

**XORTX THERAPEUTICS INC.**  
**Management Discussion and Analysis**  
**For the six months ended June 30, 2022**

This management discussion and analysis of financial position and results of operations (“**MD&A**”) is prepared as at August 11, 2022 and should be read in conjunction with the unaudited condensed interim consolidated financial statements for the three and six months ended June 30, 2022 of XORTX Therapeutics Inc. (the “**Company**” or “**XORTX**”), together with the audited financial statements of the Company for the year ended December 31, 2021, 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 Canadian 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 – 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™ 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 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:

- incorrect assessments of the value of acquisitions, licenses and development programs;
- technical, manufacturing and processing problems;
- actions by governmental authorities, including increases in taxes;
- the availability of capital on acceptable terms;
- 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 clinical-stage pharmaceutical company, focused on identifying, developing and commercializing 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 coronavirus 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 coronavirus; and
- 3/ the identification of 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 and 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 develop therapeutic products 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 Coronavirus / COVID-19 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 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 therapies 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 XRx-008 program is designed for longer term stable chronic oral dosing of xanthine oxidase inhibitors. 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 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 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 COVID-19 infection, and T2DN. We note that there is no guarantee that the FDA will approve our proposed uric acid lowering agent products 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 completed enrollment of subjects for part 1 of a 3 part bridging pharmacokinetic characterization study (the "**PK Study**") in advance of initiating a Phase 3 registration clinical trial, the last stage of clinical development before United States Food and Drug Administration ("**FDA**") approval. Similarly, a second "pharmacokinetic" study is planned to support both the XRx-008 and XRx-101 program and future late-stage clinical studies targeting attenuation or reversal of AKI in hospitalized individuals with COVID-19. XRx-225 is at the non-clinical stage and 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 therapy for ADPKD. XRx-008 is the development name given to XORTX's therapeutics program and associated proprietary oral formulation of oxypurinol. This proprietary formulation of oxypurinol has shown increased oral bioavailability compared to a control formulation and the potential for an enhanced 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 xanthine oxidase inhibitor candidates for the XRx-225 program to 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. and/or European granted patents with claims to the use of all uric acid lowering agents to treat insulin resistance or diabetic nephropathy. In both the US and Europe, XORTX has been granted patents for unique proprietary formulations of xanthine oxidase inhibitors. In addition, XORTX has also submitted two patent applications to cover the use of uric acid lowering agents for the treatment of certain health consequences of coronavirus infection, as well as a new provisional patent for novel therapeutics to treat polycystic 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 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 safety warnings 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 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 June 30, 2022, 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 March 14, 2022, the Company announced the submission of its clinical trial application (“CTA”) with Health Canada for a XRx-OXY-101 bridging pharmacokinetics study. The study is an important first clinical step in the Company’s 505(b)2 clinical and regulatory plan for 2022 and will support the XRx-008 program for ADPKD as well as the planned phase 3 registration trial.

On March 23, 2022, the Company announced the submission of a Patent Cooperation Treaty (PCT) patent application seeking international patent protection for the patent entitled “Composition and Methods for Enhancing Anti-Viral Therapies.”

On March 31, 2022, the Company announced the filing of an IND application with the FDA. This IND filing is in support of the Company’s XRx-008 program for treatment of progressing kidney disease due to ADPKD and contains the protocol for the PK Study – XRx-OXY-101 discussed below.

On April 7, 2022, the Company announced receipt of notification that the patent “Formulations of Xanthine Oxidase Inhibitors” will be granted by the United States Patent Office (USPTO). The patent covers composition for, and methods of using XORTX’s proprietary formulations of xanthine oxidase inhibitors for renal and other disease where aberrant purine metabolism has been implicated in disease progression.

On April 12, 2022, the Company announced receipt of a no objection letter from Health Canada regarding the Company’s upcoming XRx-OXY101 clinical PK Study. The XRx-OXY-101 study has been designed with three important objectives: 1) to determine which of XORTX’s novel formulations results in the best circulating oxypurinol concentrations; 2) to determine the effect of food on the bioavailability of this formulation; and 3) to determine the safety and pharmacokinetics of multiple doses of this selected formulation. Knowledge gained during the conduct of this trial will provide guidance regarding the future oral dosing of oxypurinol formulations in support of the Company’s planned phase 3 registration trial in ADPKD. Additionally, this study will provide data to support future New Drug Application (“NDA”) marketing submissions to the FDA and the European Medicines Agency (“EMA”).

On April 20, 2022, the Company announced receipt of Small and Medium Enterprise (“SME”) status for the European Union (the “EU”). This status is applicable for European Medicines Agency (“EMA”) related interactions and confirmed by the SME office – Regulatory Science and Innovation Task Force. SME status



provides reduced costs to the Company as it initiates discussions with the FDA and EMA regarding the upcoming XR<sub>x</sub>-OXY-301 phase 3 registration trial for XR<sub>x</sub>-008 and other clinical programs.

On May 3, 2022, the Company announced that dosing of human subjects has been initiated in the XR<sub>x</sub>-OXY-101 bridging pharmacokinetics study. In addition, successful recruitment for part 1 of this 3-part clinical trial has been completed with 32 subjects receiving study drug. Following administration of the first dose of drug, blood sampling and bioanalytical evaluation will be conducted to characterize the pharmacokinetics (PK) and bioavailability of the XR<sub>x</sub>-008 program's novel proprietary formulations of oxypurinol for future clinical trials development. Additionally, this PK study will provide fundamental information for the 505(b)2 marketing approval filing of the XR<sub>x</sub>-008 program.

On May 5, 2022, the Company announced receipt of official notification from the FDA that the Corporation's recent IND application has been reviewed and cleared. Accompanying this notification is a "Study May Proceed Letter" regarding the XR<sub>x</sub>-OXY-101 PK Study. This FDA approval of the IND supports the Corporation's XR<sub>x</sub>-008 program for treatment of progressing kidney disease due to ADPKD.

On July 7, 2022, following the successful regulatory filings with the FDA and Health Canada and commencement of the OXY-XR<sub>x</sub>-101 bridging pharmacokinetics study, the Company has submitted a type B pre-Phase 3 meeting request with the FDA.

On July 13, 2022, the Company announced positive topline results from Part 1 of the three part Pharmacokinetics Bridging Study – XR<sub>x</sub>-OXY-101 ("PK Clinical Trial") - showing a substantial increase in oral bioavailability of two versions of XORTX's proprietary oxypurinol formulation compared to a control formulation. In addition, accompanying the improved bioavailability findings in Part 1 of the PK Clinical Trial was a clean safety and pharmacologic profile with no drug related adverse or serious adverse events related to oral administration of oxypurinol.

On July 19, 2022, the Company announced submission of a request for "scientific advice review" to the European Medicines Agency (the "EMA") and more specifically the Committee for Medical Products for Human Use (the "CHMP") regarding the XR<sub>x</sub>-008 program. This submission for CHMP/EMA review is intended to initiate discussions regarding the status of XORTX's XR<sub>x</sub>-008 program for ADPKD, plans for its global phase 3 registration trial, and includes scientific advice pertaining to marketing approval in the EU.

### Changes in officers, directors and advisory board members

On January 20, 2022, the Company announced the appointment of Dr. David MacDonald as Chief Technology Officer. Effective May 12, 2022, Dr. David MacDonald transitioned from the position of Chief Technology Officer to consultant focused on regulatory and clinical operations for the Company.

On June 6, 2022, the Company announced the appointment of Mr. Anthony Giovinazzo to the Board of Directors and as non-Executive Chair of the Board.

### FUTURE PLANS AND OUTLOOK

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

For the balance of 2022, the Company anticipates a number of advancements and changes in its business. In 2022, XORTX is focused on advancing XR<sub>x</sub>-008 into a clinical trial, the submission of an Orphan Drug Designation application, initiation of special protocol assessment discussions with the FDA and continuing formulation development for other kidney disease applications. To achieve these objectives, XORTX's action plan includes:

1. **Complete XR<sub>x</sub>-OXY-101 Bridging Study.** This study is a three-part, single-dose; fed or fasted; then, multi-dose crossover comparative bioavailability and pharmacokinetic study in healthy volunteers. It is designed to permit XORTX to characterize the safety and relative bioavailability of

the XRx-008 formulation. Knowledge gained during the conduct of this trial will provide guidance regarding the oral dose of XRx-008 for our planned registration trial in ADPKD. Additionally, this study will provide data to support future **NDA** submissions to the FDA and the EMA. This study was initiated in April 2022 with Part 1 results announced by the Company on July 13, 2022.

2. **Complete Orphan Drug Designation.** Current research being conducted will be used to file for orphan drug designation in 2022.
3. **Commence XRX-OXY-301 Registration trial in ADPKD.** XRX-OXY-301 is a multi-site, multi-national, placebo controlled, study in ADPKD patients with progressing stage 2 or 3 kidney disease. The objective of this study is to evaluate the safety and effectiveness of XRx-008 over a 24-month period and study the ability of xanthine oxidase inhibition to decrease the rate of decline of glomerular filtration rate. An estimated 350 patients will be enrolled. This study is planned to start in the second half of 2022, or early 2023, subject to SPA negotiations with the FDA.
4. **Ongoing CMC Work.** In parallel to the XRX-OXY-101 and XRX-OXY-102 studies, XORTX will be focused on performing the necessary scale-up, process validation and stability as part of the CMC requirements for the filing of the 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 2022 and 2023.
5. **Preparation of 505(b)(2) IND.** In parallel with initiation of XRX-OXY-101 a 505(b)2 based IND was submitted and granted in the second quarter of 2022 for the XRx-008 program.
6. **Activities Related to Potential Commercial Launch.** In preparation for a possible NDA filing in 2025/2026 in the U.S. for the XRx-008 program, XORTX is planning to conduct additional commercialization studies, including nephrologist, patient, payer, pricing and/or reimbursement studies, as well as product brand name selection and filings, and plans for launch. This work will be ongoing from 2022 to 2026.
7. **Activities Related to European Registration.** XORTX intends to establish guidance from the European Union for path to approval in the European Union, including required clinical studies and reimbursement conditions. This work will be ongoing from 2022 to 2026.

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 table below sets forth unaudited quarterly results prepared by management for the eight previous quarters to June 30, 2022:

(unaudited)	2022 Q2	2022 Q1	2021 Q4	2021 Q3
Amortization of intangible and capital assets	12,454	4,781	4,739	4,526
Foreign exchange loss (gain)	(348,314)	197,398	(346,716)	12,242
Consulting	(153,266)	291,982	368,662	109,269
Directors' fees	29,554	15,000	22,700	39,500
General and administrative	157,604	151,804	146,012	6,263
Interest	(15,017)	(3,354)	1,669	1,382
Investor relations	519,707	301,833	134,543	118,947
Listing fees	48,383	33,585	148,487	36,858
Professional fees	282,152	106,805	71,246	(402,676)
Research and development	1,861,216	2,440,720	430,948	381,967
Share based payments <sup>1</sup>	424,958	86,196	143,496	62,221
Travel	14,569	-	239	-
Wages and benefits	187,370	208,700	137,678	48,000
Transaction costs on derivative warrant liability	-	-	1,537,948	-
(Gain) loss on derivative warrant liability	(1,440,006)	(412,188)	(11,895,882)	7,936,114
Total Comprehensive (loss) income	(1,581,364)	(3,423,262)	9,094,231	(8,354,613)
(Loss) earnings per share	(0.12)	(0.26)	0.74	(0.89)

(unaudited)	2021 Q2	2021 Q1	2020 Q4	2020 Q3
Amortization of intangible assets	4,373	4,244	5,140	5,154
Foreign exchange loss (gain)	7,336	387	7,006	42,230
Consulting	94,480	151,861	39,172	15,000
General and administrative	13,012	10,812	1,933	1,742
Interest	665	1,882	815	839
Investor relations	60,251	204,874	109,973	52,848
Listing fees	36,903	14,553	15,510	10,802
Professional fees	491,552	112,821	75,000	37,819
Research and development	26,423	13,786	142,548	120,033
Share based payments <sup>1</sup>	90,451	202,990	6,748	90,443
Travel	-	2,100	-	-
Wages and benefits	48,000	52,412	79,808	48,000
Transaction costs on derivative warrant liability	-	85,732	-	-
(Gain) loss on derivative warrant liability	(655,000)	1,315,000	-	-
Impairment of intangible assets	-	-	64,562	-
Recovery of provision for patent acquisition	-	-	(95,490)	-
Forgiveness of debt	-	-	-	-
Total Comprehensive loss	(218,446)	(2,173,454)	(452,725)	(424,910)
Loss per share	(0.02)	(0.26)	(0.07)	(0.06)

Notes:

- (1) Share based payments relate to the vesting of options over the period.
- (2) The loss during the three months ended June 30, 2022 relates mostly to the increase in research and development costs resulting from the commencement of various feasibility studies and clinical trial expenses as offset by gain on derivative warrant liability valuation.

### Three months ended June 30, 2022

The Company incurred a comprehensive loss of \$1,581,364 (\$0.12 per share) for the three months ended June 30, 2022, compared to \$218,446 (\$0.02 per share) in the three months ended June 30, 2021.

Variances within the loss items are as follows:

**Foreign Exchange Gain** - \$348,314 (2021 – loss of \$7,336) – Foreign exchange gain was \$348,314 for the three months ended June 30, 2022 as compared to a loss of \$7,336 in the prior year quarter primarily due to an unrealized translation gain on the U.S. dollar denominated cash balance.

**Consulting** - \$(153,266) (2021 - \$94,480) – Consulting expenses have decreased during the three months ended June 30, 2022 primarily due to a reclassification of prior quarter's consulting work to research and development.

**Directors' fees** - \$29,554 (2021 - \$nil) – Directors' fees expenses increased during the three months ended June 30, 2022, as the Company began paying annual and meeting fees to its independent directors on July 1, 2021.

**General and administrative** - \$157,604 (2021 – \$13,012) General and administrative costs increased due to an increase in the director and officer insurance premium of \$144,060 as well as an increase in Company activity.

**Investor relations** - \$519,707 (2021 - \$60,251) – Investor relations expense increased during the three months ended June 30, 2022 as the Company entered into various marketing campaign engagements.

**Professional fees** - \$282,152 (2021 - \$491,552). Professional fees, which consists mainly of accounting, audit and legal fees, decreased during the three months ended June 30, 2022 compared with the 2021 comparable period, due to decreased legal costs.

**Research and development** - \$1,861,216 (2021 - \$26,423) – Research and development expenses increased in the three months ended June 30, 2022 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.

	Q2 2022	Q2 2021	Change \$	Change %
Clinical trial expense <sup>1</sup>	678,033	-	678,033	100%
Manufacturing and related process expenses <sup>2</sup>	394,108	-	394,108	100%
Intellectual property expenses <sup>3</sup>	5,468	5,113	355	7%
Translational science expenses <sup>4</sup>	203,752	5,207	198,545	3813%
External consultants expenses <sup>5</sup>	579,855	16,103	450,347	3501%
Total Research and development	\$1,861,216	\$26,423	\$1,834,793	6944%

Notes:

1. Clinical trial 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 trial expenses are regulatory and consulting activities, contract research organization expenses, data management expenses, and other costs associated with our clinical trial program. In Q2 2022, clinical trial expense primarily related to the PK study and hence the increase in the current year quarter as no such study was conducted last year.

2. Manufacturing and related process expenses includes third party direct manufacturing costs, quality control testing and packaging costs. In Q2 2022, manufacturing costs primarily related to the Company's oxypurinol manufacturing, feasibility study and chemical compound studies. The increase in manufacturing and related process expenses in Q2 2022 as compared to Q2 2021 relates to the start of bridging study and registration trial in ADKPD planned for 2022 while no such activity occurred in Q2 2021.
3. Intellectual property expenses include legal and filing fees associated with our patent portfolio. No major change in intellectual property expenses in Q2 2022 as compared to Q2 2021.
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 Q2 2022 related to sponsored research work at the University of Denver, Colorado whereas little comparable activity was undertaken in Q2 2021.
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 Q2 2022 as compared to Q2 2021 was attributed to increased activity focused on the initiation of the Company's bridging study and thereafter a single registration trial associated to the XRx-008 program in individuals with ADKPD planned for 2022.

**Wages and benefits** - \$187,370 (2021 - \$48,000) – The wages and benefits expense increased in the three months ended June 30, 2022, as the Company's CFO and CTO were added to the payroll.

**Fair value adjustment on derivative warrant liability** – gain of \$1,440,006 (2021 – \$655,000). The gain recognized during the three months ended June 30, 2022 relates to the warrants included in the units issued under the IPO while the gain in 2021 relates to the warrants issued under the Private Placement. The warrants issued under the Private Placement were classified as a derivative financial liability as they contained a ratchet provision that provided for an adjustment in the exercise price of the warrants if shares or securities convertible to shares were sold at a price lower than the exercise price. The IPO warrants have an exercise price in US dollars and have a derivative financial liability as the exercise price is in a different currency than the functional currency of the Company. The warrants are initially recognized at fair value and subsequently measured at fair value with changes recognized through profit or loss.

### Six months ended June 30, 2022

The Company incurred a comprehensive loss of \$5,004,626 (\$0.39 per share) for the six months ended June 30, 2022, compared to a loss of \$2,391,900 (\$0.27 per share) in the six months ended June 30, 2021.

Variances within the loss items are as follows:

**Foreign Exchange Gain** - \$150,916 (2021 – loss of \$7,723) – Foreign exchange gain was \$150,916 for the six months ended June 30, 2022 as compared to a loss of \$7,723 in the six months ended June 30, 2021 primarily due to an unrealized translation gain on the U.S. dollar denominated cash balance.

**Directors' fees** - \$44,554 (2021 - \$nil) – Directors' fees expenses increased during the six months ended June 30, 2022, as the Company began paying annual and meeting fees to its independent directors on July 1, 2021.

**General and administrative** - \$309,408 (2021 – \$23,824) General and administrative costs increased significantly mostly due to an increase in the director and officer insurance premium as well as an increase in Company activity.

**Investor relations** - \$821,540 (2021 - \$265,125) – investor relations expense increased during the six months ended June 30, 2022 due to costs related to the Company's listings on the TSXV and Nasdaq stock exchanges and various marketing campaign engagements.

**Professional fees** - \$388,957 (2021 - \$604,373). Professional fees, which consists mainly of accounting, audit and legal fees, decreased during the six months ended June 30, 2022 compared with the 2021 comparable period, due to decreased legal costs.

**Research and development** - \$4,301,936 (2021 - \$40,209) – Research and development expenses increased in the six months ended June 30, 2022, compared to the same period last year as detailed in the table below.

The table below presents combined research and development costs for XRx-008, XRx-101, and XRx-225, the Company's projects are being developed in parallel and combined.

	Q2 2022	Q2 2021	Change \$	Change %
Clinical trial expense <sup>1</sup>	1,801,972	-	1,801,972	100%
Manufacturing and related process expenses <sup>2</sup>	1,260,240	-	1,260,240	100%
Intellectual property expenses <sup>3</sup>	6,779	15,149	(8,370)	(55%)
Translational science expenses <sup>4</sup>	496,917	5,207	491,710	9442%
External consultants expenses <sup>5</sup>	736,028	19,853	716,175	3607%
Total Research and development	<b>\$4,301,936</b>	<b>\$40,209</b>	<b>\$4,261,727</b>	<b>10599%</b>

Notes:

1. Clinical trial 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 trial expenses are regulatory and consulting activities, contract research organization expenses, data management expenses, and other costs associated with our clinical trial program. YTD Q2 2022, clinical trial expense primarily related to the PK study and hence the increase in the current year YTD 2022 as no such study was conducted last year.
2. Manufacturing and related process expenses include third party direct manufacturing costs, quality control testing and packaging costs. In 2022, the Company's manufacturing costs primarily related to oxypurinol manufacturing, feasibility study and chemical compound studies. The increase in manufacturing and related process expenses in 2022 as compared to 2021 is entirely attributable to increased activity geared towards the start of bridging study and registration trial in ADKPD planned for 2022.
3. Intellectual property expenses include legal and filing fees associated with our patent portfolio. The decrease in intellectual property expenses in YTD 2022 as compared to YTD 2021 related is a timing difference as we expect the intellectual property expenses in 2022 will increase as compared to 2021 as the Company expands its 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 identification of potential licensing opportunities. The translational science expense for the six-month period in 2022 related to sponsored research work at the University of Denver, Colorado and animal studies. Very little activity was undertaken in 2021. We expect translational science expense in 2022 will increase as compared to 2021 as the Company expands its patent portfolio.
5. External consultants' expense includes 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 for six months period in 2022 as compared to the six months period in 2021 was attributed to increased activity focused on the initiation of the Company's bridging study and thereafter a single registration trial associated with the XRx-008 program in individuals with ADKPD planned for 2022. We expect external consultants' expense in 2022 to increase as compared to 2021 as the Company conducts a bridging pharmacokinetic study associated with the XRx-008 drug product and thereafter initiation and conduct of a registration trial in ADKPD.

**Wages and benefits** - \$396,070 (2021 - \$100,412) – The wages and benefits expense increased in the six months ended June 30, 2022, as the Company's CFO and CTO were added to the payroll.

**Fair value adjustment on derivative warrant liability** – gain of \$1,852,194 (2021 – loss of \$660,000). The loss recognized during the six months ended June 30, 2021 relates to the warrants included in the units issued under the Private Placement, and the gain recognized during the six months ended June 30, 2022 relates to the warrants included in the units issued under the IPO. The Private Placement warrants were classified as a derivative financial liability as they contained a ratchet provision that provided for an adjustment in the exercise price of the warrants if shares or securities convertible to shares were sold at a price lower than the exercise price. The IPO warrants have an exercise price in US dollars and have 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 measured at fair value with changes recognized through profit or loss.

#### Comparison of cash flows for the six months ended June 30, 2022 and 2021

The Company realized a net cash outflow of \$5,430,608 for the six months ended June 30, 2022, compared to a cash inflow of \$4,977,243 for the six months ended June 30, 2021. The variances in the cash flow for the six months ended June 30, 2022, compared to June 30, 2021 were as follows:

**Operating activities** – Cash used in operating activities for the six months ended June 30, 2022, was \$5,570,505 (2021 - \$2,031,658). The cash used in operating activities was primarily due to the net loss during the period offset by the non-cash items.

**Investing activities** – Cash used in investing activities for the six months ended June 30, 2022, was \$23,787 (2021 - \$10,461). The cash used related to the acquisition of intangible and capital assets during the period.

**Financing activities** – Cash used in financing activities in the six months ended June 30, 2022, was \$7,875 (2021 – cash provided of \$7,019,362). In the prior year period, the cash provided was mostly related to the private placement that took place in February 2021 raising gross proceeds of \$6,121,572 through the issuance of 2,085,687 units at a subscription price of \$2.935 per unit.

#### LIQUIDITY AND CAPITAL RESOURCES

As at June 30, 2022, the Company had a cash balance of \$13,420,636 and working capital of \$13,018,832 as compared to a cash balance of \$18,851,244 and working capital of \$19,472,340 as at December 31, 2021. During the year ended December 31, 2021, the Company closed a public offering that occurred when the shares of the Company were listed on Nasdaq. The offering consisted of 2,906,000 units, with each unit consisting of one common share, no par value, and one warrant to purchase one common share at a public offering price of US\$4.13 per Unit, for gross proceeds of \$14,851,850 (US\$12,001,780) as well as the private placement that took place in February 2021 raising gross proceeds of \$6,121,572 through the issuance of 2,085,687 units at a subscription price of \$2.935 per unit. The Company's primary source of funding is by way of raising capital through the issuance of equity to third party investors.



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 15, 2021, the Company closed an underwritten public offering in the U.S. of 2,906,000 units, with each unit consisting of one common share and one warrant to purchase one common share at US\$4.13 per unit, for aggregate gross proceeds of approximately US\$12 million, prior to deducting underwriting discounts and other offering expenses (the “**US IPO Offering**”). The USD IPO Offering was undertaken by A.G.P. / Alliance Global Partners (“**A.G.P.**”) who acted as sole book-running manager. The warrants are exercisable at US\$4.77 per share and have a term of five years. In addition, the Company granted A.G.P. a 45-day option to purchase up to an additional 435,900 common shares and warrants to purchase up to an additional 435,900 common shares at US\$4.13 less underwriting discounts. On closing, A.G.P. exercised its option to purchase additional warrants to purchase up to an additional 435,900 common shares. On November 8, 2021, A.G.P. partially exercised its 45-day option to purchase 355,000 common shares at US\$4.13 per share, resulting in additional gross proceeds to the Company of approximately US\$1.47 million which increased the US IPO Offering to 3,261,000 common shares and 3,341,900 warrants.

The Company has not fully used the net proceeds of the US Offering. The proceeds that the Company has used (approximately CAD\$5.4 million as of June 30, 2022) have been used for funding operations and general corporate purposes, which has included the further research and development, clinical trials, 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 the 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 had long-term arrangements with commitments as at June 30, 2022 and December 31, 2021 as follows:

### Employment Agreements

	June 30, 2022	December 31 2021
	\$	\$
Management services – officers	482,580	476,000

The President, CEO and a director of the Company has a long-term employment agreement with the Company. The agreement has a termination clause whereby he is entitled to the equivalent of 12 times his then current monthly salary which, as of June 30, 2022 and December 31, 2021, equated to annual salary of US\$300,000.

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 6 times his then current monthly salary which as of June 30, 2022 and December 31, 2021, equated to annual salary of \$192,000.

## **Payments**

In the normal course of business, the Company has committed to payments totaling \$7,464,657 (2021 - \$1,613,142) for activities related to its clinical trial, manufacturing, collaboration programs and other regular business activities which are expected to occur over the next two years.

## **OFF BALANCE SHEET ARRANGEMENTS**

The Company has no off-balance sheet arrangements.

## **TRANSACTIONS WITH RELATED PARTIES**

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

During the three and six months ended June 30, 2022 and 2021, the Company incurred the following transactions with related parties:

- a) Wages and benefits were accrued to Allen Davidoff, the Chief Executive Officer (“**CEO**”) and Amar Keshri, Chief Financial Officer (“**CFO**”) of the Company in the amount of \$181,995 and \$379,071 (2021 - \$48,000 and \$100,412).
- b) Professional fees were accrued to 1282803 Ontario Inc., a company owned by Jim Fairbairn, former CFO of the Company in the amount of \$nil and \$nil (2021 - \$27,000 and \$34,500).
- c) Research and development fees were accrued to Haworth Biopharmaceutical, a company owned by Stephen Haworth, Chief Medical Officer (“**CMO**”) of the Company in the amount of \$71,879 and \$142,962 (2021 - \$nil and \$nil).
- d) Consulting fees were accrued to Bruce Rowlands and Allan Williams, former directors of the Company in the amount of \$nil and \$nil (2021 - \$29,000 and \$38,000).
- e) Directors’ fees were accrued to the directors of the Company in the amount of \$29,554 and \$44,554 (2021 - \$nil and \$nil).
- f) As at June 30, 2022, \$23,400 (December 31, 2021 - \$81,104) was payable to directors of the Company, \$nil (December 31, 2021 - \$25,000) was accrued to the CEO of the Company, for CEO services, and \$24,161 (December 31, 2021 - \$47,543) was accrued to the CMO of the Company, for consulting services. The balances are unsecured, non-interest bearing, and have no fixed terms of repayment.

- g) Management compensation transactions for the three and six months ended June 30, 2022 and 2021 are summarized as follows:

	Short-term employee benefits	Directors' fees	Share- based payments	Total
	\$	\$	\$	\$
Three months ended June 30, 2021				
Directors and officers	48,000	-	80,753	128,753
Three months ended June 30, 2022				
Directors and officers	<b>181,995</b>	<b>29,554</b>	<b>386,077</b>	<b>597,626</b>

	Short-term employee benefits	Directors' fees	Share- based payments	Total
	\$	\$	\$	\$
Six months ended June 30, 2021				
Directors and officers	100,412	-	183,594	284,006
Six months ended June 30, 2022				
Directors and officers	<b>379,071</b>	<b>44,554</b>	<b>428,551</b>	<b>852,176</b>

## 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 warrant liability is classified as a financial liability at FVTPL.

The fair values of these financial instruments, other than derivative warrant liability, approximate their carrying values at June 30, 2022, 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, 2021.

### Capital Management

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

Since inception, the Company's objective in managing capital is to ensure sufficient liquidity to finance its research and development activities, general and administrative expenses, expenses associated with intellectual property protection and its overall capital expenditures. There were no changes during the six

months ended June 30, 2022. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

## OUTSTANDING SHARE DATA

As at August 11, 2022, the Company had the following shares outstanding:

- Class	Common Shares
- Authorized	Unlimited, without par value
- Issued and outstanding	12,989,687

## Options Outstanding:

The following table summarizes information on the 1,128,389 stock options outstanding as at August 11, 2022:

Exercise Price	Number Outstanding	Expiry Date
\$5.87	127,760	March 19, 2023
\$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	42,588	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	127,500	January 12, 2027
\$1.60	394,822	June 6, 2027

## Warrants Outstanding:

The following table summarizes information on the 5,329,796 outstanding warrants as at August 11, 2022:

Exercise Price	Number Outstanding	Expiry date
\$4.70	1,785,176	February 9, 2026
US\$4.77	3,341,900	October 15, 2026

## 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.

### 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 subsidiaries, 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 subsidiaries, 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 recent invasion of Ukraine 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 and has financial risk exposure towards digital currencies. 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 Chief Executive Officer and Director, 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 bio-pharmaceuticals, 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 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.