

**XORTX THERAPEUTICS INC.**  
**Management Discussion and Analysis**  
**For the three months ended March 31, 2021**

This management discussion and analysis of financial position and results of operations (“MD&A”) is prepared as at May 31, 2021 and should be read in conjunction with the unaudited condensed interim consolidated financial statements for the three months ended March 31, 2021 of XORTX Therapeutics Inc. (the “Company” or “XORTX”), together with the audited financial statements of the Company for the year ended December 31, 2020, 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 Standard 34, Interim Financial Reporting, as issued by the International Accounting Standards Board (“IAS”) 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. (“APAC”), 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 principal executive offices are located at Suite 4000, 421 – 7th Avenue SW, Calgary, Alberta, Canada T2P 4K9.

## **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 developments in the United States and other countries;
- the performance of third-party manufacturers;
- 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 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 Therapeutics is a clinical-stage biotechnology company, focused on identifying, developing and commercializing therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism 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”) and acute kidney injury (“AKI”) due to 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 coronavirus induced AKI; 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 innovative technology is underpinned by well-established research and insights into the underlying biology of aberrant purine metabolism, its health consequences and of oxypurinol, a powerful uric acid lowering agent that works by effectively inhibiting xanthine oxidase. We innovate 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 infections. 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, are focused on building a robust pipeline of assets to address the unmet medical needs for patients with a variety of serious or life-threatening diseases.

Our three lead product candidates are XRx-008, a novel program for the treatment of ADPKD; XRx-101, a program for the treatment of COVID-19, AKI and associated health consequences; and XRx-225, a program for the treatment of T2DN. At XORTX Therapeutics, 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 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 disease entities 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 significant competitive advantage to our therapeutic platforms and are ultimately reflected in our programs. Some of these key advantages are:

#### **Highly Modular and Customizable**

Our platforms can be combined in multiple ways and this synergy can be applied to address acute, intermittent or chronic disease progression. For example, our XRx-101 program for acute kidney injury is designed to produce rapid suppression of hyperuricemia then maintain purine metabolism 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. 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, XRx-225 represents a new class of xanthine oxidase inhibitor with a targeted design to enhanced anti-inflammatory activity of a variety of agents. 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 high production and high purity active pharmaceutical drug product. We believe this will provide a significant 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 platforms to treat the symptoms of, and potentially delay the progression of, ADPKD, chronic, and acute kidney disease.

### **Product Candidate Pipeline**

Our lead product candidates are XRx-008, XRx-101, and XRx-225. XRx-008 is in preparations for a Phase 3 registration clinical trial, the last stage of clinical development before FDA approval. Our XRx-101 program is advancing toward preparing for a "bridging" pharmacokinetic study for the Company's Phase 3 clinical trial to slow or reverse acute kidney disease 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 at 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 proprietary oral formulation of oxypurinol, and shows increased oral bioavailability compared to oxypurinol alone. XORTX is also developing a second oral formulation of oxypurinol, XRx-101, for use in treating patients infected with the coronavirus COVID-19 infection and suppression of AKI and associated health consequences.

XORTX is currently evaluating xanthine oxidase inhibitor candidates for the XRx-225 program to treat T2DN as well as developing new chemical entities to address the large unmet medical need.

### **Patents**

XORTX is the exclusive licensee of three individual U.S. granted patents with claims to the use of all uric acid lowering agents to treat high blood pressure, insulin resistance or diabetic nephropathy counterparts for some of these patent applications have also been submitted in Europe. XORTX previously announced notice to grant in Europe, a patent for novel formulations of xanthine oxidase inhibitors that covers the XRx-008 program. Recently XORTX announced submission of two provisional patent applications to cover the use of uric acid lowering agents for the treatment of the health consequences of coronavirus COVID-19 infection. Additional patent applications to protect innovations, expand and extend coverage of uric acid lowering agents to other chronic and acute diseases are currently under preparation.

## **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 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 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;
- 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, 2021, 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**

### **Private Placement and Warrant Exercises**

In January and February 2021, 4,286,438 warrants that were issued in connection with the February 2020 private placement were exercised for aggregate proceeds of \$1,037,524. Of the warrants exercised, 3,985,656 were exercised at \$0.25 per common share and 300,782 were exercised at \$0.14 per common share in respect to certain finder's warrants that were issued in relation to that private placement.

On February 9, 2021, the Company issued 24,486,286 units in a private placement offering at a subscription price of \$0.25 per unit for gross proceeds of \$6,121,572. Each unit comprised one common share of the Company and one common share purchase warrant. Each warrant entitles the holder, on exercise, to purchase one additional common share in the capital of the Company, at a price of \$0.40, for a period of five years from the issuance of the units; provided, however, that, if, at any time following the expiry of the statutory four month hold period, the closing price of the common shares on the Canadian Securities Exchange (the "CSE") is greater than \$1.20 for 10 or more consecutive trading days, the warrants will be accelerated upon notice and the warrants will expire on the 30th calendar day following the date of such notice. In addition, the warrants are also subject to typical anti-dilution provisions and a ratchet provision that provides for an adjustment in the exercise price should the Company issue or sell common shares or securities convertible into common shares at a price (or conversion price, as applicable) less than the exercise price such that the exercise price shall be amended to match such lower price.

In connection with the private placement, the Company paid \$171,085 in cash commissions and issued 684,340 finder's warrants. Each finder's warrant is exercisable into one common share at a price of \$0.40 and having the same expiry, acceleration and anti-dilution provisions as the warrants included in the private placement. The common shares and warrants comprising the units issued pursuant to the private placement, and any common shares issued upon the exercise of the warrants or the finder's warrants, are subject to a four month hold period pursuant to applicable securities laws.

### **December 2020 Notification from European Patent Office**

On December 29, 2020, the Company announced the receipt of notification that the patent "Formulations of Xanthine Oxidase Inhibitors" will be granted by the European Patent Office. The patent covers compositions and methods of using XORTX's proprietary formulations of xanthine oxidase for, renal and other diseases where aberrant purine metabolism has been implicated in disease progression.

### **Partnership with Icahn School of Medicine**

On November 16, 2020, the Company announced the topline results from the Company's partnership with the Icahn School of Medicine at Mount Sinai, New York ("Icahn School of Medicine"). The aim of this study was to characterize the incidence of AKI and hyperuricemia in patients hospitalized with COVID-19. The results of the data analysis show that in some individuals with COVID-19 infection, hyperuricemia increases early in and is associated with AKI. The data also strongly suggests that for those individuals with very high serum uric acid levels, this can contribute to worsening kidney outcomes. These topline results indicate that further clinical studies to lower uric acid in these individuals is warranted, and may improve AKI, dialysis, recovery and mortality outcomes.

### **Appointment of LONZA Group as Manufacturer**

On April 30, 2020, the Company announced the appointment of LONZA Group as the manufacturer of GMP oxypurinol for the XRx-008 and XRx-101 clinical trial programs. The launch of oxypurinol manufacturing for



both XRx-008 and XRx-101 is the first step to advance these programs toward clinical testing. Lonza is a leading global supplier to the pharmaceutical, biotech and specialty ingredients markets.

### **COVID-19 Developments**

In March 2020, the outbreak of the novel strain of coronavirus, specifically identified as “SARS-CoV-2” which causes COVID-19 infections, resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which include the implementation of travel bans, self-imposed quarantine periods and physical distancing, have caused material disruption to business globally resulting in an economic slowdown. Global equity markets have experienced significant volatility. The duration and impact of the COVID-19 Pandemic outbreak is unknown at this time, as is the efficacy of the government and central bank interventions. It is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of the Company in future periods.

On March 16, 2020, XORTX announced the filing of a provisional patent application covering the potential use of any uric acid lowering agent, and more specifically a xanthine oxidase inhibitor XRx-101 (we believe a novel formulation of oxypurinol), to treat respiratory, kidney disease and multi-organ injury related to patients infected with SARS-COV-2 or other respiratory viruses COVID-19.

### **Changes in officers and directors**

On May 12, 2021, William Farley was appointed to the Company’s board of directors.

### **FUTURE PLANS AND OUTLOOK**

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

First, the Company is in planning stages for the XRx-008 program to treat progressive kidney disease in individuals with ADPKD. XORTX’s primary goal is initiation of a pivotal phase 3 clinical trial in ADPKD, to demonstrate the benefit of xanthine oxidase inhibition and lowering elevated uric acid as a therapy, and then commercialize by out-licensing this “first-in-class” program to a pharmaceutical partner company.

Second, XORTX is developing XRx-101 for coronavirus / COVID-19 infection as a therapy to treat and protect kidneys from acute injury and other organ injury associated with viral infection. This program is under early, rapid development with a target to initiate a clinical trial within the year and characterize the anti-viral, and kidney protective effects of this novel therapy.

Lastly, the Company continues to evaluate new xanthine oxidase inhibitors as in-licensing candidate compounds and develop new proprietary xanthine oxidase inhibitors for the treatment of progressive kidney disease due to type 2 diabetic nephropathy (see “Products” above).

In addition, XORTX plans to grow by expanding its knowledge and technical expertise into new therapeutic programs to treat a variety of other orphan diseases, fatty liver disease and health issues related to diabetes.

The Company will require additional capital to enable it to undertake these programs.

XORTX’s overall strategic goal is to initiate a pivotal clinical trial in the ADPKD program once sufficient funding is raised by the Company. Based upon recently published and successful phase 2 clinical pilot trials, progression of kidney disease in ADPKD and chronic kidney disease (~50% T2DN) can be slowed or perhaps stopped by decreasing uric acid levels into the mid-normal range of serum concentration. Recent, successful clinical trials and associated data shows the benefit of lowering uric acid levels in progressive kidney disease and accumulating positive clinical trial results published recently in patients with chronic kidney disease and more specifically type 2 diabetic nephropathy suggest an increased probability of future clinical trial success, licensing potential and program advancement to marketing approval.

With respect to ADPKD, and over the next three years, subject to sufficient funding being available, the steps towards advancing this program are:

1. Manufacture Oxypurinol and formulation in preparation for pivotal phase 3 ‘registration’ clinical trials.
2. Complete the Investigational New Drug application (“IND”) process to advance XRx-008 and characterize bioequivalence/bioavailability of XRx-008 in man.
3. Complete and receive ‘orphan drug designation’ for this program.
4. Submit the phase 3 pivotal trial protocol to demonstrate the effectiveness of uric acid lowering by XRx-008 in ADPKD patients and initiate the clinical trial under a special protocol assessment (SPA).
5. Complete licensing or co-development agreements for the ADPKD program within the next 24 months with pharmaceutical company partners in key markets. These agreements may include income to XORTX from upfront, milestone and royalty payments upon new drug application (“NDA”) approval.

A number of pharmaceutical companies have expressed an interest in the ADPKD program, once a phase 3 clinical trial, under SPA, is finalized or in the early stages of recruiting.

Regarding the XRx-101 program, over the next 12 months, subject to sufficient funding, the company will advance this program by taking the following steps:

1. Manufacture Oxypurinol and formulation in preparation for a bioequivalence study then pivotal phase 3 ‘registration’ clinical trial.
2. Submit a completed IND filing and conduct a bioequivalence/bioavailability study of XRx-101 in man.
3. Develop global partnerships with academic clinical trial centers with the goal of initiating an investigator led pilot phase 2 trial in the near future.
4. Submit the phase 3 pivotal trial protocol to demonstrate the effectiveness of uric acid lowering by XRx-101 in patients with COVID-19 infection and at risk of acute kidney injury and initiate this trial.
5. Submit NDA for approval to market XRx-101 for coronavirus COVID-19 infection associated with acute kidney injury.

## SUMMARY OF QUARTERLY RESULTS

The table below sets forth unaudited quarterly results prepared by management for the eight previous quarters to March 31, 2021:

(unaudited)	2021 Q1	2020 Q4	2020 Q3	2020 Q2
Accretion	-	-	-	425
Amortization of Intangible Assets	4,244	5,140	5,154	5,095
Foreign Exchange loss (gain)	387	7,006	42,230	90,907
Consulting	151,861	39,172	15,000	33,708
General and administrative	10,812	1,933	1,742	3,445
Interest	1,882	815	839	2,525
Investor Relations	204,874	109,973	52,848	40,081
Listing fees	14,553	15,510	10,802	14,063
Professional Fees	112,821	75,000	37,819	22,785
Research and Development	13,786	142,548	120,033	12,452
Share Based Payments <sup>2</sup>	202,990	6,748	90,443	189,524
Travel	2,100	-	-	-
Wages and Benefits	52,412	79,808	48,000	49,740
Forgiveness of debt	-	-	-	(91,014)
Transaction costs on derivative warrant	85,732	-	-	-
Loss on derivative warrant liability	1,315,000	-	-	-
Impairment of intangible assets	-	64,562	-	-
Recovery of provision for patent acquisition <sup>1</sup>	-	(95,490)	-	-
Total Comprehensive Loss	2,173,454	452,725	424,910	373,736
Loss per Share	(0.02)	(0.01)	(0.01)	(0.01)



(unaudited)	2020 Q1	2019 Q4	2019 Q3	2019 Q2
Accretion	421	420	415	406
Amortization of Intangible Assets	5,050	5,009	5,008	4,961
Foreign Exchange loss (gain)	(143,104)	10,126	(6,569)	5,651
Consulting	15,000	25,436	6,000	8,000
General and administrative	2,396	2,229	12,027	1,088
Interest	8,487	14,039	4,830	9,112
Investor Relations	38,275	14,707	5,346	3,385
Listing fees	11,763	8,776	10,479	14,870
Professional Fees	26,976	38,744	24,557	24,072
Research and Development	2,422	1,532	6,434	15,235
Share Based Payments	6,728	8,555	10,416	13,752
Travel	8,460	11,894	4,910	6,887
Wages and Benefits	50,357	48,000	48,000	48,000
Total Comprehensive Loss	33,231	189,467	131,853	155,419
Loss per Share	(0.00)	(0.00)	(0.00)	(0.00)

Note 1: The provision for patent acquisition relates to a patent rights acquisition of US\$75,000 paid in 2012. During the year ended December 31, 2020, the Company determined that the purchase was no longer feasible; therefore, the provision was reversed.

Note 2: Share based payments relate to the vesting of options over the period.

### Three months ended March 31, 2021

The Company incurred a comprehensive loss of \$2,173,454 (\$0.02 per share) for the three months ended March 31, 2021, compared to \$33,231 (\$0.00 per share) in the three months ended March 31, 2020.

Variances within the loss items are as follows:

**Consulting** - \$151,861 (2020 - \$15,000) – Consulting expenses increased during the three months ended March 31, 2021 as more consultants were engaged during 2021 due to an increase in Company activity with respect to corporate development upon competition of the financing.

**Investor relations** - \$204,874 (2020 - \$38,275) – Investor relations expenses increased in the three months ended March 31, 2021, as the result of hiring investor relations consultants and public relations firms for marketing campaigns before and after the financing.

**Professional fees** - \$112,821 (2020 - \$26,976). Professional fees for the three months ended March 31, 2021, due to increased legal fees related to the financing that was completed and work related to advancing the Company's products.

**Share-based payments** - \$202,990 (2020 - \$6,728) – The share-based payment expense increased in the three months ended March 31, 2021, as options granted in both the three month period and in 2020 vested over the period.

**Transaction costs on derivative warrant liability and loss on derivative warrant liability** - \$85,752 and \$1,315,000 respectively. These costs relate to the warrants issued as part of the common share units. The warrants are classified as a derivative financial liability as they contain a ratchet provision that provides for an adjustment in the exercise price of the original warrants if shares or securities convertible to shares are sold at a price lower than the exercise price. The warrants are initially recognized at fair value and subsequently measured at fair value with changes recognized through profit or loss. These are a non-cash item.

## Comparison of cash flows for the three months ended March 31, 2021

The Company realized a net cash inflow of \$5,872,474 for the three months ended March 31, 2021, compared to \$452,342 for the three months ended March 31, 2020. The variances in the cash flow for the three months ended March 31, 2021, compared to March 31, 2020, were as follows:

**Operating activities** – Cash used in operating activities for the three months ended March 31, 2021, was \$1,169,669 (2020 - \$1,986,137). The decrease of cash used of \$816,468 was primarily due to the contract payments of \$1,606,320 paid in the prior year quarter offset by an increase in net loss for the year.

**Investing activities** – Cash used in investing activities for the three months ended March 31, 2021, was \$186 (2020 - \$3,249). The cash used related to the acquisition of intangible assets during the period.

**Financing activities** – Cash provided by financing activities in the three months ended March 31, 2021, was \$7,042,329 (2020 - \$2,441,728). The cash provided was due primarily to the private placement that took place during the period raising gross proceeds of \$6,121,572 through the issuance of 24,486,286 units at a subscription price of \$0.25 per unit and upon exercise of the warrants.

## LIQUIDITY AND CAPITAL RESOURCES

As at March 31, 2021, the Company had a cash balance of \$6,043,745 and working capital of \$3,240,851 (on a cash basis the working capital was \$7,487,851 after adding back the non-cash derivative warrant liability in the amount of \$4,247,000, which will only be settled by issuing equity of the Company) as compared to a cash balance of \$171,271 and a working capital of \$1,021,928 as at December 31, 2020. During the year ended December 31, 2020, the Company closed a \$2,556,320 private placement and during the three months ended March 31, 2021, the Company closed a private placement with the issuance of 24,486,286 units at a subscription price of \$0.25 per unit for gross proceeds of \$6,121,572. The Company issued 4,111,313 common shares for the exercise of warrants in the amount of \$1,014,006. The Company's primary source of funding is by way of raising capital through the issuance of equity to third party investors. The Company believes that its current cash resources are sufficient for it to meet its existing monthly expenses, however additional funding to meet its obligations with regard to current outstanding accounts payable and for the Company to undertake its business plan will be required.

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, research activities will be postponed until market conditions improve. These circumstances and conditions may cast significant doubt about the Company's ability to continue as a going concern.

## COMMITMENTS

The Company has long-term arrangements with commitments as at March 31, 2021, and December 31, 2020 as follows:

	March 31 2021	December 31 2020
Management services – officers	\$ 192,000	\$ 192,000

The President and CEO of the Company has a long-term employment agreement. 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, 2021, equated to \$192,000.

## 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, 2021, the Company incurred the following transactions with related parties:

- a) Wages and benefits were accrued to an officer of the Company in the amount of \$52,412 (2020 - \$50,357).
- b) Professional fees were accrued to an officer of the Company in the amount of \$7,500 (2020 - \$7,500).
- c) Consulting fees were accrued to a director of the Company for fees in the amount of \$nil (2020 - \$9,000).
- d) As at March 31, 2021, \$5,650 (December 31, 2020 - \$52,450) was payable to the Chief Financial Officer (“CFO”) of the Company for CFO services, and \$6,780 (December 31, 2020 - \$20,340) was payable to a director of the Company for directors’ fees, and \$12,201 owing to the Chief Executive Officer (“CEO”) of the Company, for expense reimbursement. The balances are unsecured, non-interest bearing, and has no fixed terms of repayment.
- e) As at March 31, 2021, \$nil (December 31, 2020 - \$518,084) was accrued to the Chief Executive Officer (“CEO”) of the Company, for CEO services. The balance is unsecured, non-interest bearing and has no fixed terms of repayment.
- f) Management compensation transactions for the three months ended March 31, 2021 and 2020 are summarized as follows:

	Short-term employee benefits	Share-based payments	Total
	\$	\$	\$
Three months ended March 31, 2020			
Directors and officers	50,357	3,939	54,296
Three months ended March 31, 2021			
Directors and officers	<b>52,412</b>	<b>102,841</b>	<b>155,253</b>

## FINANCIAL AND CAPITAL RISK MANAGEMENT

The Company’s financial instruments consist of cash, accounts payable and accrued liabilities, and warrant liability (non cash). Cash is classified as a financial asset at FVTPL, accounts payable and accrued liabilities are classified as financial liabilities at amortized cost and warrant liability is classified as a financial liability at FVTPL.

The fair values of cash and accounts payable and accrued liabilities approximate their fair values at March 31, 2021, 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, 2020.

### Capital Management

The Company defines capital that it manages as 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:

<b>Equity is comprised of:</b>	<b>March 31 2021</b>	<b>December 31 2020</b>
	<b>\$</b>	<b>\$</b>
Share capital	12,278,312	8,258,395
Share-based payments and warrants reserve	1,372,011	1,003,609
Obligation to issue shares	32,238	32,238
Deficit	(10,211,452)	(8,037,998)

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. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

### OUTSTANDING SHARE DATA

As at May 31, 2021, the Company had the following shares outstanding:

- Class	Common Shares
- Authorized	Unlimited, without par value
- Issued and outstanding	110,076,717

### Options Outstanding:

The following table summarizes information on stock options outstanding as at May 31, 2021:

<b>Exercise Price</b>	<b>Number Outstanding</b>	<b>Expiry Date</b>
\$0.50	1,500,000	March 19, 2023
\$0.50	250,000	November 5, 2023
\$0.14	2,600,000	June 23, 2025
\$0.24	150,000	August 27, 2025
\$0.28	700,000	January 11, 2026
\$0.16	500,000	May 12, 2026

## Warrants Outstanding:

The following table summarizes information on outstanding warrants as at May 31, 2021:

<b>Exercise Price</b>	<b>Number Outstanding</b>	<b>Expiry date</b>
\$0.40	25,170,626	February 9, 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 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 conduct clinical trials, which may not conduct such trials with good laboratory practices; 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 favourable 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 favourable 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.

## **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.