, 2024 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.

	Q3 2024	Q3 2023	Change \$	Change %
Clinical trials expenses <sup>1</sup>	5,679	275,066	(269,387)	(98%)
Manufacturing and related process expenses <sup>2</sup>	596	96,209	(95,613)	(99%)
Intellectual property expenses <sup>3</sup>	547	27,342	(26,795)	(98%)
Translational science expenses 4	-	81,363	(81,363)	(100%)
External consultants expenses 5	27,919	89,733	(61,814)	`(69%)
Total Research and development	\$34,741	\$569,713	\$(534,972)	(94%)

#### 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 2024, 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 2024, manufacturing costs primarily related to the Company's oxypurinol quality control and stability related costs.
- (3) Intellectual property expenses include legal and filing fees associated with our patent portfolio.
- (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.
- (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 2024 as compared to Q3 2023 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* - \$nil (2023 - \$14,267) – Travel decreased during the three months ended September 30, 2024, as compared with the 2023 period due to a decrease in travel to investor conferences.

Gain on derivative warrant liability - \$244,000 (2023 - \$nil) – During the three months ended September 30, 2024, the gain was primarily due to a decrease in the Company's share price and a decrease in the remaining terms of the warrants which decrease the value of the derivative warrant liability. The warrants included in the units issued under the offering in Q1-2024 have an exercise price in CAD dollars and are considered a derivative financial liability as the exercise price is in a different currency than the functional currency of the entity. The warrants are initially recognized at fair value and subsequently remeasured at fair value with changes recognized through profit or loss.

## Nine months ended September 30, 2024

The Company incurred a loss of \$3,435,881 (\$1.25 per share) for the nine months ended September 30, 2024, compared to a loss of \$4,857,289 (\$2.46 per share) in the nine months ended September 30, 2023.

Variances within the loss items are as follows:

**Consulting, wages and benefits** - \$798,678 (2023 - \$776,951) - Consulting expenses were broadly consistent from the same period last year.



**General and administrative** - \$248,943 (2023 - \$281,938) – General and administrative expenses decreased due to lower directors' and officers' insurance premiums.

*Investor relations* - \$1,178,273 (2023 - \$640,556) – Investor relations expense increased during the nine months ended September 30, 2024 as the Company increased its marketing, and promotional efforts with additional investor relations consultants, attendance to investor and marketing conferences.

**Professional fees** - \$590,372 (2023 - \$457,900). Professional fees, which consists mainly of accounting, audit and legal fees, increased during the nine months ended September 30, 2024 as compared with the 2023 period, due to the Company's increased corporate activity in relation to financings and various compliance requirements for the SEC.

**Research and development** - \$176,067 (2023 - \$2,284,583) — Research and development expenses decreased in the nine months ended September 30, 2024, 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.

	Q3 2024	Q3 2023	Change \$	Change %
Clinical trials expenses 1	13,118	1,051,632	(1,038,514)	(99%)
Manufacturing and related process expenses <sup>2</sup>	49,774	412,108	(362,334)	(88%)
Intellectual property expenses 3	10,866	29,367	(18,501)	(63%)
Translational science expenses 4	-	219,729	(219,729)	(100%)
External consultants' expenses 5	102,309	571,747	(469,438)	`(82%)
Total Research and development	\$176,067	\$2,284,583	\$(2,108,516)	(92%)

#### 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 2024, 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 2024, manufacturing costs primarily related to the Company's oxypurinol quality control and stability related costs.
- (3) Intellectual property expenses include legal and filing fees associated with our patent portfolio. No significant change in intellectual property expenses in Q3 2024 as compared to Q3 2023.
- (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.
- (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 2024 as compared to Q3 2023 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* - \$18,335 (2023 - \$138,416) – Travel decreased during the nine months ended September 30, 2024, as compared with the 2023 period due to a decrease in travel to investor conferences.

Gain on derivative warrant liability - \$164,756 (2023 - \$nil) – During the period ended September 30, 2024, the gain was primarily due to a decrease in the Company's share price and a decrease in the remaining terms of the warrants which decrease the value of the derivative warrant liability. The warrants included in the units issued under the offering in Q1-2024 have an exercise price in CAD dollars and are considered a derivative financial liability as the exercise price is in a different currency than the functional currency of the entity. The warrants are initially recognized at fair value and subsequently remeasured at fair value with changes recognized through profit or loss.



### Comparison of cash flows for the nine months ended September 30, 2024 and 2023

The Company realized a net cash outflow of \$1,146,918 for the nine months ended September 30, 2024, compared to a cash outflow of \$5,364,963 for the nine months ended September 30, 2023. The variances in the cash flow for the nine months ended September 30, 2024, compared to September 30, 2023 were as follows:

**Operating activities** – Cash used in operating activities for the nine months ended September 30, 2024, was \$2,792,240 (2023 - \$5,285,098). The cash used in operating activities decreased primarily due to decreases in research and development costs incurred.

*Investing activities* – Cash used in investing activities for the nine months ended September 30, 2024, was \$34,888 (2023 - \$36,568). The cash used was related to the acquisition of intangible assets and equipment during the periods.

**Financing activities** – Cash provided by financing activities in the nine months ended September 30, 2024, was \$1,672,472 (2023 – cash used of \$48,791). The cash provided was mostly related to the non-brokered offerings that took place in February and March raising gross proceeds of CAD \$2,699,151 through the issuance of 899,717 units at a subscription price of CAD \$3.00 per unit.

## LIQUIDITY AND CAPITAL RESOURCES

As at September 30, 2024, the Company had a cash balance of \$2,300,747 and working capital of \$693,643 as compared to a cash balance of \$3,447,665 and working capital of \$3,242,845 as at December 31, 2023. Working capital included a non-cash component related to derivative warrant liability of \$1,329,000 (December 31, 2023 - \$531,000) if this non-cash amount was excluded, working capital would have been \$2,022,643 (December 31, 2023 - \$3,773,845). During the nine months ended September 30, 2024, the Company closed two offerings that consisted of 899,717 common share units at CAD \$3.00 per unit for aggregate gross proceeds of CAD \$2,699,151.

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. The Company's current cash burn is approximately \$265,000 per month, however dependent on the timing of financing activities, expenditures will be adjusted to ensure a 12 month cash runway.

## **USE OF FINANCING PROCEEDS**

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: 98%; XRx-101: 1%; XRx-225: 1%.



#### **COMMITMENTS**

The Company has long-term arrangements with commitments that are not recognized as liabilities as at September 30, 2024 and December 31, 2023 are as follows:

## **Employment Agreements**

	September 30, 2024	December 31, 2023
	\$	\$
Management services – officers	321,000	321,000

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 current monthly salary which, as of September 30, 2024 and December 31, 2023, equated to an annual salary of \$321,000.

### **Payments**

In the normal course of business, the Company has committed to payments totaling \$173,000 (December 31, 2023 - \$446,000) 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 fair value. 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, 2024 and 2023, 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"), in the amount of \$80,219 and \$292,930 (2023 \$80,250 and \$244,582).
- 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 \$37,790 and \$113,374 (2023 \$38,325 and \$118,340 (paid or accrued to the CFO and former CFO)).
- 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 \$24,000 and \$86,445 (2023 \$56,250 and \$165,479).
- d) Consulting fees were paid or accrued to Stacy Evans, the Chief Business Officer ("CBO") of the Company in the amount of \$37,500 and \$120,000 (2023 \$75,000 and \$225,000).
- e) Directors' fees were paid or accrued to the directors of the Company in the amount of \$40,144 and \$125,676 (2023 \$45,278 and \$136,862). The amount includes director fees payment of \$27,574 and \$91,786 for the three and nine months ended September 30, 2024 (2023 \$34,064 and \$100,148) to Anthony Giovinazzo, Chairman of the Company.
- f) As at September 30, 2024, \$12,594 (December 31, 2023 \$6,805) was payable to directors of the Company, \$48,150 (December 31, 2023 - \$nil) was payable and accrued to the CEO of the Company for CEO services, \$12,686 (December 31, 2023 - \$14,631) was payable and accrued to the CFO of the



Company for CFO services, \$22,445 (December 31, 2023 - \$8,000) was payable and accrued to the CMO of the Company for consulting services, and \$12,500 (December 31, 2023 - \$15,000) 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, 2024 and 2023 are summarized as follows:

	Management Compensation	Directors' fees	Share- based payments	Total
Three months ended September 30, 2023	\$	\$	\$	\$
Directors and officers	249,825	45,278	11,874	306,977
Three months ended September 30, 2024 Directors and officers	179,509	40,144	8,158	227,811

	Management Compensation	Directors' fees	Share- based payments	Total
	\$	\$	\$	\$
Nine months ended September 30, 2023				
Directors and officers	753,401	136,862	55,820	946,083
Nine months ended September 30, 2024				
Directors and officers	612,749	125,676	79,584	818,009

## FINANCIAL AND CAPITAL RISK MANAGEMENT

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

The fair values of these financial instruments approximate their carrying values at September 30, 2024, 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, 2023.

### **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:

Equity is comprised of:	September 30, 2024	December 31 2023
	\$	\$
Share capital	17,870,948	17,056,535
Reserves	5,581,279	5,468,257
Obligation to issue shares	24,746	24,746
Accumulated other comprehensive loss	(52,605)	(52,605)
Deficit	(21,290,788)	(17,854,907)

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, 2024. 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, 2024	(number)
Issued and outstanding	3,223,565
Stock options	134,763
Share purchase warrants	3,371,845
Fully diluted shares outstanding	6,730,173

#### **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 and the Form 20-F for the year ended December 31, 2023, and the "Forward Looking Statements" section of this MD&A.

## **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 regulations, or other regulatory delays.

#### 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.

## 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. 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.

## **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.

## **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.

## INTERNAL CONTROLS OVER FINANCIAL REPORTING

#### Disclosure controls and procedures

Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by the Company 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 the securities legislation and include controls and procedures designed to ensure that information required to be disclosed by the Company in its annual filings, interim filings or other reports filed or submitted under securities legislation is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

#### Internal controls over financial reporting

Internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with IFRS. Management is also responsible for the design of the Company's internal control over financial reporting in order to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS.

The Company's internal controls over financial reporting include policies and procedures that: pertain to the maintenance of records that, in reasonable detail accurately and fairly reflect the transactions and disposition of assets; provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with IFRS and that receipts and expenditures are being made only in accordance with the authorization of management and directors of the Company; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or



disposition of assets that could have a material effect on the financial statements.

As at September 30, 2024, there has not been any material change to disclosure controls and procedures and internal controls over financial reporting for the period. Management, including the Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures and internal controls over financial reporting. As of September 30, 2024, the Chief Executive Officer and Chief Financial Officer have each concluded that the Company's disclosure controls and procedures and internal controls over financial reporting, as defined in National Instrument 52-109 – *Certification of Disclosure in Issuer's Annual and Interim Filings*, are effective to achieve the purpose for which they have been designed. Because of their inherent limitations, internal controls over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Furthermore, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. The control framework used to evaluate the effectiveness of the design and operation of the Company's internal controls over financial reporting is the 2013 Internal Control – *Integrated Framework* published by the Committee of Sponsoring Organizations of the Treadway Commission.

## **Changes in Internal Control Over Financial Reporting**

There has been no change in the Company's design of internal controls and procedures over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting during the period covered by this MD&A.

