UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of April 2022

Commission File Number: 001-40858

XORTX Therapeutics Inc.

Suite 2400 - 745 Thurlow Street, Vancouver, British Columbia, Canada, V6E 0C5

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XORTX THERAPEUTICS INC.
(Registrant)

Date: April 12, 2022

By: */s/ Allen Davidoff*
Name: Allen Davidoff
Title: Chief Executive Officer

EXHIBIT INDEX

99.1	Amended and Restated Annual Information Form for the year ended December 31, 2021
99.2	Form 52-109F1R – CEO Certification of Refiled Annual Information Form
99.3	Form 52-109F1R – CFO Certification of Refiled Annual Information Form

XORTX THERAPEUTICS INC.

AMENDED AND RESTATED ANNUAL INFORMATION FORM

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2021

APRIL 12, 2022

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XORTX THERAPEUTICS INC.

ANNUAL INFORMATION FORM

REFERENCE INFORMATION

In this annual information form (the "**AIF**"), a reference to the "Company", "XORTX", "we", "us", "our" and similar words refer to XORTX Therapeutics Inc. and its subsidiaries or any one of them as the context requires.

All references herein to "dollars" and "$" are to Canadian dollars, unless otherwise indicated.

Unless otherwise stated, the information set forth in this AIF is as of December 31, 2021.

CAUTION REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this AIF constitute forward-looking statements. These statements relate to future events or the Company's (as defined herein) future performance. All statements other than statements of historical fact are forward-looking statements. The use of any of the words "anticipate", "plan", "contemplate", "continue", "estimate", "expect", "intend", "propose", "might", "may", "will", "shall", "project", "should", "could", "would", "believe", "predict", "forecast", "pursue", "potential" and "capable" and similar expressions are intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause actual results or events to differ materially from those anticipated in such forward-looking statements. No assurance can be given that these expectations will prove to be correct and such forward-looking statements included in this AIF should not be unduly relied upon. These statements speak only as of the date of this AIF. In addition, this AIF may contain forward-looking statements and forward-looking information attributed to third party industry sources.

In particular, forward-looking statements in this AIF include, but are not limited to, 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 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.

All forward-looking statements, including, without limitation, our examination of historical operating trends, are based upon our current expectations and various assumptions. Certain assumptions made in preparing the forward-looking statements include:

- the availability of capital to fund planned expenditures;
- prevailing regulatory, tax and environmental laws and regulations;
- the ability to secure necessary personnel, equipment, supplies and services;
- our ability to manage our growth effectively;
- the absence of material adverse changes in our industry or the global economy;
- trends in our industry and markets;
- our ability to maintain good business relationships with our strategic partners;
- our ability to comply with current and future regulatory standards;
- our ability to protect our intellectual property rights;
- our continued compliance with third-party license terms and the non-infringement of third-party intellectual property rights;
- our ability to manage and integrate acquisitions; and
- our ability to raise sufficient debt or equity financing to support our continued growth.

We believe there is a reasonable basis for our expectations and beliefs, but they are inherently uncertain. We may not realize our expectations, and our beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements. The following uncertainties and factors, among others (including those set forth under "Risk Factors"), could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements:

- our ability to obtain regulatory approval for our product candidates without significant delays;
- the predictive value of our current or planned clinical trials;
- delays with respect to the development and commercialization of our product candidates, which may cause increased costs or delay receipt of product revenue;
- our ability to enroll subjects in clinical trials and thereby complete trials on a timely basis;
- the design or our execution of clinical trials may not support regulatory approval;
- the potential for our product candidates to have undesirable side effects;

- our ability to face significant competition;
- no regulatory agency has made a determination that any of our product candidates are safe or effective for use by the general public or for any indication;
- the competitive threat of generic or other follow-on products;
- the likelihood of broad market acceptance of our product candidates;
- our ability to obtain Orphan Drug Designation or exclusivity for some or all of our product candidates;
- our ability to commercialize products outside of the United States;
- the outcome of reimbursement decisions by third-party payors relating to our products;
- our expectations with respect to the market opportunities for any product candidate that we or our strategic partners develop;
- our ability to pursue product candidates that may be profitable or have a high likelihood of success;
- our ability to use and expand our therapeutic platforms to build a pipeline of product candidates;
- our ability to meet the requirements of ongoing regulatory review;
- the threat of product liability lawsuits against us or any of our strategic partners;
- changes in product candidate manufacturing or formulation that may result in additional costs or delay;
- the potential disruption of our business and dilution of our shareholdings associated with acquisitions and joint ventures;
- the potential for foreign governments to impose strict price controls;
- the risk of security breaches or data loss, which could compromise sensitive business or health information;
- current and future legislation that may increase the difficulty and cost of commercializing our product candidates;
- economic, political, regulatory and other risks associated with international operations;
- our exposure to legal and reputational penalties as a result of any of our current and future relationships with various third parties;
- our ability to comply with export control and import laws and regulations;
- our history of significant losses since inception;
- our ability to generate revenue from product sales and achieve profitability;
- our requirement for substantial additional funding;
- the potential dilution to our shareholders associated with future financings;
- unstable market and economic conditions;

- currency fluctuations and changes in foreign currency exchange rates;
- restrictions on our ability to seek financing, which may be imposed by future debt providers;
- our ability to maintain existing and future strategic partnerships;
- our ability to realize the anticipated benefits of our strategic partnerships;
- our ability to secure future strategic partners;
- our intention to rely on third-party manufacturers to produce our clinical product candidate supplies;
- our reliance on third parties to oversee clinical trials of our product candidates and, in some cases, maintain regulatory files for those product candidates;
- our reliance on the performance of independent clinical investigators and CROs;
- our reliance on third parties for various operational and administrative aspects of our business including our reliance on third parties' cloud-based software platforms;
- our ability to operate without infringing the patents and other proprietary rights of third parties;

- our ability to obtain and enforce patent protection for our product candidates and related technology;
- we may be unable to obtain an orphan drug designation in one or more jurisdictions;
- our patents could be found invalid or unenforceable if challenged;
- our intellectual property rights may not necessarily provide us with competitive advantages;
- we may become involved in expensive and time consuming patent lawsuits;
- we may be unable to protect the confidentiality of our proprietary information;
- the risk that the duration of our patents will not adequately protect our competitive position;
- our ability to obtain protection under the Hatch-Waxman Amendments and similar foreign legislation;
- our ability to comply with procedural and administrative requirements relating to our patents;
- the risk of claims challenging the inventorship of our patents and other intellectual property;
- our intellectual property rights for some of our product candidates are dependent on the abilities of third parties to assert and defend such rights;
- patent reform legislation and court decisions can diminish the value of patents in general, thereby impairing our ability to protect our product candidates;
- we may not be able to protect our intellectual property rights throughout the world;
- we will require US Food and Drug Administration ("**FDA**") approval for any proposed product candidate names and any failure or delay associated with such approval may adversely affect our business;
- the risk of employee misconduct including noncompliance with regulatory standards and insider trading;

- our ability to market our products in a manner that does not violate the law and subject us to civil or criminal penalties;
- if we do not comply with law regulating the protection of the environment and health and human safety, our business could be adversely affected;
- we risk losing our "foreign private issuer" status;
- our ability to retain key executives and attract and retain qualified personnel; and
- our ability to manage organizational growth.

Consequently, forward-looking statements should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. We do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events, except as required by law.

CORPORATE STRUCTURE

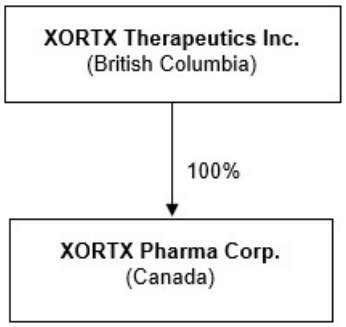
The Company was incorporated to carry on business under the *Business Corporations Act* (British Columbia) (the "**BCBCA**") as "APAC Resources Inc." on May 31, 2011 and with registration number BC0911882.

ReVasCor, Inc. was incorporated under the laws of Alberta, Canada on August 24, 2012 and was continued under the Canada Business Corporations Act on February 27, 2013 under the name of XORTX Pharma Corp. ("**XORTX Pharma**").

XORTX Pharma completed a reverse take-over transaction on January 10, 2018 (the "**RTO**") with the Company. As part of this transaction, the Company changed its name to its current name: "XORTX Therapeutics Inc.". XORTX Pharma remains as the wholly owned subsidiary of the Company.

Our registered office is located at Suite 4000, 421 – 7th Avenue SW, Calgary, Alberta, Canada T2P 4K9 and our telephone number is (403) 455-7727. Our website address is www.xortx.com. The information contained on, or that can be accessed through, our website is not a part of this AIF. We have included our website address in this AIF solely as an inactive textual reference.

The Company has one wholly owned subsidiary called XORTX Pharma Corp. Our organizational chart is below:



GENERAL DEVELOPMENT OF THE BUSINESS

Recent Developments

Since January 1, 2022, the Company, as a clinical-stage biotechnology company, has continued its focus of 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**");
- larger, more prevalent type 2 diabetic nephropathy ("**T2DN**"); and
- acute kidney injury ("**AKI**") due to coronavirus infection.

On January 20, 2022, the Company announced the appointment of Dr. David MacDonald as Chief Technology Officer.

On January 31, 2022, XORTX announced that in 2022, XORTX is focused on advancing XRx-008 into a clinical trial, and will pursue the submission of an Orphan Drug Designation, the initiation of special protocol assessment discussions with the FDA and will continue formulation development for other kidney disease applications.

On March 14, 2022, the Company announced that it submitted a clinical trial application with Health Canada for a XRX-OXY-101 bridging pharmacokinetics study. This study is a three-part, single-dose, fed or fasted, then, multi-dose crossover comparative bioavailability and pharmacokinetic study in healthy volunteers. It is designed to permit XORTX to characterize the safety and relative bioavailability of the XRx-008 formulation. Knowledge gained during the conduct of this trial will provide guidance regarding the oral dose of XRx-008 for our planned registration trial in ADPKD. Additionally, this study will provide data to support future New Drug Application (" **NDA**") submissions to the FDA and the European Medicines Agency ("**EMA**"). This study is planned to start in the second quarter of 2022.

On March 23, 2022, XORTX announced the submission of a Patent Cooperation Treaty ("**PCT**") patent application seeking international patent protection for the patent entitled "Compositions and Methods for Enhancing Anti-Viral Therapies". This patent is based on retrospective clinical data from XORTX's scientific partners suggesting that an important therapeutic opportunity lies with addressing aberrant purine metabolism combined with hyperuricemia in patients most at risk to severe COVID-19 outcome.

On March 31, 2022, the Company announced the filing of an investigational new drug ("**IND**") application with the FDA. This IND filing is in support of the Company's XRx-008 program for treatment of progressing kidney disease due to ADPKD and contains the protocol for the above referenced bridging pharmacokinetics study for XRX-OXY-101.

On April 7, 2022, XORTX announced receipt of notification that the patent "Formulations of Xanthine Oxidase Inhibitors" will be granted by the United States Patent Office ("**USPTO**"). The patent covers compositions for, and methods of using, XORTX's proprietary formulations of xanthine oxidase inhibitors for renal and other diseases where aberrant purine metabolism and chronically high serum uric acid has been implicated in disease progression.

On April 12, 2022, the Company announced receipt of a no objection letter from Health Canada regarding the Company's upcoming XRX-OXY101 clinical bridging pharmacokinetics study referenced above.

For the balance of 2022, the Company anticipates a number of further advancements and changes in its business as it pursues its business objectives. To achieve its objectives, XORTX's action plan includes:

1. **Initiate and Complete the XRX-OXY-101 Bridging Study.** As referenced above, this study is a three-part, single-dose, fed or fasted, then, multi-dose crossover comparative bioavailability and pharmacokinetic study in healthy volunteers. It is designed to permit XORTX to characterize the safety and relative bioavailability of the XRx-008 formulation. Knowledge gained during the conduct of this trial will provide guidance regarding the oral dose of XRx-008 for our planned registration trial in ADPKD. Additionally, this study will provide data to support future NDA submissions to the FDA and EMA, and is planned to start in the second quarter of 2022.

2. **Initiate the XRX-OXY-102 Bridging Study.** This study is a multi-dose crossover comparative bioavailability and pharmacokinetic study in healthy volunteers. It is designed to permit XORTX to characterize the safety and relative bioavailability of the XRx-101 formulation options. Knowledge gained during the conduct of this trial will provide guidance regarding the oral dose of XRx-101 for future clinical and commercial planning. Additionally, this study will provide data to support future NDA submissions to the FDA and EMA. This study is planned to start in the second quarter of 2022.

3. **Complete Orphan Drug Designation Filing.** Current research being conducted will be used to file for orphan drug designation in 2022.

4. **Commence XRX-OXY-301 Registration Trial in ADPKD.** XRX-OXY-301 is a multi-site, multi-national, placebo controlled, study in ADPKD patients with progressing stage 2 or 3 kidney disease. The objective of this study is to evaluate the safety and effectiveness of XRx-008 over a 24-month period and study the ability of xanthine oxidase inhibition to decrease the rate of decline of glomerular filtration rate. An estimated 300 patients will be enrolled. This study is planned to start in the second half of 2022, subject to SPA negotiations with the FDA.

5. **Ongoing CMC Work.** In parallel to the XRX-OXY-101 and XRX-OXY-102 studies, XORTX will be focused on performing the necessary scale-up, process validation and stability as part of the CMC requirements for the filing of the Investigative New Drug ("**IND**"), as well as future clinical and commercial supplies. All development will be performed according to current GMP methodology. This work will be ongoing throughout 2022 and 2023.

6. **Preparation of 505(b)(2) IND.** In parallel with initiation of XRX-OXY-101 a 505(b)2 based IND is expected to be submitted in the first half of 2022 for the XRx-008 program.

7. **Activities Related to Potential Commercial Launch.** In preparation for a possible NDA filing in 2025 in the U.S. for XRx-008, XORTX is planning to conduct additional commercialization studies, including nephrologist, patient, payer, pricing and/or reimbursement studies, as well as product brand name selection and filings, and plans for launch. This work will be ongoing from 2022 to 2025.

8. **Activities Related to European Registration.** XORTX intends to obtain guidance from the European Union for path to approval in the European Union, including required clinical studies and reimbursement conditions. This work will be ongoing from 2022 to 2025.

To achieve the above goals, XORTX will continue to pursue non-dilutive and dilutive funding and expand discussions to partner with a major pharma / biotech companies with a global reach. XORTX will also increase financial and healthcare conference participation to further strengthen and expand our investor base.

Three Year History

The three year history of the Company and its business are outlined below:

2019

Letter of Intent with Teijin Pharma Limited

On March 11, 2019, the Company signed a non-binding letter of intent with Teijin Pharma Limited from Japan for the exclusive global rights (excluding Japan) to develop TMX-049, a new generation of xanthine oxidoreductase inhibitor, for the treatment of progressive kidney disease. Discussions to complete a definitive agreement ensued but, as of the date of this AIF, no definitive agreement has been entered into.

2020

Private Placement

On February 28, 2020, the Company closed a first tranche of a 3,066,439 Unit private placement with the issuance of 1,555,317 Units for gross proceeds of $900,000 in cash and $50,000 on the conversion of certain payables into Units (while $1,606,320 in Units were issued in exchange for services to be provided). Each Unit was priced at $1.64 and comprised one common share and one common share purchase warrant exercisable at $2.94 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 TSXV is greater than $4.11 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 20th business day following the date of such notice, unless exercised by the holder before such date. The objective of this funding round was to advance ADPKD program toward a phase 3 registration trial in ADPKD. Please note that the details above have been adjusted to reflect the Share Consolidation referenced below under "***2021***".

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 and on March 15, 2021, a PCT application claiming priority to said provisional application covering the potential use of any uric acid lowering agent, and more specifically a xanthine oxidase inhibitor in the form of its XRx-101 product candidate to treat acute kidney injury related in patients infected with COVID-19.

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 provider of integrated healthcare solutions.

Partnership with Icahn School of Medicine at Mount Sinai in New York

On November 16, 2020, the Company announced the topline results from the Company's partnership with the Icahn School of Medicine at Mount Sinai in New York. 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.

December 2020 Notification from European Patent Office

On December 8, 2020, the Company received 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 inhibitors for renal and other diseases where aberrant purine metabolism has been implicated in disease progression.

2021

Private Placement

On February 9, 2021, the Company issued 2,085,687 units in a private placement offering at a subscription price of $2.94 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 $4.70, for a period of 5 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 TSX Venture Exchange (the "**TSXV**") is greater than $14.09 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 February 9, 2021, private placement, the Company paid $171,085 in cash commissions and issued 58,291 finder's warrants. Each finder's warrant is exercisable into one common share at a price of $4.70 and having the same expiry, acceleration and anti-dilution provisions as the warrants included in the private placement.

Please note that the details above have been adjusted to reflect the Share Consolidation referenced below under "***2021***".

United States Initial Public Offering

On October 15, 2021, the Company announced the closing of an underwritten public offering of 2,906,000 units, with each unit consisting of one common share, no par value, and one warrant to purchase one common share at a public offering price of US$4.13 per unit, for aggregate gross proceeds of approximately US$12,000,000, prior to deducting underwriting discounts and other offering expenses (the "**US Offering**"). The warrants have an initial exercise price of US$4.77 per share, are immediately exercisable, and have a term of approximately five years. In addition, the Company granted the underwriters a 45-day option to purchase up to an additional 435,900 common shares and/or warrants to purchase up to an additional 435,900 common shares at the US Offering price less the underwriting discounts. On October 15, 2021, the underwriters exercised its option to purchase additional warrants to purchase up to an additional 435,900 common shares. On November 9, 2021, the Company announced that it had issued an additional

355,000 common shares at the US Offering price resulting in additional gross proceeds of approximately US$1.47 million pursuant to the partial exercise of the underwriters' over-allotment option, before deducting underwriting discounts and commissions.

In connection with the US Offering, the Company received conditional approval to list its common shares on the Nasdaq under the symbol "XRTX" on October 13, 2021. The Company's common shares began to trade on the Nasdaq on October 15, 2021. In order to qualify for listing on Nasdaq, the Company completed a consolidation of its shares on a one (1) post-consolidated share for 11.74 pre-consolidated shares basis which took effect on September 23, 2021 (the "**Share Consolidation**").

Changes in Officers, Directors and Advisory Board Members

On May 12, 2021, William Farley was appointed to the Board of Directors of the Company.

On June 16, 2021, Jacqueline Le Saux was appointed to the Board of Directors to replace Allan Williams who resigned effective that date.

On July 1, 2021, Stephen Haworth was appointed as the Chief Medical Officer of the Company.

On July 14, 2021, Amar Keshri was appointed as Chief Financial Officer to replace James Fairbairn.

On August 31, 2021, the Company announced the appointment of Dr. Charles Edelstein to the Company's clinical advisor board.

On December 20, 2021, Raymond Pratt was elected to, and Bruce Rowlands retired from, the Board of Directors of the Company.

DESCRIPTION OF THE BUSINESS

General

XORTX 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 ADPKD and T2DN, as well as AKI due to coronavirus infection.

Our focus is on developing three therapeutic products to:

- slow or reverse the progression of chronic kidney disease in patients at risk of end stage kidney failure;
- address the immediate need of individuals facing coronavirus induced AKI; and
- identify other opportunities where our existing and new intellectual property can be leveraged to address health issues.

We believe that our technology is underpinned by research and insights into the underlying biology of aberrant purine metabolism, its health consequences and of oxypurinol, a uric acid lowering agent that works by effectively inhibiting xanthine oxidase. We are developing innovative therapeutic products that include new or existing drugs that can be adapted to address different disease indications where aberrant purine metabolism and/or elevated uric acid is a common denominator, including polycystic kidney disease, pre-diabetes, insulin resistance, metabolic syndrome, diabetes, diabetic nephropathy, and infection. 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 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 program for the treatment of ADPKD;
- **XRx-101**, a program to treat AKI associated with Coronavirus/ COVID-19 infection, AKI and associated health consequences; and
- **XRx-225**, a program for the treatment of T2DN.

At XORTX, we aim to redefine the treatment of kidney diseases by developing medications to improve the quality-of-life of patients with life threatening diseases by modulating aberrant purine and uric acid metabolism, including lowering elevated uric acid as a therapy.

Our Proprietary Therapeutic Platforms

Our expertise and understanding of the pathological effects of aberrant purine metabolism combined with our understanding of uric acid lowering agent structure and function, has enabled the development of our proprietary therapeutic platforms. These are a complementary suite of therapeutic formulations 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 a competitive advantage to our therapeutic platforms and are ultimately reflected in our programs. Some of these key advantages are:

Highly Modular and Customizable

Our platforms can be combined in multiple ways and this synergy can be applied to address acute, intermittent or chronic disease progression. For example, our XRx-101 program for acute kidney injury is designed to produce rapid suppression of hyperuricemia then maintain purine metabolism at a low level during viral infection and target management of acute organ injury. Our XRx-008 program is designed for longer term stable chronic oral dosing of xanthine oxidase inhibitors. The capabilities of our formulation technology allow us to manage the unique challenges of cardiovascular and renal disease by modulating, purine metabolism, inflammatory and oxidative state.

Fit-for-purpose

Our platforms can also be utilized to engineer new chemical entities and formulations of those agents that have enhanced properties. For example, our XRx-225 product

candidate program, some of the intellectual property for which we license from third parties, represents a potential new class of xanthine oxidase inhibitor with a targeted design to enhance anti-inflammatory activity. The capability of tailoring the therapeutic benefit of this class of new agents permits us to identify targets and disease that we wish to exploit and then through formulation design optimize those small molecules and proprietary formulations to maximize clinically meaningful therapeutic effect.

Readily scalable and transferable

Our in-house small molecule and formulations design expertise is positioned to create a steady succession of product candidates that are scalable, efficient to manufacture (by us or a partner or contract manufacturing organization), and produce high production and high purity active pharmaceutical drug product. We believe this will provide a competitive advantage, new intellectual property and opportunity to provide first-in-class products that target unmet medical needs and clinically meaningful quality of life.

Our team's expertise in uric acid lowering agents, specifically in the development and use of xanthine oxidase inhibitors, has enabled the development of our therapeutic product candidates to treat the symptoms of, and potentially delay the progression of ADPKD, AKI due to COVID-19 infection, and T2DN. There is no guarantee that the FDA will approve our proposed uric acid lowering agent products for the treatment of kidney disease or the health consequences of diabetes.

Product Candidate Pipeline

Our lead product candidates are XRx-008, XRx-101, and XRx-225. 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 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 with associated AKI.

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 two U.S. granted patents with claims to the use of all uric acid lowering agents to treat insulin resistance or diabetic nephropathy, and two U.S. patent applications with similar claims for the treatment of metabolic syndrome, diabetes, and fatty liver disease. Counterparts for some of these patent applications have also been submitted in Europe. In both the US and Europe, XORTX owns composition of matter patent applications for unique proprietary formulations of xanthine oxidase inhibitors, and the European patent application has been granted. XORTX has also submitted two patent applications to cover the use of uric acid lowering agents for the treatment of the health consequences of coronavirus.

RISK FACTORS

Following is a list of risks that the Company faces in its normal course of business. The risks and uncertainties set out below are not the only ones the Company is facing. There are additional risks and uncertainties that the Company does not currently know about or that the Company currently considers immaterial which may also impair the Company's business operations and cause the price of the common shares of the Company to decline. If any of the following risks actually occur, the Company's business may be harmed and the Company's financial condition and results of operations may suffer significantly.

Investors should carefully consider the risk factors set out below and consider all other information contained herein and in the Company's other public filings before making an investment decision. The risks set out below are not an exhaustive list and should not be taken as a complete summary or description of all the risks associated with the Company's business and the biotechnology business generally.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.

We are a clinical-stage biotechnology company. We have incurred significant losses since our inception. Our net losses for the years ended December 31, 2019, 2020 and 2021 were $629,576, $1,284,602 and $1,652,282, respectively. As of December 31, 2021, our accumulated deficit was approximately $9,690,280. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. For example, our expenses could increase if we are required by the FDA to perform trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates.

To become and remain profitable, we must succeed in developing and commercializing product candidates with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including developing product candidates, obtaining regulatory approval for such product candidates, and manufacturing, marketing and selling those product candidates for which we may obtain regulatory approval. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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 are currently advancing two of our product candidates through preclinical and clinical development as well as other potential product candidates through discovery. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to

conduct clinical trials for each indication for each of our product candidates. We will continue to require additional funding to complete the development and commercialization of our product candidates and to continue to advance the development of our other product candidates and such funding may not be available on acceptable terms or at all.

Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we believe that the net proceeds from the US Offering, together with our existing cash and cash equivalents will enable us to advance the clinical development of XRx-008, XRx-101 and XRx-225 product candidates. 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 research and development and to commercialize our product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

- the number and characteristics of other product candidates that we pursue;
- the scope, progress, timing, cost and results of research, preclinical development, and clinical trials;
- the costs, timing, requirements and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing our product candidates and establishing sales, marketing and distribution capabilities;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing strategic partnerships, and any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through a combination of public and private equity offerings. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our development programs or our business operations.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish substantial rights.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the Company's capital structure will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of common shareholders. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through partnerships, collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.

Global credit and financial markets experienced extreme disruptions at various points over the last decade, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current strategic partners, service providers, manufacturers and other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

We have not generated any revenue to date and may never be profitable.

We have devoted substantially all of our financial resources and efforts to developing our proprietary pipeline-in-a-product, strategy identifying potential product candidates and conducting preclinical studies and preparing for clinical trials. We and our partners are still in the early stages of developing our product candidates, and we have not completed development of any products. Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue. We do not expect to generate significant product revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. While the XRx-008 and XRx-101 product candidate programs are advancing towards Phase 3 clinical trials, these programs will require additional preclinical studies or clinical development as well as regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We face significant development risk as our product candidates advance further through clinical development. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our preclinical studies and our current and future clinical trials, which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to complete IND-enabling studies and successfully submit INDs or comparable applications to allow us to initiate clinical trials for our current or any future product candidates;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities the safety, efficacy, and acceptable risk-to-benefit profile of our product

candidates or any future product candidates;

- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA or similar foreign regulatory authorities;
- the willingness of physicians and patients to utilize or adopt any of our product candidates or future product candidates;

- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP requirements;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; and
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control, and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biotechnology company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, initiating and conducting clinical trials, undertaking preclinical studies, in-licensing product candidates for development, and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. Our primary development program is at a late clinical stage. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Related to Our Business and the Development of Our Product Candidates

We have a limited number of product candidates, all which are still in preclinical or early clinical development. If we do not obtain regulatory approval of one or more of our product candidates, or experience significant delays in doing so, our business will be materially adversely affected.

We currently have no product candidates approved for sale or marketing in any country, and may never be able to obtain regulatory approval for any of our product candidates. As a result, we are not currently permitted to market any of our product candidates in the United States or in any other country until we obtain regulatory approval from the FDA or comparable regulatory authorities outside the United States. Our product candidates are in various stages of development and we have not submitted an application, or received marketing approval, for any of our product candidates. Furthermore, the fact that our core competencies have been recognized through strategic partnerships does not improve our product candidates' outlook for regulatory approval. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Obtaining regulatory approval of our product candidates will depend on many factors, including, but not limited to, the following:

- successfully completing formulation and process development activities;
- completing clinical trials that demonstrate the efficacy and safety of our product candidates;
- seeking and obtaining marketing approval from applicable regulatory authorities; and
- establishing and maintaining commercial manufacturing capabilities through relationships with third parties.

Many of these factors are wholly or partially beyond our control, including clinical advancement, the regulatory submission process and changes in the competitive landscape. If we do not achieve one or more of these factors in a timely manner, we could experience significant delays or an inability to develop our product candidates at all.

Clinical trials are very expensive, time consuming and difficult to design and implement and involve uncertain outcomes. Furthermore, the results of previous preclinical studies and early-stage clinical trials may not be predictive of future results. Initial results or observations in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

Positive or timely results from preclinical or early-stage trials do not ensure positive or timely results in late-stage clinical trials or product approval by the FDA or comparable foreign regulatory authorities. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for their intended use(s) in a diverse population before we can seek regulatory approvals for their commercial sale. Our planned clinical trials may produce negative or inconclusive results, and we or any of our current and future strategic partners may decide, or regulators may require us, to conduct additional clinical or preclinical testing.

Success in preclinical studies or early-stage clinical trials does not mean that future clinical trials or registration clinical trials will be successful, or otherwise provide adequate data to demonstrate the safety and efficacy of a therapeutic candidate. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities, despite having progressed through preclinical studies and initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. Similarly, interim results of a clinical trial do not necessarily predict final results. There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development, including development in registration-enabling trials, of any of our therapeutic candidates, and any setbacks in our clinical development could have a material adverse effect on our business and operating results.

If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.

We plan to initiate a Phase 3 clinical trial for XRx-008 product candidate program in the treatment of ADPKD, and a Phase 3 clinical trial for XRx-101 product candidate program in the treatment of AKI in COVID-19 infections. We may experience delays in our ongoing or future clinical trials, and we do not know whether future clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement or completion of these planned clinical trials could be substantially delayed or prevented by many factors, including:

- inability to generate satisfactory preclinical, toxicology or other in vivo or in vitro data capable of supporting the initiation or continuation of clinical trials;
- further discussions with the FDA or other regulatory agencies regarding the scope or design of our clinical trials;
- the limited number of, and competition for, suitable sites to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- any delay or failure to obtain approval or agreement from regulatory authorities to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required to finance a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient supplies of the product candidate for our clinical trials;
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or clinical research organizations ("**CROs**"), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delay or failure to obtain institutional review board, ("**IRB**"), approval to conduct a clinical trial at each prospective clinical trial site;
- slower than expected trial subject rates of patient recruitment and enrollment, or other failures to recruit and enroll subjects, which could be particularly challenging for our trials relating to AKI in COVID-19 patients;
- failure of subjects to complete the clinical trial;
- the inability to enroll a sufficient number of subjects in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by clinical trial subjects, including possible deaths;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of subjects or clinical investigators to follow our clinical trial protocols;
- inability to monitor subjects adequately during or after treatment by us or our CROs;
- our CROs, clinical study sites or investigators failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing; and
- our clinical trials may be suspended or terminated upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future strategic partners that have responsibility for the clinical development of any of our product candidates.

Changes in regulatory requirements, policies and guidelines may also occur and we may need to significantly amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us.

Any failure or significant delay in commencing or completing clinical trials for our product candidates would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

If we experience delays or difficulties in the enrollment of subjects in clinical trials, we will be unable to complete these trials on a timely basis.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Trial subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including:

- the severity of the disease under investigation;
- the size and nature of the patient population;
- the proximity and availability of clinical trial sites for prospective subjects;

- the eligibility criteria for the trial;
- the design of the clinical trial;
- our payments for conducting clinical trials;
- the patient referral practices of physicians;
- the ability to obtain and maintain research subject consents;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies; and
- including any new drugs that may be approved for the indications we are investigating.

In particular, we are developing certain of our products for the treatment of rare diseases, which have limited pools of patients from which to draw for clinical testing. If we are unable to enroll a sufficient number of patients to complete clinical testing, we will be unable to gain marketing approval for such product candidates and our business will be harmed. Further, should any competitors have ongoing clinical trials for therapeutic candidates treating the same indications as our therapeutic candidates, patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' therapeutic candidates. Our inability to enroll a sufficient number of patients for any of our clinical trials could result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and in delays to commercially launching our product candidates, if approved, which would materially harm our business.

The design or our execution of clinical trials may not support regulatory approval.

The design or execution of a clinical trial can determine whether its results will support regulatory approval and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our strategic partners may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registration trials. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial that has the potential to result in FDA or other agencies' approval. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is obtained, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Our products are in varied stages of development ranging from preclinical to late stage clinical trial development. All of our product candidates are required to undergo ongoing safety testing in humans through well-designed and IRB-approved clinical trials. However, not all adverse effects of product candidates can be predicted or anticipated. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved by regulatory authorities, after the approved product has been marketed and is used by a greater number of patients.

The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA or other regulatory authorities with restrictive label warnings, limited patient populations or potential product liability claims. Even if we believe that our Phase 1 clinical trial and preclinical studies demonstrate the safety and efficacy of our product candidates, only the FDA or other comparable regulatory agencies may ultimately make such determination. No regulatory agency has made a determination that any of our product candidates are safe or effective for use for any indication.

If any of our product candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications to the approved product's label or the dissemination of safety alerts to physicians, pharmacies, and patients;
- we may be required to change the way the product is administered, conduct additional clinical trials or develop a REMS for the product;

- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our current or future strategic partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of any future products.

Changes in drug supply manufacturers or methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the

development program, such as manufacturer, manufacturing methods and formulation, are changed along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. FDA and other regulatory agencies may in some cases need to be informed of such changes, and they may require additional information or otherwise cause further delay in development programs. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials, or they may alter the safety or risk profile of the product candidate that could involve further FDA or other regulatory agency inquiries. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability, or our strategic partners' ability, to commence product sales and generate revenue in the future.

For our clinical trials that we may conduct at sites outside the United States, particularly in countries that are experiencing heightened impact from the COVID-19 pandemic, in addition to the risks listed above, we may experience the following adverse impacts:

- delays in receiving approval from local or centralized regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- the refusal of the FDA and Health Canada and other regulatory agencies to accept data from clinical trials in these affected geographies.

The global outbreak of the Sars-CoV-2 coronavirus that causes COVID-19 infections continues to rapidly evolve. The extent to which the COVID-19 pandemic may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in Canada and other countries, business closures or business disruptions and the effectiveness of actions taken in Canada and other countries to contain and treat the disease.

If we are unable to take full advantage of regulatory programs designed to expedite drug development or provide other incentives, our development programs may be adversely impacted.

There are a number of incentive programs administered by the FDA and other regulatory bodies to facilitate development of drugs in areas of unmet medical need, such as fast track designation and breakthrough therapy designation. Our product candidates may not qualify for or maintain designations under these or any of the other of FDA's existing or future programs to expedite drug development in areas of unmet medical need. Our inability to fully take advantage of these incentive programs may require us to run larger trials, incur delays, lose opportunities that may not otherwise be available to us, lose marketing exclusivity for which we would otherwise be eligible and incur greater expense in the development of our product candidates.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, similar foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval and licensure procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining similar foreign regulatory approvals and compliance with similar foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products and services from being developed, approved or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes and other events that may otherwise affect FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved or cleared by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global pandemic of COVID-19 and public health emergency declaration in the U.S., on March 10, 2020 the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products, and it subsequently postponed routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. As of May 2021, the FDA noted it was continuing to ensure timely reviews of applications for prescription drug products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission-critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. Utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus's trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, FDA is

either continuing to, on a case-by-case basis, conduct only mission-critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace and delays or setbacks are possible in the future.

Should FDA determine that an inspection is necessary for NDA approval and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Additionally, regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our development and regulatory approval strategy in the U.S. depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products. If the FDA concludes that our product candidates do not meet the requirements of Section 505(b)(2), approval of such product candidates may be delayed, limited or denied, any of which would adversely affect our ability to generate operating revenues.

The Hatch-Waxman Amendments added section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, (the "**FDCA**"), as well as several other provisions. Section 505(b)(2) of the FDCA permits the filing of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets section 505(b)(2) of the FDCA, for the purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA may also require the applicant to perform additional clinical trials or measurements to support any deviation from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the section 505(b)(2) applicant. The FDA may require an applicant's product label to have all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require the label to have additional limitations, contraindications, warnings or precautions. We plan to use the 505(b)(2) NDA pathway for our future marketing application, if the ongoing clinical trials of our product candidates are successful and the totality of the data collected are sufficient to support NDA approval.

If the FDA determines that our product candidates do not meet the requirements of Section 505(b)(2) we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval applicable to a traditional NDA submitted pursuant to Section 505(b)(1). If our product candidates do not meet the requirements of Section 505(b)(2) of the FDCA or are otherwise ineligible for approval via the Section 505(b)(2) regulatory pathway, the time and financial resources required to obtain FDA approval for these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, a 505(b)(2) application will not be approved until any non-patent exclusivity listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. An inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and other actors have objected to the FDA's interpretation of Section 505(b)(2) of the FDCA to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit in the future. Moreover, the FDA has adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if it does not rely on the previously-approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's interpretation, the approval of one or more of our product candidates may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with our product candidates, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Moreover, even if these product candidates are approved under the Section 505(b)(2) regulatory pathway the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Risks Related to Our Business and the Commercialization of Our Product Candidates

Even if we complete the necessary clinical trials for our product candidates, the marketing approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required marketing approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

To date, we have not received approval from the FDA or regulatory authorities in other jurisdictions to market any of our product candidates for any indications. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication in the relevant patient population to establish the product candidate's safety and effectiveness for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Regulatory authorities may determine that our unapproved product candidates or any potential future product candidate is not effective, is only moderately effective or has undesirable or unintended side effects, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval for the product or that limit or restrict its commercial use.

The process of obtaining marketing approvals is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. 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.

The research, testing, manufacturing, labeling, licensure, sale, marketing and distribution of small molecule products are subject to extensive regulation by the FDA and similar regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the

United States or in any foreign countries until they receive the requisite marketing approval from the applicable regulatory authorities of such jurisdictions.

The FDA and similar foreign regulatory authorities can delay, limit or deny marketing authorization of our product candidates for many reasons, including any one or more of the following:

- our inability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authority that any of our product candidates are safe and effective for their proposed indications;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocols, trial designs or implementation of the trials;
- the FDA or similar foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or similar foreign regulatory authorities for marketing approval, or that regulatory agencies may require us to include a larger number of patients than we anticipated;
- upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate or may identify other GCP deficiencies related to the trials;
- the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies may fail to meet the requirements of the FDA or comparable foreign regulatory authorities;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates, including any potential companion diagnostics, may be insufficient or inadequate;

- the medical standard of care or the approval policies or regulations of the FDA or similar foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for marketing approval; or
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a new drug application or other comparable marketing submissions in foreign jurisdictions or to obtain approval of our product candidates in the United States or elsewhere.

Any of these factors, many of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. Of the large number of small molecule products in development, only a small percentage successfully complete the FDA or similar regulatory approval processes and are commercialized. Even if we eventually complete clinical testing and receive marketing authorization from the FDA or similar foreign regulatory authorities for any of our product candidates, the FDA or similar foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. The FDA or similar foreign regulatory agency also may approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA similar other foreign regulatory agency, may not approve our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such product candidates.

In addition, even if the trials are successfully completed, preclinical and clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or similar foreign regulatory authorities will interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or similar foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects.

We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive and subject to rapid and significant technological change. We are currently developing product candidates that will compete with other drugs and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA approval or discovering, developing and commercializing products in our field before we do.

Specifically, there are a large number of companies developing or marketing treatments for polycystic kidney disease, AKI, COVID-19 infection and diabetes, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, as well as biologics that work by using next-generation antibody therapeutic platforms to address specific metabolic targets. In addition, other companies including Pfizer, Teijin, Takeda, Merck, are developing new treatments for cardiovascular, kidney disease or diabetes that may affect the progression of acute, intermittent or chronic kidney disease.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

These third-parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the pharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Our product candidates, for which we intend to seek approval, may face competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our future pharmaceutical products may face direct competition from generic and other follow-on drug products. Any of our product candidates that may achieve regulatory approval in the future may face competition from generic products earlier or more aggressively than anticipated, depending upon how well such approved products perform in the United States prescription drug market. Our ability to compete may also be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Generic products are expected to become available over the coming years. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive generic products, if any have been approved by then.

In addition to creating the 505(b)(2) NDA pathway, the Hatch-Waxman Amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to abbreviated new drug applications ("**ANDA**"). An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug ("**RLD**"), and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is "bioequivalent" to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD. If any such competitor or third party is able to demonstrate bioequivalence without infringing our patents, then this competitor or third party may then be able to introduce a competing generic product onto the market.

We cannot predict the interest of potential follow-on competitors or how quickly others may seek to come to market with competing products, whether approved as a direct ANDA competitor or as a 505(b)(2) NDA referencing one of our future product candidates. If the FDA approves generic versions of our product candidates in the future, should they be approved for commercial marketing, such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval, which could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those product candidates.

If any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales would be limited.

Our product candidates are in preclinical and clinical development, and we may never have an approved product that is commercially successful. Even when available on the market, the commercial success of our product candidates will depend upon their acceptance among physicians, patients and the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, many of which are beyond our control, including but not limited to:

- limitations, precautions, or warnings contained in the approved summary of product characteristics, patient information leaflet, prescribing information, or instructions for use;
- changes in the standard of care for the targeted indications for any approved products;
- limitations in the approved clinical indications for our approved products;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects, or the prevalence and severity of adverse events;
- sales, marketing and distribution support;
- availability of coverage and reimbursement amounts from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the cost-effectiveness of our approved products;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products; the extent to which the product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular diseases;
- whether the product can be used effectively with other therapies to achieve higher response rates;
- adverse publicity about our approved products or favorable publicity about competitive products;
- relative convenience, ease of use, ease of administration and other perceived advantages of our products over alternative products; and
- potential product liability claims.

Even if any of our product candidates are approved, they may not achieve an adequate level of acceptance by physicians, patients and the medical community, such that we may not generate sufficient revenue from these products and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful, which would prevent us from generating significant revenue or becoming profitable.

We may seek orphan drug status for one or more of our product candidates, but even if it is granted, we may be unable to maintain any benefits associated with orphan drug status, including market exclusivity in specific indications for XRx-008 or XRx-101 or in future product candidates that we may develop. If our competitors are able to obtain orphan product exclusivity for their products in specific indications, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We may seek Orphan Drug Designation for specific indications for XRx-008 and XRx-101 and potentially for additional product candidates in the future. Orphan Drug Designation neither shortens the development time or regulatory review time of a product candidate nor gives the drug any advantage in the regulatory review or approval process.

We may seek orphan drug status for one or more of our product candidates, but the FDA may not approve any such request. Even if the FDA grants orphan drug status to one or more of our candidates, exclusive marketing rights in the United States may be limited if we seek FDA marketing approval for an indication broader than the orphan designated indication. Even if we were to obtain orphan drug exclusivity upon approval of the XRx-008 or XRx-101 product candidate programs for designated renal indications, or for any other product candidates and renal indications that receive an Orphan Drug Designation in the future, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Further, in the United States, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition submitted by a competitor if the FDA concludes that the later drug is clinically superior in that it is shown to exhibit greater safer in a substantial portion of the target population, greater effectiveness, or (in unusual cases) otherwise makes a major contribution to patient care. Accordingly, others may obtain orphan drug status for products addressing the same diseases or conditions as product candidates we are developing, thus limiting our ability to compete in the markets addressing such diseases or conditions for a significant period of time.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any product candidates outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding the safety and efficacy or prescription drug products. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives could harm our business in the future.

There is increasing pressure on biotechnology companies to reduce healthcare costs. In the United States, these pressures come from a variety of sources, such as managed care groups and institutional and government purchasers. Increased purchasing power of entities that negotiate on behalf of federal healthcare programs and private sector beneficiaries could increase pricing pressures in the future. Such pressures may also increase the risk of litigation or investigation by the government regarding pricing calculations. The biotechnology industry will likely face greater regulation and political and legal actions in the future.

Adverse pricing limitations may hinder our ability to recoup our investment in one or more future product candidates, even if our future product candidates obtain regulatory approval. Adverse pricing limitations prior to approval will also adversely affect us by reducing our commercial potential. Our ability to commercialize any potential products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments becomes available from third-party payors, including government health administration authorities, private health insurers and other organizations. Third-party payors decide which medications they will pay for and establish reimbursement levels. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize in the future and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval in the future. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Our inability to promptly obtain coverage and adequate reimbursement from third-party payors for approved products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize potential products and our overall financial condition.

If the market opportunities for any product candidate that we or our strategic partners develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our independent product candidate development on treatments for ADPKD and AKI due to COVID-19 infections. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. If any of the foregoing estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our

spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

We may not be successful in our efforts to use and expand our therapeutic platforms to build a pipeline of product candidates.

An important element of our strategy is to use and expand our therapeutic platforms to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of multiple diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various diseases, we may not be able to develop product candidates that are safe and effective. In addition, although we expect that our therapeutic platforms will allow us to develop a steady stream of product candidates, they may not prove to be successful at doing so. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenue in future periods, which could result in significant harm to our financial position and adversely affect our share price.

Even if we receive regulatory approval to commercialize any of the product candidates that we develop, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. If we fail to comply with United States and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties. Any unfavorable regulatory action may materially and adversely affect our future financial condition and business operations.

Even if we receive marketing and commercialization approval for a product candidate, we will be subject to continuing post-marketing regulatory requirements. Our potential products, further development activities and manufacturing and distribution of a future product, once developed and determined, will be subject to extensive and rigorous regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our therapeutic candidates and, if approved, our future products. The process of obtaining marketing approval or clearance from the FDA and comparable foreign bodies for new products, or for enhancements, expansion of the indications or modifications to existing products, could:

- take a significant, indeterminate amount of time;
- require the expenditure of substantial resources;
- involve rigorous preclinical and clinical testing, and possibly post-market surveillance;
- require design changes of our potential products; or
- result in our never being granted the regulatory approval we seek.

Any of these occurrences may cause our operations or potential for success to suffer, harm our competitive standing and result in further losses that adversely affect our financial condition. In addition, any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, and may contain requirements for potentially costly post-approval trials, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the marketed product.

The FDA, as well as its foreign regulatory counterparts, also have significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. We will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. Additionally, the FDA regulates the promotional claims that may be made about prescription products, such as our products, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. However, we may share truthful and not misleading information with healthcare providers and payors that is otherwise consistent with the product's FDA approved labeling.

We will have ongoing responsibilities under these and other FDA and international regulations, both before and after a product candidate is approved and commercially released. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA and foreign regulatory agencies. In addition, manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring quality control and manufacturing procedures conform to cGMP regulations and corresponding foreign regulatory manufacturing requirements. Accordingly, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA submission to the FDA or any other type of domestic or foreign marketing application.

If a regulatory agency discovers previously unknown problems with a future product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or it disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or on us, including requiring withdrawal of the product from the market. Accordingly, if we or our collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things:

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market or voluntary or mandatory product recalls;

- fines, warning letters, adverse regulatory inspection findings, or holds on clinical trials;
- delay of approval or refusal by the FDA or another applicable regulatory authority to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- suspension or revocation of a product's regulatory approvals;
- product seizure or administrative detention of products, or refusal to permit the import or export of products; and
- operating restrictions, exclusion of eligibility from government contracts, injunctions or the imposition of civil or criminal penalties or prosecution.

Occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively commercializing our potential products and harm our business, and any government investigation of alleged violations of law would require us to expend significant time and resources in response and could generate adverse publicity. In addition, negative publicity and product liability claims resulting from any adverse regulatory action or government investigation could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Further, the FDA's or other regulatory authority's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects. If any product liability lawsuits are successfully brought against us or any of our strategic partners, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of investigational product candidates for which we or our collaborators may conduct clinical trials. In particular, we face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our strategic partners by participants enrolled in our clinical trials, as well as patients, healthcare providers or others using, administering or selling any of our future approved products. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing any approved products, these claims could result in an FDA investigation of the safety and effectiveness of our future commercial products, our manufacturing processes and facilities (or the manufacturing processes and facilities of our third-party manufacturers) or our marketing programs, a recall of our products or more serious enforcement action, limitations on the approved indications for which the product may be used or suspension or withdrawal of approvals.

If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in:

- decreased demand for any future approved products;
- injury to our reputation;

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- increased regulatory scrutiny;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients or other claimants;
- product recalls or a change in the indications for which products may be used;
- loss of revenue;
- a decline in our stock price;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products manufactured and distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive.

We may need to have in place increased product liability coverage when we begin the commercialization of our product candidates.

Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

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.

In the ordinary course of our business, we collect and store terabytes of sensitive data, including legally protected health information, personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or our strategic partners. We manage and maintain our applications and data by utilizing a combination of on-site systems and third-party cloud-based data center systems. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information and business and financial information. The primary risks we face relative to protecting this critical information include loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of being unable to adequately monitor our controls over the first three risks.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure and that of any third-party billing and collections provider we may utilize, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly

disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such the federal privacy rules for health information promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) or state securities laws, and regulatory penalties. We are in the process of implementing security measures to prevent unauthorized access to our valuable trade secrets, patient data, and other confidential information, there is no guarantee that we can continue to protect our systems from breach. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or providers, process claims and appeals, conduct research and development activities, collect, process and prepare company financial information, provide information about any future products, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

The U.S. Office of Civil Rights in the Department of Health and Human Services enforces the HIPAA privacy and security rules and may impose penalties on us or our CROs if we, or our CROs, do not fully comply with requirements of HIPAA. Penalties will vary significantly depending on factors such as whether we, or our CROs, knew or should have known of the failure to comply, or whether our failure, or that of our CROs, to comply was due to willful neglect. These penalties include civil monetary penalties of US$100 to US$50,000 per violation, up to an annual cap of US$1,500,000 for identical violations. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to US$50,000 per violation and up to one-year imprisonment. The criminal penalties increase to US$100,000 per violation and up to five years imprisonment if the wrongful conduct involves false pretenses, and to US$250,000 per violation and up to 10-years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain, or malicious harm. The U.S. Department of Justice is responsible for criminal prosecutions under HIPAA. Furthermore, in the event of a breach as defined by HIPAA, we have specific reporting requirements to the Office of Civil Rights under the HIPAA regulations as well as to affected individuals, and we may also have additional reporting requirements to other state and federal regulators, including the attorney generals of various states, the Federal Trade Commission, and to the media. Depending on the data breached, we may also be obligated under the laws of certain states to provide credit monitoring services to affected individuals for a year or more. Issuing such notifications and providing such services can be costly, time and resource intensive, and can generate significant negative publicity. Breaches of HIPAA or state data protection laws may also constitute contractual violations that could lead to contractual damages or terminations.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, the European Union, or EU, and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy and security regulations vary between states, may differ significantly from country to country, and may vary based on whether testing or processing of data is performed in the United States or in the local country. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

For example, under the EU General Data Protection Regulation ("**GDPR**") we would be obligated to ensure that we maintain appropriate technical and organizational measures to ensure a level of security appropriate to the risk for all personal data, and heightened measures for health-related information, which can pose a significant risk to individuals if it is breached or otherwise compromised. The GDPR also contains numerous complex requirements, with requirements, which we may inadvertently fail to achieve despite our reasonable efforts. Violations of the GDPR may result in fines up to up €20 million, or 4% of the previous financial year's worldwide annual revenue, whichever is the higher of the two.

We may also be subject to litigation for data security breaches under various state laws. The California Consumer Privacy Act ("**CCPA**"), which has been effective only since January 1, 2020, has already resulted in numerous class action lawsuits for companies suffering data breaches in which they are accused of failing to use reasonable security measures to protect the personal information of California residents. In addition, if we violate the CCPA and we are not able to cure the violation within thirty (30) days of notice, we may be subject to penalties ranging from US$2,500 for a non-intentional violation to US$7,500 for an intentional violation. Many other states are in the process of adopting similar laws, so we may potentially face litigation and penalties under the laws of other states as well.

Furthermore, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Current and future legislation may increase the difficulty and cost for us to commercialize any products that we or our strategic partners develop and affect the prices we may obtain.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change healthcare systems in ways that could affect our ability to sell any of our product candidates profitably, if such product candidates are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. Moreover, among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

In addition, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not pre-empt the states' ability to regulate pharmaceutical benefit managers (PBMs) and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-approval testing and other requirements.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our strategic partners are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our strategic partners are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to laws and regulations affecting international trade and transactions administered by the U.S. Government and other governments in the jurisdictions in which we conduct business, including but not limited to the U.S. Export Administration Regulations, U.S. Customs Regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. International Travel Act of 1977, and various anti-money laundering laws and regulations. Anti-corruption laws are interpreted broadly and generally prohibit companies and their employees, agents, contractors, and other representatives from authorizing, promising, offering, or providing, directly or indirectly, payments or anything else of value to recipients in the public sector for the purpose of influencing official action or decision, inducing an unlawful act, inducing official influence over government action, or securing an improper advantage. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the illegal activities of our employees, agents, contractors, and other representatives, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment from participation in government procurements, tax reassessments, civil litigation, reputational harm, and other consequences.

We operate in many jurisdictions and utilize foreign currency and are subject to currency fluctuation risks.

Our operations and expenditures are to some extent paid in foreign currencies. As a result, we are exposed to market risks resulting from fluctuations in foreign currency exchange rates. A material drop in the value of any such foreign currency could result in a material adverse effect on our cash flow and revenues. Amendments to current taxation laws and regulations which alter tax rates and/or capital allowances could have a material adverse impact on us. To the extent that revenues and expenditures denominated in or strongly linked to foreign currencies (such as the U.S. dollar) are not equivalent, we are exposed to exchange rate risk. For example, we would be exposed to the extent U.S. dollar revenues do not equal U.S. dollar expenditures. We are not currently using exchange rate derivatives to manage exchange rate risks.

We currently have no marketing and sales organization and have no experience in marketing prescription drug products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved for commercial sale, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities in any country and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our product candidates, if licensed. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas for which we are able to obtain regulatory approval.

The COVID-19 pandemic may materially and adversely affect our business and financial results.

Our business could be adversely affected by health epidemics in regions where we have clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. Since then, the novel strain of coronavirus has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic and the U.S. government imposed travel restrictions on travel between the United States, Europe and certain other countries. Further, the President of the United States declared the COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response. We have a registered office in Calgary, Alberta, Canada, and engage contract laboratories in various locations in North America. Effective December 13, 2020, the Province of Alberta ordered that all employees work from home unless the employer requires the employee's physical presence to operate effectively, in order to mitigate the impact of the COVID-19 pandemic. Subsequent orders permitted a phased and progressive opening of businesses and permitted some limited gatherings at private residences and public venues. On July 1, 2021, Alberta entered Stage 3 of their reopening plan, lifting all public health measures, except for isolation/quarantine requirements and some restrictions in health care settings and public transit. However, a resurgence in the spread of severity of the pandemic may result in Alberta reinstating certain restrictions.

In response to public health directives and orders and to help minimize the risk of the virus to our employees, we have taken precautionary measures, including implementing work-from-home policies for certain employees. The effects of our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines and any future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, financial condition and results of operations, including our ability to obtain financing.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in Canada, the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

In addition, any clinical trials for our product candidates may be further affected by the COVID-19 pandemic, including:

- delays or difficulties in enrolling patients in the clinical trial, including patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, who, as healthcare providers, may have heightened exposure to the coronavirus that leads to COVID-19 infections and adversely impact our clinical trial operations;

- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or provincial governments, employers and others; and
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or

the desire of employees to avoid contact with large groups of people.

Risks Related to Our Securities

Our share price is likely to be volatile and the market price of our common shares may drop.

You should consider an investment in our securities as risky and invest only if you can withstand a significant loss and wide fluctuations in the market value of your investment. You may be unable to sell your securities at or above the price you paid for them. An investment in the Company's securities is subject to risky due to fluctuations in the market price of our common shares arising from changes in our operating performance or prospects. In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common shares to fluctuate or decrease below the price paid by you include:

- results and timing of our clinical trials and clinical trials of our competitors' products;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or future approved products;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;
- competition from existing products or new products that may emerge;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- announcements by us, our strategic partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- changes in estimates or recommendations by securities analysts, if any cover our common shares;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- litigation;
- future sales of our common shares;

- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of healthcare payment systems in the United States or overseas;
- failure of any of our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;
- general market conditions and market conditions for pharmaceutical stocks;
- overall fluctuations in U.S. equity markets; and
- other factors that may be unanticipated or out of our control.

In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our shareholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

Substantial future sales of our common shares, or the perception that these sales could occur, may cause the price of our common shares to drop significantly, even if our business is performing well.

A large volume of sales of our common shares could decrease the prevailing market price of our common shares and could impair our ability to raise additional capital through the sale of equity securities in the future. Even if a substantial number of sales of our common shares does not occur, the mere perception of the possibility of these sales could depress the market price of our common shares and have a negative effect on our ability to raise capital in the future.

We will incur significant increased costs as a result of operating as a public company in the United States, and our management will be required to devote substantial time to corporate governance standards.

As a recently listed public company in the United States as of October 15, 2021, we will incur additional significant legal, accounting and other expenses that we have not incurred as a public company in Canada. In addition, our administrative staff will be required to perform additional tasks. For example, before becoming a public company in the United States, we will adopt additional internal controls, disclosure controls and procedures and policies specific to complying with the requirements of a public company in the United States. We will bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the applicable securities laws.

In addition, while we are currently listed on the TSXV, Nasdaq and Frankfurt Borse exchanges, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and the related rules and regulations implemented by the SEC, the applicable Canadian securities regulators, or Nasdaq, will increase legal

and financial compliance costs and will make some compliance activities more time consuming. We are currently evaluating these rules, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In connection with the US Offering, we increased our directors' and officers' insurance coverage which will increase our insurance cost. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Under the corporate governance standards of Nasdaq, a majority of our board of directors and each member of our audit committee must be an independent director no later than the first anniversary of the completion of the US Offering. Subject to certain limited exceptions, Canadian securities laws require each member of the audit committee to be independent and financially literate within the meaning of Canadian securities laws. We may encounter difficulty in attracting qualified persons to serve on our board of directors and the audit committee, and our board of directors and management may be required to divert significant time and attention and resources away from our business to identify qualified directors. If we fail to attract and retain the required number of independent directors, we may be subject to the delisting of our common shares from Nasdaq.

We are a "foreign private issuer" and may have disclosure obligations that are different from those of U.S. domestic reporting companies. As a foreign private issuer, we are subject to different U.S. securities laws and rules than a domestic U.S. issuer, which could limit the information publicly available to our shareholders.

As a "foreign private issuer", we are subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. We are required to file or furnish to the SEC the continuous disclosure documents that we are required to file in Canada under Canadian securities laws. For example, we are not required to issue quarterly reports, proxy statements that comply with the requirements applicable to U.S. domestic reporting companies, or individual executive compensation information that is as detailed as that required of U.S. domestic reporting companies. We will also have four months after the end of each fiscal year to file our annual reports with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our officers, directors and principal shareholders are exempt from the insider reporting and short-swing profit recovery requirements in Section 16 of the Exchange Act. Accordingly, our shareholders may not know on as timely a basis when our officers, directors and principal shareholders purchase or sell their common shares, as the reporting deadlines under the corresponding Canadian insider reporting requirements are longer (we have four days to report). As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) which, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. As a result of such varied reporting obligations, shareholders should not expect to receive the same information at the same time as information provided by U.S. domestic companies.

In addition, as a foreign private issuer, we have the option to follow certain Canadian corporate governance practices rather than those of the United States, except to the extent that such laws would be contrary to U.S. securities laws, provided that we disclose the requirements we are not following and describe the Canadian practices we follow instead. As a result, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all domestic U.S. corporate governance requirements.

We may lose our "foreign private issuer" status in the future, which could result in additional costs and expenses to us.

We are a "foreign private issuer," as such term is defined in Rule 405 under the Securities Act and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the Securities and Exchange Commission, or SEC. We may in the future lose foreign private issuer status if a majority of our common shares are held in the United States and we fail to meet the additional requirements necessary to avoid loss of foreign private issuer status, such as if: (i) a majority of our directors or executive officers are U.S. citizens or residents; (ii) a majority of our assets are located in the United States; or (iii) our business is administered principally in the United States. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer will be significantly more than the costs incurred as a Canadian foreign private issuer. If we are not a foreign private issuer, we would be required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are generally more detailed and extensive than the forms available to a foreign private issuer. In addition, we may lose the ability to rely upon exemptions from corporate governance requirements that are available to foreign private issuers.

We are an "emerging growth company," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not "emerging growth companies," including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 ("**Section 404**"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" for up to five years following the completion of the US Offering, although, if we have more than US$1.07 billion in annual revenue, if the market value of our common shares held by non-affiliates exceeds US$700 million as of June 30 of any year, or we issue more than US$1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an "emerging growth company" as of the following December 31. Investors could find our common shares less attractive if we choose to rely on these exemptions. If some investors find our common shares less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common shares and our share price may be more volatile. We have elected not to take advantage of the extended transition period allowed for emerging growth companies for complying with new or revised accounting guidance as allowed by Section 107 of the JOBS Act and Section 7(a)(2)(B) of the Securities Act.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years following the US Offering. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation. We have elected not to take advantage of the extended transition period allowed for emerging growth companies for complying with new or revised accounting guidance as allowed by Section 107 of the JOBS Act and Section 7(a)(2)(B) of the Securities Act.

There is no public market for our convertible securities.

There is no established public trading market for any of our current convertible securities, including the Warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the Warrants on any national securities exchange or other nationally recognized trading system, including the TSXV or Nasdaq, and we may not list any future issued convertible securities. Without an active market, the liquidity of the Warrants or any future issued convertible securities will be limited, which may adversely affect their value.

An active trading market for our common shares may never develop or be sustained.

Our common shares are listed on the TSXV, Nasdaq and Frankfurt Borse. We cannot assure you that an active trading market for our common shares will develop on the TSXV, Nasdaq, Frankfurt Borse or elsewhere or, if developed, that any market will be sustained. Accordingly, we cannot assure you of the likelihood that an active trading market for our common shares will develop or be maintained, the liquidity of any trading market, which may affect the ability to sell our common shares when desired, or the trading prices that you may obtain for your common shares.

We cannot assure you that the market price of our common shares will remain high enough to have the intended effect of complying with Nasdaq's minimum price requirement.

In connection with the US Offering and the co-listing of our common shares on Nasdaq, we effected the Share Consolidation to achieve the requisite increase in the market price of our common shares to obtain Nasdaq's approval of our listing application. However, there can be no assurance that the market price of our common shares following the Share Consolidation will remain at the level required for continuing compliance with that requirement. It is not uncommon for the market price of a company's common shares to decline in the period following a share consolidation. If the market price of our common shares declines following the effectuation of the Share Consolidation, the percentage decline may be greater than would occur in the absence of a share consolidation. In any event, other factors unrelated to the number of common shares outstanding, such as negative financial or operational results, could adversely affect the market price of our common shares and thus jeopardize our ability to maintain the Nasdaq's minimum price requirement. If we are unable to satisfy these requirements or standards going forward, we may be required to de-list from Nasdaq which could have an adverse effect on the value of our securities. We can provide no assurance that any such action taken by us would allow our common shares to remain listed, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the minimum bid price requirement, or prevent future non-compliance with the listing requirements.

Nasdaq may delist our securities from its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

In the future, our securities may fail to meet the continued listing requirements to be listed on Nasdaq. If Nasdaq delists our common shares from trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a determination that our common shares is a "penny stock" which will require brokers trading in our common shares to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common shares;
- a limited amount of news and analyst coverage for our Company; and

- a decreased ability to issue additional securities or obtain additional financing in the future.

We are governed by the corporate laws of Canada which in some cases have a different effect on shareholders than the corporate laws of the United States.

We are governed by the BCBCA and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a U.S. jurisdiction, and may, together with our charter documents, have the effect of delaying, deferring or discouraging another party from acquiring control of our company by means of a tender offer, a proxy contest or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the BCBCA and Delaware General Corporation Law, or DGCL, that may have the greatest such effect include, but are not limited to, the following: (i) for certain corporate transactions (such as mergers and amalgamations or amendments to our articles) the BCBCA generally requires the voting threshold to be a special resolution approved by 66 2/3% of shareholders, or as set out in the articles, as applicable, whereas DGCL generally only requires a majority vote; and (ii) under the BCBCA a holder of 5% or more of our common shares can requisition a special meeting of shareholders, whereas such right does not exist under the DGCL. We cannot predict whether investors will find our company and our common shares less attractive because we are governed by foreign laws.

In addition, a non-Canadian must file an application for review with the Minister responsible for the*Investment Canada Act* (Canada) and obtain approval of the Minister prior to acquiring control of a "Canadian Business" within the meaning of the *Investment Canada Act* (Canada), where prescribed financial thresholds are exceeded. Finally, limitations on the ability to acquire and hold our common shares may be imposed by the *Competition Act* (Canada). The *Competition Act* (Canada) establishes a pre-merger notification regime for certain types of merger transactions that exceed certain statutory shareholding and financial thresholds. Transactions that are subject to notification cannot be closed until the required materials are filed and the applicable statutory waiting period has expired or been waived by the Commissioner. However, the *Competition Act* (Canada) permits the Commissioner of Competition to review any acquisition or establishment, directly or indirectly, including through the acquisition of shares, of control over or of a significant interest in us, whether or not it is subject to mandatory notification. Otherwise, there are no limitations either under the laws of Canada, or in our articles of incorporation, or "articles," or amended and restated bylaws, or "bylaws," on the rights of non-Canadians to hold or vote our common shares. Any of these provisions may discourage a potential acquirer from proposing or completing a transaction that may have otherwise presented a premium to our shareholders. We cannot predict whether investors will find our Company and our common shares less attractive because we are governed by foreign laws.

U.S. civil liabilities may not be enforceable against us, our directors, our officers or certain experts named in this AIF.

We are governed by the BCBCA and our principal place of business is in Canada. Many of our directors and officers, as well as certain experts named herein, reside outside of the United States, and all or a substantial portion of their assets as well as all or a substantial portion of our assets are located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon us and such directors, officers and experts or to enforce judgments obtained against us or such persons, in U.S. courts, in any action, including actions predicated upon the civil liability provisions of U.S. federal securities laws or any other laws of the United States. Additionally, rights predicated solely upon civil liability provisions of U.S. federal securities laws or any other laws of the United States may not be enforceable in original actions, or actions to enforce judgments obtained in U.S. courts, brought in Canadian courts, including courts in the Provinces of British Columbia and Alberta.

Provisions in our articles provide that, unless we consent in writing to the selection of an alternative forum, the Court of Queen's Bench of Alberta and the appellate courts therefrom, to the fullest extent permitted by law, will be the sole and exclusive forum for certain actions or proceedings brought against us, our directors and/or our officers.

U.S. holders of the Company's shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

The rules governing "passive foreign investment companies," ("**PFICs**"), can have adverse effects on U.S. holders of the Company's shares (a "**U.S. Holder**") for U.S. federal income tax purposes. Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets (generally, using a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income (including cash), we would be characterized as a PFIC for U.S. federal income tax purposes. The determination of whether we are a PFIC, which must be made annually after the close of each taxable year, depends on the particular facts and circumstances and may also be affected by the application of the PFIC rules, which are subject to differing interpretations. Our status as a PFIC will depend on the composition of our income and the composition and value of our assets (including goodwill and other intangible assets), which will be affected by how, and how quickly, we spend any cash that was raised in the US Offering or in any other subsequent financing transaction. Moreover, our ability to earn specific types of income that will be treated as non-passive for purposes of the PFIC rules is uncertain with respect to future years. We believe we were classified as a PFIC during the taxable year ended December 31, 2021. Based on current business plans and financial expectations, we may be a PFIC for our taxable year ending December 31, 2021, or future taxable years, and we cannot provide any assurances regarding our PFIC status for any current or future taxable years.

If we are a PFIC, a U.S. Holder would be subject to adverse U.S. federal income tax consequences, such as ineligibility for certain preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. A U.S. Holder may in certain circumstances mitigate adverse tax consequences of the PFIC rules by filing an election to treat the PFIC as a qualified electing fund, or QEF, or, if shares of the PFIC are "marketable stock" for purposes of the PFIC rules, by making a mark-to-market election with respect to the shares of the PFIC. Investors should consult your own tax advisors regarding the potential consequences to you if we were or were to become a PFIC, including the availability, and advisability, of, and procedure for making, QEF elections and mark-to-market elections.

Our bylaws provide that any derivative actions, actions relating to breach of fiduciary duties and other matters relating to our internal affairs will be required to be litigated in Canada, which could limit shareholders' ability to obtain a favorable judicial forum for disputes with us.

We have included a forum selection provision in our bylaws that provides that, unless we consent in writing to the selection of an alternative forum, the Supreme Court of Alberta and appellate courts therefrom (or, failing such Court, any other "court" as defined in the CBCA, having jurisdiction, and the appellate courts therefrom), will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action or proceeding asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us, (3) any action or proceeding asserting a claim arising pursuant to any provision of the CBCA or our articles or bylaws; or (4) any action or proceeding asserting a claim otherwise related to our "affairs" (as defined in the CBCA). Our forum selection provision also provides that our shareholders are deemed to have consented to personal jurisdiction in the Province of Alberta and to service of process on their counsel in any foreign action initiated in violation of our provision. Therefore, it may not be possible for shareholders to litigate any action relating to the foregoing matters outside of the Province of Alberta. To the fullest extent permitted by law, our forum selection provision will also apply to claims arising under U.S. federal securities laws. In addition, investors cannot waive compliance with U.S. federal securities laws and the rules and regulations thereunder.

Our forum selection provision seeks to reduce litigation costs and increase outcome predictability by requiring derivative actions and other matters relating to our affairs to be litigated in a single forum. While forum selection clauses in corporate charters and bylaws/articles are becoming more commonplace for public companies in the United States and have been upheld by courts in certain states, a recent decision of the Supreme Court of Canada has cast some uncertainty as to whether forum selection clauses would be upheld in Canada. Accordingly, it is possible that the validity of our forum selection provision could be challenged and that a court could rule that such provision is inapplicable or unenforceable. If a court were to find our forum selection provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions and we may not obtain the benefits of limiting jurisdiction to the courts selected.

Future sales and issuances of our common shares or rights to purchase common shares, including pursuant to our Stock Option and Incentive Plan, could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including conducting clinical trials, expanded research and development activities, and costs associated with operating as a public company. To raise capital, we may sell common shares, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common shares, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common shares.

We do not expect to pay dividends in the future. As a result, any return on investment may be limited to the value of our common stock.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors as our board of directors may consider relevant. If we do not pay dividends, our common shares may be less valuable because a return on an investment in our common shares will only occur if our stock price appreciates.

Risks Related to Our Dependence on Third Parties

Our existing strategic partnerships are important to our business, and future strategic partnerships will likely also be important to us. If we are unable to maintain our strategic partnerships, or if these strategic partnerships are not successful, our business could be adversely affected.

We have limited capabilities for product candidate development and do not yet have any capability for sales, marketing or distribution.

Accordingly, we have entered into strategic partnerships with other companies that we believe can provide such capabilities, including collaboration and license agreements with the Icahn School of Medicine at Mt. Sinai in New York, University of Florida, Dr. Richard Johnson, and Dr. Takahiko Nakagawa. Our existing strategic partnerships, and any future strategic partnerships we enter into, may pose a number of risks, including the following:

- strategic partners have significant discretion in determining the efforts and resources that they will apply to these partnerships;
- strategic partners may not perform their obligations as expected;
- strategic partners may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the partners' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- strategic partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct

new clinical trials or require a new formulation of a product candidate for clinical testing;

- strategic partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the strategic partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than our product candidates;

- product candidates discovered in collaboration with us may be viewed by our strategic partners as competitive with their own product candidates or products, which may cause strategic partners to cease to devote resources to the commercialization of our product candidates;

- a strategic partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidates;

- disagreements with strategic partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- strategic partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- strategic partnerships may be terminated for the convenience of the partner and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

We may not realize the anticipated benefits of our strategic partnerships.

If our strategic partnerships do not result in the successful development and commercialization of product candidates or if one of our partners terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. Moreover, our estimates of the potential revenue we are eligible to receive under our strategic partnerships may include potential payments in respect of therapeutic programs for which our partners have discontinued development or may discontinue development in the future. Furthermore, our strategic partners may not keep us informed as to the status of their in-house research activities and they may fail to exercise options embedded within certain agreements. Any discontinuation of product development by our strategic partners could reduce the amounts receivable under our strategic partnerships below the stated amounts we are eligible to receive under those agreements. If we do not receive the funding we expect under these agreements, our development of our therapeutic platforms and product candidates could be delayed and we may need additional resources to develop product candidates and our therapeutic platforms. All of the risks relating to product development, regulatory approval and commercialization described in this AIF also apply to the activities of our program strategic partners.

Additionally, subject to its contractual obligations to us, if one of our strategic partners is involved in a business combination, the partner might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our strategic partners terminates its agreement with us, we may find it more difficult to attract new partners.

We face significant competition in seeking new strategic partners.

For some of our product candidates, we may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The strategic partner may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Strategic partnerships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future strategic partners. If we are unable to reach agreements with suitable strategic partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into strategic partnerships and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our therapeutic platforms and our business may be materially and 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. We may not be able to obtain regulatory approval for our product candidates or commercialize any products that may result from our development efforts, if we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us.

We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third-party strategic partners, to monitor, support, conduct and oversee preclinical studies and clinical trials of our current and future product candidates. We also rely on third parties to perform clinical trials on our current and future product candidates when they reach that stage. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials with our own personnel.

If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA or other regulatory agencies.

Ultimately, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with cGCP regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA could determine that any of our clinical trials fail or have failed to comply with applicable cGCP regulations. In addition, our clinical trials must be conducted with product produced under the cGMP regulations enforced by the FDA, and our clinical trials may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and increase our costs. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Part of our reliance and partnerships with CROs includes reliance on third-party doctors, nurses or healthcare workers in our clinical trials. Fraud caused by third party errors or omissions, including intentional or unintentional failure to administer drugs as whole, failure to administer in a timely fashion, failure to accurately record data or complete the assigned measures or tests in order to complete the data that is part of the clinical trial presents risk. Any of these failures can have negative impact on trial outcomes, processes, timeliness and cost. While it falls under a CRO's delegated responsibilities, ultimately, we have oversight as the sponsor and must act accordingly.

If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. Further, if our relationship with any of our CROs is terminated, we may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all.

Switching or adding CROs or other suppliers can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or supplier commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture and supply our product candidates, if approved for commercial marketing. The development of product candidates and the commercialization of any product candidates, if approved, could be stopped, delayed or made less profitable if any of these third parties fail to provide us with sufficient quantities of product candidates or approved products, fail to do so at acceptable quality levels or prices, or fail to maintain or achieve satisfactory regulatory compliance.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to develop and manufacture our product candidates for use in the conduct of our trials or for commercial supply, if our product candidates are approved for commercial marketing. Instead, we rely on, and expect to continue to rely on third-party providers to manufacture the supplies for our preclinical studies and clinical trials. We currently rely on a limited number of third-party contract manufacturers for all of the required raw materials for our preclinical research and clinical trials, as well as for the manufacture of our product candidates. To the extent any of our manufacturing partners is unable to fulfill these obligations in a timely manner, including as a result of circumstances relating to the COVID-19 pandemic, our clinical trials may be delayed and our business may be adversely affected. In general, reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the operational processes of the contract manufacturing organizations with whom we contract, and we are dependent on these third parties for the production of our product candidates in accordance with relevant regulations (such as cGMP), which include, among other things, quality control and the maintenance of records and documentation.

Risks Related to Our Intellectual Property

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position.

We are also aware of third-party patents and patent applications containing claims that are related to administering a xanthine oxidase inhibitor as an adjunct in combination with other primary compounds for treating related indications. If our product candidates or our strategic partners' products were to be found to infringe any such patents, and we were unable to invalidate those patents, or if licenses for them are not available on commercially reasonable terms, or at all, our business could be materially harmed. These patents may not expire before we receive marketing authorization for our product candidates, and could delay the commercial launch or one or more future products. There is also no assurance that there are not third-party patents or patent applications of which we are aware, but which we do not believe are relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position.

Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any technology that we require may also materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

In the pharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our strategic partners may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties, to obtain a judgment that our product candidates or processes do not infringe those third parties' patents or to obtain a judgement that those parties' patents are unenforceable;

- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;

- if third parties' initiate litigation claiming that our processes or product candidates infringe their patent or other intellectual property rights or initiate other proceedings, including post-grant proceedings and reviews of inter parties, we and our strategic partners will need to defend against such proceedings; and

- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or product candidates infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our strategic partners would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. There is a risk that a court would decide that we or our strategic partners are infringing the third party's patents and would order us or our strategic partners to stop the activities covered by the patents. In that event, we or our strategic partners may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us or our strategic partners to pay third party damages or some other monetary award, depending upon the jurisdiction. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties, potentially including treble damages and attorneys' fees if we are found to have willfully infringed, and we may be required to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

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.

Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we have licensed from third parties. Therefore, our owned or in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issues from such applications, and then only to the extent the issued claims cover the technology. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries.

Moreover, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The issuance of a patent does not ensure that it is valid or enforceable. Third parties may challenge the validity, enforceability or scope of our issued patents, and such patents may be narrowed, invalidated, circumvented, or deemed unenforceable. In addition, changes in law may introduce uncertainty in the enforceability or scope of patents owned by pharmaceutical companies. If, our patents are narrowed, invalidated or held unenforceable, third parties may be able to commercialize our technology or product candidates and compete directly with us without payment to us. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the issuance, validity, enforceability, scope and commercial value of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product candidate and practicing our own patented technology.

Our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, for example, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

Our intellectual property rights will not necessarily provide us with competitive advantages.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we or our strategic partners own or have exclusively licensed;

- others may independently develop similar or alternative technologies without infringing our intellectual property rights;

- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- we may obtain patents for certain compounds many years before we obtain marketing approval for product candidates containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may fail to develop additional proprietary technologies that are patentable;

- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or vice versa, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and

- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time consuming and unsuccessful.

Third parties may seek to market small molecule versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Even after they have issued, our patents and any patents that we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we or our strategic partners may initiate litigation or other proceedings against third parties to enforce our patent and trade secret rights;

- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;

- third parties may initiate opposition or re-examination proceedings challenging the validity or scope of our patent rights, requiring us or our strategic partners and/or licensors to participate in such proceedings to defend the validity and scope of our patents;

- there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being owned by or licensed to us;

- the USPTO may initiate an interference between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our strategic partners and/or licensors to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or

- third parties may seek approval to market small molecule drug versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. Adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. There is a risk that a court or administrative body would decide that our patents are invalid or not infringed or trade secrets not misappropriated by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents or trade secrets could limit our ability to assert our patents or trade secrets against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;

- we might not have been the first to make the inventions covered by patents or pending patent applications;

- we might not have been the first to file patent applications for these inventions;

- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable or that afford meaningful trade secret protection.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened compared to expectations and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

If we are unable to protect the confidentiality of our proprietary information, the value of our technology and product candidates could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. For example, we treat our proprietary computational technologies, including unpatented know-how and other proprietary information, as trade secrets. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, strategic partners and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome is unpredictable. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced and our business and competitive position could be harmed. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer.

Litigation may be necessary to defend against these claims. Such trade secrets or other proprietary information could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or product candidates. Such license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship or ownership of our patents, we may in the future be subject to claims that former employees, strategic partners or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. For example, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, or we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims

challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Patent protection and patent prosecution for some of our product candidates may be dependent on, and the ability to assert patents and defend them against claims of invalidity may be maintained by, third parties.

There may be times in the future when certain patents that relate to our product candidates or any approved products are controlled by our licensees or licensors. Although we may, under such arrangements, have rights to consult with our strategic partners on actions taken as well as back-up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers.

If any current or future licensee or licensor with rights to prosecute, assert or defend patents related to our product candidates fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or found to be enforceable in our patents, in our strategic partners' patents or in third-party patents. The United States has enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity, scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation.

The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties disclosing or claiming the same invention. A third party that has filed, or does file a patent application in the USPTO after March 16, 2013 but before us, could be awarded a patent covering a given invention, even if we had made the invention before it was made by the third party. This requires us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current product candidates or future products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Recent United States Supreme Court cases have narrowed the scope of what is considered patentable subject matter, for example, in the areas of software and diagnostic methods involving the association between disease state treatment outcome and biomarkers. This could impact our ability to patent certain aspects of our technology in the United States.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We will need to obtain FDA approval for any proposed product candidate names, and any failure or delay associated with such approval may adversely affect our business.

Any proprietary name or trademark we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product candidate names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any product candidate names we propose, we may be required to adopt an alternative name for the product candidate. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic, descriptive, non-distinctive, or otherwise invalid or determined to be infringing on other marks. We rely on common law (unregistered) protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive office actions from the USPTO or comparable agencies in foreign jurisdictions objecting to the registration of our trademarks. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks.

Opposition or cancellation proceedings or lawsuits may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Our proprietary position depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition-of-matter patents on the active pharmaceutical ingredient, or API, in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because such patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. We currently have granted U.S. patents with claims to the use of uric acid lowering agents to treat insulin resistance or diabetic nephropathy, and patent applications filed in the U.S., EU and under the Patent Cooperation Treaty 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.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals and engage consultants who were previously or are currently employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are not successful, we could lose access or exclusive access to valuable intellectual property.

We may be subject to damages resulting from claims that we, our employees or our consultants have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our consultants were previously or are currently employed at other, third party, biotechnology and pharmaceutical companies, and this many include our competitors or potential competitors. We may be subject to claims that we, our employees or our consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these third parties. In addition, we may in the future be subject to claims that we caused an employee of a third party to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, financial condition and results of operations.

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We license technology from the University of Florida, and Dr. Richard Johnson.

These agreements impose numerous obligations, such as diligence and payment obligations. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. These licenses do and future licenses may include provisions that impose obligations and restrictions on us. This could delay or otherwise negatively impact a transaction that we may wish to enter into.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including disputes concerning:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are

described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize product candidates could suffer.

If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business.

We are a party to license agreements with University of Florida, and others, pursuant to which we in-license key patent and patent applications for use in one or more of our product candidates. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensors may have the right to terminate the licenses, in which event we would not be able to develop or market the product candidates covered by such licensed intellectual property.

We rely on certain of our licensors to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them and may continue to do so in the future. We have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that any licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- pending patent applications that we own or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensors) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;

- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could materially harm our business and the results of our operation.

Risks Related to Additional Legal and Compliance Matters

Our employees and independent contractors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees or independent contractors. Misconduct by these parties could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we may establish for our product candidates, to comply with federal and state data privacy, security, fraud and abuse laws and other healthcare regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics ("**Code of Conduct**"), but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, monetary damages, fines, disgorgement, imprisonment, loss of eligibility to obtain marketing approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, reputational harm, diminished profits and future earnings, additional reporting requirements if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and the curtailment or restructuring of our operations.

If we market products in a manner that violates healthcare fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on the marketing of pharmaceutical products, federal and state healthcare laws restrict certain business practices in the pharmaceutical industry. Although we currently do not have any products on the market, we may be subject, and once our product candidates are approved and we begin commercialization will be subject, to additional healthcare laws and regulations enforced by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These state and federal healthcare laws, commonly referred to as "fraud and abuse" laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry, and include, but are not limited to, anti- kickback, false claims, data privacy and security and transparency statutes and regulations.

For example, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other.

Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as:

- providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers;
- reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates;
- engaging in off-label promotion; and
- submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

If our operations are found to be in violation of any of the healthcare laws or regulations that may apply to us, we may be subject to penalties, including potentially significant criminal, civil or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion of products from reimbursement under government programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products will be sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post- marketing requirements, including safety surveillance, fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development involves, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. We do not maintain workers' compensation insurance. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business expertise of Dr. Allen Davidoff, our President and Chief Executive Officer, Amar Keshri, our Chief Financial Officer, Dr. Stephen Haworth, our Chief Medical Officer, Dr. David MacDonald, our Chief Technology Officer, as well as other members of our senior management, scientific and clinical team. We currently do not maintain "key person" insurance coverage for Dr. Davidoff and Amar Keshri. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited talent pool in our industry due to the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Intense competition for attracting key skill-sets may limit our ability to retain and motivate these key personnel on acceptable terms. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We will need to grow our organization, and we may experience difficulty in managing this growth, which could disrupt our operations.

As of the date of this AIF, we had three full-time employees and nine consultants. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. Additionally, as our product candidates enter and advance through preclinical studies and any clinical trials, we will need to expand our development, manufacturing, regulatory sales and marketing capabilities or contract with other organizations to provide these capabilities for us. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity amongst remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend on our ability to effectively manage any future growth.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

DIVIDENDS

We have never paid any dividends on our common shares or any of our other securities. We currently intend to retain any future earnings to finance the growth and development of our business, and we do not anticipate that we will declare or pay any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements, restrictions under any future indebtedness and other factors the board of directors deems relevant.

CAPITAL STRUCTURE

General

The authorized share capital of the Company consists of an unlimited number of common shares, each without par value. We have no preferred shares authorized under our notice of articles or articles.

Common Shares

Outstanding Shares

As of the date of this AIF, our authorized share capital consists of an unlimited number of common shares, each without par value, of which 12,989,687 are issued and outstanding. In addition, we have 733,567 common shares issuable pursuant to outstanding stock options, 5,329,796 common shares issuable upon the exercise of outstanding common share purchase warrants. We had approximately 23 holders of record and approximately 1,237 beneficial owners of our common shares as of December 31, 2021.

Voting Rights

Under our articles, the holders of our common shares will be entitled to one vote for each common share held on all matters submitted to a vote of the shareholders, including the election of directors. Our notice of articles and articles do not provide for cumulative voting rights. Because of this, the holders of a plurality of the common shares entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose.

Dividends

Subject to priority rights that may be applicable to any then outstanding shares, and the applicable provisions of the BCBCA, holders of our common shares are entitled to receive dividends, as and when declared by our board of directors, in their sole discretion as they see fit. For more information, see the section above titled "**Dividends**".

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common shares will be entitled to share ratable in the net assets legally available for distribution to shareholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding preferred shares.

Rights and Preferences

Our common shares contain no pre-emptive or conversion rights and have no provisions for redemption or repurchase for cancellation, surrender or sinking or purchase funds. There are no provisions in our notice of articles and articles requiring holders of common shares to contribute additional capital. The rights, preferences and privileges of the holders of our common shares are subject to and may be adversely affected by, the rights of the holders of any series of new preferred shares that may be created, authorized, designated, and issued in the future.

MARKET FOR SECURITIES

Our common shares are listed in Canada on the TSXV and in the United States on Nasdaq under the trading symbol XRTX. Our common shares are also posted for trading on the Frankfurt Burse under the trading symbol ANU.

The following table sets forth, for the periods indicated, the reported high and low prices (in Canadian dollars) and volume traded on the CSE and TSXV.

Month	High	Low	Close	Volume
January 2021	$0.39	$0.15	$0.30	12,851,068
February	$0.38	$0.26	$0.27	6,007,730
March	$0.29	$0.19	$0.20	3,454,244
April	$0.20	$0.16	$0.18	2,651,006
May	$0.26	$0.15	$0.20	1,817,091
June	$0.23	$0.13	$0.17	6,375,099
July	$0.23	$0.16	$0.18	6,436,304
August	$0.52	$0.17	$0.45	33,555,999
September[(1)]	$9.98	$4.66	$6.16	21,818,240
October	$7.90	$3.07	$3.50	2,194,522
November[(2)]	$5.15	$3.18	$4.80	594,391
November[(2)]	$3.31	$2.25	$2.70	339,000
December	$2.75	$2.20	$2.21	162,700
January 2022	$2.75	$1.88	$1.91	209,600
February	$2.22	$1.65	$1.85	117,000
March	$3.00	$1.44	$2.43	279,400

Notes:
(1) On September 23, 2021, the common shares were consolidated on a 11.74:1 basis.
(2) On November 5, 2021, the common shares were delisted from the CSE and listed on the TSXV.

The following table sets forth, for the periods indicated, the reported high and low prices (in United States dollars) and volume traded on Nasdaq.

Month	High	Low	Close	Volume
October 2021[(1)]	$5.89	$2.12	$2.33	62,776,900
November	$2.61	$1.73	$2.05	2,205,600
December	$2.19	$1.75	$1.80	462,200
January 2022	$2.19	$1.45	$1.54	583,500
February	$1.78	$1.20	$1.47	315,200
March	$2.48	$1.15	$1.95	5,315,700

Note:
(1) On October 13, 2021, the common shares were listed on Nasdaq.

PRIOR SALES

The following table summarizes, on a post Share Consolidation basis, issuances of our common shares and securities convertible or exchangeable into common shares during the 12-month period preceding the date of this AIF.

Date of Issuance	Type of Security	Number of Securities Issued	Issuance/ Exercise Price per Security ($)
January 11, 2021	Stock Options	59,625	3.29
January 12, 2021	Shares	17,035	—
January 13, 2021	Shares	836	—
January 13, 2021	Warrants	9,866	1.64
February 1, 2021	Shares	8,517	—
February 4, 2021	Shares	12,168	2.94
February 9, 2021	Shares	2,085,687	2.94
February 9, 2021	Warrants	2,183,693	4.70
February 17, 2021	Shares	4,816	1.64
February 17, 2021	Warrants	5,050	1.64
February 18, 2021	Shares	85,178	2.94
February 19, 2021	Shares	12,776	2.94
February 22, 2021	Warrants	5,653	2.94
February 22, 2021	Shares	17,035	2.94
February 22, 2021	Shares	10,703	1.64
February 25, 2021	Shares	171,817	2.94
February 26, 2021	Warrants	5,050	2.94
March 1, 2021	Shares	8,517	—
March 1, 2021	Shares	17,827	2.94
March 31, 2021	Shares	8,517	—
October 15, 2021	Shares	2,906,000	5.11
October 15, 2021	Warrants	2,906,000	0.001
November 9, 2021	Shares	355,000	5.14

ESCROWED SECURITIES AND SECURITIES SUBJECT TO CONTRACTUAL RESTRICTIONS ON TRANSFER

As at December 31, 2021, there were no common shares of the Company subject to escrow

Also as at December 31, 2021, there were 977,318 shares held by Prevail Partners LLC ("**Prevail**") that are subject to a contractual restriction on transfer such that no shares may be transferred by Prevail until such time as all the services contemplated pursuant to the Master Services and Technology Agreement between the Company and Prevails affiliate, Prevail InfoWorks, Inc. ("**InfoWorks**"), dated February 28, 2020 have been completed. Pursuant to this agreement, the Company paid a deposit of $1,606,320 (US$1,200,000 at the exchange rate on the date of the transaction) to Prevail to support two clinical trials on behalf of the Company. Prevail and InfoWorks are clinical research organizations that are key partners in our future clinical plans and are anticipated to participate in our future clinical trials to support XRx-008, XRx-101 and XRx-225 programs.

DIRECTORS AND EXECUTIVE OFFICERS

The following sets forth the names and province or state and country of residence of our directors and executive officers, the offices held by them in the Company, their current principal occupations, all as of the date hereof, their principal occupations during the last five years and the month and year in which they became directors or officers. The term of each director expires on the date of our next annual meeting.

Name, Province / State and Country of Residence	Position with the Company	Date Became a Director / Officer	Principal Occupation Last Five Years

Allen Davidoff Alberta, Canada	President and Chief Executive Officer and Director	January 9, 2018	Current President and Chief Executive Officer of the Company since January 9, 2018 and its predecessor company, XORTX Pharma Corp. since July 2012; former Chief Scientific Officer and co-founder, Stem Cell Therapeutics Inc. (November 2004 to December 2011).
William Farley New York, United States	Director	May 12, 2021	Over 35 years' experience in business development, sales and leading efforts in drug discovery, development and partnering. Current Vice President, Business Development, Sorrento Therapeutics, Inc. and its subsidiary companies Levena BioPharma Co., Ltd. and Scilex Pharmaceutics, Inc. as well as its Sofusa division since 2016 and current Director, Globestar Therapeutics Corporation since April 2021.
Stephen Haworth Pennsylvania, United Sates	Chief Medical Officer	July 1, 2021	Current Chief Medical Officer of the Company; Principal Consultant, Haworth Biopharmaceutical Consulting Services Inc. since July 2013; former Executive Medical Director, Cormedix Inc. (2017 to 2018); former Vice President, VaxInnate Corporation (2015 to 2015).
Amar Keshri Alberta, Canada	Chief Financial Officer	July 14, 2021	Current Chief Financial Officer of the Company; President, Next Level Consultants Inc., a company that provides consulting and accounting advisory services to private and start-up companies since 2018; and former Controller, Secure Energy Services Inc. (2014 to 2018).

Name, Province / State and Country of Residence	**Position with the Company**	**Date Became a Director / Officer**	**Principal Occupation Last Five Years**
Ian Klassen(1) British Columbia, Canada	Director	August 27, 2020	Director and CEO, Grande Portage Resources Ltd. since March 2006; Director and CEO, GMV Minerals Inc. since December 2007; Director ExeBlock Technology Corporation since September 2017 and currently its Interim CEO; former Director of Canabo Medical Corp., now Aleafia Health Inc. (March 2014 to March 2018), G6 Materials Corp. (January 2012 to May 2016); Sixty North Gold Mining Ltd. (July 2017 to September 2019) and Transcanna Holdings Inc. (August 2019 to March 2020).
Jacqueline Le Saux(1) Ontario, Canada	Director	June 16, 2021	Retired, experienced Canadian health care legal executive focused on securities, pharmaceutical regulatory and intellectual property law. Former Vice President, Legal and Compliance, Purdue Pharma (Canada) (2009 to 2018).
David MacDonald British Columbia, Canada	Chief Technology Officer	January 20, 2022	Current Chief Technology Officer of the Company and current President, Mathylation Sciences Inc. since 2017 and former Chief Technology Officer (2008 through 2017); former Chief Technology Officer, ImmunoFlex (2020 to 2021).
Raymond Pratt Michigan, United States	Director	December 20, 2021	Current Chief Development Officer and former Chief Medical Officer, Rockwell Medical, Inc. since 2012.
Paul Van Damme(1) Ontario, Canada	Director and Chair	January 25, 2018	Former Director, OncoQuest Inc., a subsidiary of Quest PharmaTech Inc. (November 2015 to February 2020); former Chief Financial Officer, Mind Medicine (MindMed) Inc. (Augest 2019 to April 2020); former Chief Financial Officer, Structural Genomics Consortium (May 2012 to June 2019); former Chief Financial Officer, Bradmer Pharmaceuticals Inc. (September 2007 to July 2018).

Note:
(1) Member of Audit Committee.

As at December 31, 2021, our directors and executive officers owned, or exercised control of or direction over, directly or indirectly, less than 5% of our outstanding common shares.

Directors and Executive Officers

The following are short biographies of our directors and executive officers:

Allen Davidoff, PhD

Dr. Allen Davidoff has been the President and Chief Executive Officer of the Company since 2018 and of its predecessor company, XORTX Pharma Corp. since 2012. Dr. Davidoff is also a Director. Prior to that, Dr. Davidoff founded and served as Chief Scientific Officer of Stem Cell Therapeutics (Trillium Therapeutics). Dr. Davidoff holds a Ph.D. degree in Cardiovascular Physiology and Biophysics from the University of Calgary. Dr. Davidoff has a broad range of professional experience including clinical, regulatory and senior management experience in pharmaceutical research and development, including two IND applications or supplemental IND's, two Phase I studies, seven Phase II studies and one NDA.

William Farley, BSc

William Farley was appointed as a director of the Company in May 2021. Mr. Farley has over 35 years of experience in leadership, business development, and sales related to drug discovery, development, and partnering. Mr. Farley has held a senior leadership position at Sorrento Therapeutics, Inc. since 2016. Mr. Farley began his career at Johnson and Johnson, and has also held senior management positions at Pfizer, HitGen Ltd., WuXi Apptec, Inc., and ChemDiv, where he created, built and led global business development teams, and led numerous efforts to create new therapeutic companies in CNS, oncology and anti-infectives. Mr. Farley currently serves on the board of directors of SOMA and as a consultant to various executive management teams, and also advises several boards of directors on the commercialization of assets. He received his Bachelor of Science degree in Chemistry from State University of New York, Oswego and has taken graduate courses at Rutgers and University of California, Irvine.

Dr. Stephen Haworth, MB BS, MRCP

Dr. Stephen Haworth joined XORTX as the Chief Medical Officer effective July 1, 2021. Dr. Haworth holds a medical degree from University College Hospital Medical School, University of London having graduated with Honors. Dr. Haworth brings to XORTX more than 25 years of successful global drug development and leadership in both start up and Fortune 500 pharmaceutical firms in both the United States and Europe. Dr. Haworth has a broad clinical and regulatory experience that ranges from infectious

disease through nephrology, cardiovascular disease and most recently on programs for treatment and prevention of SARS-CoV infection. He has held key roles in numerous FDA and EMA submissions and has been involved in several licensing and M&A transactions. Since 2011, Dr. Haworth has served as the principal consultant for Haworth Biopharmaceutical Consulting Services. In addition, from 2016 to 2018, Dr. Haworth served as the Executive Director Medical Science for Cormedix, Inc. a biopharmaceutical company.

Amar Keshri, CA, CPA

Amar Keshri was appointed Chief Financial Officer of the Company on July 14, 2021. Mr. Keshri was most recently involved in providing consulting services to US-based start-ups in the process of going public. He has also worked with a number of large organizations in Canada and internationally involved in a number of service sectors including the life science industry, oil and gas sector and various public practice audit and finance and accounting consulting roles, including with Suncor Energy, PricewaterhouseCoopers LLP and Ernst & Young. Mr. Keshri is a Member of the Institute of Chartered Accountants of Alberta and India. From 2014 to 2018, Mr. Keshri served as a controller for Secure Energy Services Inc. Since April 2021, Mr. Keshri has been the President of Next Level Consultants Inc., which provides consulting and advisory services to private and start-up companies.

Ian Klassen, B.A.

Ian Klassen has served as a director of the Company since 2020. Mr. Klassen has served as director and chief executive officer of Grande Portage Resources Ltd. since 2007. Mr. Klassen has served as director and chief executive officer of GMV Minerals Inc. since 2007. Mr. Klassen has served as director of eXeBlock Technology Corporation since September 2017. Mr. Klassen served as director of Canabo Medical Corp., now Aleafia Health Inc., from 2014 to 2018, G6 Materials Corp. from 2012 to 2016, Sixty North Gold Mining Ltd. from 2017 to 2019 and Transcanna Holdings Inc. from 2019 to 2020. Mr. Klassen brings almost 30 years of business management, public relations and government affairs experience to the Company. He has extensive experience in the administration of public companies, finance, government policy, media relationship strategies, business/government project management and legislative decision-making. Mr. Klassen has extensive experience chairing governance, audit, and risk assessment and compensation committees. He holds a B.A. (Honours) from the University of Western Ontario and is a recipient of the Commemorative Medal for the 125th anniversary of the Confederation of Canada in recognition of his significant contribution to his community and country.

Jacqueline Le Saux, BScL, MBA, LLB

Jacqueline Le Saux is a seasoned Canadian health care legal executive who has held senior positions at large and small public and private life science companies. Jacqueline's legal experience is focused on securities, pharmaceutical regulatory and intellectual property law. As a Vice President, Legal in both public and private companies Ms. Le Saux has led multiple financings, mergers and acquisitions and product licensing transactions, mitigating risk and executing strategies in the Canadian healthcare industry. Her broad industry experience spans big pharma to early and late-stage research and development, as well as consumer products and pharmaceutical manufacturing. Prior to entering the health care industry, she was a partner at a top tier Canadian law firm, specializing in securities and corporate law. From 2009 to 2018, Ms. Le Saux served as Vice-President, Legal and Compliance for Purdue Pharma L.P. In 2019, she worked as counsel to Purdue Pharma Canada on certain select issues. Ms. Le Saux holds a BScL from Laurentian University, an MBA from the University of Ottawa, and an LLB from the University of Toronto.

Dr. David MacDonald, PhD

Dr. MacDonald joined XORTX as Chief Technology Officer on January 20, 2022. Prior to joining the Company, Company, held the positions of CTO and later President of MSI Methylation Sciences Inc. a clinical-stage pharmaceutical company ("MSI") where he led R&D, pharmaceutical product and clinical development. Prior to his position at MSI, David acted as President and CEO of Active Pass Pharmaceutics. In addition, he has held leadership positions in several small and large pharma biotech companies during which he was responsible for a broad range of technical departments and stages of development covering basic research, IND-enabling studies, formulation, CMC, clinical trials, intellectual property, and regulatory submissions and inspections. Dr. MacDonald is an inventor on over 20 patents issued globally and has published 14 manuscripts in peer reviewed journals. He obtained his Ph.D. in Chemistry from the University of Alberta where his research was focused on enzymology.

Dr. Raymond Pratt, MD FACP

Dr. Pratt is an accomplished Physician Executive with 40 years' experience in both clinical medicine and Nephrology. In his 25 years in the pharmaceutical industry, he has led global clinical trials, clinical pharmacology, drug safety and regulatory affairs in both large and small companies. His leadership has led to the approval of drugs for renal, hematology and CNS patients in the US and other global markets. Dr. Pratt is the current Chief Development Officer and former Chief Medical Officer, Rockwell Medical, Inc. since 2012, the former Vice President, Strategic Drug Development, Quintiles Transnational and former Vice President, R&D and Scientific Leader and various other senior management positions with Shire Pharmaceutical Development.

Paul Van Damme, B Comm, CPA, MBA

Paul Van Damme has served as a director of the Company and chairman of the audit committee since 2018. Mr. Van Damme served as director of OncoQuest Inc., a subsidiary of Quest PharmaTech Inc. from 2015 to 2020. Mr. Van Damme served as chief financial officer of Structural Genomics Consortium 2012 to 2019 and as chief financial officer of Bradmer Pharmaceutics Inc. from 2007 to 2018. Mr. Van Damme holds a B.Comm. from the University of Toronto and a MBA from the Rotman School of Management. Mr. Van Damme is a Chartered Professional Accountant, who worked for PricewaterhouseCoopers in its Toronto and London, UK offices.

CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS

Cease Trade Orders

To the knowledge of the Company, no director or executive officer of the Company (nor any personal holding company of any of such persons) is, as of the date of this AIF, or was within ten years before the date of this AIF, a director, chief executive officer or chief financial officer of any company (including the Company), that: (a) was subject to a cease trade order (including a management cease trade order), an order similar to a cease trade order or an order that denied the relevant company access to any exemption under securities legislation, in each case that was in effect for a period of more than 30 consecutive days (collectively, an "**Order**"), that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer; or (b) was subject to an Order that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

Bankruptcies

To the knowledge of the Company no director or executive officer of the Company (nor any personal holding company of any of such persons), or Shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company: (a) is, as of the date of this AIF, or has been within the ten years before the date of this AIF, a director or executive officer of any company (including the Company) that, while that person was acting in that capacity, or within a year of that person ceasing to

act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or (b) has, within the ten years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the director, executive officer or Shareholder.

Penalties or Sanctions

To the knowledge of the Company, no director or executive officer of the Company (nor any personal holding company of any of such persons), or Shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company, has been subject to: (a) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or (b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

Conflicts of Interest

Certain officers and directors of the Company are also officers and/or directors of other companies engaged in the biotechnology industry. As a result, situations may arise where the interest of such directors and officers conflict with their interests as directors and officers of other companies. The resolution of such conflicts is governed by applicable corporate laws, which require that directors act honestly, in good faith and with a view to the best interests of the Company. Conflicts, if any, will be handled in a manner consistent with the procedures and remedies set forth in the BCCA. The BCCA provides that in the event that a director has an interest in a contract or proposed contract or agreement, the director shall disclose his interest in such contract or agreement and shall refrain from voting on any matter in respect of such contract or agreement unless otherwise provided by the BCCA.

AUDIT COMMITTEE INFORMATION

Audit Committee Charter

The Audit Committee Charter is attached as Schedule "A".

Composition and Relevant Education and Experience

The Company's Audit Committee is comprised of three directors: Ian Klassen, Jacqueline Le Saux and Paul Van Damme (Chair).

Relevant Education and Experience

Paul Van Damme (Chair) – Paul Van Damme is a Chartered Professional Accountant with over 45 years business experience. He holds a Bachelor of Commerce degree from the University of Toronto and a MBA from the Rotman School of Management. He is an experienced accountant having worked for Pricewaterhouse Coopers in their Toronto and London, UK offices and he has held the position of CFO with a number of Canadian and US private and public companies including Allelix Biopharmaceuticals Inc., Vasogen Inc. and Structural Genomics Consortium, a UK-based charity. Mr. Van Damme is financially literate and an independent director of the Company for the purpose of NI 52-110.

Ian Klassen – Mr. Klassen has close to 30 years of business experience in the administration of public companies and finance. He is the current President and CEO of two gold exploration companies listed on the TSXV and was a founding director of Canabo Medical Corp., a public company that completed a business combination with Aleafia Health Inc. in March 2018. He has extensive experience chairing governance, audit, risk assessment and compensation committees. Mr. Klassen has a B.A. (Honours) from the University of Western Ontario. Mr. Klassen is financially literate and an independent director of the Company for the purpose of NI 52-110.

Jacqueline Le Saux -- Ms. Le Saux has over 30 years business experience in the public and private markets in the areas of biotechnology, legal compliance and as legal counsel. She is the former Vice President, Legal and Compliance, Purdue Pharma (Canada) from 2009 to 2018, former General Counsel and Corporate Secretary for Patheon Inc. and former Vice President, Corporate and Legal Affairs for Vasogen Inc. Ms. Le Saux is financially literate and an independent director of the Company for the purpose of NI 52-110**.**

Pre-Approval Policies and Procedures for the Engagement of Non-Audit Services

All audit and non-audit services performed by our auditors for the twelve-month period ended December 31, 2021 were pre-approved by our Audit Committee. It is our policy that all audit and non-audit services performed by our auditors will continue to be pre-approved by our Audit Committee.

External Auditor Service Fees

Both our independent auditors and internal financial personnel regularly meet privately with the audit committee and have unrestricted access to this committee. Smythe LLP was retained as auditor of the Company's predecessor, XORTX Pharma Corp., and continued as auditor of the Company effective January 9, 2018, the date of the reverse take-over between APAC Resources Inc. and XORTX Pharma Corp. to form XORTX Therapeutics Inc. Prior to Smythe LLP being retained, Manning Elliott LLP acted as auditor of the Company from May 31, 2011 to January 9, 2018. Aggregate fees billed by our independent auditors, Smythe LLP for the year ended December 31, 2021 were $67,897.

	December, 31 2021 ($)	December, 31 2020 ($)	December, 31 2019 ($)	December, 31 2018 ($)
Audit Fees	$ 49,000	$ 18,750	$ 19,500	$ 13,500
Audit-Related Fees	$ 397	—	—	—
Tax Fees	$ 2,500	—	$ 6,000	$ 3,000
All Other Fees	$ 16,000	—	—	$ 950
Total Fees Paid	$ 67,897	$ 18,750	$ 25,500	$ 17,450

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

There are no legal proceedings XORTX is or was a party to, or that any of its property is or was the subject of, during XORTX's most recent financial year, nor are any such legal proceedings known to XORTX to be contemplated, that involves a claim for damages, exclusive of interest and costs, exceeding 10% of the current assets of XORTX.

There are no: (a) penalties or sanctions imposed against XORTX by a court relating to securities legislation or by a securities regulatory authority since XORTX's inception; (b)

other penalties or sanctions imposed by a court or regulatory body against XORTX that would likely be considered important to a reasonable investor in making an investment decision; and (c) settlement agreements XORTX entered into before a court relating to securities legislation or with a securities regulatory authority since XORTX's inception.

INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Since January 1, 2019, no director or executive officer of the Company or any person or company who beneficially owns, or controls or directs, directly or indirectly more than 10% of the outstanding Common Shares or any known associate or affiliate of such persons, has or has had any material interest direct or indirect, in any transaction or in any proposed transaction that has materially affected or is reasonably expected to material affect the Company except for Prevail, which owns 977,318 common shares, currently representing approximately 7.5% of the issued and outstanding common shares of the Company. Prevail acquired the 977,318 common shares as part of the private placement that closed on February 28, 2020, in connection with an agreement between the Company and Prevail wherein the Company paid a deposit of $1,606,320 (US$1,200,000 at the exchange rate on the date of the transaction) to Prevail to support two clinical trials on behalf of the Company. Prevail, a clinical research organization, is a key partner in XORTX Therapeutics future clinical plans and is anticipated to participate in clinical trials to support XRx-008, XRx-101 and XRx-225 programs in the future.

Other than as described elsewhere in this AIF, there are no material interests, direct or indirect, of any of our directors or executive officers, any shareholder that beneficially owns, or controls or directs (directly or indirectly), more than 10% of any class or series of our outstanding voting securities, or any associate or affiliate of any of the foregoing persons, in any transaction within the three years before the date hereof that has materially affected or is reasonably expected to materially affect us or any of our subsidiaries.

TRANSFER AGENTS AND REGISTRARS

The transfer agent and registrar for our common shares will be TSX Trust Company at its principal office in Toronto, Canada. Our co-transfer agent is Continental Stock Transfer & Trust Company.

Smythe LLP, located at 1700 – 475 Howe Street, Vancouver, British Columbia, Canada V6C 2B3 is our independent registered public accounting firm and has been appointed as our independent auditor.

MATERIAL CONTRACTS

Except for contracts entered into in the ordinary course of business, the only material contracts that the Company has entered into within the last financial year, or before the last financial year which are still in effect, are the following**:**

1. Patent Rights Purchase Agreement dated effective May 26, 2014 between Dr. Richard Johnson, Dr. Takahiko Nakagawa and the Company pursuant to which the Company acquired certain patents and patent applications;
2. Standard Exclusive License Agreement With Know How dated effective June 23, 2014 between the Company and the University of Florida Research Foundation, Inc. ("**UFRF**") pursuant to which the Company acquired the exclusive license to certain intellectual property related to the use of all uric acid lowering agents to treat insulin resistance, as more particularly described in the Company's audited financial statements for the year ended December 31, 2020;
3. Equity Agreement dated effective June 23, 2014 between the Company and UFRF pursuant to which UFRF acquired certain equity interests in the Company;
4. Agreement dated July 20, 2017 between the Company and Cato Research Canada Inc. to manage future regulatory and clinical trial programs;
5. Master Service and Technology Agreement dated effective February 25, 2019 between Prevail InfoWorks, Inc. (a clinical research organization) and the Company to support two clinical trials;
6. Side Letter between Prevail InfoWorks, Inc. Prevail Partners LLC and the Company dated February 24, 2020 in connection with the payment of services provided to the Company through the issuance of common shares of the Company to Prevail Partners LLC;
7. Sponsored Research Agreement between the Regents of the University of Colorado ("**UofC**") and the Company dated May 27, 2021 pursuant to which the UofC has agreed to provide certain research services to the Company;
8. Combined Master Services Agreement made on July 19, 2021 between the Company and Quotient Sciences Limited pursuant to which Quotient Sciences Limited may perform research and related services on the Company's pharmaceutical products;
9. Development and Clinical Manufacturing Services Agreement dated effective August 17, 2021 between the Company and Lonza Ltd. for the manufacturing of the active pharmaceutical ingredient for XRx-008 and XRx-101; and
10. Global Master Services Agreement between Altasciences Company Inc., (a contract research organization) and the Company dated effective December 22, 2021 for the management of the Company's planned bridging pharmacokinetic study in support of the XRx-008 and XRx-101 programs.

Copies of the foregoing may be viewed on the SEDAR website at www.sedar.com.

INTERESTS OF EXPERTS

Our auditor is Smythe LLP, independent registered public accounting firm, located at 1700 – 475 Howe Street, Vancouver, British Columbia, Canada V6C 2B3. Smythe LLP has reported on our fiscal 2020 audited consolidated financial statements, which have been filed with the securities regulatory authorities. As of the date of this AIF, Smythe LLP is independent with respect to the Company within the meaning of the Rules of Professional Conduct of the Chartered Professional Accountants of British Columbia and under all relevant U.S. professional and regulatory standards, including PCAOB Rule 3520.

ADDITIONAL INFORMATION

Additional information relating to the Company can be found on the SEDAR website at www.sedar.com and on the SEC website at https://www.sec.gov/edgar.shtml. Additional information, including directors' and officers' remuneration and indebtedness, principal holders of the Company's securities and securities authorized for issuance under equity compensation plans, if applicable, will be contained in the Company's management proxy circular dated in November 8, 2021, relating to the annual general meeting of Shareholders held on December 20, 2021. Additional financial information is provided in the financial statements and management's discussion and analysis of the Company for the year ended December 31, 2020 and the interim period ended September 30, 2021, which are accessible on the SEDAR website at www.sedar.com and the SEC website at https://www.sec.gov/edgar.shtml.

We also maintain a website at www.xortx.com Information contained in, or accessible through, our website is not a part of this AIF, and the inclusion of our website address in this AIF is an inactive textual reference.

SCHEDULE "A"
AUDIT COMMITTEE CHARTER

GENERAL

1. Purpose and Responsibilities of the Committee

1.1 Purpose

The primary purpose of the Committee is to assist Board oversight of:

(a) the integrity of the Company's financial statements;

(b) the Company's compliance with legal and regulatory requirements;

(c) the External Auditor's qualifications and independence; and

(d) the performance of the Company's internal audit function and the External Auditor.

2. Definitions and Interpretation

2.1 Definitions

In this Charter:

(a) "**Board**" means the board of directors of the Company;

(b) "**Chair**" means the chair of the Committee;

(c) "**Committee**" means the audit committee of the Board;

(d) "**Company**" means XORTX Therapeutics Inc.;

(e) "**Director**" means a member of the Board; and

(f) "**External Auditor**" means the Company's independent auditor.

2.2 Interpretation

The provisions of this Charter are subject to the articles and by-laws of the Company and to the applicable provisions of the*Business Corporations Act* (British Columbia), and any other applicable legislation.

CONSTITUTION AND FUNCTIONING OF THE COMMITTEE

3. Establishment and Composition of the Committee

3.1 Establishment of the Audit Committee

The Committee is hereby continued with the constitution, function and responsibilities herein set forth.

3.2 Appointment and Removal of Members of the Committee

(a) *Board Appoints Members.* The members of the Committee shall be appointed by the Board.

(b) *Annual Appointments*. The appointment of members of the Committee shall take place annually at the first meeting of the Board after a meeting of the shareholders at which Directors are elected, provided that if the appointment of members of the Committee is not so made, the Directors who are then serving as members of the Committee shall continue as members of the Committee until their successors are appointed.

(c) *Vacancies.* The Board may appoint a member to fill a vacancy which occurs in the Committee between annual elections of Directors. If a vacancy exists on the Committee, the remaining members shall exercise all of their powers so long as a quorum remains in office.

(d) *Removal of Member.* Any member of the Committee may be removed from the Committee by a resolution of the Board.

3.3 Number of Members

The Committee shall consist of three or more Directors.

3.4 Independence of Members

Each member of the Committee shall be independent for the purposes of all applicable regulatory and stock exchange requirements. Each member of the Committee

must not have participated in the preparation of the financial statements of the Corporation or any current subsidiary of the Corporation at any time during the past three years.

3.5 Financial Literacy

(a) *Financial Literacy Requirement.* Each member of the Committee shall be financially literate or must become financially literate within a reasonable period of time after his or her appointment to the Committee, and at least one member of the Committee shall have past employment experience in finance or accounting, requisite professional certification in accounting or any other comparable experience or background which results in the individual's financial sophistication, including being or having been a chief executive officer, chief financial officer or other senior officer with financial oversight responsibilities, as each such qualification is interpreted by the Board in its business judgment. In addition, at least one member of the Committee shall be an "audit committee financial expert" as such term is defined by the U.S. Securities and Exchange Commission.

(b) *Definition of Financial Literacy.* "**Financially literate**" means the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Company's financial statements.

4. Committee Chair

4.1 Board to Appoint Chair

The Board shall appoint the Chair from the members of the Committee who are unrelated directors (or, if it fails to do so, the members of the Committee shall appoint the Chair from among its members).

4.2 Chair to be Appointed Annually

The designation of the Committee's Chair shall take place annually at the first meeting of the Board after a meeting of the members at which Directors are elected, provided that if the designation of Chair is not so made, the Director who is then serving as Chair shall continue as Chair until his or her successor is appointed.

5. Committee Meetings

5.1 Quorum

A quorum of the Committee shall be two members.

5.2 Secretary

The Chair shall designate from time to time a person who may, but need not, be a member of the Committee, to be Secretary of the Committee.

5.3 Time and Place of Meetings

The time and place of the meetings of the Committee and the calling of meetings and the procedure in all things at such meetings shall be determined by the Committee; provided, however, the Committee shall meet at least four times per year on a quarterly basis.

5.4 In Camera Meetings

On at least an annual basis, the Committee shall meet separately with each of:

(a) management; and

(b) the External Auditor.

5.5 Right to Vote

Each member of the Committee shall have the right to vote on matters that come before the Committee.

5.6 Voting

Any matters to be determined by the Committee shall be decided by a majority of votes cast at a meeting of the Committee called for such purpose; actions of the Committee may be taken by an instrument or instruments in writing signed by all of the members of the Committee, and such actions shall be effective as though they had been decided by a majority of votes cast at a meeting of the Committee called for such purpose.

5.7 Invitees

The Committee may invite Directors, officers, employees and consultants of the Company or any other person to attend meetings of the Committee to assist in the discussion and examination of the matters under consideration by the Committee. The External Auditor shall receive notice of each meeting of the Committee and shall be entitled to attend any such meeting at the Company's expense.

5.8 Regular Reporting

The Committee shall report to the Board at the Board's next meeting the proceedings at the meetings of the Committee and all recommendations made by the Committee at such meetings.

6. Authority of Committee

6.1 Retaining and Compensating Advisors

The Committee shall have the sole authority to engage independent counsel and any other advisors as the Committee may deem appropriate in its sole discretion and to

set the compensation for any advisors employed by the audit committee. The Committee shall not be required to obtain the approval of the Board in order to retain or compensate such consultants or advisors.

6.2 Funding

The Committee shall have the authority to authorize the payment of:

(a) compensation to any external auditor engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Company (National Instrument 52-110 – *Audit Committees* requires disclosure of fees by category paid to the External Auditor);

(b) compensation for any advisors employed by the audit committee under Section 6.1 hereof; and

(c) ordinary administrative expenses of the Committee that are necessary or appropriate in carrying out its duties.

6.3 Subcommittees

The Committee may form and delegate authority to subcommittees if deemed appropriate by the Committee.

6.4 Recommendations to the Board

The Committee shall have the authority to make recommendations to the Board, but shall have no decision-making authority other than as specifically contemplated in this Charter.

6.5 Compensation

The Committee has the authority to communicate directly with External Auditors and the internal auditors.

7. Remuneration of Committee Members

7.1 Remuneration of Committee Members

Members of the Committee and the Chair shall receive such remuneration for their service on the Committee as the Board may determine from time to time.

7.2 Directors' Fees

No member of the Committee may earn fees from the Company or any of its subsidiaries other than directors' fees (which fees may include cash and/or shares or options or other in-kind consideration ordinarily available to directors, as well as all of the regular benefits that other directors receive). For greater certainty, no member of the Committee shall accept, directly or indirectly, any consulting, advisory or other compensatory fee from the Company.

SPECIFIC DUTIES AND RESPONSIBILITIES

8. Integrity of Financial Statements

8.1 Review and Approval of Financial Information

(a) *Annual Financial Statements*. The Committee shall review and discuss with management and the External Auditor the Company's audited annual financial statements and related management's discussion and analysis ("**MD&A**") together with the report of the External Auditor thereon and, if appropriate, recommend to the Board that it approve the audited annual financial statements.

(b) *Interim Financial Statements.* The Committee shall review and discuss with management and the External Auditor and, if appropriate, approve the Company's interim unaudited financial statements and related MD&A.

(c) *Material Public Financial Disclosure.* The Committee shall discuss with management and the External Auditor:

(i) the types of information to be disclosed and the type of presentation to be made in connection with profit or loss or earnings press releases; and

(ii) financial information and earnings guidance (if any) provided to analysts and rating agencies.

(d) *Procedures for Review*. The Committee shall be satisfied that adequate procedures are in place for the review of the Company's disclosure of financial information extracted or derived from the Company's financial statements (other than financial statements, MD&A and profit or loss or earnings press releases, which are dealt with elsewhere in this Charter) and shall periodically assess the adequacy of those procedures.

(e) *General*. To the extent the Committee deems it necessary or appropriate, the Committee may review and discuss with management and the External Auditor:

(i) major issues regarding accounting principles and financial statement presentations, including any significant changes in the Company's selection or application of accounting principles;

(ii) major issues as to the adequacy of the Company's internal controls over financial reporting and any special audit steps adopted in light of material control deficiencies;

(iii) prepared by management and/or the External Auditor setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of alternative accounting methods on the financial statements;

(iv) the effect on the financial statements of the Company of regulatory and accounting initiatives, as well as off-balance sheet transaction structures, obligations (including contingent obligations) and other relationships of the Company with unconsolidated entities or other persons that have a material current or future effect on the financial condition, changes in financial condition, results of operations, liquidity, capital resources, capital reserves or significant components of revenues or expenses of the Company;

(v) the extent to which changes or improvements in financial or accounting practices, as approved by the Committee, have been implemented;

(vi) any financial information or financial statements in prospectuses and other offering documents;

(vii) the management certifications of the financial statements as required under applicable securities laws in Canada or otherwise; and

(viii) any other relevant reports or financial information submitted by the Company to any governmental body or the public.

9. External Auditor

9.1 External Auditor

(a) *Authority with Respect to External Auditor.* As a representative of the Company's shareholders, the Committee shall be directly responsible for the appointment, compensation and oversight of the work of the External Auditor engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Company. In the discharge of this responsibility, the Committee shall:

(i) have sole responsibility for recommending to the Board the person to be proposed to the Company's shareholders for appointment as External Auditor for the above-described purposes and recommending such External Auditor's compensation;

(ii) determine at any time whether the Board should recommend to the Company's shareholders that the incumbent External Auditor should be removed from office;

(iii) review the terms of the External Auditor's engagement, discuss the audit fees with the External Auditor and be solely responsible for approving such audit fees; and

(iv) require the External Auditor to confirm in its engagement letter each year that the External Auditor is accountable to the Board and the Committee as representatives of shareholders.

(b) *Independence*. The Committee shall satisfy itself as to the independence of the External Auditor. As part of this process the Committee shall:

(i) require the External Auditor to submit on a periodic basis to the Committee a formal written statement delineating all relationships between the External Auditor and the Corporation consistent with The Public Company Accounting Oversight Board Rule 3526 and engage in a dialogue with the External Auditor with respect to any disclosed relationships or services that may impact the objectivity and independence of the External Auditor and recommend that the Board take appropriate action in response to the External Auditor's report to satisfy itself of the External Auditor's independence;

(ii) unless the Committee adopts pre-approval policies and procedures, approve any non-audit services provided by the External Auditor, provided the Committee may delegate such approval authority to one or more of its independent members who shall report promptly to the Committee concerning their exercise of such delegated authority; and

(iii) review and approve the policy setting out the restrictions on the Company partners, employees and former partners and employees of the Company's current or former External Auditor.

(c) *Issues Between External Auditor and Management*. The Committee shall:

(i) review any problems experienced by the External Auditor in conducting the audit, including any restrictions on the scope of the External Auditor's activities or access to requested information; and

(ii) review any significant disagreements with management and, to the extent possible, resolve any disagreements between management and the External Auditor.

(d) *Non-Audit Services*:

(i) The Committee shall either:

(A) approve any non-audit services provided by the External Auditor or the external auditor of any subsidiary of the Company to the Company (including its subsidiaries); or

(B) adopt specific policies and procedures for the engagement of non-audit services, provided that such pre-approval policies and procedures are detailed as to the particular service, the audit committee is informed of each non-audit service and the procedures do not include delegation of the audit committee's responsibilities to management.

(ii) The Committee may delegate to one or more independent members of the Committee the authority to pre-approve non-audit services in satisfaction of the requirement in the previous section, provided that such member or members must present any non-audit services so approved to the full Committee at its first scheduled meeting following such pre-approval.

(iii) The Committee shall instruct management to promptly bring to its attention any services performed by the External Auditor which were not recognized by the Company at the time of the engagement as being non-audit services.

10. Other

10.1 Related Party Transactions

The Committee shall review and approve all related party transactions in which the Company is involved or which the Company proposes to enter into.

10.2 Expense Accounts

The Committee shall review and make recommendations with respect to:

(a) the expense account summaries submitted by the President and Chief Executive Officer on an annual basis;

(b) the Company's expense account policy, and rules relating to the standardization of the reporting on expense accounts.

10.3 Whistle Blowing

The Committee shall put in place procedures for:

(a) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters; and

(b) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.

11. Performance Evaluation

On a regular basis, the Committee shall follow the process established by the Board for assessing the performance and effectiveness of the Committee.

12. Charter Review

The Committee shall review and assess the adequacy of this Charter on an annual basis and recommend to the Board any changes it deems appropriate.

Approved and adopted by the Board on August 9, 2021.

FORM 52-109F1R
CERTIFICATION OF REFILED ANNUAL FILINGS

This certificate is being filed on the same date that XORTX Therapeutics Inc. (the "issuer") has refiled its voluntarily filed annual information form (the "AIF") for the financial year ended December 31, 2021.

I, Allen Davidoff, Chief Executive Officer of the issuer, certify the following:

1. ***Review:*** I have reviewed the AIF, if any, annual financial statements and annual MD&A, including, for greater certainty, all documents and information that are incorporated by reference in the AIF (together, the "annual filings") of the issuer for the financial year ended December 31, 2021.

2. ***No misrepresentations:*** Based on my knowledge, having exercised reasonable diligence, the annual filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, for the period covered by the annual filings.

3. ***Fair presentation:*** Based on my knowledge, having exercised reasonable diligence, the annual financial statements together with the other financial information included in the annual filings fairly present in all material respects the financial condition, financial performance and cash flows of the issuer, as of the date of and for the periods presented in the annual filings.

Date: April 12, 2022.

Signed: "Allen Davidoff"
Allen Davidoff
Chief Executive Officer

NOTE TO READER

In contrast to the usual certificate required for non-venture issuers under National Instrument 52-109*Certification of Disclosure in Issuers' Annual and Interim Filings* (NI 52-109), namely, Form 52-109F1, this Form 52-109F1 - IPO/RTO does not include representations relating to the establishment and maintenance of disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as defined in NI 52-109. In particular, the certifying officers filing this certificate are not making any representations relating to the establishment and maintenance of

(i) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and

(ii) a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP.

The issuer's certifying officers are responsible for ensuring that processes are in place to provide them with sufficient knowledge to support the representations they are making in this certificate.

Investors should be aware that inherent limitations on the ability of certifying officers of an issuer to design and implement on a cost effective basis DC&P and ICFR as defined in NI 52-109 in the first financial period following:

- completion of the issuer's initial public offering in the circumstances described in s. 4.3 of NI 52-109;
- completion of a reverse takeover in the circumstances described in s. 4.4 of NI 52-109; or
- the issuer becoming a non-venture issuer in the circumstances described in s. 4.5 of NI 52-109;

may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

FORM 52-109F1R
CERTIFICATION OF REFILED ANNUAL FILINGS

This certificate is being filed on the same date that XORTX Therapeutics Inc. (the "issuer") has refiled its voluntarily filed annual information form (the "AIF") for the financial year ended December 31, 2021.

I, Amar Keshri, Chief Financial Officer of the issuer, certify the following:

1. ***Review:*** I have reviewed the AIF, if any, annual financial statements and annual MD&A, including, for greater certainty, all documents and information that are incorporated by reference in the AIF (together, the "annual filings") of the issuer for the financial year ended December 31, 2021.

2. ***No misrepresentations:*** Based on my knowledge, having exercised reasonable diligence, the annual filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, for the period covered by the annual filings.

3. ***Fair presentation:*** Based on my knowledge, having exercised reasonable diligence, the annual financial statements together with the other financial information included in the annual filings fairly present in all material respects the financial condition, financial performance and cash flows of the issuer, as of the date of and for the periods presented in the annual filings.

Date: April 12, 2022.

Signed: "Amar Keshri"
Amar Keshri
Chief Financial Officer

NOTE TO READER

In contrast to the usual certificate required for non-venture issuers under National Instrument 52-109*Certification of Disclosure in Issuers' Annual and Interim Filings* (NI 52-109), namely, Form 52-109F1, this Form 52-109F1 - IPO/RTO does not include representations relating to the establishment and maintenance of disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as defined in NI 52-109. In particular, the certifying officers filing this certificate are not making any representations relating to the establishment and maintenance of

(i) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and

(ii) a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP.

The issuer's certifying officers are responsible for ensuring that processes are in place to provide them with sufficient knowledge to support the representations they are making in this certificate.

Investors should be aware that inherent limitations on the ability of certifying officers of an issuer to design and implement on a cost effective basis DC&P and ICFR as defined in NI 52-109 in the first financial period following:

- completion of the issuer's initial public offering in the circumstances described in s. 4.3 of NI 52-109;
- completion of a reverse takeover in the circumstances described in s. 4.4 of NI 52-109; or
- the issuer becoming a non-venture issuer in the circumstances described in s. 4.5 of NI 52-109;

may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.