#### XORTX THERAPEUTICS INC.

# Management Discussion and Analysis For the three months ended March 31, 2020

This management discussion and analysis of financial position and results of operations ("MD&A") is prepared as at June 1, 2020 and should be read in conjunction with the unaudited interim consolidated financial statements for the three months ended March 31, 2020 of XORTX Therapeutics Inc. (the "Company" or "XORTX"), together with the audited financial statements of the Company for the year ended December 31, 2019, 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.

# **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 listing statement, 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.

## **Business Overview**

XORTX is a bio-pharmaceutical company, dedicated to the development and commercialization of therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism in orphan disease. Clinical indications for these therapies include autosomal dominant polycystic kidney disease (ADPKD), type 2 diabetic nephropathy (T2DN) and more recently, the potential to treat acute kidney injury due to coronavirus COVID-19 infection. The Company's focus is on developing these therapeutic products to slow and/or reverse the progression of kidney disease in patients at risk of end stage kidney failure, and to address coronavirus COVID-19 induced acute kidney injury. The Company



continues to monitor scientific developments to identify other opportunities where the Company's intellectual property can be leveraged to address important health issues.

The primary development program for XORTX is at a late clinical stage and is focused on demonstrating the effectiveness and potential of a first-in-class therapy for ADPKD, an orphan disease. In addition, XORTX continues to evaluate new chemical entities for the treatment of T2DN.

The coronavirus COVID-19 treatment indication focuses on protecting kidney function when viral infection may lead to acute kidney injury, to protect kidney structure and function (see "Products" below).

## **Principal Products and Patents**

#### **Products**

The Company's most advanced development program, XRx-008 is at a late clinical stage program focused on demonstrating the potential of our first-in-class 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 acute kidney injury and associated health consequences. (see "Future Plans and Outlook" below). XORTX continues working with Teijin to develop, XRx-221, and with the exclusivity period having expired, the Company is also evaluating other candidate compounds for in-licensing to treat T2DN and chronic kidney disease. On March 19, 2019, the Company had entered into a non-binding letter of intent ("LOI") to co-develop TMX-049, a "next generation" xanthine oxidoreductase drug with Teijin Pharma Limited ("Teijin"). XORTX and Teijin recently co-announced positive phase 2a clinical trial results for TMX-049. The Company continues to evaluate TMX-049 and other clinical stage compounds for possible licensing relating to the T2DN indication.

#### **Patents**

XORTX has three 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, and four U.S. patent applications with similar claims for the treatment of metabolic syndrome, diabetes, fatty liver disease as well as a composition of matter patent for formulations of xanthine oxidase inhibitors. Counterparts for some of these patent applications have also been submitted in Europe, Japan, and other jurisdictions. Recently XORTX announced submission of a provisional patent application to cover the use of uric acid lowering agents for the treatment of the health consequences of coronavirus COVID-19 infection. Additional patents to expand and extend coverage of uric acid lowering agents are currently under preparation.



# **Recent Developments**

In March 2020, the outbreak of the novel strain of coronavirus, specifically identified as "COVID-19", 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 and weakness. The duration and impact of the COVID-19 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 XRx-101 (Oxypurinol) to treat respiratory and kidney disease injury related to patients infected with the coronavirus / COVID-19. To pursue this potential indication the Company is actively seeking the additional capital necessary to pursue this research program.

On February 28, 2020, the Company closed a 36,000,000 Unit Private Placement with the issuance of 18,259,427 Units for gross proceeds of \$2,556,319. Each Unit was priced at \$0.14 and comprised one common share and one common share purchase warrant exercisable at \$0.25 for a period of one year 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 ("CSE") is greater than \$0.35 for 10 or more consecutive trading days, the Company may notify the holder, by way of news release, that the warrants will expire on the 20<sup>th</sup> business day following the date of such notice, unless exercised by the holder before such date. The objective of this funding round is to advance ADPKD program toward a phase 3 registration trial in ADPKD. In addition, current events have unfolded such that there is now a compelling opportunity to develop XRx-101 for the treatment of coronavirus / COVID-19 infection to suppress the severity of symptoms.

# **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 program to a pharmaceutical partner company.

Second, XORTX is developing XRx-101 for coronavirus / COVID-19 infection as a therapeutic treatment to suppress virus, symptoms and protect kidneys from acute failure. 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 negotiate with Teijin and is also evaluating licensing of other candidate compounds 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 (Han et al, 2015). Recent, successful clinical trials and associated data shows the benefit of lowering uric acid levels in progressive kidney disease and accumulating recently published positive clinical trial results 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 thee 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 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 is finalized or in the early stages of recruiting the phase 3 trial. The Company will seek to undertake the phase 3 trial under SPA.



## **Summary of Quarterly Results**

The table below sets forth unaudited quarterly results prepared by management for the eight previous quarters to March 31, 2020:

(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 (gain) loss	(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)
(unaudited)	2019 Q1	2018 Q4	2018 Q3	2018 Q2
Accretion	397	401	397	462
Amortization of Intangible Assets	4,922	4,922	4,873	4,760
Foreign Exchange loss (gain)	17,189	(27,051)	9,192	(10,239)
Consulting	7,125	6,000	12,720	43,569
General and administrative	2,000	5,208	2,491	479
Interest	7,595	7,011	3,262	7,673
Investor Relations	11,344	8,836	10,807	1,139
Listing fees	8,370	9,010	8,372	15,052
Professional Fees	21,054	22,414	19,593	13,050
Research and Development	16,696	20,175	137,921	121,953
Share Based Payments	(6,406)	8,652	18,983	24,904
Travel	12,385	4,478	30,214	3,730
Wages and Benefits	50,166	46,904	48,000	48,347
Charge related to public company listing	-	30,503	-	-
Total Comprehensive Loss	152,837	147,463	306,825	274,879
Loss per Share	(0.00)	(0.00)	(0.00)	(0.00)

The majority of the expenses are fairly consistent over the past eight quarters. Expenses that have fluctuated include foreign exchange gain, research and development expenses and charge related to public company listing as further explained below:

Foreign Exchange (gain) loss - The Company incurred a foreign exchange gain of \$143,104 during Q1 2020 primarily relating the impact of exchange rate movement on the deposits paid in USD to both Cato Research Canada Inc. ("Cato") and Prevail Partners LLC.

Research and Development - Due to funding constraints, Research and development expenses have decreased over the majority of the last eight quarters, however with a financing having been completed in Q1 2020, it is anticipated that Research and development expenses will increase.

Charge related to public company listing – This expense relates to the reverse takeover transaction with APAC Resources Inc. ("APAC") on January 10, 2018.



#### Three months ended March 31, 2020

The Company incurred a comprehensive loss of \$33,231 (\$0.00 per share) for the three months ended March 31, 2020 compared to \$152,837 (\$0.00 per share) in the three months ended March 31, 2019. Variances within the loss items are as follows:

Foreign exchange gain/loss –The Company incurred a gain of \$143,104 (2019 – loss of \$17,189) primarily relating the impact of exchange rate movement on the USD denominated deposits currently held with both Cato Research Canada Inc. ("Cato") and Prevail Partners LLC. During the three months ended March 31, 2020 the Canadian dollar weakened against the US dollar with the foreign exchange rate changing from 1.2988 CAD: 1 USD at December 31, 2019 to 1.4187 CAD: 1 USD at March 31, 2020. During the prior period quarter, the Canadian dollar strengthened from 1.3642 CAD: 1 USD at December 31, 2018 to 1.3363 CAD: 1 USD at March 31, 2019.

Consulting - \$15,000 (2019 - \$7,125) – Consulting expenses increased during the three months ended March 31, 2020 due to an increase in consultants used in the quarter.

*Investor relations*- \$38,275 (2019 - \$11,344) – Investor relations expenses increased in Q1 2020 as the Company had representatives actively seeking investment into the Company leading up to the private placement in Q1 2020.

*Professional fees* - \$26,976 (2019 - \$21,054). Professional fees for the period increased due to increased accounting and audit fees.

Research and development - \$2,422 (2019 - \$16,696) – Research and development expenses decreased during the first quarter of 2020 as less research work was performed.

#### Comparison of cash flows for the years ended March 31, 2020 and 2019

The Company realized a net cash inflow of \$452,342 for the three months ended March 31, 2020 compared to a net cash outflow of \$117,251 for the three months ended March 31, 2019. The variances in the cash flow for the three months ended March 31, 2020 and 2019 were as follows:

Operating activities – Cash used in operating activities for the three months ended March 31, 2020 was \$1,986,137 (2019 - \$117,251). The increased use of cash was primarily due to an increase from a deposit by Prevail Partners LLC, who have agreed to support two clinical trials. This deposit of \$1,606,320 was funded during the period through the issuance of units to Prevail Partners LLC as part of the private placement (US\$1,200,000 at the exchange rate on date of the transaction).

*Investing activities* – Cash used in investing activities for the three months ended March 31, 2020 was \$3,249 (2019 - \$nil). 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, 2020 was \$2,441,728 (2019 - \$nil). The cash provided was due primarily to the private placement that took place during the period raising gross proceeds of \$2,556,320 through the issuance of 18,259,427 units (the "Units"), at a price of \$0.14 per Unit. As at December 31, 2019, \$70,000 of the cash proceeds were received and recorded as share subscriptions received in advance and funds held in trust by the Company's lawyer.



# **Liquidity and Capital Resources**

As at March 31, 2020, the Company had a cash balance of \$510,956 and working capital of \$1,917,734 as compared to a cash balance of \$58,614 and a working capital deficiency of \$484,450 as at December 31, 2019. During the period, the Company closed a private placement, see "Recent Developments". The Company's primary source of funding is by way of raising capital through the issuance of equity to third party investors. Given the nature of the Company's low monthly expenses and that favorable repayment agreements relating to existing outstanding accounts payable, including that \$541,660 of the existing accounts payable and accrued liability balances are due to related parties, the Company believes that its current cash resources are sufficient for it to meet its existing cash monthly operating expenses. However additional funding is required to meet its obligations with regard to current outstanding accounts payable and for the Company to undertake its business plan.

Although there is no certainty, management is of the opinion that additional funding for its projects and operations can be obtained and is actively seeking new equity investment as well as grant funding for its projects. 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 (see "Risks Related to the Business" below). 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, 2020 and December 31, 2019 as follows:

	March 31	December 31
	2020	2019
	\$	\$
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, 2020 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, 2020 and 2019, the Company incurred the following transactions with related parties:

- a) Wages and benefits were paid or accrued to Allen Davidoff, the Chief Executive Officer of the Company for CEO services in the amount of \$50,357 (2019 \$50,166).
- b) Professional fees were paid or accrued to of Jim Fairbairn, the Chief Financial Officer of the Company related to CFO services in the amount of \$7,500 (2019 \$7,500).
- c) Consulting fees were paid or accrued to Bruce Rowlands, a director of the Company for other services in the amount of \$9,000 (2019 \$nil).
- d) As at March 31, 2020, \$48,025 (December 31, 2019 \$39,550) was payable to Jim Fairbairn, the Chief Financial Officer of the Company for CFO services, and \$10,170 (December 31, 2018 \$nil) was payable to Bruce Rowlands, a director of the Company for other services. The balance is unsecured, non-interest bearing, and has no fixed terms of repayment.
- e) As at March 31, 2020, \$468,110 (December 31, 2019 \$502,110) has accrued to Allen Davidoff, the Chief Executive Officer of the Company, for CEO services, which amount is unsecured, non-interest bearing and has no fixed terms of repayments.
- f) Management compensation transactions for the three months ended March 31, 2020 and 2019 are summarized as follows:

	Short-term employee benefits	Share-based payments	Total
Three months ended March 31, 2019	\$	\$	\$
Directors and officers	50,166	10,475	60,641
Three months ended March 31, 2020 Directors and officers	50,357	3,939	54,296

# **Financial and Capital Risk Management**

The Company's financial instruments consist of cash, accounts payable and accrued liabilities, and the liability component on convertible loans. These financial instruments are classified as financial assets at FVTPL and financial liabilities at amortized cost. The fair values of these financial instruments approximate their carrying values at March 31, 2020, 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, 2019.



# **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:

Equity is comprised of:	March 31 2020	December 31 2019
	\$	\$
Share capital	8,349,692	5,863,872
Share-based payments and warrants reserve	625,597	607,803
Share subscriptions received in advance	-	70,000
Equity component on convertible loans	5,202	5,202
Deficit	(6,791,829)	(6,758,598)

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 June 1, 2020, the Company had the following shares outstanding:

- Class- Authorized- AuthorizedClass A Common Shares- Unlimited, without par value

- Issued and outstanding 81,179,118

#### **Options Outstanding:**

The following table summarizes information on stock options outstanding at June 1, 2020:

Exercise Price	Number Outstanding	Expiry Date	
\$0.50	1,750,000	March 19, 2023	
\$0.50	150,000	October 9, 2023	
\$0.50	250,000	November 5, 2023	

## **Warrants Outstanding:**

The following table summarizes information on outstanding warrants as at June 1, 2020:

Exercise Price	Number Outstanding	Expiry date	
\$0.25	18,259,427	February 28, 2021	
\$0.14	139,657	February 28, 2021	



#### **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.

#### Access to Further Funding

Funding continues to be difficult to access and the ability of the Company to continue as a going concern, realize its assets and discharge its liabilities in the normal course of business and continue with, or expand upon its development programs is contingent upon securing additional financing. The timing and availability of additional financing will be determined largely by market conditions, legal restrictions, and the results of the Company's ongoing programs. There is no certainty that the Company will be able to raise funds as they are required in the future. The Company's consolidated financial statements do not give effect to adjustments that would be necessary to the carrying values and classification of assets, liabilities and reported expenses should the Company be unable to continue as a going concern. These adjustments could be material.



## 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; licensing or import/export restrictions for cannabinoid-based pharmaceuticals; 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. If Dr. Davidoff were to leave the Company or were otherwise unable to perform his duties, the Company's business may fail and shareholders may lose their investment.

#### COVID-19

In March 2020, the outbreak of the novel strain of coronavirus, specifically identified as "COVID-19", 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 and weakness. The duration and impact of the COVID-19 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.

# **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.

