

**XORTX THERAPEUTICS INC.**  
**Management Discussion and Analysis**  
**For the three months ended March 31, 2023**

This management discussion and analysis of financial position and results of operations (“**MD&A**”) is prepared as at May 15, 2023 and should be read in conjunction with the unaudited condensed interim consolidated financial statements for the three months ended March 31, 2023 of XORTX Therapeutics Inc. (the “**Company**” or “**XORTX**”), together with the audited financial statements of the Company for the year ended December 31, 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. 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<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. 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, 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™”, 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.sedar.com](http://www.sedar.com).

## 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 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 lead product candidates are XR<sub>x</sub>-008, for the treatment of ADPKD; XR<sub>x</sub>-101, to treat AKI associated with respiratory virus infection, AKI and associated health consequences; and XR<sub>x</sub>- 225, 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 XR<sub>x</sub>-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 XR<sub>x</sub>-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 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™ (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. 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 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™. XORLO™ 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 second oral formulation of oxypurinol, 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;
- the COVID-19 pandemic may materially and adversely affect our business and financial results;
- 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 March 31, 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 it submitted an Orphan Drug Designation (“**ODD**”) Request to the FDA for the XRx-008 program and specifically for XORLO™ 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™ 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™ 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-301 study, and proposed future clinical development program plans for XORLO™, 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™ 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 intends to initiate and pursue a SPA with the FDA for the XRX-OXY-301 program to further de-risk the development program for XORLO™ for the treatment of ADPKD.

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

Determination of functional currency may involve certain judgments to determine the primary economic environment, and we reconsider the functional currency of our entities 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.

Concurrent with the change in functional currency, the Company has also changed the reporting currency from Canadian dollars to United States dollars. This change in reporting currency is to better reflect our business activities, following the increased presence in the U.S. Unless otherwise indicated, all references to "\$" in this MD&A refer to USD.

The change in functional currency from CAD to USD is accounted for prospectively from January 1, 2023. Prior period comparable information has been restated to reflect the change in presentation currency. The Company elected to apply the exchange rate at December 31, 2022 of US\$1 equal to C\$1.3544 to translate prior period comparable information to reflect the change in presentation currency as at December 31, 2022. 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.

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.

### **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 has 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 will continue to trade on the Nasdaq Capital Market. If at any time before the 180 calendar day period, the bid price of the shares closes at or above US\$1.00 per share for a minimum of 10 consecutive business days, Nasdaq has the discretion to provide written notification that the Company has achieved compliance with the minimum bid price requirement and consider such deficiency matters closed. As at the date of this MD&A, the Company has not cured the minimum bid price requirement. The Company intends to make an application to extend the compliance period for a further 180 days. Although the Company believes it qualifies for such extension of time to regain the US\$1.00 minimum bid price for the required period of time, there is no assurance that Nasdaq will grant such request for an extension.

## 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 be focused on advancing XORLO™ as part of the XR-008 for ADPKD into Phase 3 clinical trial program, initiation of special protocol assessment (“SPA”) discussions with the FDA and initiation of commercialization activities, if approved, for XORLO™ as well as advancing research in other kidney disease applications. To achieve these objectives, XORTX's action plan includes:

1. **Initiate the Phase 3 clinical trial, XR-008, to support an application for “Accelerated Approval” of XORLO™ for individuals with ADPKD (the “XR-008 Clinical Trial”).** The XR-008 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. The XR-008 Clinical Trial will provide data to support future “Accelerated Approval” NDA submissions to the FDA and MAA to the EMA. The XR-008 Clinical Trial is planned to start in the second half of 2023 and will enroll individuals with stage 2, 3 or 4 ADPKD and presenting with chronically high uric acid. The objective of the XR-008 Clinical Trial is to evaluate the ability of XORLO™ to slow the expansion of total kidney volume over a 12-month treatment period.
2. **Prepare and Communicate with the FDA and EMA regarding the XR-009 Registration trial in ADPKD (the “XR-009 Clinical Trial”).** The XR-009 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 XR-009 Clinical Trial is to evaluate the safety and effectiveness of XORLO™ for the XR-008 program over a 24-month treatment period. The aim of the XR-009 Clinical Trial is to characterize the ability of XO1 to potentially decrease the rate of decline of glomerular filtration rate. An estimated 300 patients will be enrolled. The XR-009 Clinical Trial is planned to start in the second half of 2024, subject to Special Protocol Assessment review by FDA.
3. **Ongoing CMC Work.** In parallel with the XR-008 and XR-009 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 future clinical and commercial supplies. All development will be performed according to current GMP methodology. This work will be ongoing throughout 2023.
4. **Activities Related to Potential Commercial Launch.** In preparation for a possible “Accelerated Approval” NDA filing in 2025 in the US for XORLO™ for XR-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 2025.
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 2023 through 2026, and will include a future request for orphan drug status.

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 March 31, 2023:

(unaudited)	2023 Q1	2022 Q4	2022 Q3	2022 Q2
Amortization of intangible and capital assets	66,847	21,542	22,057	9,756
Foreign exchange loss (gain)	(8,457)	194,541	(507,859)	(272,869)
Consulting	30,840	18,293	111,563	(120,069)
Directors' fees	44,238	42,077	45,495	23,153
General and administrative	101,499	88,226	117,236	123,467
Interest income	(66,802)	(53,716)	(35,460)	(11,764)
Investor relations	180,288	182,192	100,706	407,138
Listing fees	47,361	31,280	25,105	37,903
Professional fees	140,858	92,434	56,244	221,038
Research and development	1,046,957	1,903,204	1,472,856	1,458,077
Share based payments <sup>(1)</sup>	39,550	70,896	19,268	332,912
Travel	55,384	11,041	84	11,413
Wages and benefits	153,472	200,890	132,559	146,786
Transaction costs on derivative warrant liability	-	926,456	-	-
(Gain) on derivative warrant liability	-	(1,579,802)	(362,688)	(1,128,101)
Total (loss)	(1,832,035)	(2,149,554)	(1,197,166)	(1,238,840)
(Loss) per share	(0.11)	(0.15)	(0.09)	(0.09)

(unaudited)	2022 Q1	2021 Q4	2021 Q3	2021 Q2
Amortization of intangible assets	3,776	3,761	3,592	3,561
Foreign exchange loss (gain)	155,905	(275,154)	9,716	5,974
Consulting	230,607	292,570	86,727	76,945
Directors' fees	11,847	18,015	31,351	-
General and administrative	119,895	115,875	4,971	10,597
Interest (income)/expense	(2,649)	1,325	1,097	542
Investor relations	238,388	106,773	94,408	49,068
Listing fees	26,525	117,839	29,254	30,054
Professional fees	84,355	56,541	(319,604)	400,320
Research and development	1,927,681	342,000	303,167	21,519
Share based payments <sup>(1)</sup>	68,078	113,878	49,385	73,663
Travel	-	190	-	-
Wages and benefits	164,831	109,261	38,098	39,091
Transaction costs on derivative warrant liability	-	1,220,516	-	-
(Gain)/loss on derivative warrant liability	(325,546)	(9,440,572)	6,298,894	(533,432)
Total (loss) income	(2,703,693)	7,217,182	(6,631,056)	(177,902)
(Loss) earnings per share	(0.21)	0.59	(0.71)	(0.02)

Notes:

- (1) Share based payments relate to the vesting of options over the period.
- (2) The loss during the three months ended March 31, 2023 relates mostly to the increase in research and development costs resulting from the commencement of various feasibility studies and clinical trial expenses.

### Three months ended March 31, 2023

The Company incurred a loss of \$1,832,035 (\$0.11 per share) for the three months ended March 31, 2023, compared to a loss of \$2,703,693 (\$0.21 per share) in the three months ended March 31, 2022.

Variances within the loss items are as follows:

**Foreign Exchange Gain** - \$8,457 (2022 – loss of \$155,905) – Foreign exchange gain was \$8,457 for the three months ended March 31, 2023 as compared to a loss of \$155,905 in the prior year quarter primarily due to an unrealized translation gain on the CAD dollar denominated cash balance in the current quarter as compared to unrealized translation loss on the U.S. dollar denominated cash balance in the previous

year quarter.

**Consulting** - \$30,840 (2022 - \$230,607) – Consulting expenses decreased during the three months ended March 31, 2023, as fewer consultants were engaged during the interim period due to a decrease in Company activity with respect to corporate development.

**Directors' fees** - \$44,238 (2022 - \$11,847) – Directors' fees expenses increased during the three months ended March 31, 2023 mainly due to monthly Director fee payment to Anthony Giovinazzo, Chairman of the Company. Anthony Giovinazzo joined the Company effective June 6, 2022 and thus no similar payments exist in the prior year quarter.

**General and administrative** - \$101,499 (2022 - \$119,895) – General and administrative expenses decreased slightly mainly due to lower directors and officer insurance premium.

**Investor relations** - \$180,288 (2022 - \$238,388) – Investor relations expense decreased during the three months ended March 31, 2023 due to a decrease in Company's activity with respect to dissemination of information and outreach initiatives.

**Listing fees** - \$47,361 (2022 - \$26,525) – Listing fees increased during the three months ended March 31, 2023 primarily due to the various filing fees paid to maintain compliance with the SEC/Nasdaq.

**Professional fees** - \$140,858 (2023 - \$84,355). Professional fees, which consists mainly of accounting, audit and legal fees, increased during the three months ended March 31, 2023 as compared with the 2022 period, due to the Company's increased corporate activity in relation to various registration statements with SEC and other compliance requirements for TSXV.

**Research and development** - \$1,046,957 (2022 - \$1,927,681) – Research and development expenses decreased in the three months ended March 31, 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.

	Q1 2023	Q1 2022	Change \$	Change %
Clinical trials expense <sup>1</sup>	467,987	887,686	(419,699)	(47%)
Manufacturing and related process expenses <sup>2</sup>	197,596	683,899	(486,303)	(71%)
Intellectual property expenses <sup>3</sup>	1,570	1,036	534	52%
Translational science expenses <sup>4</sup>	97,684	231,542	(133,858)	(58%)
External consultants' expenses <sup>5</sup>	282,120	123,518	158,602	128%
Total Research and development	\$1,046,957	\$1,927,681	\$880,724	(46%)

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 Q1 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 Q1 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 Q1 2023 as compared to Q1 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 Q1 2023 related to new sponsored research at the University of Denver, Colorado as compared to Q1 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 increase in

external consultants' expenses in Q1 2023 as compared to Q1 2022 was attributed to increased activity associated with completion of the XRX-OXY-101 PK Clinical Trial versus the previous year quarter the activities were just starting to increase with the start of XRX-OXY-101 PK Clinical Trial.

**Wages and benefits** - \$153,472 (2022 - \$164,831) – There was no significant variant in the current quarter for the wages and benefits expense as compared to previous year quarter.

**Gain on derivative warrant liability** - \$nil (2022 - \$325,546) –During the period ended March 31, 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 three months ended March 31, 2023 and 2022

The Company realized a net cash outflow of \$2,525,735 for the three months ended March 31, 2023, compared to a cash outflow of \$2,457,881 for the three months ended March 31, 2022. The variances in the cash flow for the three months ended March 31, 2023, compared to March 31, 2022 were as follows:

**Operating activities** – Cash used in operating activities for the three months ended March 31, 2023, was \$2,483,808 (2022 - \$2,503,662). The cash used in operating activities was primarily due to the net loss during the period.

**Investing activities** – Cash used in investing activities for the three months ended March 31, 2023, was \$19,731 (2022 - \$2,640). The cash used related to the acquisition of intangible assets and equipment during the period.

**Financing activities** – Cash used in financing activities in the three months ended March 31, 2023, was \$23,356 (2022 - \$nil). The cash used was mostly related to the payment of lease obligations.

### LIQUIDITY AND CAPITAL RESOURCES

As at March 31, 2023, the Company had a cash balance of \$7,908,461 and working capital of \$7,613,629 as compared to a cash balance of \$10,434,196 and working capital of \$9,379,529 as at December 31, 2022. During the year ended December 31, 2022, the Company closed a public offering that consisted of 1,400,000 common share units and 3,600,000 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 \$0.9999 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) 1,400,000 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 \$1.00 per Common Share Unit, and (ii) 3,600,000 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 \$0.9999 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 Common Share Units and the Pre-Funded Warrants and Warrants contained in the Pre-Funded Units were immediately separable upon issuance. The Warrants have an initial exercise price of \$1.22 per share, are immediately exercisable, and may be exercised for five years from the date of issuance. The Pre-Funded Warrants have an exercise price of \$0.0001 per share, are immediately exercisable, and will terminate once exercised in full. On December 29, 2022 and January 19, 2023, 641,000 and 2,959,000, Pre-Funded Warrants, respectively were exercised leaving a balance of Nil outstanding as at the date of this MD&A.

The Company has not fully used the net proceeds of the 2022 public offering. The proceeds that the Company has used (approximately \$1 million as of March 31, 2023) 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%.

## COMMITMENTS

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

### Employment Agreements

	March 31, 2023	December 31, 2022
	\$	\$
Management services – officers	472,800	441,754

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 March 31, 2023 and December 31, 2022, equated to an annual salary of \$321,000 and \$300,000 respectively.

The CFO 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 March 31, 2023 and December 31, 2022, equated to an annual salary of CAD \$205,440 and CAD \$192,000 respectively.

### Payments

In the normal course of business, the Company has committed to payments totaling \$1,514,514 (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 months ended March 31, 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, the Chief Financial Officer (“CFO”), and David MacDonald, former Chief Technology Officer (“CTO”) in the amount of \$125,229 (2022 - \$155,399).
- b) 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 \$52,979 (2022 - \$56,250).
- c) Consulting fees were paid or accrued to Stacy Evans, the Chief Business Officer (“CBO”) of the Company in the amount of \$75,000 (2022 - \$nil).
- d) Consulting fees were paid to a private entity controlled by the spouse of the Company’s CEO in the amount of \$nil (2022 - \$197).
- e) Directors’ fees were paid or accrued to the directors of the Company in the amount of \$47,089 (2022 - \$12,131). The amount includes director fees payment of \$35,842 for the three months ended March 31, 2023 (2022 - \$nil) to Anthony Giovinazzo, Chairman of the Company.
- f) As at March 31, 2023, \$11,084 (December 31, 2022 - \$14,914) was payable to directors of the Company, \$28,846 (December 31, 2022 - \$28,846) was accrued to the CEO of the Company, for CEO services, \$10,913 (December 31, 2022 - \$10,904) 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 months ended March 31, 2023 and 2022 are summarized as follows:

	Short-term employee benefits	Directors’ fees	Share- based payments	Total
	\$	\$	\$	\$
Three months ended March 31, 2022				
Directors and officers	212,130	11,847	33,546	257,523
Three months ended March 31, 2023				
Directors and officers	<b>256,060</b>	<b>44,237</b>	<b>24,654</b>	<b>324,951</b>



## 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 March 31, 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.

### 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:	March 31 2023	December 31 2022
	\$	\$
Share capital	17,056,535	16,524,354
Share-based payments, warrant reserve and other	9,559,226	10,051,561
Obligation to issue shares	24,746	24,746
Accumulated other comprehensive loss	(47,144)	(14,213)
Deficit	(17,534,338)	(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 three months ended March 31, 2023. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

## OUTSTANDING SHARE DATA

As at May 15, 2023, the Company had 17,989,687 common shares outstanding.

### Options Outstanding:

The following table summarizes information on the 1,039,335 stock options outstanding as at May 15, 2023:

Exercise Price (CAD)	Number Outstanding	Expiry Date
\$5.87	21,294	November 5, 2023
\$1.64	170,354	June 23, 2025
\$2.82	12,776	August 27, 2025
\$3.29	59,624	January 11, 2026
\$1.88	21,294	May 12, 2026
\$1.76	21,294	June 16, 2026
\$2.41	63,882	July 14, 2026
\$2.54	86,495	December 21, 2026
\$2.54	117,500	January 12, 2027
\$1.60	394,822	June 6, 2027
\$1.38	70,000	November 25, 2027

### Warrants Outstanding:

The following table summarizes information on the 10,579,796 outstanding warrants as at May 15, 2023:

Exercise Price	Number Outstanding	Expiry date
CAD\$4.70	1,842,596	February 9, 2026
\$4.77	2,577,200	October 15, 2026
\$1.17	910,000	October 15, 2026
\$1.22	5,250,000	October 7, 2027

## 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.

### 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 operation and financial condition.

### **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 a 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.