Table of Contents

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

**FORM 20-F**

**(Mark One)**

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

**OR**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2022**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**OR**

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report . . . . . .

**For the transition period from_____to_____**

Commission file number: 001-40858

## XORTX Therapeutics Inc.

(Exact name of Registrant as specified in its charter)

**N/A**

(Translation of Registrant's name into English)

**British Columbia, Canada**

(Jurisdiction of Incorporation or Organization)

**3710 — 33rd Street NW, Calgary, Alberta, T2L 2M1, Canada**

(Address of Principal Executive Offices)

**Amar Keshri, Chief Financial Officer**
**Telephone: 1-403-455-7727**
**E-mail: akeshri@xortx.com**
**3710 — 33rd Street NW, Calgary, Alberta, T2L 2M1, Canada**

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Shares | XRTX | The Nasdaq Stock Market LLC |

Securities registered or to be registered pursuant to Section 12(g) of the Act

None

(Title of Class)

Securities for which there is a reporting obligation pursuant to section 15(d) of the Act

None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 15,030,687

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

□Yes ☒No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

□Yes ☒No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒Yes □No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files)

☒Yes □No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer □ Accelerated filer □ Non-accelerated filer ☒
Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

□

† The term "new or revised financial accounting standard" refers to any updated issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on an attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

□

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

□

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b)

□Yes □No

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP □ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other □

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

□ Item 17 □ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

□Yes ☒No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court

□Yes □No

**TABLE OF CONTENTS**

## GENERAL MATTERS

Unless otherwise noted or the context indicates otherwise "we", "us", "our", the "Company" or "XORTX" refer to XORTX Therapeutics Inc. and its subsidiaries.

Unless otherwise indicated, financial information in this Annual Report on Form 20-F (the "**Annual Report**") has been prepared in accordance with International Financial Reporting Standards ("**IFRS**") as issued by the International Accounting Standards Board ("**IASB**"). Unless otherwise noted herein, all references to "$," "Canadian dollars," or "dollars" are to the currency of Canada and "US$," "United States dollars," or "U.S. dollars" are to the currency of the United States.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 ("**JOBS Act**"), and as such, we have elected to comply with certain reduced U.S. public company reporting requirements.

The Company prepares and reports its consolidated financial statements in accordance with IFRS. However, this Annual Report may refer to certain non-IFRS measures including key performance indicators used by management. These measures are not recognized measures under IFRS and do not have a standardized meaning prescribed by IFRS and are therefore unlikely to be comparable to similar measures presented by other companies. Rather, these measures are provided as additional information to complement those IFRS measures by providing further understanding of the Company's results of operations from management's perspective. Accordingly, these measures should not be considered in isolation nor as a substitute for analysis of the Company's financial information reported under IFRS.

Unless otherwise indicated, the Company has obtained the market and industry data contained in this Annual Report from its internal research, management's estimates and third-party public information and other industry publications. While the Company believes such internal research, management's estimates and third-party public information is reliable, such internal research and management's estimates have not been verified by any independent sources and the Company has not verified any third-party public information. While the Company is not aware of any misstatements regarding the market and industry data contained in this Annual Report, such data involves risks and uncertainties and are subject to change based on various factors, including those described under "Cautionary Statement Regarding Forward-Looking Information and Statements" and "Item 3.D. Risk Factors".

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this Annual Report 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 Annual Report should not be unduly relied upon. These statements speak only as of the date of this Annual Report. In addition, this Annual Report may contain forward-looking statements and forward-looking information attributed to third party industry sources.

In particular, forward-looking statements in this Annual Report 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 XRx-008, also referred to by its trademarked named XORLO™ herein. XORTX's proprietary formulation of oxypurinol, and any other product candidates we may develop, and the labeling under any approval we may obtain;
- regulatory approvals and discussions and other regulatory developments in the United States, the EU and other countries;

- the performance of third-party manufacturers and contract research organizations;
- our plans to develop and commercialize our product candidates;
- our plans to advance research in other kidney disease applications;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the successful development of our sales and marketing capabilities;
- the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available; and
- the loss of key scientific or management personnel.

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.

## RISK FACTORS SUMMARY

The following is a summary of the uncertainties and factors, among others (including those set forth under "Risk Factors"), that 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 clinical research organizations ("**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 Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the "**Hatch-Waxman Amendments**" to the FDCA 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.

## PART I

### ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

#### 1.A. Directors and Senior Management

The Company's directors and senior management include the following individuals:

| Name | Position with the Company |
|---|---|
| Allen Davidoff | President and Chief Executive Officer and Director |
| Stacy Evans | Chief Business Officer |
| William Farley | Director |
| Anthony J. Giovinazzo | Non-Executive Chair |
| Stephen Haworth | Chief Medical Officer |
| Amar Keshri | Chief Financial Officer |
| Ian Klassen | Director |
| Jacqueline Le Saux | Director |
| Raymond Pratt | Director |
| Paul Van Damme | Director |

The business address for each of the above is c/o XORTX Therapeutics Inc., 3710 – 33rd Street NW, Calgary, Alberta, T2L 2M1. For additional information, including the background and business experience of our officers and directors, see "Item 6.A. – Directors and Senior Management"

#### 1.B. Advisers

Not required.

#### 1.C. Auditors

Smythe LLP ("**Smythe**"), of Vancouver, Canada, (Public Company Accounting Oversight Board ("**PCAOB**") Firm ID No. 995) serves as the Company's auditor. Smythe has served as the Company's auditor since 2018.

### ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not required.

### ITEM 3. KEY INFORMATION

#### 3.A.

[Reserved]

#### 3.B. Capitalization and Indebtedness

Not required.

#### 3.C. Reasons for the Offer and Use Of Proceeds

Not required.

### 3.D. 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, without par value of the Company (the "**Common Shares**") 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, 2020, 2021 and 2022 were $1,284,602, $1,652,282, and $9,485,309, respectively. As of December 31, 2022, our accumulated deficit was approximately $19,175,589. 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 U.S. Food and Drug Administration ("**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.

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 operation.

***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, recent bank failures, 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 (a product candidate in development for autosomal dominant polycystic kidney disease "**ADPKD**") and XRx-101 (product candidate in development for respiratory virus infections) 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 Investigational New Drug ("**IND**") application-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 current Good Manufacturing Practices ("**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 late 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, some of which are still in preclinical 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 preclinical and 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.***

Subject to further discussions with FDA, we plan to initiate a Phase 3 clinical trial for the 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 acute kidney injury ("**AKI**") in respiratory virus 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 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 respiratory virus infection 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 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 contraindications, warnings and precautions, limitations of use, 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 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 and limitations of use 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 ("**Risk Evaluation and Mitigation Strategy**") 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, if the product candidate is approved, 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, IRBs 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 extent to which the COVID-19 pandemic may impact our business and clinical trials will depend on future developments. Although it is difficult for the Company to accurately predict the extent to which it might be so affected, the Company will continue to monitor all developments regarding COVID-19 on an ongoing basis.

***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. Even if a product candidate qualifies for one of these programs, it may not receive approval on an expedited basis or at all. In addition, the regulatory body may later decide that the product candidate no longer meets the criteria for designation and revoke it.

***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 product candidates, if approved, 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. In July 2021, the FDA resumed standard inspectional operations of domestic facilities. The FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Beginning on February 7, 2022, FDA resumed conducting domestic surveillance inspections given the decline in COVID-19 cases across the country. The FDA continues to conduct both foreign and domestic mission-critical inspections, proceed with previously planned foreign surveillance inspections, and assess priorities for future inspections.

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 current good clinical practices ("**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, respiratory virus infections, such as 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 opportunities 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 (if at all) 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.

***FDA has granted the Company's Orphan Drug Designation request for XRx-008. We will continue to seek orphan drug status for one or more of our product candidates, including in jurisdictions outside the U.S., but even where it is granted, we may be unable to maintain any benefits associated with orphan drug status, including market exclusivity for any of the product candidates that we are developing. 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. XRx-008 has received Orphan Drug Designation. We plan to seek Orphan Drug Designation for 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.

Although we have received Orphan Drug Designation for XRx-008, the FDA may not approve any such request for our other product candidates. Even if the FDA grants orphan drug status, as it has done with XRx-008, 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 for any of our other product candidates 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.

***Healthcare legislation, including potentially unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives could harm our business in the future.***

We operate in a highly regulated industry. The commercial potential for our approved products, if any, could be affected by changes in healthcare spending and policy in the United States and abroad. New laws, regulations or judicial decisions or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could adversely affect our business, operations and financial condition. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product candidates, if approved. The United States government, state legislatures and foreign governments have taken action to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs and biologics.

In the United States, the Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our product candidates, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

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 and for which we receive approval.

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 respiratory virus 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 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 or healthcare programs, 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 approved.

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, if approved.***

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, as amended ("**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 for which we receive approval 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 residual impacts of the COVID-19 pandemic on our business are uncertain.***

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. In response to the outbreak, governmental authorities in Canada and internationally introduced various recommendations and measures to try to limit the pandemic, including travel restrictions, border closures, non- essential business closures, quarantines, self-isolations, shelters-in-place, and social distancing. The COVID-19 outbreak and the response of governmental authorities to try to limit its effects have had a significant impact on the private sector and individuals, including unprecedented business, employment, and economic disruptions.

The presence and spread of COVID-19 nationally and globally could have a material adverse impact on the Company's business, operations, financial results, and position and prospects, including through employee attrition and disruptions to the Corporation's activities, as well as a deterioration of general economic conditions including a possible national or global recession.

**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 costs as a result of operating as a public company in the United States, and our management is 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 is required to perform additional tasks. For example, we adopted 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 U.S. securities laws.

In addition, while we are currently listed on the TSX Venture Exchange ("**TSXV**"), the Nasdaq Stock Market LLC ("**Nasdaq**") and the Frankfurt, Munich, Berlin, and Stuttgart Stock Exchanges under the trading symbol "ANU", regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and the related rules and regulations implemented by the Securities and Exchange Commission (the "**SEC**"), the applicable Canadian securities regulators, or Nasdaq, have increased legal and financial compliance costs and have made some compliance activities more time consuming. We are investing 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 October 15, 2021 closing of our initial public offering of securities in the U.S. (the "**US IPO Offering**"), we increased our directors' and officers' insurance coverage which increased 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. 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 are 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 U.S. Exchange Act of 1934, as amended (the "**Exchange Act**"). Accordingly, our shareholders may not know on as timely a basis as with U.S. domestic issuers 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 of 1933, as amended (the "**Securities Act**") and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the 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 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**"). We could be an "emerging growth company" for up to five years following the completion of the US IPO Offering, although, if we have more than US$1.235 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 if required, 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.

For so long as we remain a foreign private issuer, we are required to disclose changes made in our internal controls and procedures on an annual 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 IPO 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 the Frankfurt Stock Exchange, Munich Stock Exchange, Berlin Stock Exchange, and Stuttgart Stock Exchange under the trading symbol "ANU". We cannot assure you that an active trading market for our Common Shares will develop on the TSXV, Nasdaq, or the Frankfurt, Munich, Berlin, and Stuttgart exchanges 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.

***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.***

Even if we cure the minimum bid price deficiency, 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 *Business Corporation Act* (British Columbia) ("**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 Annual Report.***

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 (as defined below in "*Material U.S. Federal Income Tax Considerations for U.S. Holders*") of the Company's shares 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 is raised in an 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, 2022. Based on current business plans and financial expectations, we may be a PFIC for our taxable year ending December 31, 2023, or future taxable years, and we cannot provide any assurances regarding our PFIC status for any current or future taxable year.

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. Investors should consult their own tax advisors regarding the potential consequences if we were or were to become a PFIC, including the availability, and advisability, of, and procedure for making certain tax elections that may in certain circumstances mitigate possible adverse U.S. federal income tax consequences that may result from PFIC status.

***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 *Canada Business Corporations Act* ("**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 election 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 Shares.***

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 Annual Report 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, and for which we receive approval, 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 GCP regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP 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 GCP 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 GCP 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 United States Patent and Trademark Office ("**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 noncompetition 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 noncompetition 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 inlicensed 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 bloodborne 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. Stacy Evans, our Chief Business 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 Annual Report, we had three full-time employees and 14 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, contract manufacturing organizations 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.

## ITEM 4. INFORMATION ON THE COMPANY

### 4.A. History and Development of the Company

**Name, Address and Incorporation**

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. XORTX Pharma Corp. ("**XORTX Pharma**") was incorporated under the laws of Alberta, Canada on August 24, 2012 under the name ReVasCor Inc. and was continued under the Canada Business Corporations Act on February 27, 2013 under the name of XORTX Pharma Corp. 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 a wholly owned subsidiary of the Company and is the Company's only subsidiary.

Our registered office is located at Suite 2900, 550 Burrard Street, Vancouver, British Columbia, V6C 0A3. Our operations office and mailing address is 3710 – 33rd Street NW, Calgary, Alberta, T2L 2M1 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 Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

**General Development of the Business of the Company**

***Recent Developments***

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, product candidate in development for ADPKD, 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. In April 2023, FDA granted the Company's Orphan Drug Designation request for XRx-008.

On March 14, 2022, the Company announced that it submitted a clinical trial application with Health Canada for the XRX-OXY-101 bridging pharmacokinetics study (the "**XRX-OXY-101 PK Clinical Trial**"). The XRX-OXY-101 PK Clinical Trial was originally submitted as three-part, single-dose, fed or fasted, then, multi-dose crossover comparative bioavailability and pharmacokinetic study in healthy volunteers. It was designed to permit XORTX to characterize the safety and relative bioavailability of the XRx-008 formulation with knowledge gained during the conduct of the trial providing guidance regarding the oral dose of XRx-008 for our planned registration trial in autosomal dominant polycystic kidney disease ("**ADPKD**"). Additionally, we believe the XRX-OXY-101 PK Clinical Trial will provide data to support future New Drug Application ("**NDA**") submissions to the FDA and a Marketing Authorization Application ("**MAA**") to the European Medicines Agency ("**EMA**").

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 respiratory virus infection.

On March 31, 2022, the Company announced the filing of an investigational new drug ("**IND**") application with the FDA 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 ("**XOI**") for renal and other diseases where aberrant purine metabolism has been implicated in disease progression.

On April 12, 2022, the Company announced receipt of a no objection letter from Health Canada regarding the Company's XRX-OXY-101 Clinical Trial referenced above.

On April 20, 2022, the Company announced receipt of Small and Medium Enterprise ("**SME**") status for the European Union (the "**EU**"). This status is applicable for the EMA related interactions and confirmed by the SME office – Regulatory Science and Innovation Task Force. SME status provides reduced costs to the Company as it initiates discussions with the EMA regarding the upcoming XRX-OXY-301 phase 3 registration trial for XRx-008 and other clinical programs.

On May 3, 2022, the Company announced that dosing of human subjects had been initiated in the XRX- OXY-101 PK Clinical Study. In addition, successful recruitment for part one of the three-part (now four-part) clinical trial was completed with 32 subjects receiving study drug. Following administration of the first dose of drug, blood sampling and bioanalytical evaluation was conducted to characterize the pharmacokinetics and bioavailability of the XRx-008 program's XORLO™ for future clinical trials development. Additionally, the XRX-OXY-101 PK Clinical Trial will provide fundamental information for the 505(b)2 marketing approval filing of the XRx-008 program.

On May 5, 2022, the Company announced receipt of official notification from the FDA that the Company's recent IND application had been reviewed and cleared. Accompanying this notification was a "Study May Proceed Letter" regarding the XRX-OXY-101 PK Clinical Trial. We plan to use data collected in the XRX-OXY-101 trial to support development of XRx-008 for the treatment of progressing kidney disease due to ADPKD.

On July 7, 2022, following the successful regulatory filings with the FDA and Health Canada and commencement of the OXY-XRX-101 PK Clinical Study, the Company submitted a type B pre-Phase 3 meeting request with the FDA.

On July 13, 2022, the Company announced positive topline results from Part 1 of the three-part (now four part) XRX-OXY-101 PK Clinical Trial showing a substantial increase in oral bioavailability of two versions of XORTX's proprietary oxypurinol formulation compared to a control formulation. In addition to the substantial increase in bioavailability in part one of the XRX-OXY-101 PK Clinical Trial, XRx-008 was well-tolerated with a favorable pharmacologic profile. No drug related adverse or serious adverse events related to oral administration of oxypurinol were observed.

On July 19, 2022, the Company announced submission of a request for "scientific advice review" to the EMA and more specifically the Committee for Medical Products for Human Use (the "**CHMP**") regarding the XRx-008 program. This submission for CHMP/EMA review initiated discussions regarding the status of XORTX's XRx-008 program for ADPKD, plans for its global phase 3 registration trial, and included scientific advice pertaining to marketing approval in the EU.

On August 4, 2022, the Company announced that the pre-Phase 3 meeting request made to the FDA resulted in the grant of a virtual meeting scheduled on September 16, 2022. In advance of this meeting, XORTX submitted a "Pre-Phase-3 Briefing Package" to the FDA on July 28, 2022.

On August 22, 2022, the Company announced positive topline results from its XRX-OXY-101 PK Clinical Trial – Part 2 showing a substantial increase in oral bioavailability of XORLO™ provided with food compared to the fasted state. In addition to the substantial increase in bioavailability in part 2, XRx-008 was well-tolerated with a favorable pharmacologic profile. No drug related adverse or serious adverse events related to oral administration of oxypurinol were observed.

On September 19, 2022, the Company announced the completion of the Type B Pre-phase 3 meeting with the FDA held on September 16, 2022. A Type B meeting is a routine meeting that occurs at pre-fined end-points between the FDA and a sponsor. Type B meetings typically occur right after, or right before submission of clinical data or a new drug filing. In advance of this meeting, XORTX submitted a "Pre-Phase-3 Briefing Package" to the FDA on July 28, 2022 and received responses from, and responded to the FDA prior to the virtual meeting. The FDA provided guidance on the design of the planned Phase 3 clinical trial.

On October 26, 2022, the Company announced receipt of a further no objection letter from Health Canada regarding the Company's ongoing XRX-OXY-101 PK Clinical Trial. The Company successfully completed parts 1 and 2 of the XRX-OXY-101 PK Clinical Trial, modified part 3 and added an additional part 4. The XRX-OXY-101 PK Clinical Trial was originally designed with three objectives: 1) to evaluate which of XORTX's novel formulations results in the best circulating oxypurinol concentrations; 2) to evaluate the effect of food on the bioavailability of this formulation; and 3) to evaluate the safety and pharmacokinetics of multiple doses of this selected formulation. After completion of parts 1 and 2, XORTX redesigned part 3 to include an additional characterization of food effect and added a fourth objective - part 4 - to characterize the proportion of oxypurinol absorbed with three increasing doses of XRx-008

On November 3, 2022, the Company announced the presentation of a peer-reviewed abstract that was presented on November 4, 2022 at the American Society of Nephrology Annual Conference – Kidney Week. The Abstract presented new discoveries in two species – mouse and rat models of polycystic kidney disease ("**PKD**") and reported original work showing the harmful consequences of chronically increased uric acid on both structure and function of kidneys. The Abstract "Raising Serum Uric Acid with a Uricase Inhibitor Worsens PKD in Rat and Mouse Models" was presented during the Session Title: Genetic Diseases of the Kidneys, by Dr. Charles Edelstein of the University of Colorado and Dr. Allen Davidoff, Chief Executive Officer ("**CEO**") of XORTX. This presentation reported for the first time, that XORTX's XRx008 formulation of XOI substantially and significantly blocked the increase in kidney size associated with high circulating uric acid in a rodent model of polycystic kidney disease.

On November 25, 2022, the Company announced that it received notification from Nasdaq Listing Qualifications Department that it was not in compliance with the minimum bid price requirement set forth in Nasdaq Rule 5550(a)(2) since the closing bid price for the Company's Common Shares listed on Nasdaq was below US$1.00 for 30 consecutive business days. Nasdaq Rule 5550(a)(2) requires the shares to maintain a minimum bid price of US$1.00 per share, and Nasdaq Rule 5810(c)(3)(A) provides that failure to meet such a requirement exists when the bid price of the shares is below US$1.00 for a period of 30 consecutive business days. It was noted that these notifications do not impact the Company's listing on Nasdaq at this time. In accordance with Listing Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from the date of notification to regain compliance with the minimum bid price requirement, during which time the shares will continue to trade on the Nasdaq Capital Market. If at any time before the 180-calendar day period, the bid price of the shares closes at or above US$1.00 per share for a minimum of 10 consecutive business days, Nasdaq has the discretion to provide written notification that the Company has achieved compliance with the minimum bid price requirement and consider such deficiency matters closed.

On November 28, 2022, the Company announced the successful screening and enrollment of the last remaining subjects into the XRX-OXY-101 PK Clinical Trial, including initiation of dosing of all subjects enrolled in part 4 of the XRX-OXY-101 PK Clinical Trial.

On December 8, 2022, the Company announced new proof of concept data supporting, in a second study, the effectiveness of XOI produced by the Company's proprietary oral oxypurinol formulation, XORLO™, in a mouse model of ADPKD. This new experimental data reproduces the result reported at the American Society of Nephrology meeting held November 2022 and added further new evidence to support our belief that XOI produced by our proprietary formulation of oxypurinol at doses that would be considered moderate-to-low in man is effective at inhibiting the expansion of kidneys in ADPKD.

On December 19, 2022, the Company announced the completion of dosing in the XRX-OXY-101 PK Clinical Trial, in each of parts 1 through 4. Positive topline results from the XRX-OXY-101 PK Clinical Trial characterizing the pharmacokinetics of XORLO™ was announced on January 19, 2023. In the study, XORLO™ was well tolerated across the various dosing regimens. No safety issues were identified in any of the four parts of the XRX-Oxy-101 PK Clinical Trial on the 88 subjects who received drug.

On January 3, 2023, the Company announced the submission of a PCT patent application seeking international patent protection for the patent entitled "Compositions and Methods for Diagnosis, Treatment and Prevention of Kidney Disease".

On February 1, 2023, the Company announced it submitted an Orphan Drug Designation ("**ODD**") Request to the FDA for the XRx-008 program for the treatment of ADPKD. In April 2023, FDA granted the Company's Orphan Drug Designation request for XRx-008.

On March 14, 2023, the Company announced the submission of a Type D meeting request to the FDA and a response setting the date for a virtual meeting on May 1, 2023. A Type D meeting provides an opportunity to discuss with the FDA a narrow set of issues on a shorter timeline than with other meeting types. Additionally, a revised clinical trial protocol for XRX-OXY-301 was submitted, a data update from the XRX-OXY-101 PK Clinical Trial as well as a description of future clinical development program plans for XORLO™ for the treatment of ADPKD. We believe our prior discussions with the FDA and existing agency guidance will permit application for accelerated approval based on specified validated endpoints such as total kidney volume in ADPKD. We believe submission of this revised clinical trial protocol, XRX-OXY-301, will provide the opportunity for XORTX's XRx-008 program to potentially achieve earlier completion of our planned registration trial and importantly to potentially accelerate our application to FDA for marketing approval.

On April 21, 2023, the Company announced receipt of FDA Orphan Drug Designation for XRx-008.

For the balance of 2023, XORTX will continue its focus on advancing XORLO™ as part of the XRx-008 program for ADPKD into a Phase 3 registration clinical trial, initiation of special protocol assessment ("**SPA**") discussions with the FDA and initiation of commercialization activities, if approved, for XORLO™ as well as advancing research in other kidney disease applications. To achieve these objectives, XORTX's action plan includes:

1. **Initiate the Phase 3 clinical trial, XRX-OXY-301, to support an application for "Accelerated Approval" of XORLO™ for individuals with ADPKD** (the "**XRX-OXY-301 Clinical Trial**")**.** The XRX-OXY-301 Clinical Trial is a Phase 3, Multi-Centre, Double-Blind, Placebo Controlled, Randomized Withdrawal Design Study to Evaluate the Efficacy and Safety of a Novel Oxypurinol Formulation in Patients with Progressing Stage 2-4 ADPKD and Coexistent Hyperuricemia. XORTX anticipates that the XRX-OXY-301 Clinical Trial will provide data to support a future "Accelerated Approval" NDA submissions to the FDA and MAA to the EMA. The XRX-OXY-301 Clinical Trial is planned, subject to additional financing, to start in the second half of 2023 and will enroll individuals with stage 2, 3 or 4 ADPKD accompanied by chronically high uric acid. The objective of the XRX-OXY-301 Clinical Trial is to evaluate the ability of XORLO™ to slow the expansion of total kidney volume over a 12-month treatment period.

2. **Prepare and Communicate with the FDA and EMA regarding the XRX-OXY-302 Registration trial in ADPKD** (the "**XRX-OXY-302 Clinical Trial**")**.** The XRX-OXY-302 Clinical Trial is a Phase 3, Multi-Centre, Double-Blind, Placebo Controlled, Randomized Withdrawal Design Study to Evaluate the Efficacy and Safety of a Novel Oxypurinol Formulation in Patients with Progressing Stage 2-4 ADPKD and Coexistent Hyperuricemia with progressing stage 2, 3, or 4 kidney disease. The objective of the XRX-OXY-302 Clinical Trial is to evaluate the safety and effectiveness of XORLO™ for the XRx-008 program over a 24-month treatment period. The aim of the XRX-OXY-302 Clinical Trial is to characterize the ability of XOI to potentially decrease the rate of decline of glomerular filtration rate. An estimated 300 patients will be enrolled. The XRX-OXY-302 Clinical Trial is planned to start in the second half of 2024, subject to Special Protocol Assessment review by FDA.

3. **Ongoing Chemistry Manufacturing and Control ("CMC") Work**. In parallel with the XRX-OXY-301 and XRX-OXY-302 Clinical Trials, XORTX will be focusing on scale-up, validation and stability testing of clinical drug product supplies of XORLO™ under the Company's IND, as well as future clinical and commercial supplies. All development will be performed according to current GMP methodology. This work will be ongoing throughout 2023.

4. **Activities Related to Potential Commercial Launch.** In preparation for a possible "Accelerated Approval" NDA filing in 2025 in the US for XORLO™XRx,-008, also referred to by its trademarked name XORLO™ herein, XORTX will conduct commercialization studies to support in-depth analysis of pricing and/or reimbursement, as well as evaluate product brand name selection, prepare related filings, and conduct other launch preparation activities. This work will be ongoing from 2023 to 2025.

5. **Activities Related to European Registration.** XORTX will continue to work with and seek out guidance from the EMA to facilitate the path to potential approval of XORLO™ in the EU, including required clinical studies and reimbursement conditions. This work will be ongoing from 2023 through 2026 and will include a future request for orphan drug status.

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

**Three-Year History**

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

***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 Company's 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**") referenced below under "2021".

Intellectual Property Advancements

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 ("**AKI**") in patients due to respiratory virus infection.

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 ("**Private Placement Warrant**"). Each Private Placement 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 TSXV is greater than $14.09 for 10 or more consecutive trading days, the Private Placement Warrants will be accelerated upon notice and the Private Placement Warrants will expire on the 30th calendar day following the date of such notice. In addition, the Private Placement 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 Private Placement 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 (the "**IPO Common Share Purchase Warrants**") 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 IPO Offering**"). The IPO Common Share Purchase 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 (the "**IPO Compensation Warrants**") to purchase up to an additional 435,900 Common Shares at the US IPO Offering price less the underwriting discounts. On October 15, 2021, the underwriters partially exercised their option to purchase additional IPO Compensation Warrants to purchase up to an additional 435,900 Common Shares. On November 8, 2021, the Company issued an additional 355,000 Common Shares at the US IPO 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 IPO 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. 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.

***2022***

Private Placement

On October 7, 2022, the Company closed an underwritten public offering of: (i) 1,400,000 common share units ("**October 2022 Common Share Units**"), with each October 2022 Common Share Unit consisting of one common share, no par value, and one warrant ("**October 2022 Warrant**") to purchase one common share at a public offering price of US$1.00 per Common Share Unit, and (ii) 3,600,000 pre-funded warrant units ("**October 2022 Pre-Funded Units**" and together with the Common Share Units, the "**Units**"), with each October 2022 Pre-Funded Unit consisting of one pre-funded warrant ("**October 2022 Pre-Funded Warrant**") to purchase one common share and one October 2022 Warrant to purchase one common share at a public offering price of US$0.9999 per October 2022 Pre-Funded Unit, for aggregate gross proceeds of US$5 million, prior to deducting underwriting discounts and other offering expenses and excluding any exercise of the underwriters' option to purchase any additional securities as described herein (the "**October 2022 Offering**"). The common shares and October 2022 Warrants contained in the Common Share Units and the October 2022 Pre-Funded Warrants and October 2022 Warrants contained in the October 2022 Pre-Funded Units were immediately separable upon issuance. The October 2022 Warrants have an initial exercise price of US$1.22 per share, are immediately exercisable, and may be exercised for five years from the date of issuance. The October 2022 Pre-Funded Warrants had an exercise price of US$0.0001 per share, were immediately exercisable, and terminated once exercised in full. As of the date of this Annual Report, all 3,600,000 October 2022 Pre-Funded Warrants have been exercised. In addition, the Company granted the underwriters of the October 2022 Offering a 45-day option to purchase up to an additional 750,000 common shares and/or warrants ("**October 2022 Compensation Warrants**") to purchase up to an additional 750,000 common shares at the public offering price less the underwriting discounts.

Further to an investment in connection with the October 2022 Offering, the Company entered into an agreement, approved by the TSXV, to reduce the exercise price of certain outstanding US IPO Common Share Purchase Warrants to purchase up to 910,000 shares of common stock issued in the US IPO Offering (the "**Amended IPO Common Share Purchase Warrants**") and held by certain investors in the October 2022 Offering from US$4.77 per share to US$1.17 per share, effective upon the closing of the October 2022 Offering. All other terms of the Certain Prior US IPO Warrants remained the same.

Intellectual Property Advancements

On March 23, 2022, XORTX announced the submission of a 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 due to severe respiratory virus infection.

On April 7, 2022, XORTX announced receipt of notification that the patent "Formulations of Xanthine Oxidase Inhibitors" will be granted by the 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 has been implicated in disease progression.

Changes in Officers, Directors and Advisory Board Members

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

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

On November 16, 2022, the Company announced the appointment of Dr. Stacy Evans as Chief Business Officer ("**CBO**").

***Significant Acquisitions During 2022***

XORTX did not complete any significant acquisitions during its most recently completed financial year.

**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. The SEC's website contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. We also maintain a website at www.xortx.com. Information contained in, or accessible through, our website is not a part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference.

## 4.B. Business Overview

**Overview**

XORTX Therapeutics is a late clinical-stage biotechnology company focused on identifying, developing and potentially commercializing therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism in orphan (rate) disease indications such as ADPKD and type 2 diabetic nephropathy ("**T2DN**"), as well as AKI associate with respiratory virus infection.

Our focus is on developing three therapeutic product candidates 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 AKI associated with respiratory virus infection; and
- Treat patients with type 2 diabetic nephropathy.

We are also looking to identify other opportunities where our existing and new intellectual property can be leveraged to address health issues.

We believe that our technology is underpinned by well-established research and insights into the underlying biology of aberrant purine metabolism, its health consequences and of oxypurinol, a uric acid lowering agent that works by effectively inhibiting xanthine oxidase. We are developing innovative product candidates that include new or existing drugs that can be adapted to address different disease indications where aberrant purine metabolism and/or elevated uric acid is a common denominator, including polycystic kidney disease, pre-diabetes, insulin resistance, metabolic syndrome, diabetes, diabetic nephropathy, and infection. 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 severe virus infection 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 Programs***

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 product candidates that we believe could represent significant improvements to the standard of care in multiple acute and chronic cardiovascular diseases and specifically kidney disease.

We believe our in-house drug design and formulation capabilities confer a competitive advantage to our therapeutic platforms and are ultimately reflected in our programs. Some of these key advantages are:

Highly modular and customizable

Our platforms can be combined in multiple ways and this synergy can be applied to address acute, intermittent or chronic disease progression. For example, our XRx-101 program for AKI is designed to produce rapid suppression of hyperuricemia then maintain purine metabolism at a low level during viral infection and target management of acute organ injury. Our XRx-008 program is designed for longer term stable chronic oral dosing of xanthine oxidase inhibitors. We believe 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 potential therapeutic benefit of this class of new agents permits us to identify targets and disease that we wish to exploit and then through formulation design optimize those small molecules and proprietary formulations to maximize potentially clinically meaningful therapeutic effect.

Readily scalable and transferable

Our in-house small molecule and formulations design expertise is positioned to create a steady succession of product candidates that are scalable, efficient to manufacture (by us or a partner or contract manufacturing organization), and produce 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 respiratory virus infection, and T2DN. There is no guarantee that the FDA will approve our proposed uric acid lowering agent product candidates for the treatment of kidney disease or the health consequences of diabetes

***Product Candidate Pipeline***

Our lead product candidates are XRx-008, XRx-101, and XRx-225. XRx-008 is in preparations for a Phase 3 registration clinical trial, the last stage of clinical development before application for FDA approval. Our XRx-101 program is advancing toward preparing for a "bridging" pharmacokinetic study for the Company's Phase 3 clinical trial to potentially slow or reverse acute kidney disease in hospitalized individuals with respiratory virus infection. XRx-225 is at the non-clinical stage and advancing toward the clinical development stage.

***Products***

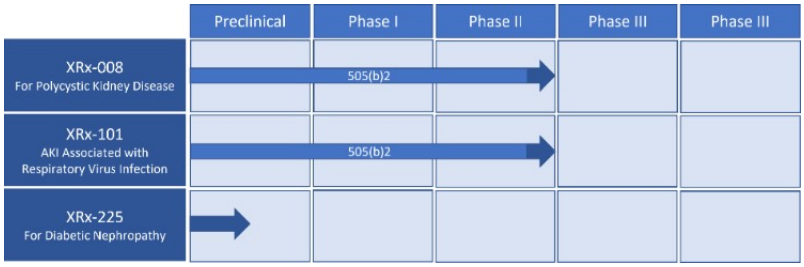
The Company's most advanced development program, XRx-008, is a late clinical stage program focused on demonstrating the potential of our novel product candidate for ADPKD. XRx-008 is the development name given to XORTX's proprietary oral formulation of oxypurinol, and shows increased oral bioavailability compared to oxypurinol alone. XORTX is also developing a second oral formulation of oxypurinol, XRx-101, for use in treating patients infected with respiratory virus infection with associated AKI.

XORTX is currently evaluating xanthine oxidase inhibitor candidates for the XRx-225 program to potentially 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 – U.S. and European patents have been granted. XORTX has also submitted two patent applications to cover the use of uric acid lowering agents for the treatment of the health consequences of respiratory virus infection.

**XORTX Therapeutics Pipeline:**




The interpretation by XORTX based upon FDA discussions is that the 505(b)(2) pathway and right of reference to the former NDA provide XORTX the ability to bypass conducting its own Phase 1 and Phase 2 studies for XRx-008 and XRx-101 programs. However, we may elect to conduct our own Phase 1 and Phase 2 studies as necessary or required to gain marketing approval in the aforementioned programs.

***Our Strategy***

Our goal is to apply our interdisciplinary expertise and pipeline-in-a-product strategy to further identify, develop and commercialize novel treatments in renal disease and indications related to health consequences associated with diabetes. To achieve this objective, we intend to pursue the following strategies:

1. Subject to discussions with FDA, submit an NDA to the FDA following the successful completion of the Phase 3 clinical registration trial of the XRx-008 product candidate program in order to establish a new standard of care for ADPKD.

2. Maximize the potential of the XRx-008 product candidate program, if approved, through independent commercialization and through opportunistic collaborations with third parties.

3. Leverage our pipeline-in-a-product strategy, developing additional proprietary formulations leveraging our experience selecting renal indications and complementing our developments through acquisitions or in-licensing opportunities in nephrology and diabetes when opportunities arise.

***Background***

Uric acid is an essential molecule necessary for excretion of excess nutrients. However, at chronically high levels, serum uric acid ("**SUA**") acts through a newly discovered mechanism to cause disease. If untreated, high uric acid levels may eventually lead to permanent bone, joint and tissue damage, kidney disease, such as ADPKD and AKI, and heart disease. Research has also shown a link between high uric acid levels and cardiovascular and renal diseases, hypertension, insulin resistance, type 2 diabetes, high blood pressure, and fatty liver disease. Figure 1 provides a background on the formation and use of uric acid in the body.

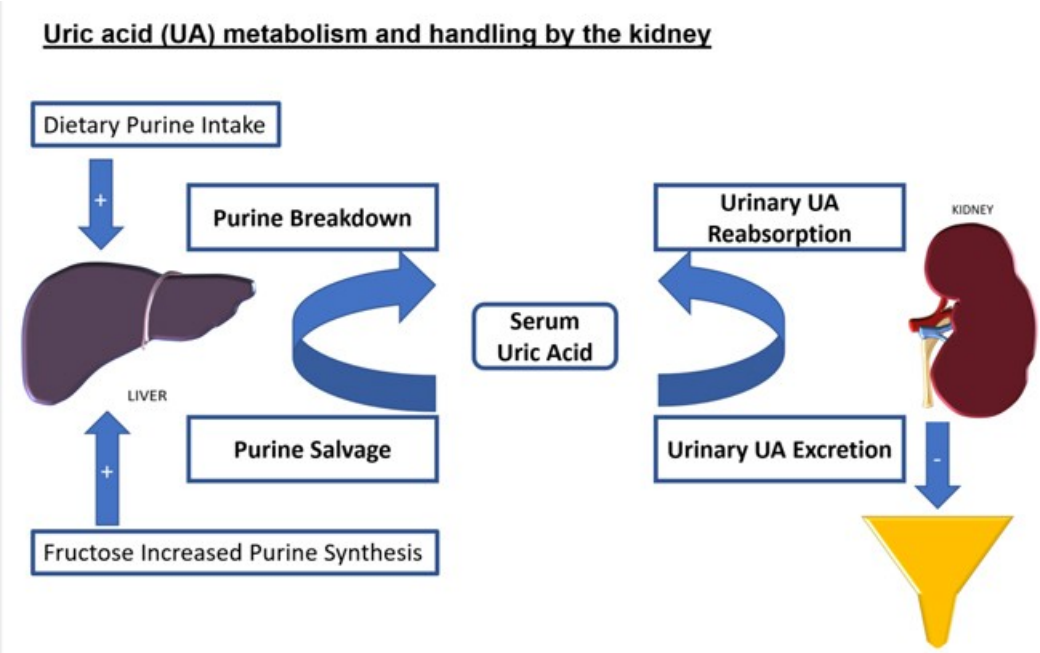



Figure 1: Dietary sources of purines such as yeast, shellfish, organ meats can lead to chronically increased nucleic acids and purines in the circulation. Both are broken down by the liver into uric acid for excretion. Fructose stimulates the liver to produce endogenous purines and can lead to increased serum uric acid. Prior to arrival at the bladder, uric acid can be reabsorbed by the kidney for re-use as a building block for new purine and nucleotide synthesis.

We are focusing on a pipeline-in-a-product strategy with new applications of selected product candidates that treat such diseases and conditions related to high SUA, particularly ADPKD.

ADPKD is caused by mutations from the PKD1 or PKD2 genes, which encode for proteins called polycystin-1 and polycystin-2, respectively. In ADPKD, fluid-filled cysts develop and enlarge in both kidneys, eventually leading to kidney failure. The average size of a typical kidney is a human fist, but polycystic kidneys can get much larger, some growing as large as a football, and can weigh up to 30 pounds each. The onset of ADPKD is often diagnosed at ages between 30 to 50 years. Common symptoms of ADPKD include increased SUA, hypertension, endothelial dysfunction, increased protein in the urine and decreased filtering capacity. ADPKD is a painful disease that impacts quality of life, and nearly 50% of individuals diagnosed with ADPKD progress to end stage renal disease ("**ESRD**"), by the age of 60. Once a person has ERSD dialysis or a transplant are the only treatment options. Approximately 5% of all individuals on dialysis are ADPKD patients. As ADPKD progresses, patients and treating physicians currently have limited therapeutic options to slow or halt progression toward ESRD.

ADPKD represents approximately 90% of polycystic kidney disease cases and is amongst the most rapidly progressing form of polycystic kidney disease and is the most significant genetic cause of kidney failure. In 2014, close to 32,000 patients on long-term renal therapy were attributable to ADPKD, making it the fourth leading cause of new kidney disease cases behind diabetes, hypertension, and glomerulonephritis in the U.S. The estimated 150,000 diagnosed cases of ADPKD in the U.S. includes an annual incidence of approximately 2,500 new patients every year, and we believe a greater number of patients remain undiagnosed. In Europe, ADPKD had a prevalence of approximately 176,000 cases and an incidence of new patients of approximately 2,800 per year. Currently in the U.S. and Europe, an average of 5% to 8% of ADPKD patients are on renal therapy and patients are typically over fifty years old. Continued efforts are underway to better understand the different roles of inflammation, mitochondrial dysfunction and uric acid in the pathophysiology ADPKD. Multiple therapeutic strategies have been attempted to slow progression to renal disease with few successes, thus ADPKD remains a significant unmet medical need. The Polycystic Kidney Disease Foundation defines ADPKD as one of the most common life-threatening genetic diseases.

Even in the absence of kidney disease, increased SUA has been associated with vascular injury and inflammation, increased blood pressure, associated with endothelial dysfunction, increase proteinuria, and initiation of kidney injury. In the setting of ADPKD, high SUA has been reported to be an independent risk factor for greater cyst number, faster cyst growth and so increased total kidney volume as well as increased rate of decline of filtering capacity.

High levels of SUA, or hyperuricemia, can increase high blood pressure, blood vessel injury, endothelial dysfunction and inflammation within the cardiovascular system and specifically the kidney. A third party coordinated and conducted Phase 2 clinical trial pilot studies show that therapy to decrease uric acid in chronic progressing kidney disease can improve endothelial dysfunction, decrease proteinuria and suggest a slowing of the rate of filtering capacity decline in patients.

Data suggests that uric acid may be a major culprit in cardiovascular disease regardless of if it is acute, intermittent or chronically increased. Increased SUA is reported to result in injury of the cardiovascular and renal system by acting through intracellular effects and extracellular effects. Increased xanthine oxidase expression is also reported in disease settings and as a mechanism of injury of the kidney. In fact, five types of data attest that high levels of uric acid, even without fully diagnosed kidney disease, is harmful. Firstly, increased endogenous uric acid concentrations correlate with endothelial dysfunction, and when oxypurinol is infused into the human brachial artery endothelial dysfunction is reversed. Secondly, endogenous uric acid concentrations correlate with endothelial dysfunction. Thirdly, population studies show uric acid is an independent predictor of mortality, including one large study in patients with chronic heart failure. Fourthly, SUA is an independent risk factor for kidney disease. Fifthly, acute increases in circulating uric acid due to tumor lysis, crushing trauma and major cardiac surgery has been associated with acute organ injury and specifically AKI. Most recently, SUA has been identified as a risk factor predicting worse AKI outcomes during respiratory virus infections, such as COVID-19 infection, and AKI severity is correlated with mortality.

***Current Therapies and Treatments in Development***

Critically, patients with hyperuricemia and chronic kidney disease currently have few treatment options.

For the vast majority of patients diagnosed with kidney disease before ESRD, the standard of care is generally to attempt to decrease the amounts of uric acid in the patient. There are three classes of uric acid lowering agents that are generally in use today: xanthine oxidase inhibitors, such as allopurinol and febuxostat; uricosurics; and injectable enzymes. In addition to the approved treatments discussed above, there are multiple therapies currently in late-stage clinical development for the treatment of patients with ADPKD, which include bardoxolone, venglustat, and GLPG2737, RGLS4326 and NV-20494.

***Prior FDA Review of Oxypurinol***

Oxypurinol was developed as an alternative therapy to allopurinol in gout patients who were intolerant of allopurinol. Oxypurinol is an active metabolite of allopurinol. In 2003, a third-party company Cardiome Pharma Corp. ("**Cardiome**") filed an NDA for the orphan indication of allopurinol intolerant gout. Cardiome announced via a press release the approvable letter for oxypurinol for allopurinol intolerant hyperuricemia that Cardiome Pharma Corp. announced it had received via a press release dated June 24, 2004 (the "**Prior FDA Review**"). The press release stated that "prior to final marketing approval, the FDA requires additional clinical and manufacturing data from Cardiome." However, the FDA did not approve oxypurinol.

***XORTX Small Molecule Therapeutics***

Small molecule therapeutics and biologics have led to improvements in kidney disease patient outcomes compared to more traditional therapies. However, some patients acquire resistance to, become refractory to, or cannot tolerate the increased toxicity of current treatments. Importantly, these treatments often only delay disease progression. As a result, there is a need for new therapies with improved, long-lasting efficacy and reduced toxicity. We believe the future of treatment of kidney diseases will be defined by multifunctional therapeutics specifically designed to act through multiple action mechanisms to enhance efficacy, overcome resistance and minimize side effects. Furthermore, we believe our proprietary small molecule discovery and formulation program innovations and engineering capabilities uniquely enable us to develop the next generation of kidney therapeutics, including new molecular entities with secondary pharmacologic effects, to help address this treatment gap. Our proprietary pipeline-in-a-product strategy uniquely allows us to utilize all of the above approaches in our mission to allow patients to manage and control the negative symptoms and progression of kidney disease.

***XORTX Competitive Advantage***

We are led by an experienced and dedicated management team whose average experience exceeds 15 years in the pharmaceutical industry, including several leading pharmaceutical companies. Our Board of Directors includes highly qualified researchers, pharmaceutical senior executives and experts in the fields of drug development, corporate development and pharmaceutical commercialization. We are supported by a highly regarded network of leading experts within the field of ADPKD, including prominent ADPKD specialists throughout the world, that serve as external advisors and investigators on clinical trials in ADPKD, chronic and acute kidney disease.

Despite a need for new therapies, there have been few new drugs developed for chronic kidney diseases. We believe our proprietary formulation of xanthine oxidase inhibitors, particularly XRx-008, could become a significant treatment option for patients suffering from ADPKD.

In addition, we are collaborating with the Polycystic Kidney Disease Foundation to evaluate the potential beneficial effects of our therapies in ADPKD patients and potentially in other forms of polycystic kidney disease as well. We believe that there are substantial benefits to working with the leading polycystic kidney disease foundation in the world and that this collaboration on the development of treatments could redefine how physicians treat this disease in the future.

The overall estimated healthcare costs to treat ADPKD patients ranges from US$7.3 billion to US$9.6 billion per year (or US$52,000 to US$68,000 per patient annually). In addition, kidney disease can progress to a stage where it requires dialysis as a treatment, which is estimated to cost patients an average of approximately US$100,000 per year. We expect our product candidates to be significantly more cost-effective for patients being treated for kidney disease, which we believe could give us a significant competitive advantage over existing treatments.

***Product Candidate Pipeline***

XRx-008

*Overview*

The XRx-008 program is designed to decrease the chronic injury associated with kidney disease in patients with ADPKD. Common symptoms of ADPKD include increased SUA, hypertension, endothelial dysfunction, increased protein in the urine and decreased filtering capacity. For many ADPKD patients, uric acid levels are increased above the normal range, and in many instances result in the onset of gout. As ADPKD progresses, patients and treating physicians currently have limited therapeutic options to slow or halt progression toward ESRD.

*Current treatment of diseases*

One of the current established treatments for gout is allopurinol, which is a xanthine oxidase inhibitor used for decreasing production of SUA. Oxypurinol, an active metabolite of allopurinol was being developed as an alternative to allopurinol for gout patients who were intolerant of allopurinol. In one study conducted by third party Cardiome Pharma Corp., approximately 70% of these individuals were able to tolerate oxypurinol well and nearly all of those individuals gained clinically meaningful benefit for their gout using this xanthine oxidase inhibitor instead of allopurinol. Oxypurinol has not been approved.

*Potential Advantages of XORLO™ formulation from the XRx-008 program for ADPKD*

XORLO™ from the XRx-008 program, under our granted formulation patent, is a product candidate intended to be administered once daily to decrease uric acid production by xanthine oxidase, thereby decreasing chronic injury associated with progressing kidney disease in patient with ADPKD. Decreasing the production of uric acid is expected to decrease systemic and kidney inflammation, decrease the rate of initiation of cyst genesis and cyst growth, reverse endothelial dysfunction, decrease proteinuria, and decrease the rate of decline of kidney filtering capacity, all to the benefit of patients with ADPKD.

We believe our proprietary formulation of xanthine oxidase inhibitor, XORLO™ from the XRx-008 program, could become a significant treatment option for patients suffering from ADPKD. We believe XORLO™ can increase the bioavailability of oxypurinol substantially and have reported findings with this result. So far, based upon the results of publicly available third-party clinical trials, over 600 patients have been treated clinically with oxypurinol, and results have shown that the rate of rash and liver enzyme elevation is substantially reduced, suggesting that oxypurinol may be superior in terms of tolerability to allopurinol. The XORLO™ product candidate includes the addition of L-Arginine as bioavailability enhancer and a nephron-protective effect has been observed. Therefore, we believe our patented formulation of oxypurinol may provide an additional benefit compared to allopurinol alone. A therapeutic intervention to reduce uric acid could provide a treatment modality that ultimately reduces inflammation and modifies the underlying disease pathology. There have been no adverse events reported that are unique to oxypurinol. Importantly, in this group of over 600 patients exposed to oxypurinol, no serious adverse events related to Stevens-Johnson Syndrome have been reported.

Clinical experience with oxypurinol is extensive and it has been administered in clinical studies to patient with gout, endothelial dysfunction, and congestive heart failure. Results of those clinical trials and other clinical and non-clinical results suggest that hyperuricemia may play a pathological role in obesity, hypertension, metabolic syndrome, polycystic kidney disease, sepsis, heart disease and other disease, as yet not rigorously tested in clinical trials. Patients with congestive heart failure, hypertension are often simultaneously treated with a number of drugs plus allopurinol. Although an evaluation has not been done yet, if XORLO™ is approved and launched commercially for patients with ADPKD, we believe that it could fit well in combination with other pulmonary and cardiovascular products. For example, Otsuka Pharmaceuticals Co., Ltd.'s ("**Otsuka**") current cardiovascular and renal portfolio includes Entresto, Jynarque, and Samsca. While XORLO™ has not been clinically evaluated in combination with other product candidates, the physicians prescribing these Otsuka products could overlap significantly with the physicians expected to prescribe XORLO™ if approved.

*Anticipated clinical development of XORLO™*

Oxypurinol, a significant part of the XORLO™ product candidate, is not yet approved for marketing anywhere in the world, though it was previously reviewed by the FDA between 2003 and 2005 as sponsored by a third-party, Cardiome but it did not receive FDA marketing approval. We plan to rely on the prior research conducted and published in peer-reviewed journals and the prior FDA Review and approval of Zyloprim (allopurinol), as well as results of studies conducted by XORTX, to support our application for the FDA approval of XORLO™. We believe XORLO™ and the XRx-008development program may utilize the FDA 505(b)(2) developmental pathway to support an application for approval of a reformulation of oxypurinol with increased bioavailability and potentially superior tolerability compared to allopurinol. Oxypurinol is an active metabolite of allopurinol. We also plan to pursue the hybrid application of the EU Centralized Procedure, a procedure for the authorization of medicines, where there is a single application, a single evaluation and a single authorization throughout the European Union pursuant to article 10(3) of Directive 2001/83/EC, for the approval of this product candidate.

Based upon this strategy, the XRx-008 program has completed a bridging pharmacokinetic study – XRX-OXY-101 – designed to describe the bioavailability of the unique proprietary formulation and characterize the oral dosing for the Company's planned Phase 3 clinical trial to slow or reverse progression of kidney disease in subjects with ADPKD. Subject to discussions with the FDA the Phase 3 registration trial's primary endpoint will characterize the benefit of uric acid lowering on the rate of total kidney volume expansion and secondarily measure glomerular filtration rate decline. Secondary endpoints will include change proteinuria and inflammatory markers.

XRx-101

*Overview*

Our second program, XRx-101, is being developed for the treatment of AKI associated with respiratory virus infections, such as COVID-19. Approximately 7.5% individuals with COVID-19 infection are hospitalized. In our study with the Icahn School of Medicine in the second half of 2020, we found that among patients hospitalized with COVID-19, 36% had AKI at the time of admission and an additional 23% developed AKI during hospitalization. Many of these individuals have SUA over 7.5 mg/dL - a concentration of SUA associated with saturation of the circulatory system, crystal formation, and acute organ injury. Uric acid crystal formation in the blood has been associated with AKI in the setting of tumor lysis after major cardiac surgery and crushing trauma. In this setting, efforts to rapidly decrease SUA concentrations have shown promise for decreasing acute injury and improve prognosis. When uric acid crystals form in the blood, acute injury to blood vessel, lungs, kidneys and heart has been described in literature. Strategically, for hospitalized patients with respiratory virus infection and evidence of high uric acid accompanied by evidence of AKI, rapidly decreasing SUA concentration may represent an important treatment to protect kidneys and other organ function.

Since over 25% of people infected with COVID-19 also had diabetes as co-morbidity, we believe that it is plausible that uric acid is also elevated in these individuals prior to infection and that XRx-101 could potentially become a valid treatment for this patient group. Elevated uric acid is highly correlated with inflammation which has been the primary diagnostic among all the more infected people with the virus which then leads to a worsen clinical outcome. Studies have shown a strong association between elevated interleukin-6 and Creatinine Reactive Protein ("**CRP**") inflammation markers and worsening outcomes leading to the Intensive Care or death. A recent study by Jamie Hirsh, et al., titled *Acute kidney injury in patients hospitalized with COVID-19* (Clinical Investigation 2020; 98: 209), analyzed health records of 5,449 hospitalized patients, and showed that 36.6% developed AKI. Among those patients with AKI, 35% died, 26% were discharged and 39% were still hospitalized as of the publishing of the Hirsh's report. In March 2021, a group of nephrologists and scientists from Yale published a peer-reviewed paper at Journal of the American Medical Association, titled *Assessment of Acute Kidney Injury and Longitudinal Kidney Function After Hospital Discharge Among Patients With and Without COVID-19* (JAMA Netw Open. 2021;4(3):e211095), showing that in a cohort study of 1,612 patients with AKI monitored after their index hospitalization, estimated glomerular filtration rate declined by 11.3 mL/min/1.73 m2 per year faster in patients with COVID-19–associated AKI compared with patients with AKI not associated with COVID-19. This finding persisted after adjusting for patient's baseline comorbidities and severity of AKI.

*Current treatment of diseases*

Currently many anti-viral drugs and monoclonal antibody therapies have been approved by the FDA for treatment of COVID-19 infections or are authorized for COVID-19 under the FDA Emergency Use Authorization ( "EUA"). They include: remdesivir, tocilizumab, baricitinib, anakinra, lagevrio, paxlovid, evusheld, acetemra, sotrovimab, propofol-lipuro, REGN-COV2, bamlanivimab in combination with etesevimab, casuvurumab plus imdevimab, COVID-19 convalescent plasma, regiocit, Fresenius kabi propoven, and vilobelimab.as Additionally, dexamethasone has been approved under the National Institute of Health Guidance. There are currently no approved drugs to treat patients with COVID-19 who are at high risk of kidney failure.

*Potential Advantages of XRx-101*

XRx-101 was designed as a potential therapeutic treatment to protect kidneys from AKI that may occur due to respiratory virus infection in patients hospitalized and treated in intensive care units ("**ICUs**"). The XRx-101 product candidate is a combination of two uric acid lowering agents in a unique treatment regimen that is intended to target both rapid and sustained uric acid lowering to protect kidney another organ systems from acute injury during hospitalization for respiratory virus infection. The aim of XRx-101 is to treat hospitalized patients early, decrease high SUA concentrations at or early after hospitalization and minimize AKI. We believe this could be a unique opportunity since currently no drugs are approved for AKI, and we believe XRx-101 will be the first product candidate intended to treat patients with respiratory virus infection who are at high risk of kidney failure.

*Anticipated clinical development of XRx-101*

While oxypurinol has not received final FDA marketing approval, as the XRx-101 product candidate includes oxypurinol, we plan to rely on the prior research conducted and published in peer-reviewed journals and the prior FDA review and approval of Zyloprim (allopurinol), as well as results of studies conducted by XORTX to support an application for the product candidate's FDA approval. We are pursuing a regulatory pathway approval of XRx-101 pursuant to Section 505(b)(2) of the FDCA, and are also considering pursuing approval via the hybrid application of the EU Centralized Procedure pursuant to article 10(3) of Directive 2001/83/EC.

In previous studies, oxypurinol has clinically demonstrated the ability to inhibit the breakdown of purine and pyrimidine nucleotides to uric acid, decreasing the production of tissue uric acid and SUA from reaching saturation and crystal formation in the circulation and specifically kidneys.

The XRx-101 clinical development program will target and characterize the potential kidney protective effects of this novel therapy and initiate a clinical trial within the next 12 months. Two key third-party studies, one in a mouse model of influenza and another in herpes infection, have shown that allopurinol can act as an anti-viral, lower uric acid, and also protect organs. In the setting of serious viral infection and acute tissue damage, we believe XRx-101 can act to inhibit xanthine oxidase expression due to hypoxia or tissue destruction, therefore preventing increased SUA concentration from reaching saturation levels at which uric acid crystals could trigger an AKI. Most importantly, we believe that excipients in the formulation such as L-arginine, a basic amino acid and nitric oxide source, can increase the aqueous solubility of uric acid thereby also decreasing crystal formation associated with tumor lysis-like syndrome due to respiratory virus infections, such as COVID-19 infections. L-arginine has been shown to protect against kidney injury in the setting of ischemia reperfusion injury.

On October 8, 2020, we announced that we received a positive written response (in lieu of meeting) from the FDA regarding our submission of a COVID-19 infection pre-IND meeting package, providing next steps for the Company with a clear development path forward for XRx-101, including a planned Phase 3 trial. We plan to leverage the results of the pharmacokinetics bridging study being conducted under the XRx-008 IND to support the XRx-101 development program as XRx-101, like XRx-008, includes oxypurinol. Subject to further discussions with FDA and supported by results of the bridging study, we plan to conduct a Phase 3 trial of XRx-101. FDA input will be required to determine the design of the Phase 3 trial and whether additional clinical trials will be required prior to initiation of the Phase 3 trial.

XRx-225

*Overview*

T2DN is a kidney disease that affects individuals with diabetes. The number of individuals with diabetes is rising. An epidemiologic study published by Wild et al., titled Global Prevalence of Diabetes (Diabetes Care; Vol. 27, No. 5, May 2004), studied and estimated the number of individuals with diabetes in the year 2000 and 2030. The total number of adults 20 years of age or older with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030. The number of individuals with diabetes who develop diabetic kidney disease is established to be between 30 and 40%. More recently, studies have predicted that “the global diabetes prevalence in 2019 is estimated to be 9.3% (463 million people) rising to 10.2% (578 million) by 2030 and 10.9% (700 million) by 2045”. Interpreted together these reports suggest an oncoming crisis of chronic kidney disease associated with rising numbers of individuals with diabetes.

T2DN affects the kidneys’ ability to do their usual work of removing waste products and extra fluid from the body. T2DN is a large unmet medical disease. Diabetic nephropathy affects approximately 12 million US citizens and an estimated 170 million individuals worldwide. Approximately half of all chronic kidney disease and kidney failure has been attributed to diabetic complications. Diabetic kidney disease is associated with high blood pressure, insulin resistance, high uric acid levels, proteinuria, cardiovascular disease and decreasing filtering capacity of kidneys. Similarly, high SUA concentration has been reported to be an independent risk factor for progressing kidney disease in these patients, and is associated with increased blood pressure, systemic inflammation, cardiovascular injury, endothelial dysfunction and progressing kidney disease.

Over many years, diabetes in some individuals slowly damages the kidneys’ filtering system and can progress to kidney failure. ESRD, which occurs when kidneys are no longer capable of filtering blood to remove metabolic waste products and uric acid, is the final stage of chronic kidney disease, and can be fatal. At that stage, the treatment options are either dialysis (the mechanical filtering of blood), or a kidney transplant.

*Current treatment of diseases*

Major therapeutic interventions to treat T2DN include near-normal blood glucose control, antihypertensive treatment, and restriction of dietary proteins. Drug classes employed include hormones (such as insulin), sulfonylureas, biguanides, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, beta-adrenergic blocking agents, calcium channel blockers, and diuretics. However, many of the treatments above might not be effective in some patients with diabetes.

*Potential Advantages of XRx-225*

Recently we reported that lowering uric acid in individuals with T2DN could decrease proteinuria to a substantial and significant degree, even in patients treated with the current standard of care. This finding is in agreement with other clinical trial reports of improved proteinuria, decreased creatinine, and decreased filtration rate of decline when uric acid is therapeutically decreased. Conceptually, lowering uric acid toward or into the normal range in T2DN would decrease harmful risk factors for kidney disease progression that may include decreased blood pressure, decreased endothelial dysfunction, decreased proteinuria, decreased inflammation and enhanced blood flow to the kidney.

*Anticipated clinical development of XRx-225*

XRx-225 is in non-clinical development stages, and we have not conducted any clinical trials to date. XORTX is in the process of manufacturing XRx-225 in preparation for non-clinical pharmacology, toxicology, and pharmacokinetic animal testing, and then contemplates advancing to Phase 1 clinical testing, and thereafter further clinical development, subject to discussions with FDA. As the XRx-225 product candidate includes oxypurinol, we plan to rely on the prior research conducted and published in peer-reviewed journals and that in the prior FDA review and approval of Zyloprim (allopurinol), as well as study results to be sponsored by XORTX for the product candidate's FDA approval.

**Strategic Partnerships and Collaborations**

On April 30, 2020, we announced the appointment of LONZA Group as manufacturer of GMP oxypurinol for the XRx-008 and XRx-101 programs. The launch of oxypurinol manufacturing for both programs is the first step to advance toward clinical testing. Lonza is a leading global provider of integrated healthcare solutions. Securing the manufacturing of oxypurinol and formulation in preparation for a bioequivalence study and the submission of the IND package with the FDA are the main priorities to enable the pivotal Phase 3 clinical trial.

On August 4, 2020, we announced a partnership with the Icahn School of Medicine at Mount Sinai, New York to study the incidence of AKI and hyperuricemia in patients hospitalized with COVID-19. This clinical study in more than 5,600 patients with COVID-19 builds upon unpublished observations from over 1,100 individuals, where greater than 60% of individuals with AKI had elevated uric acid levels above the normal range. This partnership was an investigator-led study focused on evaluation of the more than 5,600 individuals with COVID-19 infection. This group of researchers at the Ichan School of Medicine is one of the leading medical networks in the world and the ability to expand on observations that hospitalized individuals with COVID-19 have very high uric acid level will provide clarity on the association of xanthine oxidase and uric acid AKI and multi-organ injury with infection. The results of this study showed that, "in patients admitted to the hospital for COVID-19, higher uric acid levels were independently associated with MAKE and mortality in a dose-dependent manner. In addition, hyperuricemia was associated with higher procalcitonin and troponin levels." MAKE (major adverse kidney events) criteria is a composite of persistent renal function decline (>25% decline in eGFR), new requirement for hemodialysis, and death. MAKE was assessed 30-, 60-, or 90-days following AKI diagnosis.

**Intellectual Property**

Our business success will depend significantly on our ability to:

- secure, maintain and enforce patent and other proprietary protection for our core technologies, inventions and know-how;
- obtain and maintain licenses to key third-party intellectual property owned by such third parties;
- preserve the confidentiality of our trade secrets; and
- operate without infringing upon valid, enforceable third-party patents and other rights.

We seek to secure and maintain patent protection for the composition of matter, manufacturing processes and methods of use for our product candidates. We also utilize trade secrets, careful monitoring and limited disclosure of our proprietary information where patent protection is not appropriate. We also protect our proprietary information by ensuring that our employees, consultants, contractors and other advisors execute agreements requiring non-disclosure and assignment of inventions prior to their engagement. We will continue to expand our intellectual property holdings by seeking patent protection for new compositions of matter, new features and applications of our core therapeutic platforms, and innovative new therapeutic platforms, in the United States and other jurisdictions. We will also supplement internal innovation through in-licensing of new technologies and compositions of matter as appropriate. We intend to take advantage of any available data exclusivity, market exclusivity, patent term adjustment and patent term extensions.

We routinely monitor the status of existing and emerging intellectual property disclosed by third parties that may impact our business, and to the extent we identify any such disclosures, by evaluating them and taking appropriate courses of action. Such actions may include enforcement actions where appropriate.

As of the date of this Annual Report, our patent portfolio includes XORTX-owned and licensed patents and patent applications for five different active patent families.

| Patent Family No. | Patent Family Name | XRx-101 | XRx-008 | XRx-225 | Additional Potential Candidates |
|---|---|---|---|---|---|
| 1 | Xanthine Oxidase Inhibitor Formulation Patents - Kidney, Cardiovascular, Neurological | X | X | X | Other indications such as rare kidney diseases, cardiovascular and neurological diseases |
| 2 | Virus, Coronavirus, Sepsis Health Consequences - Viral Induced Acute Organ, Kidney Injury | X | | | Generally applicable to viral infections, including respiratory and health consequences. |
| 3 | Methods of Enhancing Anti-Viral Therapies - Viral and Bacterial Infection | X | | | Generally applicable to Viral infections, including respiratory and health consequences |
| 4 | Compositions and Methods for Treatment and Prevention of Insulin Resistance | | | X | |
| 5 | Uric Acid Lowering Agents for Metabolic Syndrome (Treatment of Diabetic Nephropathy) | | | X | |
| 6 | Compositions and Methods for Diagnosis, Treatment, and Prevention of Kidney Disease | X | | X | |

Patent Family Member No. 1 is XORTX-owned and includes granted U.S. patent and European patent with the validation state selection in progress. Patent Family Member No. 2 is XORTX-owned includes a pending PCT, application. XORTX-owned Patent Family Member No. 3 includes a pending PCT application. These three families relate to our key product candidates and programs including XRx-101, XRx-008 and XRx-225 and our therapeutic platform technology, described elsewhere in this Annual Report, and also for additional potential product candidates. Patent Family Member No. 4 includes an issued U.S. patent for which XORTX is the licensee. Patent Family Member No. 5 includes an issued U.S. and European patent, each of which XORTX is the licensee. Family Member No. 6 includes a provisional patent application.

The XORTX owned and licensed patent family members include claims to cover AKI, and other acute organ injury due to respiratory virus infection - a program which could ultimately be expanded to a larger patient population with unmet medical needs including other viral and sepsis patients. The value of patents for reformulation or repurposed drugs is additive as is the case of orphan programs given that FDA grant of orphan drug status would provide the Company with a seven-year marketing exclusivity in the U.S. which would be

more than adequate to generate acceptable rewards, given the premium pricing environment available to rare disease opportunities. Notably, this exclusivity is 10 years in Europe and Japan.

XORTX neither owns nor licenses oxypurinol, our technology is based upon proprietary formulations of oxypurinol that improve oral bioavailability.

***Technology Licensing and In-Licensed Intellectual Property***

We identify and selectively enter into technology licensing agreements and intellectual property in-licensing agreements to support pipeline advancement.

The Company has licensed intellectual property from various third parties as described below after giving effect to the Share Consolidation:

In December 2012, the Company entered into an agreement, dated as of December 2012 (the "**Vendors Agreement**"), between the Company, Dr. Richard Johnson and Dr. Takahiko Nakagawa (the "**Vendors**") to license, and subject to certain conditions thereunder, to purchase, certain intellectual property relating to the use of all uric acid lowering agents to improve the treatment of metabolic syndrome. Under the Vendors Agreement, the Company issued 102,215 Common Shares.

a) The Company also had the option to pay the Vendors an additional US$75,000 to purchase the patents which was set up as a provision in the year ended December 31, 2018.

   During the year ended December 31, 2020, the Company determined that it was no longer feasible to complete the purchase and as such, indicators of impairment existed leading to a test of recoverable amount of the license, which resulted in an impairment loss of $64,562. As this valuation technique requires management's judgement and estimates of the recoverable amount, it is classified within level 3 of the fair value hierarchy.

   The Company will pay the Vendors a royalty, at a rate in the low single digits, based on the cumulative net revenues from the sale or sublicense of the product covered under the licensed intellectual property until the later of (i) the expiration of the last patent right covering the product and (ii) the expiration of 10 years from the date of the first commercial sales of a product. The royalty rate increases to the mid-single digits in the event that our research and development expenditures decrease below 15%.

   Some of the patents used in our XRx-225 product candidate are licensed by the Company under the terms of this license agreement.

b) Pursuant to the University of Florida Research Foundation, Inc. ("**UFRF**") License Agreement dated June 23, 2014, between the Company and the UFRF, the Company acquired the exclusive license to the certain intellectual property related to the use of all uric acid lowering agents to treat insulin resistance. The Company has paid or is obligated to pay UFRF the following consideration:

   i) an annual license fee of US$1,000;

   ii) reimburse UFRF for United States and/or foreign costs associated with the maintenance of the licensed patents;

   iii) the issuance or agreement to issue to UFRF of 51,423 shares of common stock of the Company;

   iv) milestone payments of US$500,000 upon receipt of FDA approval to market licensed product in the United States of America and US$100,000 upon receipt of regulatory approval to market each licensed product in each of other jurisdictions;

   v) royalty payments of up to 1.5% of net sales of products covered by the license until the later of (i) the expiration of any patent claims or (ii) 10 years from the date of the first commercial sale of any covered product in each country. Following commencement of commercial sales, the Company will be subject to certain annual minimum royalty payments that will increase annually up to a maximum of US$100,000 per year; and

vi) UFRF is entitled to receive a royalty of 5% of amounts received from any sub-licensee that are not based directly on product sales, excluding payments received for research and development or purchases of the Company's securities at not less than fair market value.

UFRF may terminate the UFRF License Agreement if the Company fails to meet the following specified outstanding milestones:

i) in the event that the first sale to a retail customer does not occur on or before January 30th, 2025;

ii) in the event that we do not target submission of an NDA with the FDA or other foreign regulatory agency for approval to market an indication in the insulin resistance, diabetes, or improved thiazide – uric acid lowering agent product group by December, 2023; and

iii) in the event we do not have the first sale of a licensed product by January 2025.

Some of the patents used in our XRx-225 product candidate are licensed by the Company under the terms of this license agreement.

**Manufacturing**

We rely on third party contract manufacturing organizations to provide manufacturing for our product candidate for our non-clinical and clinical studies. To retain focus on our expertise in developing new product candidates, we do not currently plan to develop or operate in-house manufacturing capacity. Our manufacturing candidates require standard manufacturing and CMC processes typical of those required for similar drug manufacturing. We therefore expect to continue to be able to develop product candidates that can be manufactured in a cost-effective fashion by our network of well-validated third-party contract manufacturing organizations.

Through our contract manufacturing organizations, we are currently manufacturing a sufficient supply of our product candidates to carry out ongoing and planned preclinical and clinical studies. We plan to identify redundant suppliers and manufacturing prior to submission to the FDA.

**Competition**

The small molecule therapeutics industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

With respect to target discovery activities, competitors and other third parties, including academic and clinical researchers, may be able to access rare families and identify targets before we do.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, recruiting patients for clinical trials, and by acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, the effectiveness of alternative products, the level of competition and the availability of coverage and adequate reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products or therapies that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Our product candidates will compete with the therapies and currently marketed drugs discussed below.

- *XRx-008*: XORLO™ from the XRx-008 program is intended to treat patients with ADPKD. Currently, the only FDA approved ADPKD-targeted therapy is tolvaptan, which is marketed as Jynarque from Otsuka Pharmaceuticals Co., Ltd.

- *XRx-101*: XRx-101 is intended to treat patients AKI due to respiratory virus infection.

Currently many anti-viral drugs and monoclonal antibody therapies have been approved by the FDA for treatment of COVID-19 infections or are authorized for COVID-19 under the FDA Emergency Use Authorization ( "EUA"). They include: remdesivir, tocilizumab, baricitinib, anakinra, lagevrio, paxlovid, evusheld, acetemra, sotrovimab, propofol-lipuro, REGN-COV2, bamlanivimab in combination with etesevimab, casuvurumab plus imdevimab, COVID-19 convalescent plasma, regiocit, Fresenius kabi propoven and vilobelimab. Additionally, dexamethasone has been approved under the National Institute of Health Guidance.

- *XRx-225*: XRx-225 is intended to treat patients with T2DN. Currently approved therapeutic interventions to treat T2DN include near-normal blood glucose control, antihypertensive treatment, and restriction of dietary proteins.

Applications for approval of our product candidates are subject to review by the FDA and corresponding regulatory authorities to determine whether our product candidates are safe and effective. No regulatory agency has made any such determination that any of our product candidates are safe and effective for use.

**Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of pharmaceutical products such as those we are developing. Our therapeutic candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations, requires the expenditure of substantial time and financial resources.

***U.S. Small Molecule Drug Product Development Process***

In the United States, pharmaceutical products are subject to extensive regulation by the FDA, pursuant to the FDCA. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, voluntary product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

The process required by the FDA before a small molecule drug product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies conducted according to good laboratory practices ("**GLPs**") and other applicable regulations;

- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials according to GCPs, to establish the safety and efficacy of the proposed product for its intended use;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced to assess readiness for commercial manufacturing and conformance to the manufacturing-related elements of the application, to conduct a data integrity audit, and to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity; and

- FDA review and approval of the NDA.

Once a pharmaceutical candidate is identified for development, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

The IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data to the FDA as part of the IND. Some nonclinical testing may continue even after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds at any time during the life of an IND, due to safety concerns or non-compliance, and a clinical hold may affect one or more specific studies, or all studies conducted under the IND. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical study will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's GCP requirements, including the requirement that all research subjects provide informed consent to participate in the clinical study. Further, each clinical study must be reviewed and approved by an independent IRB, at or servicing each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical study subject or his or her legal representative. The IRB must monitor the clinical study until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product candidate is initially introduced into healthy human volunteers and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- Phase 2. The product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labelling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. In certain instances, FDA may mandate the performance of Phase 4 clinical trials. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. Conversely, the results of Phase 4 clinical trials can raise new safety or effectiveness issues that were not apparent during the original review of the product, which may result in product restrictions or even withdrawal of product approval.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of certain FDA-regulated products are required to register and disclose certain clinical trial information on a public registry maintained by the U.S. National Institutes of Health ("**NIH**"), which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Although sponsors are also obligated to discuss the results of their clinical trials after completion, disclosure of the results of these trials may be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA have signaled the government's willingness to begin enforcing those requirements against non-compliant clinical trial sponsors.

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

***U.S. Review and Approval Process***

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with detailed descriptions of the product's chemistry, manufacturing, and controls, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently over US$3.1 million for an NDA with clinical information. The manufacturer and/or sponsor under an approved NDA must also pay an annual program fee, currently over US$369,000. These fees are typically increased annually. Fee waivers or reductions are available in certain circumstances.

Section 505(b)(1) and Section 505(b)(2) of the FDCA are the provisions governing the type of NDAs that may be submitted under the FDCA. Section 505(b)(1) is the traditional pathway for new chemical entities when no other new drug containing the same active pharmaceutical ingredient or active moiety, which is the molecule or ion responsible for the action of the drug substance, has been approved by the FDA. As an alternate pathway to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. The FDA seeks to review applications for standard review drug products within ten months, and applications for priority review drugs within six months. Priority review can be applied to drugs intended to treat a serious condition and that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The review process for both standard and priority reviews may be extended by FDA for three additional months to consider additional, late-submitted information, or information intended to clarify information already provided in the submission in response to FDA review questions.

As part of the NDA review process, the FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant. The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an external advisory committee, which is typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs and the IND protocol requirements and to assure the integrity of the clinical data submitted to the FDA. Additionally, the FDA will typically inspect the facility or the facilities at which the drug is manufactured, unless the facility has recently had an FDA inspection. The FDA also typically inspects the application sponsor. The FDA will not approve the product unless compliance with current good manufacturing practice, or cGMP, requirements is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied. To ensure cGMP and GCP compliance by its employees and third-party contractors, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. The approval process is lengthy and often difficult, and notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA does not satisfy its regulatory criteria for approval and deny approval or may require additional clinical or other data and information. If the agency decides not to approve an NDA, the FDA will issue a complete response letter ("**CRL**") that describes all of the specific deficiencies in the NDA identified by the FDA. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the CRL may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter to the applicant. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug product with the accompanying approved prescribing information for specific indications. Even if a product receives regulatory approval, the approval may be limited to specific indications and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA also may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS plan in addition to the approved labeling, to help ensure that the benefits of the drug outweigh its risks. A REMS could include communication plans for healthcare professionals, medication guides for patients, and/or elements to assure safe use ("**ETASU**"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, restricted distribution requirements, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS plan. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy as described as post marketing commitments or requirements included in the approval letter. Once granted, product approvals may be withdrawn if compliance with regulatory requirements and commitments is not maintained or problems are identified following initial marketing. Moreover, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Hatch-Waxman Act and New Drug Marketing Exclusivity

Under the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute and also enacted Section 505(b)(2) of the FDCA. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug. Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the Listed Drug with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. In contrast, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. The FDA may then approve the new product for all or some of the label indications for which the Listed Drug has been approved, or for any new indication sought by the Section 505(b)(2) applicant, as applicable.

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant submits its application to the FDA, the applicant is required to certify to the FDA concerning any patents listed in the Orange Book for the Listed Drug, except for patents covering methods of use for which the follow-on applicant is not seeking approval. To the extent the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, such an applicant is also required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, an ANDA or 505(b)(2) applicant for a follow-on drug product with respect to each patent that: (i) the required patent information has not been filed by the original applicant; (ii) the listed patent already has expired; (iii) the listed patent has not expired, but will expire on a specified date and approval is sought after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the new product.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the ANDA or 505(b)(2) application.

A certification that the new product will not infringe the Listed Drug's listed patents or that such patents are invalid is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders for the Listed Drug once the applicant's NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the follow-on applicant's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay.

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the referenced Listed Drug has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of a NDA for a drug containing a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent term extension. The allowable patent term extension is calculated as half of the drug's testing phase – the time between when the IND becomes effective and NDA submission – and all of the review phase – the time between NDA submission and approval, up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the Patent and Trademark Office (PTO) must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Pediatric Clinical Trials and Exclusivity

Under the Pediatric Research Equity Act, NDAs or certain types of supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The sponsor must submit an initial Pediatric Study Plan ("**PSP**") within 60 days of an end-of-phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may grant full or partial waivers, or deferrals, for submission of pediatric assessment data.

The Best Pharmaceuticals for Children Act ("**BPCA**") provides NDA holders a six-month extension of any exclusivity – patent or non-patent – for a drug if certain conditions are met, including satisfaction of a pediatric trial(s) agreed with FDA as a Pediatric Written Request. Conditions for pediatric exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric clinical trials, and the applicant agreeing to perform, and reporting on, the requested clinical trials within the statutory timeframe. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to the written request from the FDA for such data. Those data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. Although this is not a patent term extension, it effectively extends the regulatory period during which the FDA cannot approve another application.

Orphan Drug Designation and Orphan Product Exclusivity

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to a drug candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects (i) fewer than 200,000 individuals in the United States, or (ii) more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and marketing the product for this type of disease or condition will be recovered from sales in the United States. Orphan Drug Designation must be requested before submitting an NDA. After the FDA grants Orphan Drug Designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means the FDA may not approve any other application to market the same product for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer with orphan exclusivity is unable to assure sufficient quantities of the approved orphan designated product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor's approved product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what was previously designated, it may not be entitled to orphan product exclusivity.

Expedited Development and Review Programs

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation, and priority review designation. Generally, drugs that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the NDA. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process.

In addition, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the NDA is submitted, on a case-by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on an original marketing application from ten months to six months.

Congress also created a new regulatory program in 2012 for therapeutic product candidates designated by FDA as "breakthrough therapies" upon a request made by the IND sponsor. A drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers. Drugs designated as breakthrough therapies are also eligible for accelerated approval of their future marketing applications. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Fast track designation, priority review, and breakthrough therapy designation do not change the standards for approval and may not ultimately expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Accelerated Approval

A product candidate may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. Accelerated approval allows the FDA to approve the product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. The FDA may also grant accelerated approval for such a drug when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("**IMM**"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug.

Discussions with the FDA about the feasibility of an accelerated approval typically begin early in the development of the drug in order to identify, among other things, an appropriate endpoint. The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

As a condition of approval, the FDA generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify and describe the anticipated effect on IMM or other clinical endpoints. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval. Because the accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the drug. Under the Food and Drug Omnibus Reform Act of 2022 ("**FDORA**"), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. In addition, all promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved drug product are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA. Prescription drug promotional materials also must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the approved drug product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies or clinical trials.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities' satisfaction before any product is approved and our commercial products can be manufactured. These manufacturers must comply with cGMPs that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including recall.

Once an approval of a prescription drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; and
- mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("**PDMA**"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Most recently, the Drug Supply Chain Security Act ("**DSCSA**") was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of prescription drug products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

***Additional Regulation***

In addition to the foregoing, local, state and federal U.S. laws regarding environmental protection and hazardous substances affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

***Anti-Corruption Laws***

We are subject to the U.S. Foreign Corrupt Practices Act of 1977 ("**FCPA**"), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the Canadian Corruption of Foreign Public Officials Act and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities, such as the United Kingdom ("**UK**") Bribery Act 2010 and the UK Proceeds of Crime Act 2002, collectively, Anti-Corruption Laws. Among other matters, such Anti-Corruption Laws prohibit corporations and individuals from directly or indirectly paying, offering to pay or authorizing the payment of money or anything of value to any foreign government official, government staff member, political party or political candidate, or certain other persons, in order to obtain, retain or direct business, regulatory approvals or some other advantage in an improper manner. We can also be held liable for the acts of our third-party agents (including CROs) under the FCPA, the Canadian Corruption of Foreign Public Officials Act, the UK Bribery Act 2010 and possibly other Anti-Corruption Laws. In the healthcare sector, anti-corruption risk can also arise in the context of improper interactions with doctors, key opinion leaders, and other healthcare professionals who work for state-affiliated hospitals, research institutions, or other organizations.

***Data Privacy and the Protection of Personal Information***

We are subject to laws and regulations governing data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which will continue to affect our business. In the United States, we may be subject to state security breach notification laws, state laws protecting the privacy of health and personal information and federal and state consumer protections laws which regulate the collection, use, disclosure and transmission of personal information. These laws overlap and often conflict and each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties. Our future customers and research partners must comply with laws governing the privacy and security of health information, including HIPAA and state health information privacy laws. If we knowingly obtain health information that is protected under HIPAA, called "protected health information," our customers or research collaborators may be subject to enforcement and we may have direct liability for the unlawful receipt of protected health information or for aiding and abetting a HIPAA violation.

State laws protecting health and personal information are becoming increasingly stringent. For example, California has implemented the California Confidentiality of Medical Information Act that imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information, and California has recently adopted the CCPA. The CCPA mirrors a number of the key provisions of the GDPR. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Additionally, a new privacy law, the California Privacy Rights Act ("**CPRA**"), was approved by California voters in the election on November 3, 2020. The CPRA will modify the CCPA significantly, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Other states in the U.S. are considering privacy laws similar to CCPA, with Virginia enacting its own such law in early 2021.

***Government Regulation Outside of the United States***

In addition to regulations in the United States, we are a Canadian registered company and subject to Canadian law, similarly partnering or co-development agreements within the year could substantially alter what jurisdictions and government regulations the company is subject to and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials, the privacy of personal data and commercial sales and distribution of our product candidates, if approved.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application ("**CTA**") must be submitted to the competent national health authority and to independent ethics committees in each country in which a company plans to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trials may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the European Union member states resulting from the national implementation of underlying E.U. legislation. In all cases, the clinical trials are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain a marketing license for a new drug, or medicinal product in the European Union, the sponsor must obtain approval of a MAA. The way in which a medicinal product can be approved in the European Union depends on the nature of the medicinal product.

The centralized procedure results in a single marketing authorization granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein, and Norway. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated "orphan drugs" (drugs used for rare human diseases) and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used for human drugs which do not fall within the above mentioned categories if the human drug (a) contains a new active substance which was not authorized in the European Community; or (b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in the centralized procedure is in the interests of patients or animal health at the European Community level.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP), with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: the seriousness of the disease to be treated; the absence of an appropriate alternative therapeutic approach, and anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

The mutual recognition procedure ("**MRP**") for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the European Union. Basically, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products and is based on the principle of recognition of an already existing national marketing authorization by one or more member states. In the MRP, a marketing authorization for a drug already exists in one or more member states of the EU and subsequently marketing authorization applications are made in other European Union member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states. After a product assessment is completed by the reference member state, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations within individual member states shall be granted within 30 days after acknowledgement of the agreement.

Should any member state refuse to recognize the marketing authorization by the reference member state, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, member states shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA committee is then forwarded to the European Commission, for the start of the decision-making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products or Veterinary Medicinal Products, as appropriate.

For countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Europe - Data Privacy

On May 25, 2018, the GDPR went into effect, implementing a broad data protection framework that expanded the scope of EU data protection law, including to non-EU entities that process, or control the processing of, personal data relating to individuals located in the EU, including clinical trial data. The GDPR sets out a number of requirements that must be complied with when handling the personal data of European Union-based data subjects including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be "forgotten" and rights to data portability, as well as enhanced current rights (e.g. access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data where the latter is used to uniquely identify an individual are all classified as "special category" data under the GDPR and afforded greater protection and require additional compliance obligations. Further, EU member states have a broad right to impose additional conditions—including restrictions—on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). As the EU states continue to reframe their national legislation to harmonize with the GDPR, we will need to monitor compliance with all relevant EU member states' laws and regulations, including where permitted derogations from the GDPR are introduced.

We will also be subject to evolving EU laws on data export, if we transfer data outside the EU to ourselves or third parties outside of the EU. The GDPR only permits exports of data outside the EU where there is a suitable data transfer solution in place to safeguard personal data (e.g., the European Union Commission approved Standard Contractual Clauses). On July 16, 2020, the Court of Justice of the European Union ("**CJEU**"), issued an opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), called *Schrems II.* This decision calls into question certain data transfer mechanisms as between the EU member states and the US. The CJEU is the highest court in Europe and the *Schrems II* decision heightens the burden on data importers to assess U.S. national security laws on their business and future actions of EU data protection authorities are difficult to predict. Consequently, there is some risk of any data transfers from the European Union being halted. If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under GDPR to enter into contractual arrangements to help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause customers to lose trust in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the transfer of personal data from the EU to us in the United States will require greater scrutiny and assessments as required under *Schrems II* and may have an adverse impact on cross-border transfers of personal data and increase costs of compliance. The GDPR provides an enforcement authority to impose large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. We will be subject to the GDPR when we have a European Union presence or "establishment" (e.g., EU based subsidiary or operations), when conducting clinical trials with EU based data subjects, whether the trials are conducted directly by us or through a vendor or partner, or offering approved products or services to EU-based data subjects, regardless of whether involving an EU based subsidiary or operations.

***Pharmaceutical Coverage, Pricing and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government programs such as Medicare or Medicaid, managed care plans, private health insurers, and other organizations. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Third-party payors may attempt to control costs by limiting coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication, and by limiting the amount of reimbursement for particular procedures or drug treatments. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. The Medicare and Medicaid programs are often used as models by private payors and other governmental payors to develop their coverage and reimbursement policies for drugs. However, one third-party payor's decision to cover a particular drug product does not ensure that other payors will also provide coverage for the product, or will provide coverage at an adequate reimbursement rate.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates to obtain third-party payor coverage, in addition to the costs required to obtain any FDA marketing approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product candidate development.

Some third-party payors also require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our product candidates will be considered medically reasonable and necessary for a specific indication, that our product candidates will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

***Healthcare Reform and Potential Changes to Healthcare Laws***

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our future products profitably. 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 or 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. The FDA's and other regulatory authorities' 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 otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. 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 the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of our product and product candidates, if approved, are the following:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, which was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 to March 31, 2022. As of July 2, 2022, the 2% sequester reduction resumed. The sequester will remain in place through 2030. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Affordable Care Act has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions.

Further changes to and under the Affordable Care Act remain possible but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. We also expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product and product candidates, if approved. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors.

The Inflation Reduction Act of 2022, or IRA, contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations, and growth prospects. The effects of the IRA on our business and the pharmaceutical industry in general is not yet known.

***Other Healthcare Laws and Compliance Requirements***

As we are commercializing our product candidates, if they are approved by the FDA or comparable foreign regulatory agencies for marketing, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by federal government and the states and foreign governments in the jurisdictions in which we conduct our business. Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any other product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval.

Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, prohibit, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the U.S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Actions under these laws may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government uses these laws, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices;

- HIPAA created new federal, civil and criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, among other things, imposes reporting requirements on manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report, on an annual basis, to the Centers for Medicare & Medicaid Services ("**CMS**"), information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors and, beginning in 2022 for payments and other transfers of value provided in the previous year, certain advanced non-physician healthcare practitioners), teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("**HITECH**"), and their respective implementing regulations impose specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, which include certain healthcare providers, health plans, and healthcare clearinghouses, that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions;

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers;

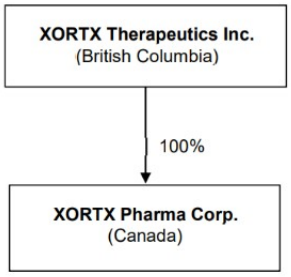
- State laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act, as well as state and local laws that require the registration of pharmaceutical sales representatives; and

- State laws and foreign laws and regulations (particularly European Union laws regarding personal data relating to individuals based in Europe) that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Ensuring that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws and that governmental authorities may conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal and administrative penalties, including monetary penalties, damages, fines, disgorgement, imprisonment, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, injunctions, reputational harm, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business in the future is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. We may also be subject to additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement with a governmental entity to resolve allegations that we have violated these laws. To the extent that any of our product candidates are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

### 4.C. Organizational Structure

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




### 4.D. Property, Plant and Equipment

Not applicable.

## ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The management's discussion and analysis of the Company for the year ended December 31, 2022 is included in this Annual Report in Exhibit 15.1.

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

### 6.A Directors and Senior Management

The following table sets forth the name, office held, age, and functions and areas of experience in the Company of each of our directors and senior management:

| Name, Province / State and Country of Residence | Age | Position with the Company | Date Became a Director / Officer | Principal Occupation Last Five Years |
|---|---|---|---|---|
| Allen Davidoff Alberta, Canada | 63 | 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). |
| Stacy Evans California, United States | 49 | Chief Business Officer | November 16, 2022 | Over 20+ years' experience in business development in the biopharmaceutical industry with leading biopharmaceutical companies. Current Chief Business Officer of the Company since November 16, 2022 and independent industry consultant since 2015. |
| William Farley New York, United States | 69 | 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. |
| Anthony J. Giovinazzo Ontario, Canada | 66 | Non-Executive Chair | June 3, 2022 | Lead Independent Director, Titan Medical Inc. (since September 2020); Executive Chair, Kalgene Inc., a private company; former Director and CEO (November 2009 to March 2017), Cynapsus Therapeutics Inc., a TSX and Nasdaq listed company, that was acquired in an all-cash transaction with Sunovion Pharmaceuticals Inc. for CAD $841 million. Former Director, ProMIS Neurosciences Inc. (March 2017 to September 2020), Pond Technologies Holdings Inc. (October 2020 to June 2021); and Microbix Biosystems Inc. (December 2020 to March 2022). |
| Stephen Haworth Pennsylvania, United Sates | 73 | 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, Vaxlnnate Corporation (2015 to 2015). |
| Amar Keshri Alberta, Canada | 45 | 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). |
| Ian Klassen[(1)] British Columbia, Canada | 57 | 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 | 70 | 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). |
| Raymond Pratt Michigan, United States | 73 | Director | December 20, 2021 | Current Chief Medical Officer, Savara, Inc. since November 2022 and Principal, RDP Pharma Consulting since April 2022; former Chief Development Officer and Chief Medical Officer, Rockwell Medical, Inc. (2012 – 2022). |
| Paul Van Damme[(1)] Ontario, Canada | 73 | Director | 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. (August 2019 to April 2020); Structural Genomics Consortium (May 2012 to June 2019); Bradmer Pharmaceuticals Inc. (September 2007 to July 2018) and Galaxy Digital Holdings Ltd. (September 2007 to July 2018). |

(1) Member of the Audit Committee

There are no family relationships between any of the persons named above. There are no arrangements or understandings with major shareholders, customers, suppliers or others pursuant to which any person named above was selected as a director or member of senior management.

**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 central nervous system, 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.

***Anthony Giovinazzo, MBA, LLB, BA***

Anthony J. Giovinazzo is an internationally recognized expert in intellectual property, drug development and commercialization, including numerous licensing agreements, with more than 25 years' experience in Central Nervous System diseases. Most recently, he was co-inventor, Chief Executive Officer and Director of Cynapsus Therapeutics, a NASDAQ listed specialty pharmaceutical company that developed the first successful sublingual apomorphine thin film strip for Parkinson's disease, the drug today known as Kynmobi, was approved for commercialization by the FDA and Health Canada in 2020. At Cynapsus, Mr. Giovinazzo built the leadership team, raised US $136 million including an over-subscribed IPO and NASDAQ and led the negotiations with several pharmaceutical companies that resulted in the CAD $841 million all cash acquisition by Sunovion Pharmaceuticals (Dainippon Sumitomo Pharmaceuticals), a 120% premium to market close on the day of announcement.

Mr. Giovinazzo is the co-author of several peer reviewed papers and author of several papers on strategic and financing issues in the biopharmaceutical industry. He was a Canadian finalist in Life Sciences for the E&Y Entrepreneur of the Year (2014). In 2017, he was the recipient of the Finance Monthly Game Changers award and an inaugural recipient of the Bloom Burton Award, which honors a single winner from several candidates, as the best of the best in Canadian Life Sciences as judged by a panel of US experts. He is a Chartered Director and Audit Committee Certified, both from The Directors College, a degree granting affiliate of McMaster University, Hamilton, Ontario. He also completed the Leadership and Strategy in Pharmaceuticals and Biotech from Harvard Business School, Boston, Massachusetts in 2006, a Master's of Business Administration from IMD, Geneva, Switzerland in 1986, a Graduate Certificate Studies in Canadian Law from Osgoode Hall Law School, York University, Toronto, Ontario in 1984, and a Bachelor of Arts in Economics and Accounting from McMaster University in 1978.

***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 125$^{th}$ 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 (Canada). 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. 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 central nervous system patients in the US and other global markets. Dr. Pratt is the current Chief Medical Officer of Savara, Inc. since November 2022 and was the former Chief Development Officer and Chief Medical Officer, Rockwell Medical, Inc. from 2012 through 2022, 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 an 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.

**6.B. Compensation**

**Introduction**

The following section describes the significant elements of our executive and director compensation program. Our named executive officers for the year ended December 31, 2022 include our principal executive officer, our principal accounting officer, our principal medical officer and our principal business officer. See Item 6.C. Board Practices, of this Annual Report for a discussion of any contracts for service that we have with our directors.

**Overview**

***Compensation Philosophy***

The goal of our compensation program is to attract, retain and motivate our employees and executives. The Board of Directors is responsible for setting our executive compensation and establishing corporate performance objectives. However, in connection with this offering and a potential listing on Nasdaq we will form a compensation committee. In considering executive compensation, the Board of Directors strives to ensure that our total compensation is competitive within the industry in which we operate and supports our overall strategy and corporate objectives. The combination of base salary, annual incentives and long-term incentives that we provide our executive officers is designed to accomplish this. The compensation committee considers the implications of the risks associated with our compensation policies and practices. For additional details regarding the relevant education and experience of each member of our compensation committee see Item 6.A. above. Our named executive officers and directors are not permitted to purchase financial instruments, including, for greater certainty, prepaid variable forward contracts, equity swaps, collars, or units of exchange funds that are designed to hedge or offset a decrease in market value of equity securities granted as compensation or held, directly or indirectly, by the named executive officer or director.

***Components of Compensation Package***

Compensation for the executive officers is composed primarily of three components: base compensation, performance bonuses and the granting of options. Performance bonuses may be considered from time to time.

*Determining Compensation*

Our Board of Directors is responsible for ensuring that the Company has in place an appropriate plan for executive compensation ensuring that total compensation paid to all executive officers is fair and reasonable and is consistent with the Company's compensation philosophy and in line with industry practice. In connection with the offering and the potential listing on Nasdaq, the Company formed a compensation committee.

Our Board of Directors and the compensation committee do not have a pre-determined compensation plan, but rather review the performance of the executive officers and consider a variety of factors, when determining compensation levels. These factors, which are informally discussed by the Board of Directors and the compensation committee, include the long-term interests of the Company and its Shareholders, the financial and operating performance of the Company and each executive officer's individual performance, contribution towards meeting corporate objectives, responsibilities and length of service. Our Board of Directors believes that the compensation arrangements for the Company's executive officers are commensurate with the executive officer's position, experience and performance. The directors and the compensation committee of the Company will continue to review compensation philosophy to ensure that the Company is competitive and that compensation is consistent with the performance of the Company.

**Other Compensation**

Amounts shown in the "All Other Compensation" column in the Summary Compensation Table relate to contributions to our registered retirement savings plan, provincial healthcare premium, life insurance premiums through our group extended benefit plan, extended medical benefits premiums, parking charges at our office and fitness plan reimbursement.

**Director Compensation**

In addition to the granting of options, during the period ended December 31, 2022, the non-executive directors of the Company received compensation of $3,000 per quarter for director services and $300 per committee meeting, with the Chair of each committee receiving $700 per committee meeting. Anthon Giovinazzo, Chair of the Company, receives annual compensation of US$125,000.

Each member of our Board of Directors is entitled to reimbursement for reasonable travel and other expenses incurred in connection with attending board meetings and meetings for any committee on which he or she serves.

**Summary Compensation Table**

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers and our non-executive directors for the years ended December 31, 2022, 2021 and 2020 after giving effect to the Share Consolidation. We do not have compensation in the form of share-based awards (other than stock options), non-equity incentive plan compensation or non-qualified deferred compensation.

| | | Table of Compensation Excluding Compensation Securities | | | | | |
|---|---|---|---|---|---|---|---|
| **Name and Position** | **Year** | **Salary, Consulting Fee, Retainer or Commission ($)** | **Bonus ($)** | **Committee or Meeting Fees ($)** | **Value of Stock Option ($)** | **Value of All Other Compensation ($)** | **Total Compensation** |
| Allen Davidoff *CEO* | 2022 | 485,618 | — | — | 81,116 | 4,750 | 571,484 |
| | 2021 | 221,840 | 25,000 | — | 63,072 | — | 309,912 |
| | 2020 | 196,097 | — | — | 63,072 | — | 259,169 |
| Amar Keshri[1] *Chief Financial Officer ("**CFO**")* | 2022 | 214,603 | — | — | 32,150 | — | 246,753 |
| | 2021 | 85,000 | — | | 17,446 | — | 102,446 |
| | 2020 | n/a | n/a | n/a | n/a | n/a | n/a |
| Stacy Evans[2] *Chief Business Officer ("**CBO**")* | 2022 | 115,644 | — | — | — | — | 115,644 |
| | 2021 | n/a | n/a | n/a | n/a | n/a | n/a |
| | 2020 | n/a | n/a | n/a | n/a | n/a | n/a |
| Dr. Stephen Haworth[3] *Chief Medical Officer ("**CMO**")* | 2022 | 295,482 | 16,930 | n/a | 32,150 | — | 344,562 |
| | 2021 | 106,366 | — | n/a | 17,446 | — | 124,812 |
| | 2020 | n/a | n/a | n/a | n/a | n/a | n/a |
| William Farley[4], BSc *Director* | 2022 | 12,000 | — | 1,800 | 36,326 | — | 50,126 |
| | 2021 | 6,000 | — | 1,200 | 55,963 | — | 63,163 |
| | 2020 | n/a | n/a | n/a | n/a | n/a | n/a |
| Anthony Giovinazzo[5], MBA, LLB, BA *Director* | 2022 | 86,154 | — | — | 181,628 | — | 267,782 |
| | 2021 | n/a | n/a | n/a | n/a | n/a | n/a |
| | 2020 | n/a | n/a | n/a | n/a | n/a | n/a |
| Ian Klassen, B.A. *Director* | 2022 | 12,000 | — | 4,600 | 36,326 | — | 52,926 |
| | 2021 | 6,000 | — | 2,200 | 86,728 | — | 94,928 |
| | 2020 | — | — | — | 30,988 | — | 30,998 |
| Jacqueline Le Saux[6], BScL, MBA, LLB *Director* | 2022 | 12,000 | — | 4,600 | 36,326 | — | 50,826 |
| | 2021 | 6,000 | — | 2,300 | 54,463 | — | 62,763 |
| | 2020 | n/a | n/a | n/a | n/a | n/a | n/a |
| Dr. Raymond Pratt[7], MD FACP *Director* | 2022 | 12,000 | — | 600 | 36,326 | — | 48,926 |
| | 2021 | — | — | 300 | 57,922 | — | 58,222 |
| | 2020 | n/a | n/a | n/a | n/a | n/a | n/a |
| Paul Van Damme, B Comm, CPA, MBA *Director* | 2022 | 12,000 | — | 5,400 | 36,326 | — | 53,726 |
| | 2021 | 6,000 | — | 3,600 | 41,841 | — | 51,441 |
| | 2020 | — | — | — | 33,387 | — | 33,387 |

Notes:
(1) Amar Keshri was appointed CFO on July 14, 2021. The amounts included for 2021 reflect the period from July 14, 2021 to December 31, 2021.

(2) Stacy Evans commenced consulting on behalf of the Company on September 1, 2022 and was appointed CBO on November 16, 2022. The amounts included for 2022 reflect the period from September 1, 2022 to December 31, 2022.
(3) Stephen Haworth was appointed CMO on July 1, 2021. The amounts included for 2021 reflect the period from July 1, 2021 to December 31, 2021.
(4) William Farley was appointed as a director on May 16, 2021.
(5) Anthony Giovinazzo was appointed as a director on June 3, 2022.
(6) Jacqueline Le Saux was appointed as a director on June 16, 2021.
(7) Raymond Pratt was elected as a director on December 20, 2021.

**Outstanding Equity Awards at 2022 Fiscal Year End**

| Name and Position | Type of Compensation Security | Number of Compensation Securities, Number of underlying Securities and Percentage of Class | Date of Issue or Grant | Issue, Conversion or Exercise Price | Closing Price of Security or Underlying Security on Date of Grant ($) | Expiry Date |
|---|---|---|---|---|---|---|
| Allen Davidoff *CEO* | Stock option | 42,589 | Jun23-20 | $ 1.64 | $ 1.64 | Jun23-25 |
| | Stock option | 20,000 | Jan12-22 | $ 2.54 | $ 2.54 | Jan12-27 |
| | Stock option | 94,822 | Jun06-22 | $ 1.60 | $ 1.60 | Jun05-27 |
| | | *15.1 %* | | | | |
| Amar Keshri *CFO* | Stock option | 21,294 | Jul14-21 | $ 2.41 | $ 2.41 | Jul14-26 |
| | Stock option | 10,000 | Jan12-22 | $ 2.54 | $ 2.54 | Jan12-27 |
| | Stock option | 15,000 | Nov25-22 | $ 1.38 | $ 1.38 | Nov25-27 |
| | | *4.9 %* | | | | |
| William Farley, BSc *Director* | Stock option | 21,294 | May12-21 | $ 1.88 | $ 1.88 | May21-26 |
| | Stock option | 13,706 | Dec21-21 | $ 2.54 | $ 2.54 | Dec21-26 |
| | Stock option | 30,000 | Jun06-22 | $ 1.60 | $ 1.60 | Jun06-27 |
| | | 6.3 | | | | |
| Anthony Giovinazzo, MBA, LLB, BA *Director* | Stock option | 150,000 | Jun06-22 | $ 1.60 | $ 1.60 | Jun06-27 |
| | | *14.4 %* | | | | |
| | | | | | | |
| Dr. Stephen Haworth, MB BS, MRCP *Director* | Stock option | 21,294 | Jul14-21 | $ 2.41 | $ 2.41 | Jul14-26 |
| | Stock option | 10,000 | Jan12-22 | $ 2.54 | $ 2.54 | Jan12-27 |
| | Stock option | 20,000 | Nov25-22 | $ 1.38 | $ 1.38 | Nov25-27 |
| | | *4.9 %* | | | | |
| Ian Klassen, B.A., *Director* | Stock option | 12,776 | Aug27-20 | $ 2.82 | $ 2.82 | Aug27-27 |
| | Stock option | 29,812 | Jan11-21 | $ 3.29 | $ 3.29 | Jan11-26 |
| | Stock option | 7,412 | Dec21-21 | $ 2.54 | $ 2.54 | Dec21-26 |
| | Stock option | 30,000 | Jun06-22 | $ 1.60 | $ 1.60 | Jun06-27 |
| | | *7.7 %* | | | | |
| Jacqueline Le Saux, BScL, MBA, LLB *Director* | Stock option | 21,294 | Jun16-21 | $ 1.76 | $ 1.76 | Jun16-26 |
| | Stock option | 13,706 | Dec21-21 | $ 2.54 | $ 2.54 | Dec21-26 |
| | Stock option | 30,000 | Jun06-22 | $ 1.60 | $ 1.60 | Jun06-27 |
| | | *6.3 %* | | | | |
| Dr. Raymond Pratt, MD FACP, *Director* | Stock option | 30,000 | Dec21-21 | $ 2.54 | $ 2.54 | Dec21-26 |
| | Stock option | 30,000 | Jun06-22 | $ 1.60 | $ 1.60 | Jun06-27 |
| | | *5.8 %* | | | | |
| Paul Van Damme, B Comm, CPA, MBA, *Director* | Stock option | 25,553 | Jun23-21 | $ 1.64 | $ 1.64 | Jun23-26 |
| | Stock option | 21,671 | Dec21-21 | $ 2.54 | $ 2.54 | Dec21-26 |
| | Stock option | 30,000 | Jun06-22 | $ 1.60 | $ 1.60 | Jun06-27 |
| | | *7.4 %* | | | | |

## 6.C. Board Practices

All of our directors are elected at the annual general meeting of our shareholders and each holds such office until his or her successor is elected or appointed, unless his or her office is earlier vacated by way of the director's resignation or death or under any of the relevant provisions of our Articles or the BCBCA.

***Employment, Consulting and Directors' Service Contracts and Termination and Change in Control Benefits***

The Company employs Dr. Allen Davidoff as the Company's President and Chief Executive Officer at an annual salary of US$321,000, pursuant to an Employment Agreement dated January 1, 2018, between the Company and Dr. Allen Davidoff (the "**Davidoff Agreement**"). The Davidoff Agreement contains standard confidentiality and non-compete clauses and has an indefinite term. The

Davidoff Agreement can be terminated by Dr. Davidoff or the Company by providing 30 days' notice. In the case of the Company providing termination notice, Dr. Davidoff would receive the equivalent of six times his then current monthly salary in a lump sum payment if terminated prior to the first anniversary and if after the first anniversary, Dr. Davidoff is entitled to a lump sum payment of 12 times his then current monthly salary. In the case of a change of control, as defined in the Davidoff Agreement, the Davidoff Agreement provides for a lump sum payment equal to 12 times his monthly base salary amount in effect at the time. As well, all unvested options then held by Dr. Davidoff shall be deemed to have vested upon any such termination.

The Company employs Amar Keshri as the Company's Chief Financial Officer at an annual salary of $205,540, pursuant to an employment agreement dated November 1, 2021 (the "**Keshri Agreement**"). The Keshri Agreement provides for a discretionary bonus up to 30% of the annual salary and contains standard confidentiality and non- compete clauses and has an indefinite term. The Keshri Agreement can be terminated by Mr. Keshri or the Company by providing 30 days' notice. In the case of the Company providing termination notice, Mr. Keshri would receive the equivalent of six times his then current monthly salary in a lump sum payment if terminated prior to the first anniversary and if after the first anniversary, Mr. Keshri is entitled to a lump sum payment of 12 times his then current monthly salary. In the case of a change of control, the Keshri Agreement provides for a lump sum payment equal to 12 times his monthly base salary amount in effect at the time.

The Company entered into a contract with Haworth Biopharmaceutical Consulting Services Inc., dated July 1, 2021 and effective July 1, 2021, as amended by the Consulting Amending Agreement, dated as of January 27, 2022, by and between the Company and Stephen Haworth, for consulting services to the Company to appoint Stephen Haworth as the appointed consultant to act in the capacity as chief medical officer, pursuant to which Haworth Biopharmaceutical Consulting Services Inc. is entitled to compensation for the provision of such services of base fees of US$20,062.50 per month, with a discretionary bonus of up to 30% of the total value of the contract, subject to the discretion of the Compensation Committee. This agreement may be terminated at any time and for any reason by either party with 30 days' notice or by the Company with no notice but payment of one month's fee for services.

The Company entered into a contract with Stacy Evans, dated September 1, 2022 and effective September 1, 2022 for a one-year term expiring September 1, 2023, by and between the Company and Stacy Evans, for consulting services to the Company. On November 16, 2022, the Company appointed Stacy Evans to act in the capacity as chief business officer, pursuant to which he is entitled to compensation for the provision of such services of base fees of US$20,000 per month for the first 90 days and US$25,000 thereafter, such amount to be reduced should the Company engage an external party. Stacy Evans is also entitled to a transaction bonus of 0.75% or 1.25%, calculated on the value of strategic partnerships, for consummation of a transaction, with 0.75% being paid on a transaction that originated as a Company lead and 1.25% being paid on a transaction that originated as a Consultant lead, such 1.25% amount to be reduced to 0.75% should a broker-dealer be entitled to a success fee. This agreement may be terminated at any time and for any reason by either party with 30 days' notice or by the Company with no notice but payment of one month's fee for services.

The Company entered into a contract with W.B. Rowlands & Co. Ltd. and Rowlands for consulting services to the Company, dated December 20, 2021 (the "**WBR Consulting Agreement**"), pursuant to which, in lieu of any additional cash compensation, Rowland's 51,106 stock options issued under the Company's stock option plan will remain outstanding in accordance with the stock option plan for the term of the WBR Consulting Agreement. Of those stock options, 12,776 are exercisable at $5.87 and 38,330 are exercisable at $1.64. The WBR Consulting Agreement will be in effect for an eighteen (18) month period, and may only be terminated for cause.

In addition to the arrangements set forth above, the Company entered into a contract with W.B. Rowlands & Co. Ltd. for consulting services to the Company, dated March 1, 2018 (the "**Rowlands Consulting Agreement**"), pursuant to which W.B. Rowlands & Co. Ltd. is entitled to compensation for the provision of such services of a base fee of $3,000 per month, with a one-time grant of options to purchase at least 200,000 shares of the Company's common stock, vesting 25% at the effective date of the Rowlands Consulting Agreement, and 25% on the anniversary of each year thereafter until the option grant is fully vested. This agreement may be terminated at any time and for any reason by either party with 30 days' notice.

The Company does not have in place any pension or retirement plan. In connection with or related to the retirement, termination or resignation of such person and the Company has provided no compensation to such persons as a result of change of control of the Company, its subsidiaries or affiliates.

***Audit Committee***

The Audit Committee is a committee of the Board to which the Board delegates its responsibility for oversight of the financial reporting process. The Audit Committee is also responsible for managing, on behalf of our shareholders, the relationship between the Company and the external auditor.

*Audit Committee Terms of Reference*

The Company has a written charter which sets out the duties and responsibilities of its Audit Committee. The Audit Committee Charter is attached hereto as Exhibit 15.2.

*Audit Committee Composition*

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*

All audit and non-audit services performed by our auditors for the twelve-month period ended December 31, 2022 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.

***Compensation Committee***

The Compensation Committee has the responsibility of assisting Board oversight of executive and director compensation. Without limiting the generality of the foregoing, the Compensation Committee has the following responsibilities:

(a) reviewing and approving corporate goals and objectives relevant to CEO compensation, evaluating the CEO's performance in light of these goals and objectives and, either as a committee or together with other independent directors, determining and approving the CEO's compensation level based on this evaluation;

(b) recommending to the Board non-CEO compensation, incentive-based plans, equity-based plans and policies relating to the determination and payment of bonuses;

(c) reviewing compensation disclosure in public documents, and producing the Compensation Committee's annual report on executive compensation for inclusion in the company's information (proxy) circular, in accordance with applicable rules and regulations; and

(d) performing any other activities consistent with the charter of the Compensation Committee.

The Compensation Committee is composed of independent directors, being William Farley, Ian Klassen and Paul Van Damme. The Chair of the Compensation Committee is Ian Klassen. 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 Compensation Committee; provided, however, the Compensation Committee shall meet at least on an annual basis.

***Corporate Governance and Nominating Committee***

The Corporate Governance & Nominating Committee has the responsibility of assisting the Board of Directors in fulfilling its corporate governance responsibilities under applicable law, to promote a culture of integrity throughout the Company. Without limiting the generality of the foregoing, the Corporate Governance & Nominating Committee has the following responsibilities:

(a) recommending suitable candidates for nominees for election or appointment as directors and specifying which of the criteria, listed in the charter of the Corporate Governance & Nominating Committee, governing the overall composition of the Board and governing the desirable individual characteristics for directors, form the basis of each recommendation;

(b) maintaining an overview of the entire membership of the Board ensuring that qualifications required under any applicable laws and governance policies are maintained and advise the Chairman of the Board on the disposition of a tender of resignation which a director is expected to offer;

(c) reviewing annually the credentials of nominees for re-election to be named in the Management's Proxy materials for re-election considering factors set forth in the charter of the Corporate Governance & Nominating Committee;

(d) whenever considered appropriate, directing the Chairman of the Board and/or Lead Director to advise each candidate prior to the appointment of the credentials underlying the recommendation of the candidate's appointment;

(e) recommending to the Board at the annual meeting of the Directors, the allocation of Board members to each of the Board Committees. Where a vacancy occurs at any time in the membership of any Board Committee, recommending to the Board a member to fill such vacancy;

(f) subject to Section (m) under the header "Composition and Meetings" set forth in the charter of the Corporate Governance & Nominating Committee, having sole authority to retain and terminate any search firm to be used to identify director candidates, including sole authority to approve fees and other terms of the retention;

(g) annually assessing the performance of the Board, its Committees and Board members and making recommendations to the Board; and

(h) monitoring on a continuing basis and, whenever considered appropriate, making recommendations to the Board concerning the corporate governance of the Company.

The Corporate Governance & Nominating Committee is composed of independent directors, being William Farley, Jacqueline Le Saux and Raymond Pratt. The Chair of the Corporate Governance & Nominating Committee is Jacqueline Le Saux. The Corporate Governance & Nominating Committee shall meet at least semi-annually at the discretion of the Chair of the Corporate Governance & Nominating Committee or a majority of its members, as circumstances dictate or as may be required by applicable legal or listing requirements.

**6.D. Employees**

As at December 31, 2022, we had 3 full-time employee and 14 consultants. None of our employees or consultants are represented by a labor organization or are party to a collective bargaining arrangement. We consider our relationship with our employee to be good.

**6.E. Share Ownership**

The following table indicates information as of April 28, 2023, regarding the beneficial ownership of our Common Shares, after giving effect to the sale of Common Shares offered in this offering and to the Share Consolidation, for:

- each person who is known by us to beneficially own more than 5% of our Common Shares;

- each named executive officer;
- each of our directors; and
- all of our directors and executive officers as a group.

Unless otherwise indicated in the footnotes to the table, and subject to community property laws where applicable, the following persons have sole voting and investment control with respect to the shares beneficially owned by them. In accordance with SEC rules, if a person has a right to acquire beneficial ownership of any Common Shares on or within 60 days of April 28, 2023, upon conversion or exercise of outstanding securities or otherwise, the shares are deemed beneficially owned by that person and are deemed to be outstanding solely for the purpose of determining the percentage of our shares that person beneficially owns. These shares are not included in the computations of percentage ownership for any other person. As of April 28, 2023, we had 15 record holders of our Common Shares, with eight record holders in Canada, representing 44.48% of our outstanding Common Shares, and six record holders in the United States, representing 55.22% of our outstanding Common Shares.

Except as otherwise indicated, the address of each of the persons in this table is 3710 – 33rd Street NW, Calgary, Alberta, T2L 2M1.

| Name and Address of Beneficial Owner | Shares Beneficially Owned | Percentage of Shares Beneficially Owned |
|---|---|---|
| **5% and Greater Shareholders:** | | |
| Prevail Partnerships LLC (1) | 977,318 | 5.43 % |
| Davidoff, Allen (2) | 559,774 | 3.1 % |
| Armistice Capital, LLC (3) | 1,502,516 | 8.35 % |
| | | |
| **Directors and Named Executive Officers:** | | |
| Davidoff, Allen (2) | 559,774 | 3.1 % |
| Evans, Stacy | — | * |
| Farley, William (4) | 65,000 | * |
| Giovinazzo, Anthony (5) | 150,000 | * |
| Haworth, Stephen (6) | 22,214 | * |
| Keshri, Amar (7) | 30,714 | * |
| Klassen, Ian (8) | 122,759 | * |
| Le Saux, Jacqueline (9) | 65,000 | * |
| Pratt, Raymond (10) | 60,000 | * |
| Van Damme, Paul (11) | 141,217 | * |
| All executive officers and directors as a group (10 persons) | 1,216,678 | 6.76 % |

* Indicates beneficial ownership of less than 1%.

1) Consists of 977,318 Common Shares held by Prevail Partnerships LLC ("**Prevail**"). The address of prevail is Attn: Mary Schaheen, President, 211 North 13th Street, 6th Floor, Philadelphia, PA 19107.

2) Consists of 467,617 Common Shares, warrants exercisable for 8,517 Common Shares, and options exercisable for 83,640 Common Shares within 60 days of April 28, 2023, held personally by Mr. Davidoff. The options include 42,589 options expiring June 23, 2025 and exercisable at a purchase price of $1.64, 13,706 options expiring December 21, 2026 and exercisable at a purchase price of $2.54 and 31,607 options expiring June 6, 2027 and exercisable at a purchase price of $1.60.

3) Information sourced from a Schedule 13G filed with the SEC on February 14, 2023, Armistice Capital, LLC ("**Armistice Capital**") is the investment manager of Armistice Capital Master Fund Ltd. (the "**Master Fund**"), the direct holder of the Shares, and pursuant to an Investment Management Agreement, Armistice Capital exercises voting and investment power over the securities of the Issuer held by the Master Fund and thus may be deemed to beneficially own the securities of the Issuer held by the Master Fund. Mr. Boyd, as the managing member of Armistice Capital, may be deemed to beneficially own the securities of the Issuer held by the Master Fund. The Master Fund specifically disclaims beneficial ownership of the securities of the Issuer directly held by it by virtue of its inability to vote or dispose of such securities as a result of its Investment Management Agreement with Armistice Capital. The address of Armistice Capital and Mr. Boyd is 510 Madison Avenue, 7th Floor, New York, New York 10022.

4) Consists of options exercisable for 65,000 Common Shares within 60 days of April 28, 2023, held personally by Mr. Farley. The options include 21,294 options expiring May 12, 2026 and exercisable at a purchase price of $1.88, 13,706 options expiring December 21, 2026 and exercisable at a purchase price of $2.54 and 30,000 options expiring June 6, 2027 expiring June 6, 2027 and exercisable at a purchase price of $1.60.

5) Consists of options exercisable for 150,000 Common Shares within 60 days of April 28, 2023, held personally by Mr. Giovinazzo. The 150,000 options expire June 6, 2027 and are exercisable at a purchase price of $1.60.

6) Consists of options exercisable for 22,214 Common Shares within 60 days of April 28, 2023, held personally by Mr. Haworth. The options include 13,604 options expiring July 14, 2026 and exercisable at a purchase price of $2.41, 4,722 options expiring January 12, 2027 and exercisable at a purchase price of $2.54 and 3,888 options expiring November 25, 2027 and exercisable at a purchase price of $1.38.

7) Consists of 8,500 Common Shares and options exercisable for 22,214 Common Shares within 60 days of April 28, 2023, held personally by Mr. Keshri. The options include 13,604 options expiring July 14, 2026 and exercisable at a purchase price of $2.41, 4,722 options expiring January 12, 2027 and exercisable at a purchase price of $2.54 and 3,888 options expiring November 25, 2027 and exercisable at a purchase price of $1.38.

8) Consists of 42,759 Common Shares, and options exercisable for 80,000 Common Shares within 60 days of April 28, 2023, held personally by Mr. Klassen. The options include 12,776 options expiring August 27, 2025 and exercisable at a purchase price of $2.82, 29,812 options expiring January 11, 2026 and exercisable at a purchase price of $3.29, 7,412 options expiring December 21, 2026 and exercisable at a purchase price of $2.54 and 30,000 options expiring June 6, 2027 and exercisable at a purchase price of $1.60.

9) Consists of options exercisable for 65,000 Common Shares within 60 days of April 28, 2023, held personally by Ms. Le Saux. The options include 21,294 options expiring June 16, 2026 and exercisable at a purchase price of $1.76, 13,706 options expiring December 21, 2026 and exercisable at a purchase price of $2.54 and 30,000 options expiring June 6, 2027 and exercisable at a purchase price of $1.60.

10) Consists of options exercisable for 60,000 Common Shares within 60 days of April 28, 2023, held personally by Mr. Pratt. The options include 30,000 options expiring December 21, 2026 and exercisable at a purchase price of $2.54 and 30,000 options expiring June 6, 2027 and exercisable at a purchase price of $1.60.

11) Consists of 63,993 Common Shares and options exercisable for 77,224 Common Shares within 60 days of April 28, 2023, held personally by Mr. Van Damme. The options include 25,553 options expiring June 23, 2025 and exercisable at a purchase price of $1.64, 21,671 options expiring December 21, 2026 and exercisable at a purchase price of $2.54 and 30,000 options expiring June 6, 2027 and exercisable at a purchase price of $1.60.

***Share Compensation Plan***

The Company maintains a Stock Option Plan (the "**Plan**") for the benefit of directors, officers, employees, consultants and other service providers of the Company and its subsidiaries in order to assist the Company in attracting, retaining and motivating such persons by providing them with the opportunity, through stock options ("**Options**"), to acquire an increased proprietary interest in the Company.

The Plan authorizes the issuance of Options up to an aggregate of 10% of the issued Common Shares from time to time. There are currently 17,989,687 Common Shares of the Company issued and outstanding, and therefore the current 10% threshold is 1,798,969 Common Shares available for Options grants under the Plan. Options may be granted under the Plan with a maximum exercise period of up to ten (10) years, as determined by the Board of Directors of the Company.

The Plan limits the number of Options which may be granted to any one individual to not more than 5% of the total issued Common Shares in any 12-month period (unless otherwise approved by the disinterested Shareholders), and not more than 10% of the total issued Common Shares to all insiders at any time or granted over any 12-month period. The number of Options granted to any one consultant or person employed to provide investor relations activities in any 12-month period must not exceed 2% of the total issued Common Shares. Any Options granted under the Plan will not be subject to any vesting schedule, unless otherwise determined by the Board of Directors.

Options under the Plan may be granted at an exercise price which is at or above the current discounted market price on the date of the grant. In the event of the death or permanent disability of an optionee, any Option granted to such optionee will be exercisable upon the earlier of 365 days from the date of death or permanent disability, or the expiry date of the option. In the event of the resignation, or the termination or removal of an optionee without just cause, any Option granted to such optionee will be exercisable for a period of 90 days thereafter. In the event of termination for cause, any Option granted to such optionee will be cancelled as at the date of termination.

A copy of the Plan is attached as Exhibit 4.18 to this Annual Report.

### 6.F. Disclosure of a Registrant's Action to Recover Erroneously Award Compensation

Not applicable.

## ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### 7.A. Major Shareholders

See Item 6.E. above. Armistice Capital acquired all of its shares in the Company during 2022. Prevail acquired all of its shares in the Company during 2020. The voting rights of both Armistice Capital and Prevail to the securities held by each are the same as those that apply to any other securityholder of similar securities.

### 7.B. Related Party Transactions

Other than as described below, since January 1, 2020, 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 and Armistice Capital. Prevail owns 977,318 Common Shares, currently representing approximately 5.43% 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, XRx101 and XRx-225 programs in the future.

Pursuant to the October 7, 2022 Letter Agreement between the Company and Armistice Capital, for a period until 18 months from October 7, 2022, upon any offering by the Company of its common shares, Armistice Capital shall have the right to participate in such an offering in an amount equal to 50% of the offering on the same terms, conditions, and prove provided for, up to a 19.9% ownership in the Company, subject to not creating a control person transaction that would require the Company to obtain shareholder approval prior to the Subsequent Financing. In addition, for a one-year period from October 7, 2022, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its subsidiaries of Shares or Share Equivalents (or a combination of units thereof) involving a Variable Rate Transaction.

During the years ended December 31, 2020 - 2022, the Company entered into various transactions with related parties. All related party transactions were measured at the amount of consideration established and agreed to by the related parties. All amounts due from/payable to related parties are unsecured, non-interest bearing and have no fixed terms of repayment.

The Company entered into the following during the year ended December 31, 2022:

- Wages and benefits were paid or accrued to Allen Davidoff, CEO, Amar Keshri, CFO, and David MacDonald, former CTO of the Company in the amount of $775,259 (2021 - $311,840).
- Professional fees were paid or accrued to 1282803 Ontario Inc., a company owned by Jim Fairbairn, a former CFO of the Company in the amount of $nil (2021 - $58,500).
- Research and development fees were paid or accrued to Haworth Biopharmaceutical, a company owned by Stephen Haworth, CMO of the Company in the amount of $312,412 (2021 - $106,366).

- Consulting fees were paid or accrued to Stacy Evans, CBO of the Company in the amount of $61,018 (2021 - $nil).
- Consulting fees were paid to Bruce Rowlands and Allan Williams, former directors of the Company in the amount of $nil (2021 - $54,950).
- Consulting fees were paid to a private entity controlled by the spouse of the Company's CEO in the amount of $4,750 (2021 - $nil).
- Directors' fees were paid or accrued to the directors of the Company in the amount of $161,054 (2021 - $62,200). The amount includes a directors fee payment of $90,871 for the year ended December 31, 2022 (2021 - $nil) to Anthony Giovinazzo, Chairman of the Company.
- As at December 31, 2022, $20,200 (2021 - $81,104) was payable to directors of the Company, $39,069 (2021 - $25,000) was accrued to the CEO of the Company for CEO services, $14,769 (2021 - $nil) was accrued to the CFO of the Company for CFO services, $67,720 (2021 - $47,543) was payable and accrued to the CMO of the Company for consulting services, and $33,860 (2021 - $nil) was payable and accrued to the CBO of the Company for consulting services. The balances are unsecured, non-interest bearing, and have no fixed terms of repayment.

During the year ended December 31, 2021, the Company incurred the following transactions with related parties:

- Wages and benefits were paid or accrued to officers of the Company in the amount of $278,840 (2020 - $196,097).
- Professional fees were paid or accrued to a former officer of the Company in the amount of $58,500 (2020 - $30,000).
- Professional fees were paid or accrued to an officer of the Company in the amount of $53,000 (2020 - $nil).
- Research and development fees were paid or accrued to an officer of the Company in the amount of $106,366 (2020 - $nil).
- Consulting fees were accrued to directors of the Company in the amount of $34,950 and directors' fees (2020 - $36,000) were accrued to the directors of the Company in the amount of $62,200 (2020 - $nil).
- As at December 31, 2021, $nil (2020 - $52,450) was payable to the former Chief Financial Officer ("CFO") of the Company for CFO services, and $81,104 (2020 - $20,340) was payable to directors of the Company, $25,000 (2020 - $518,084) was accrued to the Chief Executive Officer ("CEO") of the Company, for CEO services, and $47,543 (2020 - $nil) was accrued to the Chief Medical Officer ("CMO") of the Company, for consulting services. The balances are unsecured, non-interest bearing, and have no fixed terms of repayment.

During the year ended December 31, 2020, the Company incurred the following transactions with related parties:

- Wages and benefits were paid or accrued to an officer of the Company in the amount of $196,097 (2019 - $194,166).
- Professional fees were paid or accrued to an officer of the Company in the amount of $30,000 (2019 - $30,000).
- Consulting fees were paid or accrued to a director of the Company for directors' fees in the amount of $36,000 (2019 - $nil).
- As at December 31, 2020, $52,450 (2019 - $39,550) was payable to the Chief Financial Officer ("CFO") of the Company for CFO services, and $20,340 (2019 - $nil) was payable to a director of the company for directors' fees. The balance is unsecured, non-interest bearing, and has no fixed terms of repayment.
- As at December 31, 2020, $518,084 (2019 - $502,110) was accrued to the Chief Executive Officer ("CEO") of the Company, for CEO services. The balance is unsecured, non-interest bearing and has no fixed terms of repayment.

The Company's management compensation transactions for the fiscal years ending December 31, 2020 – 2022 are summarized as follows:

| | Short-term employee benefits | Directors' fees | Share-based payments | Total |
|---|---|---|---|---|
| | $ | $ | $ | $ |
| Year ended December 31, 2020 | | | | |
| Directors and officers | 226,097 | — | 217,816 | 443,913 |
| Year ended December 31, 2021 | | | | |
| Directors and officers | 531,656 | 62,200 | 331,809 | 925,665 |
| Year ended December 31, 2022 | | | | |
| Directors and officers | 1,153,439 | 166,923 | 519,741 | 1,840,103 |

Other than as described elsewhere in this Annual Report, 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), 10% or more 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.

### 7.C. Interests of Experts and Counsel

Not applicable.

## ITEM 8. FINANCIAL INFORMATION

The audited consolidated financial statements for the years ended December 31, 2022, 2021, and 2020 can be found under "Item 18. Financial Statements".

### 8.B. Significant Changes

We are not aware of any significant change that has occurred since December 31, 2022, the date of the audited consolidated financial statements included in this Annual Report, and that has not been disclosed elsewhere in this Annual Report.

## ITEM 9. THE OFFER AND LISTING.

### 9.A. Offer and Listing Details

The Common Shares are listed and posted for trading on each of the TSXV and Nasdaq under the trading symbol "XRTX" and on each of the Frankfurt Stock Exchange, Munich Stock Exchange, Berlin Stock Exchange, and Stuttgart Stock Exchange under the trading symbol "ANU".

### 9.B. Plan of Distribution

Not applicable.

### 9.C. Markets

A discussion of all stock exchanges and other regulated markets on which our securities are listed is provided under "Item 9.A. Offer and Listing Details."

### 9.D. Selling Shareholders

Not applicable.

### 9.E. Dilution

Not applicable.

**9.F. Expenses of the Issue**

Not applicable.

**ITEM 10. ADDITIONAL INFORMATION**

**10.A. Share Capital**

Not applicable.

**10.B. Memorandum and Articles of Association**

1. The Company was incorporated to carry on business without restrictions under 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.

   The Company's Notice of Articles and Articles (collectively, the "**Articles**") do not specify the objects or purposes of the Company.

2. A director or senior officer who holds a disclosable interest (as that term is used in the BCBCA) in a contract or transaction into which the Company has entered or proposes to enter is liable to account to the Company for any profit that accrues to the director or senior officer under or as a result of the contract or transaction only if and to the extent provided in the BCBCA.

   A director who holds a disclosable interest in a contract or transaction into which the Company has entered or proposes to enter is not entitled to vote on any directors resolution to approve that contract or transaction, unless all the directors have a disclosable interest in that contract or transaction, in which case any or all of those directors may vote on such resolution.

   A director who holds a disclosable interest in a contract or transaction into which the Company has entered or proposes to enter and who is present at the meeting of directors at which the contract or transaction is considered for approval may be counted in the quorum at the meeting whether or not the director votes on any or all of the resolutions considered at the meeting.

   A director or senior officer who holds any office or possesses any property, right or interest that could result, directly or indirectly, in the creation of a duty or interest that materially conflicts with that individual's duty or interest as a director or senior officer, must disclose the nature and extent of the conflict as required by the BCBCA.

The Company, if authorized by the directors, may:

a) borrow money in the manner and amount, on the security, from the sources and on the terms and conditions that they consider appropriate;

b) issue bonds, debentures and other debt obligations either outright or as security for any liability or obligation of the Company or any other person and at such discounts or premiums and on such other terms as they consider appropriate;

c) guarantee the repayment of money by any other person or the performance of any obligation of any other person; and

d) mortgage, charge, whether by way of specific or floating charge, grant a security interest in, or give other security on, the whole or any part of the present and future assets and undertaking of the Company.

The Articles do not contain an age limit requirement for the retirement or non-retirement of directors and they do not require directors to hold a minimum number of shares of the Company to qualify as a director.

3. 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 Articles.

   As of the date hereof, our authorized share capital consists of an unlimited number of Common Shares, each without par value, of which 17,989,687 are issued and outstanding. In addition, we have 1,154,319 Common Shares issuable pursuant to outstanding stock options, and 10,579,796 Common Shares issuable upon the exercise of outstanding Common Share purchase warrants. We had approximately 16 holders of record and approximately 891 beneficial owners of our Common Shares as of December 31, 2022.

   Under our articles, the holders of our Common Shares are 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.

   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.

   In the event of our liquidation, dissolution or winding up, holders of our Common Shares will be entitled to share ratably 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.

   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.

4. Subject to the provisions of the following paragraph and the BCBCA, the Company may by resolution of the directors:

   a) create one or more classes or series of shares or, if none of the shares of a class or series of shares are allotted or issued, eliminate that class or series of shares;

   b) increase, reduce or eliminate the maximum number of shares that the Company is authorized to issue out of any class or series of shares or establish a maximum number of shares that the Company is authorized to issue out of any class or series of shares for which no maximum is established;

   c) if the Company is authorized to issue shares of a class of shares with par value;

      i) decrease the par value of those shares; or

      ii) if none of the shares of that class of shares are allotted or issued, increase the par value of those shares

   d) subdivide all or any of its unissued or fully paid issued shares in any manner;

   e) change all or any of its unissued, or fully paid issued, shares with par value into shares without par value or any of its unissued shares without par value into shares with par value;

   f) alter the identifying name of any of its shares; or

   g) otherwise alter its shares or authorized share structure when required or permitted to do so by the BCBCA;

   and, if applicable, alter its Notice of Articles and, if applicable, its Articles accordingly.

Subject to the BCBCA, the Company may by special resolution (i.e., a resolution passed by not less than two-thirds of the votes cast in respect of that resolution, or a written resolution signed by all the shareholders entitled to vote on the resolution):

a) create special rights or restrictions for, and attach those special rights or restrictions to, the shares of any class or series of shares, whether or not any or all of those shares have been issued; or

b) vary or delete any special rights or restrictions attached to the shares of any class or series of shares, whether or not any or all of those shares have been issued;

and alter its Notice of Articles and Articles accordingly.

5. Unless an annual general meeting is deferred or waived in accordance with the BCBCA, the Company must hold its first annual general meeting within 18 months after the date on which it was incorporated or otherwise recognized, and after that must hold an annual general meeting at least once in each calendar year and not more than 15 months after the last annual reference date at such time and place as may be determined by the directors.

If all the shareholders who are entitled to vote at an annual general meeting consent by a unanimous resolution under the BCBCA to all of the business that is required to be transacted at that annual general meeting, the annual general meeting is deemed to have been held on the date of the unanimous resolution. The shareholders must, in any such unanimous resolution, select as the Company's annual reference date a date that would be appropriate for the holding of the applicable annual general meeting.

The directors may, whenever they think fit, call a meeting of shareholders, to be held at such time and place as may be determined by the directors.

The Company must send notice of the date, time and location of any meeting of shareholders, in the manner provided in the Articles, or in such other manner, if any, as may be prescribed by ordinary resolution (whether previous notice of the resolution has been given or not), to each shareholder entitled to attend the meeting, to each director and to the auditor of the Company, unless the Articles otherwise provide, at least the following number of days before the meeting:

a) if and for so long as the Company is a public company, 21 days;

b) otherwise, 10 days.

The directors may set a date as the record date for the purpose of determining shareholders entitled to notice of any meeting of shareholders. The record date must not precede the date on which the meeting is to be held by more than two months or, in the case of a general meeting requisitioned by shareholders under the BCBCA, by more than four months. The record date must not precede the date on which the meeting is held by fewer than:

a) if and for so long as the Company is a public company, 21 days;

b) otherwise, 10 days.

If no record date is set, the record date is 5 p.m. on the day immediately preceding the first date on which the notice is sent or, if no notice is sent, the beginning of the meeting.

The directors may set a date as the record date for the purpose of determining shareholders entitled to vote at any meeting of shareholders. The record date must not precede the date on which the meeting is to be held by more than two months or, in the case of a general meeting requisitioned by shareholders under the BCBCA, by more than four months. If no record date is set, the record

date is 5 p.m. on the day immediately preceding the first date on which the notice is sent or, if no notice is sent, the beginning of the meeting.

The accidental omission to send notice of any meeting to, or the non-receipt of any notice by, any of the persons entitled to notice does not invalidate any proceedings at that meeting. Any person entitled to notice of a meeting of shareholders may, in writing or otherwise, waive or reduce the period of notice of such meeting.

If a meeting of shareholders is to consider special business within the meaning set out in the Articles, the notice of meeting must:

a) state the general nature of the special business; and

b) if the special business includes considering, approving, ratifying, adopting or authorizing any document or the signing of or giving of effect to any document, have attached to it a copy of the document or state that a copy of the document will be available for inspection by shareholders:

i) at the Company's records office, or at such other reasonably accessible location in British Columbia as is specified in the notice; and

ii) during statutory business hours on any one or more specified days before the day set for the holding of the meeting.

6. Except as provided for by the BCBCA, no share may be issued until it is fully paid. A share is fully paid when:

a. consideration is provided to the Company for the issue of the share by one or more of the following:

i. past services performed for the Company;

ii. property;

iii. money; and

b. the value of the consideration received by the Company equals or exceeds the issue price set for the share.

7. The Articles contain no provisions that would have an effect of delaying, deferring or preventing a change of control of the Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving the Company (or any of its subsidiaries). However, certain types of change of control transactions will require shareholder approval of the Company's shareholders and calling the necessary shareholder meeting for such transaction would delay the completion of the transaction.

8. There are no provisions in the Articles or bylaws that require disclosure of share ownership above a specified threshold.

9. With respect to the items above, the BCBCA and the Company's Articles are not significantly different from U.S. law.

10. The conditions imposed by the Articles governing changes in the Company's capital that are more stringent than the BCBCA are outlined in paragraph 4 above.

**10.C. Material Contracts**

Other than as described below, there are no material contracts entered into by the Company within the two most recently completed financial years, or before the two most recently completed financial years but which are still in effect, other than contracts entered into in the ordinary course of business. Additional details concerning the Company's contracts with its executive offices may be found under "Item 6.C. – Board Practices."

1. Investigator Initiated-Clinical Trial Agreement, dated effective August 3, 2020, by and between the Company and Icahn School of Medicine at Mount Sinai, pursuant to which the Company funded a clinical trial in the field of Nephrology and AKI due to COVID-19;

2. Employment Agreement, dated effective August 1, 2021, by and between the Company and Allen Davidoff, pursuant to which the Company employed Allen Davidoff as President and Chief Executive Officer for an annual salary of $190,000.00;

3. Master Services Agreement, dated effective July 20, 2017, by and between the Company and Cato Research Canada Inc., pursuant to which the Company retained Cato Research Canada Inc. to assist with certain aspects of the evaluation, development, commercialization or marketing of biologics, pharmaceutical agents, medical devices and/or other life sciences technologies;

4. Master Service and Technology Agreement, dated effective February 25, 2019, by and between the Company and Prevail InfoWorks, Inc. (a clinical research organization) and the Company to support two clinical trials;

5. Side Letter to Master Service and Technology Agreement, dated effective February 24, 2020, by and between the Company and Prevail InfoWorks, Inc. in connection with the payment of services provided to the Company through the issuance of Common Shares of the Company to Prevail Partners LLC;

6. Subscription Agreement, dated effective February 28, 2020, by and between the Company and Prevail Partners LLC, pursuant to which Prevail Partners LLC subscribed for and agreed to purchase 8,571,428 units of the Company for Cdn.$1,602,132;

7. Standard Exclusive License Agreement with Know How, dated effective as of June 23, 2014, by and between the Company and 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;

8. Consulting Agreement, dated effective July 1, 2021, by and between the Company and Haworth Biopharmaceutical Consulting Services Inc., pursuant to which the Company retained Stephen Haworth as Chief Medical Officer for USD$11,700.00 per month, with a 30% bonus eligibility based on the total of the contract at the time of the grant of the bonus, subject to the discretion of the compensation committee, and 250,000 options based on the discretion of the Management and Board Directors;

9. Consulting Amending Agreement, dated January 27, 2022 and effective November 1, 2021 by and between the Company and Mr. Stephen Haworth, to extend the provision of services to the Company by Mr. Haworth through October 31, 2022 and increase Mr. Haworth's compensation to US$18,750 per month a 30% bonus eligibility based on the total of the contract at the time of the grant of the bonus, subject to the discretion of the compensation committee;

10. Patent Rights Purchase Agreement, dated effective as of December 5, 2012, by and between Dr. Richard Johnson, Dr. Takahiko Nakagawa, and Revascor Inc., pursuant to which Revascor Inc. purchased Dr. Richard Johnson and Dr. Takahiko Nakagawa's ownership interests in certain patent and patent applications covering inventions relating to the treatment of cardiovascular diseases;

11. Form of Warrant Agency Agreement with Continental Stock Transfer & Trust Company, pursuant to which the Company retained Continental Stock Transfer & Trust Company to act on behalf of the Company in connection with the issuance, registration, transfer, exchange, exercise and replacement of the warrants issued under that certain Underwriting Agreement, dated October 15, 2021, by and between the Company and A.G.P./Alliance Global Partners;

12. Form of Warrant Agency Agreement with Continental Stock Transfer & Trust Company, as Warrant Agent, pursuant to which the Company retained Continental Stock Transfer & Trust Company to act on behalf of the Company in connection with the issuance, registration, transfer, exchange, exercise and replacement of the warrants issued under that certain Underwriting Agreement, dated October 4, 2022, by and between the Company and A.G.P./Alliance Global Partners;

13. Consulting Agreement, dated effective March 1, 2018, by and between the Company and W.B. Rowlands & Co. Ltd., pursuant to which the Company retained W.B. Rowlands & Co. Ltd. to act as a consultant with respect to such matters and projects as are mutually agreed from time to time between the parties;

14. Consulting Services Agreement, dated effective December 20, 2021, by and between the Company, W.B. Rowlands & Co. Ltd., and William Bruce Rowlands, pursuant to which the Company retained William Bruce Rowlands to act as a consultant for, in lieu of any additional cash consideration, 51,106 stock options issued to William Bruce Rowlands' under the Company's stock option plan to remain outstanding in accordance with the stock option plan for the term of the agreement;

15. Stock Option Plan pursuant to which the Company may grant eligible persons options, exercisable over periods of up to ten years as determined by the Board of Directors;

16. 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;

17. Equity Agreement dated effective June 23, 2014 between the Company and UFRF pursuant to which UFRF acquired certain equity interests in the Company;

18. Agreement dated July 20, 2017 between the Company and Cato Research Canada Inc. to manage future regulatory and clinical trial programs;

19. 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;

20. 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;

21. 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;

22. 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;

23. Proposal for XORTX Therapeutics Inc., dated February 21, 2022, by and between the Company and Covar Pharmaceuticals Inc., setting forth the terms governing development of a prototype;

24. Proposal for XORTX Therapeutics Inc., dated December 6, 2021, by and between the Company and Covar Pharmaceuticals Inc., setting forth the scope and budget estimate for preparation and testing of a formulation; and

25. Proposal, dated as of March 29, 2022, by and between the Company and Curia Spain, S.A.U., setting forth the terms governing the program for manufacturing of a product.

26. Agreement, dated as of November 1, 2021, by and between the Company and Amar Keshri providing for his employment as CFO at a salary of $192,000 per year.

27. Consulting Agreement dated as of September 1, 2022 between the Company and Stacy Evans, M.D., M.B.A., whereby Ms. Evans has agreed to provide certain Consulting Services (as defined in the agreement) to the Company as an independent consultant for a term of 12 months, subject to extension upon the written agreement of the parties in exchange for a fixed monthly fee of US$20,000 for the first ninety days of the term and a fixed monthly fee of $25,000 for the remaining term, subject to certain adjustments as outlined in the agreement, plus expenses and certain bonus opportunities.

**10.D. Exchange Controls**

There are currently no government laws, decrees, regulations or other legislation of Canada or the United States that restrict the export or import of capital (including the availability of cash and cash equivalents) or that affect the remittance of dividends, distributions, interest or other payments to non-residents of Canada or the United States holding our Common Shares. Any remittances of dividends to United States residents and to other non-residents are, however, subject to withholding tax. See "Taxation" below.

**10.E. Taxation**

**Material U.S. Federal Income Tax Considerations for U.S. Holders**

The following is a general summary of certain U.S. federal income tax considerations applicable to a U.S. Holder (as defined below) arising from and relating to the acquisition, ownership and disposition of Common Shares.

This summary is for general information purposes only and does not purport to be a complete analysis or listing of all potential U.S. federal income tax considerations that may apply to a U.S. Holder as a result of the acquisition of Common Shares. In addition, this summary does not take into account the individual facts and circumstances of any particular U.S. Holder that may affect the U.S. federal income tax consequences to such U.S. Holder, including specific tax consequences to a U.S. Holder under an applicable tax treaty. Accordingly, this summary is not intended to be, and should not be construed as, legal or U.S. federal income tax advice with respect to any particular U.S. Holder. This summary does not address the U.S. federal net investment income, U.S. federal alternative minimum, U.S. federal estate and gift, U.S. state and local, and non-U.S. tax consequences to U.S. Holders of the acquisition, ownership, and disposition of the Common Shares. In addition, except as specifically set forth below, this summary does not discuss applicable tax reporting requirements. Each U.S. Holder should consult its own tax advisor regarding the U.S. federal, U.S. federal net investment income, U.S. federal alternative minimum, U.S. federal estate and gift, U.S. state and local, and non-U.S. tax consequences relating to the acquisition, ownership and disposition of the Common Shares.

No opinion from legal counsel or ruling from the Internal Revenue Service (the "**IRS**") has been requested, or will be obtained, regarding the U.S. federal income tax considerations applicable to U.S. Holders as discussed in this summary. This summary is not binding on the IRS, and the IRS is not precluded from taking a position that is different from, and contrary to, the positions taken in this summary. In addition, because the authorities on which this summary is based are subject to various interpretations, the IRS and the U.S. courts could disagree with one or more of the positions taken in this summary.

***Scope of this Summary***

Authorities

This summary is based on the Internal Revenue Code of 1986, as amended (the "**Code**"), Treasury Regulations (whether final, temporary, or proposed) promulgated under the Code, published rulings of the IRS, published administrative positions of the IRS and U.S. court decisions, that are in effect and available, as of the date of this document. Any of the authorities on which this summary is based could be changed in a material and adverse manner at any time, and any such change could be applied retroactively. This summary does not discuss the potential effects, whether adverse or beneficial, of any proposed legislation that, if enacted, could be applied on a retroactive or prospective basis.

U.S. Holders

For purposes of this summary, the term "U.S. Holder" means a beneficial owner of the Common Shares that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate whose income is subject to U.S. federal income taxation regardless of its source; or
- a trust that (1) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons for all substantial decisions or (2) has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

*U.S. Holders Subject to Special U.S. Federal Income Tax Rules Not Addressed*

This summary does not address the U.S. federal income tax considerations applicable to U.S. Holders that are subject to special provisions under the Code, including U.S. Holders that: (a) are tax-exempt organizations, qualified retirement plans, individual retirement accounts, or other tax-deferred accounts; (b) are financial institutions, underwriters, insurance companies, real estate investment trusts, or regulated investment companies; (c) are brokers or dealers in securities or currencies or U.S. Holders that are traders in securities that elect to apply a mark-to-market accounting method; (d) have a "functional currency" other than the U.S. dollar; (e) own Common Shares as part of a straddle, hedging transaction, conversion transaction, constructive sale, or other integrated transaction; (f) acquired the Common Shares in connection with the exercise of employee stock options or otherwise as compensation for services; (g) hold the Common Shares other than as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment purposes); (h) are partnerships and other pass-through entities (and investors in such partnerships and entities); (i) are subject to special tax accounting rules; (j) own, have owned or will own (directly, indirectly, or by attribution) 10% or more of the total combined voting power or value of our outstanding shares; (k) are U.S. expatriates or former long-term residents of the U.S.; or (l) are subject to taxing jurisdictions other than, or in addition to, the United States. U.S. Holders that are subject to special provisions under the Code, including U.S. Holders described immediately above, should consult their own tax advisors regarding the U.S. federal, U.S. federal net investment income, U.S. federal alternative minimum, U.S. federal estate and gift, U.S. state and local, and non-U.S. tax consequences relating to the acquisition, ownership and disposition of the Common Shares.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds the Common Shares, the U.S. federal income tax consequences to such entity or arrangement and the owners of such entity or arrangement generally will depend on the activities of such entity or arrangement and the status of such owners. This summary does not address the tax consequences to any such entity or arrangement or owner. Owners of entities or arrangements that are classified as partnerships for U.S. federal income tax purposes should consult their own tax advisor regarding the U.S. federal income tax consequences arising from and relating to the acquisition, ownership, and disposition of the Common Shares.

***Passive Foreign Investment Company Rules***

If we are considered a "passive foreign investment company" within the meaning of Section 1297 of the Code (a "PFIC") at any time during a U.S. Holder's holding period, the following sections will generally describe the potentially adverse U.S. federal income tax consequences to U.S. Holders of the acquisition, ownership, and disposition of the Common Shares.

We believe we were classified as a PFIC during the taxable year ended December 31, 2022. Based on current business plans and financial expectations, we may be a PFIC for our taxable year ending December 31, 2023 or future taxable years. No opinion of legal counsel or ruling from the IRS concerning our status as a PFIC has been obtained or is currently planned to be requested. The determination of whether any corporation was, or will be, a PFIC for a tax year depends, in part, on the application of complex U.S. federal income tax rules, which are subject to differing interpretations. In addition, whether any corporation will be a PFIC for any tax year depends on the assets and income of such corporation over the course of each such tax year and, as a result, our PFIC status for the current year and future years cannot be predicted with certainty as of the date of this document. Accordingly, there can be no assurance that the IRS will not challenge any PFIC determination made by us (or by one of our subsidiaries). Each U.S. Holder should consult its own tax advisor regarding our status as a PFIC and the PFIC status of each non-U.S. subsidiary.

In any year in which we are classified as a PFIC, a U.S. Holder will be required to file an annual report with the IRS containing such information as Treasury Regulations and/or other IRS guidance may require. In addition to penalties, a failure to satisfy such reporting requirements may result in an extension of the time period during which the IRS can assess a tax. U.S. Holders should consult their own tax advisors regarding the requirements of filing such information returns under these rules, including the requirement to file an IRS Form 8621.

We generally will be a PFIC for any tax year in which (a) 75% or more of our gross income for such tax year is passive income (the "**PFIC income test**") or (b) 50% or more of the value of our assets either produce passive income or are held for the production of passive income, based on the quarterly average of the fair market value of such assets (the "**PFIC asset test**"). "Gross income" generally includes sales revenues less the cost of goods sold, plus income from investments and from incidental or outside operations or sources, and "passive income" generally includes, for example, dividends, interest, certain rents and royalties, certain gains from the sale of stock and securities, and certain gains from commodities transactions. Active business gains arising from the sale of commodities generally are excluded from passive income if substantially all of a foreign corporation's commodities are stock in trade or inventory, depreciable property used in a trade or business, or supplies regularly used or consumed in the ordinary course of its trade or business, and certain other requirements are satisfied.

For purposes of the PFIC income test and PFIC asset test described above, if we own, directly or indirectly, 25% or more of the total value of the outstanding shares of another corporation, we will be treated as if we (a) held a proportionate share of the assets of such other corporation and (b) received directly a proportionate share of the income of such other corporation. In addition, for purposes of the PFIC income test and PFIC asset test described above, "passive income" does not include any interest, dividends, rents, or royalties that are received or accrued by us from a "related person" (as defined in Section 954(d)(3) of the Code), to the extent such items are properly allocable to the income of such related person that is not passive income.

Under certain attribution rules, if we are a PFIC, U.S. Holders will be deemed to own their proportionate share of any of our subsidiaries which is also a PFIC (a "Subsidiary PFIC"), and will generally be subject to U.S. federal income tax under the "Default PFIC Rules Under Section 1291 of the Code" discussed below on their proportionate share of any (i) distribution on the shares of a Subsidiary PFIC and (ii) disposition or deemed disposition of shares of a Subsidiary PFIC, both as if such U.S. Holders directly held the shares of such Subsidiary PFIC. Accordingly, U.S. Holders should be aware that they could be subject to tax under the PFIC rules even if no distributions are received and no redemptions or other dispositions of the Common Shares are made. In addition, U.S. Holders may be subject to U.S. federal income tax on any indirect gain realized on the stock of a Subsidiary PFIC on the sale or disposition of the Common Shares.

Default PFIC Rules Under Section 1291 of the Code

If we are a PFIC, the U.S. federal income tax consequences to a U.S. Holder of the acquisition, ownership, and disposition of the Common Shares will depend on whether such U.S. Holder makes a "qualified electing fund" or "QEF" election (a "QEF Election") or makes a mark-to-market election under Section 1296 of the Code (a "Mark-to-Market Election") with respect to the Common Shares. A U.S. Holder that does not make either a QEF Election or a Mark-to-Market Election (a "Non-Electing U.S. Holder") will be taxable as described below.

A Non-Electing U.S. Holder will be subject to the rules of Section 1291 of the Code with respect to (a) any gain recognized on the sale or other taxable disposition of the Common Shares and (b) any excess distribution received on the Common Shares. A distribution generally will be an "excess distribution" to the extent that such distribution (together with all other distributions received in the current tax year) exceeds 125% of the average distributions received during the three preceding tax years (or during a U.S. Holder's holding period for the Common Shares, if shorter).

Under Section 1291 of the Code, any gain recognized on the sale or other taxable disposition of the Common Shares of a PFIC (including an indirect disposition of shares of a Subsidiary PFIC), and any excess distribution received on such Common Shares (or a distribution by a Subsidiary PFIC to its shareholder that is deemed to be received by a U.S. Holder) must be ratably allocated to each day in a Non-Electing U.S. Holder's holding period for the Common Shares. The amount of any such gain or excess distribution allocated to the tax year of disposition or distribution of the excess distribution and to years before the entity became a PFIC, if any, would be taxed as ordinary income (and not eligible for certain preferential tax rates, as discussed below). The amounts allocated to any other tax year would be subject to U.S. federal income tax at the highest tax rate applicable to ordinary income in each such year, and an interest charge would be imposed on the tax liability for each such year, calculated as if such tax liability had been due in each such year. A Non-Electing U.S. Holder that is not a corporation must treat any such interest paid as "personal interest," which is not deductible.

If we are a PFIC for any tax year during which a Non-Electing U.S. Holder holds the Common Shares, it will continue to be treated as a PFIC with respect to such Non-Electing U.S. Holder, regardless of whether it ceases to be a PFIC in one or more subsequent tax years. If we cease to be a PFIC, a Non-Electing U.S. Holder may terminate this deemed PFIC status with respect to the Common Shares by electing to recognize gain (which will be taxed under the rules of Section 1291 of the Code as discussed above) as if such Common Shares were sold on the last day of the last tax year for which we were a PFIC.

QEF Election

A U.S. Holder that makes a QEF Election for the first tax year in which its holding period of its Common Shares begins generally will not be subject to the rules of Section 1291 of the Code discussed above with respect to its Common Shares. However, a U.S. Holder that makes a QEF Election will be subject to U.S. federal income tax on such U.S. Holder's pro rata share of (a) our net capital gain, which will be taxed as long-term capital gain to such U.S. Holder, and (b) our ordinary earnings, which will be taxed as ordinary income to such U.S. Holder. Generally, "net capital gain" is the excess of (a) net long-term capital gain over (b) net short-term capital loss, and "ordinary earnings" are the excess of (a) "earnings and profits" over (b) net capital gain. A U.S. Holder that makes a QEF Election will be subject to U.S. federal income tax on such amounts for each tax year in which we are a PFIC, regardless of whether such amounts are actually distributed to such U.S. Holder by us. However, for any tax year in which we are a PFIC and have no net income or gain, U.S. Holders that have made a QEF Election would not have any income inclusions as a result of the QEF Election. If a U.S. Holder that made a QEF Election has an income inclusion, such a U.S. Holder may, subject to certain limitations, elect to defer payment of current U.S. federal income tax on such amounts, subject to an interest charge. If such U.S. Holder is not a corporation, any such interest paid will be treated as "personal interest," which is not deductible.

A U.S. Holder that makes a timely QEF Election generally (a) may receive a tax-free distribution from us to the extent that such distribution represents "earnings and profits" that were previously included in income by the U.S. Holder because of such QEF Election and (b) will adjust such U.S. Holder's tax basis in the Common Shares to reflect the amount included in income or allowed as a tax-free distribution because of such QEF Election. In addition, a U.S. Holder that makes a QEF Election generally will recognize capital gain or loss on the sale or other taxable disposition of Common Shares.

The procedure for making a QEF Election, and the U.S. federal income tax consequences of making a QEF Election, will depend on whether such QEF Election is timely. A QEF Election will be treated as "timely" for purposes of avoiding the default PFIC rules discussed above if such QEF Election is made for the first year in the U.S. Holder's holding period for the Common Shares in which we were a PFIC. A U.S. Holder may make a timely QEF Election by filing the appropriate QEF Election documents at the time such U.S. Holder files a U.S. federal income tax return for such year.

A QEF Election will apply to the tax year for which such QEF Election is made and to all subsequent tax years, unless such QEF Election is invalidated or terminated or the IRS consents to revocation of such QEF Election. If a U.S. Holder makes a QEF Election and, in a subsequent tax year, we cease to be a PFIC, the QEF Election will remain in effect (although it will not be applicable) during those tax years in which we are not a PFIC. Accordingly, if we become a PFIC in another subsequent tax year, the QEF Election will be effective and the U.S. Holder will be subject to the QEF rules described above during any subsequent tax year in which we qualify as a PFIC.

However, U.S. Holders should be aware that if we determine that we are a PFIC for this year or any future taxable year, we can make no assurances that we would provide the information necessary for U.S. Holders to make a QEF Election. Thus, U.S. Holders may not be able to make a QEF Election with respect to their Common Shares.

A U.S. Holder makes a QEF Election by attaching a completed IRS Form 8621, including a PFIC Annual Information Statement, to a timely filed U.S. federal income tax return. However, if we do not provide the required information with regard to us or any of our Subsidiary PFICs, U.S. Holders will not be able to make a QEF Election for such entity and will continue to be subject to the rules of Section 1291 of the Code discussed above that apply to Non-Electing U.S. Holders with respect to the taxation of gains and excess distributions.

Mark-to-Market Election

A U.S. Holder may make a Mark-to-Market Election with respect to the Common Shares only if such shares are marketable stock. The Common Shares generally will be "marketable stock" if the Common Shares are regularly traded on (a) a national securities exchange that is registered with the SEC, (b) the national market system established pursuant to Section 11A of the U.S. Exchange Act or (c) a foreign securities exchange that is regulated or supervised by a governmental authority of the country in which the market is located, provided that (i) such foreign exchange has trading volume, listing, financial disclosure, and other requirements and the laws of the country in which such foreign exchange is located, together with the rules of such foreign exchange, ensure that such requirements are actually enforced and (ii) the rules of such foreign exchange ensure active trading of listed stocks. If such stock is traded on such a qualified exchange or other market, such stock generally will be considered "regularly traded" for any calendar year during which such stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Provided that the Common Shares are "regularly traded" as described in the preceding sentence, such shares are expected to be marketable stock. There can be no assurance that the Common Shares will be "regularly traded" in subsequent calendar quarters. U.S. Holders should consult their own tax advisors regarding the marketable stock rules.

A U.S. Holder that makes a Mark-to-Market Election with respect to its Common Shares generally will not be subject to the rules of Section 1291 of the Code discussed above with respect to such Common Shares. However, if a U.S. Holder does not make a Mark-to-Market Election beginning in the first tax year of such U.S. Holder's holding period for the Common Shares and such U.S. Holder has not made a timely QEF Election, the rules of Section 1291 of the Code discussed above will apply to certain dispositions of, and distributions on, the Common Shares.

A U.S. Holder that makes a Mark-to-Market Election will include in ordinary income, for each tax year in which we are a PFIC, an amount equal to the excess, if any, of (a) the fair market value of the Common Shares as of the close of such tax year over (b) such U.S. Holder's tax basis in such Common Shares. A U.S. Holder that makes a Mark-to-Market Election will be allowed a deduction in an amount equal to the excess, if any, of (i) such U.S. Holder's adjusted tax basis in the Common Shares, over (ii) the fair market value of such Common Shares (but only to the extent of the net amount of previously included income as a result of the Mark-to-Market Election for prior tax years).

A U.S. Holder that makes a Mark-to-Market Election generally also will adjust such U.S. Holder's tax basis in the Common Shares to reflect the amount included in gross income or allowed as a deduction because of such Mark-to-Market Election. In addition, upon a sale or other taxable disposition of such Common Shares, a U.S. Holder that makes a Mark-to-Market Election will recognize ordinary income or ordinary loss (not to exceed the excess, if any, of (a) the amount included in ordinary income because of such Mark-to-Market Election for prior tax years over (b) the amount allowed as a deduction because of such Mark-to-Market Election for prior tax years).

A U.S. Holder makes a Mark-to-Market Election by attaching a completed IRS Form 8621 to a timely filed U.S. federal income tax return. A timely Mark-to-Market Election applies to the tax year in which such Mark-to-Market Election is made and to each subsequent tax year, unless the Common Shares cease to be "marketable stock" or the IRS consents to revocation of such election. Each U.S. Holder should consult its own tax advisor regarding the availability of, and procedure for making, a Mark-to-Market Election.

Although a U.S. Holder may be eligible to make a Mark-to-Market Election with respect to the Common Shares, no such election may be made with respect to the stock of any Subsidiary PFIC that a U.S. Holder is treated as owning because such stock is not marketable. Hence, the Mark-to-Market Election will not be effective to eliminate the interest charge and other income inclusion rules described above with respect to deemed dispositions of Subsidiary PFIC stock or distributions from a Subsidiary PFIC to its shareholder.

The PFIC rules are complex, and each U.S. Holder should consult its own tax advisor regarding the PFIC rules (including the applicability and advisability of a QEF Election and Mark-to-Market Election) and how the PFIC rules may affect the U.S. federal income tax consequences of the acquisition, ownership, and disposition of the Common Shares.

***General Rules Applicable to U.S. Federal Income Tax Consequences of the Acquisition, Ownership, and Disposition of the Common Shares***

The following discussion describes the general rules applicable to the ownership and disposition of the Common Shares, but is subject in its entirety to the special rules described above under the heading "Passive Foreign Investment Company Rules."

Distributions on the Common Shares.

A U.S. Holder that receives a distribution with respect to a Common Share will be required to include the amount of such distribution in gross income as a dividend (without reduction for any Canadian income tax withheld from such distribution) to the extent of our current and accumulated "earnings and profits", as computed under U.S. federal income tax principles. A dividend generally will be taxed to a U.S. Holder at ordinary income tax rates if we are a PFIC for the tax year of such distribution or the preceding tax year. To the extent that a distribution exceeds our current and accumulated "earnings and profits," such distribution will be treated first as a tax-free return of capital to the extent of a U.S. Holder's tax basis in such Common Shares and thereafter as gain from the sale or exchange of such Common Shares (see "Sale or Other Taxable Disposition of the Common Shares" below). However, we may not maintain the calculations of earnings and profits in accordance with U.S. federal income tax principles, and each U.S. Holder may be required to assume that any distribution by us with respect to such Common Shares will constitute ordinary dividend income. Dividends received on such Common Shares generally will not be eligible for the "dividends received deduction" generally applicable to corporations. Subject to applicable limitations and provided we are eligible for the benefits of the Convention Between Canada and the United States of America with Respect to Taxes on Income and on Capital, signed September 26, 1980, as amended, or the Common Shares are readily tradable on a United States securities market, dividends paid by us to non-corporate U.S. Holders, including individuals, generally will be eligible for the preferential tax rates applicable to long-term capital gains for dividends, provided certain holding period and other conditions are satisfied, including that we not be classified as a PFIC in the tax year of distribution or in the preceding tax year. The dividend rules are complex, and each U.S. Holder should consult its own tax advisor regarding the application of such rules.

Sale or Other Taxable Disposition of the Common Shares

Upon the sale or other taxable disposition of the Common Shares, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between (a) the amount of cash plus the fair market value of any property received and (b) such U.S. Holder's tax basis in such Common Shares sold or otherwise disposed of. Gain or loss recognized on such sale or other taxable disposition generally will be long-term capital gain or loss if, at the time of the sale or other taxable disposition, such Common Shares have been held for more than one year. Preferential tax rates may apply to long-term capital gain of a U.S. Holder that is an individual, estate, or trust. There are no preferential tax rates for long-term capital gain of a U.S. Holder that is a corporation. Deductions for capital losses are subject to significant limitations under the Code.

***Additional Tax Considerations***

Receipt of Foreign Currency

The amount of any distribution paid to a U.S. Holder in foreign currency or on the sale, exchange or other taxable disposition of the Common Shares generally will be equal to the U.S. dollar value of such foreign currency based on the exchange rate applicable on the date of receipt (regardless of whether such foreign currency is converted into U.S. dollars at that time). If the foreign currency received is not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a tax basis in the foreign currency equal to its U.S. dollar value on the date of receipt. Any U.S. Holder who receives payment in foreign currency and engages in a subsequent conversion or other disposition of the foreign currency may have a foreign currency exchange gain or loss that would be treated as ordinary income or loss, and generally will be U.S. source income or loss for foreign tax credit purposes. Different rules apply to U.S. Holders who use the accrual method of tax accounting. Each U.S. Holder should consult its own U.S. tax advisor regarding the U.S. federal income tax consequences of receiving, owning, and disposing of foreign currency.

Foreign Tax Credit

Subject to the PFIC rules discussed above, a U.S. Holder that pays (whether directly or through withholding) Canadian income tax with respect to dividends paid on the Common Shares generally will be entitled, at the election of such U.S. Holder, to receive either a deduction or a credit for such Canadian income tax paid. Generally, a credit will reduce a U.S. Holder's U.S. federal income tax liability on a dollar-for-dollar basis, whereas a deduction will reduce a U.S. Holder's income subject to U.S. federal income tax. This election is made on a year-by-year basis and applies to all foreign taxes paid or accrued (whether directly or through withholding) by a U.S. Holder during a year. The foreign tax credit rules are complex and involve the application of rules that depend on a U.S. Holder's particular circumstances. Accordingly, each U.S. Holder should consult its own tax advisor regarding the foreign tax credit rules.

Information Reporting; Backup Withholding Tax

Under U.S. federal income tax laws certain categories of U.S. Holders must file information returns with respect to their investment in, or involvement in, a foreign corporation. For example, U.S. return disclosure obligations (and related penalties) are imposed on U.S. Holders that hold certain specified foreign financial assets in excess of certain threshold amounts. The definition of specified foreign financial assets includes not only financial accounts maintained in foreign financial institutions, but also, unless held in accounts maintained by a financial institution, any stock or security issued by a non-U.S. person. U. S. Holders may be subject to these reporting requirements unless the Common Shares are held in an account at certain financial institutions. Penalties for failure to file certain of these information returns are substantial. U.S. Holders should consult their own tax advisors regarding the requirements of filing information returns, including the requirement to file IRS Form 8938.

Payments made within the U.S., or by a U.S. payor or U.S. middleman, of dividends on, and proceeds arising from the sale or other taxable disposition of the Common Shares generally may be subject to information reporting and backup withholding tax, currently at the rate of 24%, if a U.S. Holder (a) fails to furnish its correct U.S. taxpayer identification number (generally on Form W-9), (b) furnishes an incorrect U.S. taxpayer identification number, (c) is notified by the IRS that such U.S. Holder has previously failed to properly report items subject to backup withholding tax, or (d) fails to certify, under penalty of perjury, that it has furnished its correct U.S. taxpayer identification number and that the IRS has not notified such U.S. Holder that it is subject to backup withholding tax. However, certain exempt persons, such as U.S. Holders that are corporations, generally are excluded from these information reporting and backup withholding tax rules. Any amounts withheld under the U.S. backup withholding tax rules will be allowed as a credit against a U.S. Holder's U.S. federal income tax liability, if any, or will be refunded, if such U.S. Holder furnishes required information to the IRS in a timely manner.

The discussion of reporting requirements set forth above is not intended to constitute a complete description of all reporting requirements that may apply to a U.S. Holder. A failure to satisfy certain reporting requirements may result in an extension of the time period during which the IRS can assess a tax and, under certain circumstances, such an extension may apply to assessments of amounts unrelated to any unsatisfied reporting requirement. Each U.S. Holder should consult its own tax advisors regarding the information reporting and backup withholding rules.

**THE ABOVE SUMMARY IS NOT INTENDED TO CONSTITUTE A COMPLETE ANALYSIS OF ALL TAX CONSIDERATIONS APPLICABLE TO U.S. HOLDERS WITH RESPECT TO THE ACQUISITION, OWNERSHIP, AND DISPOSITION OF THE COMMON SHARES. U.S. HOLDERS SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO THE TAX CONSIDERATIONS APPLICABLE TO THEM IN THEIR OWN PARTICULAR CIRCUMSTANCES.**

### 10.F. Dividends and Paying Agents

The Company has not, to date since its inception, paid any dividends to its shareholders. We intend to retain any future earnings to fund the development and growth of our business and do not currently anticipate paying dividends on the Common Shares. The determination as to when, if ever, to pay dividends will be at the discretion of the Company's Board of Directors and will depend on many factors, including, among others, the Company's financial condition, current and anticipated cash requirements, contractual restrictions and financing agreement covenants, solvency tests imposed by applicable corporate law and other factors that the Company's Board of Directors may deem relevant. As such, any procedures for non-resident holders to claim dividends and any paying agents will be determined at a later date, if, and when, the Company pays a dividend.

### 10.G. Statement by Experts

Not applicable.

### 10.H. Documents on Display

Documents concerning the Company referred to in this Annual Report may be viewed by appointment during normal business hours at our registered and records office at Suite 2900, 550 Burrard Street, Vancouver, British Columbia, V6C 0A3.

### 10.I. Subsidiary Information

Not applicable.

**10.J. Annual Report to Security Holders**

Not applicable

**ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The Company's financial instruments consist of cash and cash equivalents, accounts payable and accrued liabilities, lease obligation, derivative warrant liability, and warrants. The fair values of these financial instruments, other than derivative warrant liability and warrants, approximate their carrying values at December 31, 2022, due to their short-term nature.

The following table presents the Company's financial instruments, measured at fair value on the consolidated statements of financial position as at December 31, 2022 and 2021 and categorized into levels of the fair value hierarchy:

| | | December 31, 2022 | | December 31, 2021 | |
|---|---|---|---|---|---|
| | Level | Carrying Value | Estimated Fair Value * | Carrying Value | Estimated Fair Value * |
| | | $ | $ | $ | $ |
| **FVTPL** | | | | | |
| Cash | 1 | 14,125,522 | 14,125,522 | 18,851,244 | 18,851,244 |
| **Other financial liabilities** | | | | | |
| Accounts payable and accrued liabilities | 1 | 1,960,745 | 1,960,745 | 700,999 | 700,999 |
| Lease liability | 2 | 105,105 | 105,105 | — | — |
| **FVTPL** | | | | | |
| Derivative warrant liability | 3 | 5,220,649 | 5,220,649 | 4,597,332 | 4,597,332 |

* The Company has determined that the carrying values of its short-term financial assets and financial liabilities, including cash and accounts payable and accrued liabilities, approximate their fair value due to the short-term nature of the instruments. Information on the fair value of the derivative warrant liability is included in note 13(f) of the Financial Statements.

There were no transfers for levels of change in the fair value measurements of financial instruments for the years ended December 31, 2022 and 2021.

We are exposed in varying degrees to a variety of financial instrument related risks. Risk management is carried out by the Company's management team with guidance from the Board of Directors. The Board approves and monitors the risk management processes, inclusive of controlling and reporting structures. The Company's risk exposures and their impact on the Company's financial instruments were as follows:

**a) Credit risk**

Credit risk is the risk of financial loss to the Company if a customer of counterparty to a financial instrument fails to meet its obligations. The Company's maximum exposure to credit risk at the financial position date under its financial instruments is summarized as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| | $ | $ |
| **Cash and cash equivalents** | 14,125,522 | 18,851,244 |

All of the Company's cash is held with major financial institutions in Canada and management believes the exposure to credit risk with such institutions is minimal. The Company considers the risk of material loss to be significantly mitigated due to the financial strength of the major financial institutions where cash is held. The Company's maximum exposure to credit risk as at December 31, 2022 and 2021 is the carrying value of its financial assets.

**b) Liquidity risk**

Liquidity risk is the risk that the Company will not be able to meet its obligations associated with financial liabilities. The Company has a planning and budgeting process in place by which it anticipates and determines the funds required to support normal operation requirements as well as the growth and development of its intellectual property portfolio.

The Company's financial assets are comprised of its cash, and the financial liabilities are comprised of its accounts payable and accrued liabilities and derivative warrant liability.

The contractual maturities of these financial liabilities as at December 31, 2022 and 2021 are summarized below:

| | Payments due by period as of December 31, 2022 | | | |
|---|---|---|---|---|
| | Total | Less than 3 months | Between 3 months and 1 year | 1-3 years |
| | $ | $ | $ | $ |
| Accounts payable and accrued liabilities | 1,960,745 | 1,960,745 | — | — |
| Lease liability | 105,105 | 22,379 | 67,138 | 15,588 |
| | 2,065,850 | 1,983,124 | 67,138 | 15,588 |

| | Payments due by period as of December 31, 2021 | | | |
|---|---|---|---|---|
| | Total | Less than 3 months | Between 3 months and 1 year | 1-3 years |
| | $ | $ | $ | $ |
| Accounts payable and accrued liabilities | 700,999 | 700,999 | — | — |
| | 700,999 | 700,999 | — | — |

**c) Market Risk**

i) Interest Rate Risk

Interest rate risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate due to changes in market interest rates. The Company's bank accounts bear interest. Management believes that the credit risk concentration with respect to financial instruments included in cash is minimal.

ii) Foreign Currency Risk

As at December 31, 2022, the Company is exposed to currency risk on the following financial assets and liabilities denominated in US Dollars ("**USD**"), British Pounds ("**GBP**"), and European Euro ("**EUR**"). The sensitivity of the Company's net earnings due to changes in the exchange rate between the USD, GBP and EUR against the Canadian dollar is included in the table below in Canadian dollar equivalents:

| | USD | GBP amount | EUR | Total |
|---|---|---|---|---|
| | $ | $ | $ | $ |
| Cash | 12,907,255 | — | — | 12,907,255 |
| Accounts payable and accrued liabilities | (1,466,309) | (45,755) | (11,747) | (1,523,811) |
| **Net exposure** | 11,440,946 | (45,755) | (11,747) | 11,383,444 |
| **Effect of +/- 10% change in currency** | 1,144,095 | (4,576) | (1,175) | — |

Cash and cash equivalents is classified as a financial asset at FVTPL, accounts payable and accrued liabilities and lease obligation are classified as financial liabilities at amortized cost, and derivative warrant liability is classified as a financial liability at FVTPL.

The Company thoroughly examines the various financial instruments and risks to which it is exposed and assesses the impact and likelihood of those risks. These risks include foreign currency risk, interest rate risk, market risk, credit risk, and liquidity risk. Where material, these risks are reviewed and monitored by the Board of Directors

There have been no changes in any risk management policies since December 31, 2022

## ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

### 12.A. Debt Securities

Not applicable.

### 12.B. Warrants and Rights

Not applicable.

### 12.C. Other Securities

Not applicable.

### 12.D. American Depositary Shares

Not applicable.

## PART II

### ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

### ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

**14A. Modifications to instruments defining the rights of holders of any class of registered securities.**

On October 7, 2022, in connection with the October 2022 Offering, the Company entered into an agreement, approved by the TSXV, that reduced the exercise price of certain outstanding warrants to purchase up to 910,000 shares of common stock issued in the US IPO Offering (the "**Amended IPO Common Share Purchase Warrants**") and held by certain investors in the October 7, 2022 offering from US$4.77 per share to US$1.17 per share, effective October 7, 2022. All other terms of the Amended IPO Common Share Purchase Warrants remained the same.

**14.E. Use of Proceeds**

The effective date of the registration statement on Form F-1 (File No. 333-258741) for the Company's US IPO Offering was October 12, 2021. The offering of 2,906,000 units , with each unit consisting of one Common Share and one IPO Common Share Purchase Warrant to purchase one common share at a public offering price of US$4.13 per unit closed on October 15, 2021 for gross proceeds of approximately US$12,000,000, before deducting underwriting discounts and offering expenses of approximately U.S.$840,125 for total net proceeds to the Company from the offering of US$11,161,655. The IPO Common Share Purchase Warrants were exercisable at US$4.77 per share and have a term of five years. Alliance Global Partners ("Alliance Global") was the sole book-running manager for the offering.

In addition, Alliance Global was granted a 45-day over-allotment option following the closing date to purchase up to an additional 435,900 additional common shares and/or 435,900 IPO Compensation Warrants. On October 15, 2021, the underwriters partially exercised their option to purchase IPO Compensation Warrants to purchase up to an additional 435,900 Common Shares. On November 8, 2021, A.G.P. partially exercised its 45-day option to purchase 355,000 common shares at US$4.13 per share, resulting in additional gross proceeds to the Company of approximately US$1.47 million which increased the US IPO Offering to 3,261,000 common shares and 3,341,900 IPO Common Share Purchase Warrants. None of the net proceeds of the US IPO Offering were paid directly or indirectly to any director or officer of ours or to their associates, persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

On October 7, 2022, in connection with the October 2022 Offering, the Company entered into an agreement, approved by the TSXV, that reduced the exercise price of 910,000 Amended IPO Common Share Purchase Warrants in the US IPO Offering and held by certain investors in the October 7, 2022 offering from US$4.77 per share to US$1.17 per share, effective October 7, 2022. All other terms of the Amended IPO Common Share Purchase Warrants remained the same.

The Company has not fully used the net proceeds of the US IPO Offering. The proceeds that the Company has used (approximately US$10.5 million as of December 31, 2022) have been used for funding operations and general corporate purposes, which has included the further research and development, clinical trials, and manufacture of active pharmaceutical ingredients and drug product to support clinical trials. There has been no material change in the planned use of proceeds from our initial public offering from that described in our prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on October 12, 2021 (the "**Supplement**"). The Company intends to continue to use the remaining net proceeds of the offering, together with existing cash, for funding operations and general corporate purposes, which may include the further research and development, clinical trials, manufacture of active pharmaceutical ingredients and drug product to support clinical trials and intends to use the proceeds in approximately the following proportions: XRx-008: 29%; XRx-101: 70%; XRx-225: 1% as set out in the Supplement.

## ITEM 15. CONTROLS AND PROCEDURES

***Disclosure Controls and Procedures***

At the end of the period covered by this Annual Report, an evaluation of the effectiveness of the design and operation of the Company's "disclosure controls and procedures" (as such term is defined in Rules 13a-15(e) under the Exchange Act) was carried out by the Company's CEO and CFO. Based upon that evaluation, the Company's CEO and CFO have concluded that, as of the end of the period covered by this report, the design and operation of the Company's disclosure controls and procedures are effective.

It should be noted that while the Company's CEO and CFO believe that the Company's disclosure controls and procedures provide a reasonable level of assurance that they are effective, they do not expect that the Company's disclosure controls and procedures will prevent all errors and fraud. A control system, no matter how well conceived or operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

***Management Report on Internal Control Over Financial Reporting & Auditor Attestation***

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rule 13a-15(f) and Rule 15d-15(f) under the Securities Exchange Act of 1934, as amended) and has designed such internal control over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

In designing and evaluating the Corporation's internal control over financial reporting, the Corporation's management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its reasonable judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

Management conducted an evaluation of the effectiveness of the Corporation's internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria set forth in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("**COSO**"). Based on this evaluation, management concluded that the Corporation's internal control over financial reporting was effective as of December 31, 2022.

***Attestation Report of Independent Auditor***

In accordance with the JOBS Act enacted on April 5, 2012, the Corporation qualifies as an "emerging growth company," which entitles the Corporation to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. Specifically, the JOBS Act defers the requirement to have the Corporation's independent auditor assess the Corporation's internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act. As such, the Corporation is exempted from the requirement to include an auditor attestation report in this Annual Report for so long as the Corporation remains an EGC, which may be for as long as five years following its initial registration in the United States.

***Changes in Internal Control over Financial Reporting***

During the year ended December 31, 2022, there were no changes in the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## ITEM 16. [RESERVED]

## ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

The Company's Audit Committee, which consists exclusively of independent directors in accordance with Nasdaq listing requirements, is comprised of Ian Klassen, Jacqueline Le Saux and Paul Van Damme. Paul Van Damme is the Chair of the Audit Committee. The Board of Directors has determined that Ian Klassen, Jacqueline Le Saux and Paul Van Damme each meet the independence requirements for directors, including the heightened independence standards for members of the audit committee under Rule 10A-3 under the Exchange Act. The Board has determined that Paul Van Damme is "financially literate" within the meaning of Nasdaq listing requirements and an "audit committee financial expert" as defined by Rule 10A-3 under the Exchange Act. For a description of the education and experience of each member of the Audit Committee, see "Item 6A. Directors, Senior Management and Employees."

## ITEM 16B. CODE OF ETHICS

The Company has adopted a Code of Conduct applicable to all of its directors, officers and employees, including its CEO and CFO, which is a "code of ethics" as defined in section 406(c) of the Sarbanes-Oxley Act. The Code of Business Conduct sets out the fundamental values and standards of behavior that the Company expects from our directors, officers and employees with respect to all aspects of its business.

If the Company grants any waiver of the Code of Conduct, whether explicit or implicit, to a director or executive officer, it will disclose the nature of such waiver on its website to the extent required by, and in accordance with, the rules and regulations of the SEC.

The full text of the Code of Business Conduct and Ethics is posted on the Company's website at www.xortx.com. The information on or accessible through the website is not part of and is not incorporated by reference into this Annual Report, and the inclusion of the website address in this Annual Report is only for reference.

The Audit Committee is responsible for reviewing and evaluating the Code of Conduct periodically and will recommend any necessary or appropriate changes thereto to the Board for consideration. The Audit Committee will also assist the Board of Directors with the monitoring of compliance with the Code of Business Conduct.

## ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth information regarding the amount billed and accrued to the Company by Smythe LLP, for the fiscal years ended December 31, 2022 and 2021:

| | Year Ended December 31, | |
|---|---|---|
| **Services** | **2022** | **2021** |
| Audit Fees[(1)] | $ 82,400 | $ 49,000 |
| Audit-Related Fees[(2)] | 689 | 397 |
| Tax Fees[(3)] | 5,000 | 2,500 |
| Other Fees[(4)] | 9,000 | 16,000 |
| Total | $ 97,089 | $ 67,897 |

**Notes:**

(1) "Audit fees" means the aggregate fees billed for professional services rendered by our principal accounting firm for the audit of the Company's annual financial statements and the review of its comparative interim financial statements.

(2) "Audit-related fees" means the aggregate fees billed for professional services rendered by the Company's principal accounting firm for the assurance and related services, which mainly included the audit and review of financial statements and are not reported under "Audit fees" above.

(3) "Tax fees" means the aggregate fees billed for professional services rendered by the Company's principal accounting firm for tax compliance, tax advice and tax planning.

(4) "Other fees" means the aggregate fees incurred in each of the fiscal years listed for the professional tax services rendered by the Company's principal accounting firm other than services reported under "Audit fees," "Audit-related fees" and "Tax fees."

The policy of the Company's Audit Committee is to pre-approve all audit and non-audit services provided by Smythe LLP, its independent registered public accounting firm, including audit services, audit-related services, tax services, and other services as described above.

**ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not Applicable.

**ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

Not Applicable.

**ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT**

Not applicable.

**ITEM 16G. CORPORATE GOVERNANCE**

The Company is a foreign private issuer and its Common Shares are listed on the Nasdaq Capital Market. Rule 5615(a)(3) of the rules of the Nasdaq Stock Market LLC (the "**Nasdaq Rules**") permits a foreign private issuer to follow its home country practices in lieu of certain requirements of the 5600 Series of the Nasdaq Rules, which set forth corporate governance requirements. In order to claim such an exemption, the Company must disclose the significant differences between its corporate governance practices and those required to be followed by U.S. domestic issuers under the Nasdaq Rules. Set forth below is a brief summary of such differences.

**Quorum Requirement**

Nasdaq Listing Rule 5620(c) requires that a listed company's bylaws provide for a quorum for any meeting of the holders of the company's Common Shares of no less than 33 1/3% of the outstanding Common Shares of the Company. Pursuant to the Nasdaq corporate governance rules we, as a foreign private issuer, have elected to comply with practices that are permitted under Canadian law in lieu of the provisions of certain Nasdaq requirements. Our articles provide that a quorum of shareholders for the transaction of business at a meeting of shareholders is two shareholders, or one or more proxyholder representing two members, or one member and a proxyholder representing another member.

Except as stated above, we intend to comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq. We may in the future decide to use other foreign private issuer exemptions with respect to some of the other listing requirements. Following our home country governance practices, as opposed to the requirements that would otherwise apply to a company listed on the Nasdaq, may provide less protection than is accorded to investors under listing requirements applicable to U.S. domestic issuers.

**ITEM 16H. MINE SAFETY DISCLOSURE**

Not applicable.

**ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

**ITEM 16J. INSIDER TRADING POLICIES**

Not applicable.

## PART III

**ITEM 17: FINANCIAL STATEMENTS**

Refer to Item 18. Financial Statements.

**ITEM 18: FINANCIAL STATEMENTS**

***Financial Statements Filed as Part of this Annual Report:***

Audited Annual Financial Statements for the years ended December 31, 2022, 2021 and 2020:

Independent Auditor's Report of Smythe LLP (PCAOB ID: 995), dated March 29, 2023;

Consolidated Statements of Financial Position as at December 31, 2022 and 2021;

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2022, 2021 and 2020;

Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2022, 2021 and 2020;

Consolidated Statements of Cash Flows for the years ended December 31, 2022, 2021 and 2020;

Notes to the Consolidated Financial Statements.

## ITEM 19. EXHIBITS

The following Exhibits are being filed as part of this Annual Report, or are incorporated by reference where indicated:

| Exhibit Number | Description |
|---|---|
| 1.1 | Articles and Notice of Articles of the Company (incorporated by reference to Exhibit 3.1 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 2.1 | Form of Private Placement Warrant (incorporated by reference to Exhibit 4.4 of the Company's Amended Registration Statement on Form F-1 filed September 16, 2021) |
| 2.2 | Form of Common Share Purchase Warrant (IPO Common Share Purchase Warrant) (incorporated by reference to Exhibit 4.1 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021) |
| 2.3 | Form of Amended IPO Common Share Purchase Warrant to be issued to certain investors in the 2021 US IPO Offering that participated in the October 2022 Offering (incorporated by reference to Exhibit 4.8 of the Company's Post-Effective Amendment to its Registration Statement on Form F-1 filed on September 30, 2021) |
| 2.4 | Form of IPO Compensation Warrant (incorporated by reference to Exhibit 4.3 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021). |
| 2.5 | Form of US IPO Underwriting Agreement between XORTX Therapeutics Inc. and A.G.P./Alliance Global Partners as Representatives of the several Underwriters named on Schedule I attached thereto, (incorporated by reference to Exhibit 1.1 of the Company's Amended Registration Statement on Form F-1 filed September 16, 2021) |
| 2.6 | Underwriting Agreement dated October 4, 2022 between the Company and A.G.P./Alliance Global Partners as Representative of the Several Underwriters named on Schedule I (incorporated by reference to exhibit 99.1 of the Company's Form 6-K filed October 6, 2022). |
| 2.7 | Form of October 2022 Warrant (incorporated by reference to Exhibit 4.2 of the Company's Amended Registration Statement on Form F-1 filed on September 12, 2022) |
| 2.8 | Form of October 2022 Pre-Funded Warrant (incorporated by reference to Exhibit 4.3 of the Company's Amended Registration Statement on Form F-1 filed on September 12, 2022) |
| 2.9 | Form of October 2022 Compensation Warrant (incorporated by reference to Exhibit 4.4 of the Company's Amended Registration Statement on Form F-1 filed on September 12, 2022) |
| 2.10 | Letter Agreement, dated as of October 7, 2022 between the Company and Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 99.1 to the Company's Form 6-K filed October 7, 2022) |
| 4.1† | Investigator Initiated-Clinical Trial Agreement, dated August 3, 2020, by and between the Company and Icahn School of Medicine at Mount Sinai (incorporated by reference to Exhibit 10.1 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.2# | Employment Agreement, dated August 1, 2021, by and between the Company and Allen Davidoff (incorporated by reference to Exhibit 10.2 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021) |
| 4.3† | Master Services Agreement, dated July 20, 2017, by and between the Company and Cato Research Canada Inc. (incorporated by reference to Exhibit 10.3 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.4† | Master Service and Technology Agreement, dated February 25, 2019, by and between the Company and Prevail InfoWorks, Inc. (incorporated by reference to Exhibit 10.6 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.5† | Side Letter to Master Service and Technology Agreement, dated February 24, 2020, by and between the Company and Prevail InfoWorks, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.6† | Subscription Agreement, dated February 28, 2020, by and between the Company and Prevail Partners LLC (incorporated by reference to Exhibit 10.8 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.7† | Standard Exclusive License Agreement with Know How dated effective as of June 23, 2014, by and between the Company and the University of Florida Research Foundation, Inc. (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form F-1 Filed on August 12, 2021) |
| 4.8# | Consulting Agreement, dated July 1, 2021, by and between the Company and Haworth Biopharmaceutical Consulting Services Inc. (incorporated by reference to Exhibit 10.12 to the Company's Amendment No. 1 to the Draft Registration Statement on Form F-1 filed on July 21, 2021) |
| 4.9# | Consulting Amending Agreement, dated as of January 27, 2022, by and between the Company and Stephen Haworth (incorporated by reference to Exhibit 4.26 to the Company's Form 20-F filed May 3, 2022) |

| | |
|---|---|
| 4.10† | Patent Rights Purchase Agreement, dated effective as of December 5, 2012, by and between Dr. Richard Johnson, Dr. Takahiko Nakagawa, and Revascor Inc. (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form F-1 filed on August 12, 2021) |
| 4.11 | Form of Warrant Agency Agreement with Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 10.14 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021) |
| 4.12 | Form of Warrant Agency Agreement with Continental Stock Transfer & Trust Company, as Warrant Agent (incorporated by reference to Exhibit 10.14 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021) |
| 4.13 | Consulting Agreement, dated March 1, 2018, by and between the Company and W.B. Rowlands & Co. Ltd. (incorporated by reference to Exhibit 10.15 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021) |
| 4.14# | Consulting Services Agreement, dated effective December 20, 2021, by and between the Company, W.B. Rowlands & Co. Ltd., and William Bruce Rowlands (incorporated by reference to Exhibit 4.15 to the Company's Form 20-F filed May 3, 2022) |
| 4.15# | Stock Option Plan (incorporated by reference as Schedule B to Exhibit 99.2 to the Company's Form 6-K filed on November 23, 2021.) |
| 4.16† | Patent Rights Purchase Agreement dated effective May 26, 2014 between Dr. Richard Johnson, Dr. Takahiko Nakagawa and the Company (incorporated by reference to Exhibit 4.17 to the Company's Form 20-F filed May 3, 2022) |
| 4.17† | Equity Agreement dated effective June 23, 2014 between the Company and the University of Florida Research Foundation, Inc. (incorporated by reference to Exhibit 4.18 to the Company's Form 20-F filed May 3, 2022) |
| 4.18* | Agreement dated July 20, 2017 between the Company and Cato Research Canada Inc. to manage future regulatory and clinical trial programs |
| 4.19† | Sponsored Research Agreement dated May 27, 2021 between the Regents of the University of Colorado and the Company (incorporated by reference to Exhibit 4.19 to the Company's Form 20-F filed May 3, 2022) |
| 4.20† | Combined Master Services Agreement made on July 19, 2021 between the Company and Quotient Sciences Limited (incorporated by reference to Exhibit 4.20 to the Company's Form 20-F filed May 3, 2022) |
| 4.21 | Development and Clinical Manufacturing Services Agreement dated effective August 17, 2021 between the Company and Lonza Ltd. (incorporated by reference to Exhibit 4.21 to the Company's Form 20-F filed May 3, 2022) |
| 4.22 | Global Master Services Agreement between Altasciences Company Inc., (a contract research organization) and the Company dated effective December 22, 2021 (incorporated by reference to Exhibit 4.22 to the Company's Form 20-F filed May 3, 2022) |
| 4.23 | Proposal for XORTX Therapeutics Inc., dated February 21, 2022, by and between the Company and Covar Pharmaceuticals Inc. (incorporated by reference to Exhibit 4.23 to the Company's Form 20-F filed May 3, 2022) |
| 4.24 | Proposal for XORTX Therapeutics Inc., dated December 6, 2021, by and between the Company and Covar Pharmaceuticals Inc. (incorporated by reference to Exhibit 4.24 to the Company's Form 20-F filed May 3, 2022) |
| 4.25† | Proposal, dated as of March 29, 2022, by and between the Company and Curia Spain, S.A.U. (incorporated by reference to Exhibit 4.25 to the Company's Form 20-F filed May 3, 2022) |
| 4.26# | Agreement, dated as of November 1, 2021, by and between the Company and Amar Keshri (incorporated by reference to Exhibit 4.27 to the Company's Form 20-F filed May 3, 2022) |
| 4.27#* | Consulting Agreement dated as of September 1, 2022 between the Company and Stacy Evans, M.D., M.B.A., |
| 8.1 | Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 11.1* | Code of Conduct |
| 12.1* | Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer |
| 12.2* | Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer |
| 13.1* | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 13.2* | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 15.1* | Management Discussion and Analysis of the Company for the year ended December 31, 2022. |
| 15.2* | Audit Committee Charter |
| 15.3* | Consent of independent registered public accounting firm (Smythe LLP) |
| 101 | The following materials from the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2022, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Statements of Financial Position as of December 31, 2022 and 2021; (ii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2022, 2021 and 2020; (iii) Consolidated Statements of Changes in Shareholders' |

| | |
|---|---|
| | Equity for the years ended December 31, 2022, 2021 and 2020; (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2022, 2021 and 2020; and (v) Notes to Consolidated Financial Statements |
| 104 | Cover Page Interactive Data File (formatted as Inline eXtensible Business Reporting Language (iXBRL) and contained in Exhibit 101) |

* Filed herewith.

\# Indicates management contract or compensatory plan.

†Certain information in this exhibit has been excluded from the version of this document filed as an exhibit because it is both not material and the type of information that the Company treats as private or confidential.

**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

**XORTX THERAPEUTICS INC.**

/s/ Amar Keshri

By: Amar Keshri
Title: Chief Financial Officer

Date: April 28, 2023

Table of Contents


**CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 and 2020**
**(Expressed in Canadian Dollars)**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**TO THE SHAREHOLDERS AND DIRECTORS OF XORTX THERAPEUTICS INC.**

***Opinion on the Consolidated Financial Statements***

We have audited the accompanying consolidated statements of financial position of XORTX Therapeutics Inc. (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of comprehensive loss, changes in shareholders' equity and cash flows for the years ended December 31, 2022, 2021 and 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years ended December 31, 2022, 2021 and 2020, in conformity with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board.

***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

***Critical Audit Matters***

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate. We determined that there are no critical audit matters.

We have served as the Company's auditor since 2018.

Vancouver, Canada

March 29, 2023

**XORTX THERAPEUTICS INC.**
**Consolidated Statements of Financial Position**
**(Expressed in Canadian Dollars)**

| | Note | December 31, 2022 $ | December 31, 2021 $ |
|---|---|---|---|
| **Assets** | | | |
| **Current** | | | |
| Cash and cash equivalents | **5** | 14,125,522 | 18,851,244 |
| Accounts receivable | | 110,730 | 51,539 |
| Prepaid expenses | **6** | 514,160 | 1,270,556 |
| | | 14,750,412 | 20,173,339 |
| **Non-current** | | | |
| Contract payments | **7** | 1,606,320 | 1,606,320 |
| Intangible assets | **8** | 270,668 | 256,243 |
| Right-of-use asset | **9** | 103,471 | — |
| Equipment | **10** | 22,058 | — |
| **Total Assets** | | **16,752,929** | **22,035,902** |
| **Liabilities** | | | |
| **Current** | | | |
| Accounts payable and accrued liabilities | **11,14** | 1,960,745 | 700,999 |
| Lease obligation – short-term | **12** | 89,517 | — |
| | | 2,050,262 | 700,999 |
| **Non-current** | | | |
| Derivative warrant liability | **13(g)** | 5,220,649 | 4,597,332 |
| Lease obligation – long-term | **12** | 15,588 | — |
| **Total Liabilities** | | **7,286,499** | **5,298,331** |
| **Shareholders' Equity** | | | |
| Share capital | **13** | 20,606,705 | 20,009,154 |
| Share-based payments, warrant reserve and other | **13** | 8,003,076 | 6,386,459 |
| Obligation to issue shares | **8(c)** | 32,238 | 32,238 |
| Deficit | | (19,175,589) | (9,690,280) |
| **Total Shareholders' Equity** | | **9,466,430** | **16,737,571** |
| **Total Liabilities and Shareholders' Equity** | | **16,752,929** | **22,035,902** |

Nature of Operations (Note 1)

Commitments (Note 18)

*/s/ "Allen Davidoff"*
Director

*/s/ "Paul Van Damme"*
Director

**XORTX THERAPEUTICS INC.**
**Consolidated Statements of Comprehensive Loss**
**For the years ended December 31, 2022, 2021 and 2020**
**(Expressed in Canadian Dollars)**

| | Note | 2022<br>$ | 2021<br>$ | 2020 |
|---|---|---|---|---|
| **Expenses** | | | | |
| Amortization | **8,9,10** | 75,268 | 17,882 | 20,439 |
| Consulting | **14** | 309,156 | 724,272 | 102,880 |
| Directors' fees | **14** | 161,054 | 62,200 | — |
| General and administrative | | 582,192 | 176,099 | 9,516 |
| Investor relations | | 1,200,318 | 518,615 | 241,177 |
| Listing fees | | 157,200 | 236,801 | 52,138 |
| Professional fees | **14** | 587,851 | 272,943 | 162,580 |
| Research and development | **14** | 8,807,992 | 853,124 | 277,455 |
| Share-based payments | **13(e),14** | 632,548 | 499,158 | 293,443 |
| Travel | | 29,668 | 2,339 | 8,460 |
| Wages and benefits | **14** | 841,804 | 286,090 | 227,905 |
| **Loss before other items** | | (13,385,051) | (3,649,523) | (1,395,993) |
| Accretion | | — | — | (846) |
| Fair value adjustment on derivative warrant liability | **13(f)** | 4,470,276 | 3,299,768 | — |
| Foreign exchange gain | | 549,637 | 326,751 | 2,961 |
| Forgiveness of debt | | — | — | 91,014 |
| Interest income (expense) | | 137,575 | (5,598) | (12,666) |
| Impairment of intangible assets | **8** | | | (64,562) |
| Recovery of provision for patent acquisition | **8** | — | — | 95,490 |
| Transaction costs on derivative warrant liability | **13(b)** | (1,257,746) | (1,623,680) | — |
| **Net loss and comprehensive loss for the year** | | (9,485,309) | (1,652,282) | (1,284,602) |
| **Basic and diluted loss per common share** | | (0.71) | (0.17) | (0.19) |
| **Weighted average number of common shares outstanding** | | | | |
| Basic and diluted | | 13,319,226 | 9,847,641 | 6,664,025 |

**XORTX THERAPEUTICS INC.**
**Consolidated Statements of Changes in Shareholders' Equity**
**For the years ended December 31, 2022, 2021 and 2020**
**(Expressed in Canadian Dollars)**

| | Number of common shares | Share capital | Reserves | Obligation to issue shares | Share subscriptions received in advance | Equity component on convertible loans | Deficit | Total |
|---|---|---|---|---|---|---|---|---|
| | | $ | $ | $ | $ | $ | $ | $ |
| **Balance, December 31, 2019** | 5,359,444 | 5,863,872 | 607,803 | — | 70,000 | 5,202 | (6,758,598) | (211,721) |
| Shares issued pursuant to private placement | 1,555,314 | 2,465,023 | 91,297 | — | (70,000) | — | — | 2,486,320 |
| Share issuance costs | — | (70,500) | 11,066 | — | — | — | — | (59,434) |
| Convertible loan debt forgiveness | — | — | — | — | — | (5,202) | 5,202 | — |
| Obligation to issue shares | — | — | — | 32,238 | — | — | — | 32,238 |
| Share-based payments | — | — | 293,443 | — | — | — | — | 293,443 |
| Net loss for the year | — | — | — | — | — | — | (1,284,602) | (1,284,602) |
| **Balance, December 31, 2020** | **6,914,758** | **8,258,395** | **1,003,609** | **32,238** | **—** | | **(8,037,998)** | **1,256,244** |
| Shares issued pursuant to private placement | 2,085,687 | 763,572 | — | — | — | — | — | 763,572 |
| Shares issued pursuant to public listing | 3,261,000 | 9,252,009 | — | — | — | — | — | 9,252,009 |
| Reclassification of derivative warrant liability | — | — | 4,460,000 | — | — | — | — | 4,460,000 |
| Share issuance costs | — | (1,377,364) | 521,251 | — | — | — | — | (856,113) |
| Options exercised | 51,106 | 149,172 | (65,172) | — | — | — | — | 84,000 |
| Warrants exercised | 651,583 | 2,888,370 | (32,387) | — | — | — | — | 2,855,983 |
| Shares issued for services | 25,553 | 75,000 | — | — | — | — | — | 75,000 |
| Share-based payments | — | — | 499,158 | — | — | — | — | 499,158 |
| Net loss for the year | — | — | — | — | — | — | (1,652,282) | (1,652,282) |
| **Balance, December 31, 2021** | **12,989,687** | **20,009,154** | **6,386,459** | **32,238** | **—** | **—** | **(9,690,280)** | **16,737,571** |
| Shares issued pursuant to private placement | 1,400,000 | 493,474 | — | — | — | — | — | 493,474 |
| Pre-funded warrants issued | — | — | 1,268,439 | | | | | 1,268,439 |
| Share issuance costs | — | (121,852) | (58,528) | — | — | — | — | (180,380) |
| Pre-funded warrants exercised | 641,000 | 225,929 | (225,842) | — | — | — | — | 87 |
| Share-based payments | — | — | 632,548 | — | — | — | — | 632,548 |
| Net loss for the year | — | — | — | — | — | — | (9,485,309) | (9,485,309) |
| **Balance, December 31, 2022** | **15,030,687** | **20,606,705** | **8,003,076** | **32,238** | **—** | **—** | **(19,175,589)** | **9,466,430** |

The accompanying notes are an integral part of these consolidated financial statements.

**XORTX THERAPEUTICS INC.**
**Consolidated Statements of Cash Flows**
**For the years ended December 31, 2022, 2021 and 2020**
**(Expressed in Canadian Dollars)**

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| | $ | $ | $ |
| **Cash provided by (used in):** | | | |
| **Operating activities** | | | |
| Net loss for the year | (9,485,309) | (1,652,282) | (1,284,602) |
| Items not affecting cash: | | | |
| Accretion | — | — | 846 |
| Amortization | 75,268 | 17,882 | 20,439 |
| Fair value adjustment on derivative warrant liability | (4,470,276) | (3,299,768) | — |
| Fair value of finders' warrants allocated to derivative liability | 189,230 | — | — |
| Forgiveness of debt | — | — | (91,014) |
| Impairment of intangible assets | — | — | 64,562 |
| Lease Interest expense | 5,024 | — | — |
| Recovery of provision for patent acquisition | — | — | (95,490) |
| Share-based payments | 632,548 | 499,158 | 293,443 |
| Shares issued for services | — | 75,000 | — |
| Unrealized foreign exchange (gain) | (881,468) | (325,741) | 1,201 |
| Changes in non-cash operating assets and liabilities: | | | |
| Accounts receivable | (59,191) | (37,188) | — |
| Prepaid expenses | 762,798 | (1,006,357) | (42,998) |
| Accounts payable and accrued liabilities | 1,263,174 | (333,214) | 405,212 |
| | (11,968,202) | (6,062,510) | (728,401) |
| **Investing activities** | | | |
| Acquisition of intangible assets | (34,237) | (39,809) | (14,350) |
| Acquisition of equipment | (25,779) | — | — |
| | (60,016) | (39,809) | (14,350) |
| **Financing activities** | | | |
| Proceeds from issuance of equity instruments | 6,855,506 | 22,798,581 | 900,000 |
| Cash share issuance costs | (369,608) | (856,113) | (44,592) |
| Options exercised | — | 84,000 | — |
| Pre-funded warrants and warrants exercised | 87 | 2,430,083 | — |
| Payment of lease obligation | (55,125) | — | — |
| | 6,430,860 | 24,456,551 | 855,408 |
| **Effect of foreign exchange (gain) on cash and cash equivalents** | 871,636 | 325,741 | — |
| **(Decrease) increase in cash and cash equivalents** | (4,725,722) | 18,679,973 | 112,657 |
| **Cash and cash equivalents, beginning of year** | 18,851,244 | 171,271 | 58,614 |
| **Cash and cash equivalents, end of year** | 14,125,522 | 18,851,244 | 171,271 |
| **Supplemental Cash Flow and Non-Cash Investing and Financing Activities Disclosure** | | | |
| Recognition of derivative warrant liabilities | — | 12,783,000 | — |
| Fair value of agent's warrants | 254,684 | — | — |
| Derivative warrant liability reclassified to reserves | — | 4,460,000 | — |
| Derivative warrant liability reclassified to share capital on exercise of warrants | — | 425,900 | — |
| Recognition of right-of-use asset | 155,206 | — | — |
| Transfer of funds held in trust | — | — | 70,000 |
| Shares issued for deposit | — | — | 1,606,320 |
| Shares issued to settle debt | — | — | 50,000 |
| Obligation to issue shares | — | — | 32,238 |
| Application of deposits against accounts payable | — | — | 436,240 |

The accompanying notes are an integral part of these consolidated financial statements.

(Expressed in Canadian Dollars)

## 1. Nature of operations

XORTX Therapeutics Inc. (the "Company" or "XORTX") was incorporated under the laws of Alberta, Canada on August 24, 2012.

XORTX is a public company listed on the TSX Venture Exchange (the "TSXV") and on the Nasdaq Stock Market ("Nasdaq") under the symbol "XRTX". The Company's operations and mailing address is 3710 – 33rd Street NW, Calgary, Alberta, Canada T2L 2M1 and its registered address is located at 550 Burrard Street, Suite 2900, Vancouver, British Columbia, V6C 0A3.

XORTX is a late stage clinical pharmaceutical company focused on developing innovative therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism in orphan disease indications such as autosomal dominant polycystic kidney disease, and larger, more prevalent type 2 diabetic nephropathy, as well as acute kidney injury associated with respiratory virus infection. The Company's current focus is on developing products to slow and/or reverse the progression of kidney disease in patients at risk of end stage kidney failure.

The Company is subject to a number of risks associated with the successful development of new products and their marketing and the conduct of its clinical studies and their results. The Company will have to finance its research and development activities and its clinical studies. To achieve the objectives in its business plan, the Company plans to raise the necessary capital and to generate revenues. Although there is no certainty, management is of the opinion that additional funding for future projects and operations can be raised as needed. The products developed by the Company will require approval from the U.S. Food and Drug Administration and equivalent organizations in other countries before their sale can be authorized. If the Company is unsuccessful in obtaining adequate financing in the future, research activities will be postponed until market conditions improve.

In March 2020, the World Health Organization declared coronavirus COVID-19 a global pandemic. This contagious disease outbreak adversely affected workforces, economies, and financial markets globally. To date, COVID-19 has had little impact on the Company's operations. The extent to which the COVID-19 pandemic may impact our business and clinical trials will depend on future developments. Although it is difficult for the Company to accurately predict the extent to which it might be so affected, the Company will continue to monitor all developments regarding COVID-19 on an ongoing basis.

## 2. Basis of preparation

### Statement of Compliance

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

### Basis of Measurement and Presentation

These consolidated financial statements have been prepared using the historical cost convention except for financial instruments which have been measured at fair value. These consolidated financial statements were prepared on an accrual basis except for cash flow information.

These consolidated financial statements incorporate the financial statements of the Company and its 100% owned subsidiary. The accounts of the Company's subsidiary are prepared for the same reporting period as the parent company, using consistent accounting policies. Inter-company transactions, balances and unrealized gains or losses on transactions are eliminated. The Company's subsidiary is the following:

| Name | Place of Incorporation | Ownership Percentage |
|---|---|---|
| XORTX Pharma Corp. | Canada | 100 % |

These consolidated financial statements were approved for issue by the Board of Directors on March 29, 2023.

## 3. Accounting policies

These consolidated financial statements have been prepared using the following accounting policies:

**Financial Instruments**

**a) Classification**

The Company classifies its financial instruments in the following categories: at fair value through profit or loss ("FVTPL"), at fair value through other comprehensive income (loss) ("FVTOCI") or at amortized cost. The Company determines the classification of financial assets at initial recognition. The classification of debt instruments is driven by the Company's business model for managing the financial assets and their contractual cash flow characteristics.

Equity instruments that are held for trading are classified as FVTPL. For other equity instruments, on the day of acquisition the Company can make an irrevocable election (on an instrument-by-instrument basis) to designate them as at FVTOCI. Financial liabilities are measured at amortized cost, unless they are required to be measured at FVTPL (such as instruments held for trading or derivatives) or if the Company has opted to measure them at FVTPL.

The following are the Company's financial instruments as at December 31, 2022:

| | Classification |
|---|---|
| Cash and cash equivalents | FVTPL |
| Accounts payable and accrued liabilities | Amortized cost |
| Derivative warrant liability | FVTPL |
| Lease obligations | Amortized cost |

**b) Measurement**

**Financial assets at FVTOCI**

Elected investments in equity instruments at FVTOCI are initially recognized at fair value plus transaction costs. Subsequently they are measured at fair value, with gains and losses recognized in other comprehensive income (loss).

**Financial assets and liabilities at amortized cost**

Financial assets and liabilities at amortized cost are initially recognized at fair value plus or minus transaction costs, respectively, and subsequently carried at amortized cost less any impairment.

**Financial assets and liabilities at FVTPL**

Financial assets and liabilities carried at FVTPL are initially recorded at fair value and transaction costs are expensed in the consolidated statements of comprehensive loss. Realized and unrealized gains and losses arising from changes in the fair value of the financial assets and liabilities held at FVTPL are included in the consolidated statements of comprehensive loss in the period in which they arise. Where management has opted to recognize a financial liability at FVTPL, any changes associated with the Company's own credit risk will be recognized in other comprehensive loss.

**3. Accounting policies (continued)**

**Financial Instruments (continued)**

**b) Impairment of financial assets at amortized cost**

The Company recognizes a loss allowance for expected credit losses on financial assets that are measured at amortized cost.

At each reporting date, the Company measures the loss allowance for the financial asset at an amount equal to the lifetime expected credit losses if the credit risk on the financial asset has increased significantly since initial recognition. If at the reporting date, the financial asset has not increased significantly since initial recognition, the Company measures the loss allowance for the financial asset at an amount equal to the twelve month expected credit losses. The Company shall recognize in the consolidated statements of comprehensive loss, as an impairment gain or loss, the amount of expected credit losses (or reversal) that is required to adjust the loss allowance at the reporting date to the amount that is required to be recognized.

**c) Derecognition**

**Financial assets**

The Company derecognizes financial assets only when the contractual rights to cash flows from the financial assets expire, or when it transfers the financial assets and substantially all of the associated risks and rewards of ownership to another entity. Gains and losses on derecognition are generally recognized in profit or loss. However, gains and losses on derecognition of financial assets classified as FVTOCI remain within accumulated other comprehensive income (loss).

**Financial liabilities**

The Company derecognizes financial liabilities only when its obligations under the financial liabilities are discharged, cancelled or expired. Generally, the difference between the carrying amount of the financial liability derecognized and the consideration paid and payable, including any non-cash assets, is recognized in the consolidated statements of comprehensive loss.

**Cash and cash equivalents**

Cash and cash equivalents include cash on hand, held at banks, or held with investment brokers as well as short-term investments with an original maturity of 90 days or less, which are readily convertible into known amounts of cash.

**Equipment**

Equipment is recorded at cost less accumulated amortization and accumulated impairment losses. The cost of an item of equipment includes expenditures that are directly attributable to the acquisition thereof. Amortization is calculated on bases and rates designed to amortize the cost of the assets over their estimated useful lives. Amortization is recorded using the straight-line method with an expectation of the following useful life estimates:

| | |
|---|---|
| Computer equipment | 3 years |

**3. Accounting policies (continued)**

**Leases**

At inception of a contract, the Company assesses whether a contract is, or contains, a lease determining whether the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. To assess whether a contract conveys the right to control the use of an identified asset, we assess whether:

- the contract involves the use of an identified asset;
- the Company has the right to obtain substantially all of the economic benefits from use of the identified asset throughout the period of use; and
- the Company has the right to direct the use of the identified asset.

The right-of-use asset and corresponding lease obligation is recognized at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease obligation adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received. The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the end of the lease term or its useful life, whichever is shorter. The lease term includes periods covered by an option to extend if the Company is reasonably certain to exercise that option. In addition, the right-of-use asset is reduced by impairment losses and adjusted for certain remeasurements of the lease obligation, if any.

The lease obligation is initially measured at the present value of the lease payments that are not paid at the commencement date. The lease payments are discounted using the implicit interest rate in the lease. If the rate cannot be readily determined, the Company's incremental rate of borrowing is used. The lease obligation is subsequently measured at amortized cost using the effective interest method. The lease obligation is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in our estimate of the amount expected to be payable under a residual value guarantee, if we change our assessment of whether we will exercise a purchase, extension or termination option, or if the underlying lease contract is amended.

The Company has elected not to separate fixed non-lease components from lease components and instead account for each lease component and associated fixed non-lease components as a single lease component.

The Company has elected not to recognize right-of-use assets and lease obligations for short-term leases that have a lease term of 12 months or less and for leases of low value assets. The lease payments associated with those leases are recognized as an expense on a straight-line basis over the lease term.

**Research and development costs**

Research costs including clinical trial costs are expensed as incurred, net of recoveries until a drug product receives regulatory approval. Development costs that meet specific criteria related to technical, market and financial feasibility will be capitalized. To date, all research and development costs have been expensed.

**Intangible assets**

Intangible assets are measured at cost less accumulated amortization and accumulated impairment losses. Costs incurred for patents, patents pending and licenses are capitalized and amortized from the date of capitalization on a straight-line basis over the shorter of their respective remaining estimated lives or 20 years.

**3. Accounting policies (continued)**

**Government assistance**

Amounts received or receivable resulting from government assistance programs, including grants and investment tax credits for research and development, are recognized where there is reasonable assurance that the amount of government assistance will be received and all attached conditions will be complied with. Investment tax credits relating to qualifying scientific research and experimental development expenditures that are recoverable are recognized as a reduction of expenses.

**Impairment of long-lived assets**

Intangible assets and equipment are tested for impairment when events or changes in circumstances indicate that the carrying amount may not be recoverable. For the purpose of measuring recoverable amounts, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units or CGUs). The recoverable amount is the higher of an asset's fair value less costs to sell and value in use (being the present value of the expected future cash flows of the relevant asset or CGU). An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The Company evaluates impairment losses for potential reversals when events or circumstances warrant such consideration.

**Derivative warrant liabilities**

Derivative warrant liabilities issued in relation to equity offerings that fail to meet the definition of equity are classified as derivative liabilities and measured at fair value with changes in fair value recognized in the consolidated statement of comprehensive loss at each period end. In instances where units consisting of a common share and a warrant classified as a derivative liability are issued, the Company recognizes the unit as a compound financial instrument. Derivatives are accounted for at fair value with changes in fair value recorded in profit or loss. In accordance with IAS 32 Financial Instrument: Presentation, when a compound instrument has been determined to contain a financial liability and an equity component, the fair value of the instrument is bifurcated by first determining the fair value of the liability, and then allocating any residual value to the equity instrument.

The derivative liabilities will ultimately be converted into the Company's equity (common shares) when the warrants are exercised or will be extinguished on the expiry of the outstanding warrants and will not result in the outlay of any cash by the Company. Immediately prior to exercise, the warrants are remeasured at their intrinsic value (the intrinsic value being the share price at the date the warrant is exercised less the exercise price of the warrant), and this value is transferred to Share Capital on exercise. Any remaining fair value is recorded through profit or loss as part of the change in estimated fair value of the derivative warrant liabilities.

The Company uses the Black-Scholes option pricing model to estimate fair value at each period end date. The key assumptions used in the model are described in Note 13(f).

**Share-based payments**

The Company has a stock option plan that is described in Note 13 and grants share options to acquire common shares of the Company to directors, officers, employees and consultants. Share-based payments to employees are measured at the fair value of the instruments granted. Share-based payments to non-employees are measured at the fair value of the goods or services received or the fair value of the equity instruments issued as calculated using the Black-Scholes option pricing model. The offset to the recorded expense is to reserve.

Consideration received on the exercise of stock options is recorded as share capital and the recorded amount in reserves is transferred to share capital.

**3. Accounting policies (continued)**

**Share capital**

Common shares are classified as equity. Costs directly identifiable with share capital financing are charged against share capital. Share issuance costs incurred in advance of share subscriptions are recorded as deferred assets. Share issuance costs related to uncompleted share subscriptions are charged to operations in the period they are incurred.

The Company's common shares, pre-funded warrants, warrants (other than derivative warrants) and options are classified as equity instruments. Incremental costs directly related to the issue of new shares or options are shown in equity as a deduction from the proceeds. For equity offerings of units consisting of a common share and warrant, when both instruments are classified as equity, the Company allocates proceeds first to common shares based on the estimated fair value of the common shares at the time the units are issued, with any excess value allocated to warrants.

From time to time in connection with private placements and other equity offerings, the Company issues compensatory warrants ("Finders' Warrants") or warrant units ("Finders' Warrant Units") to agents as commission for services. Awards of Finders' Warrants and Finders' Warrant Units are accounted for in accordance with the fair value method of accounting and result in share issue costs and a credit to reserves when Finders' Warrants and Finders' Warrant Units are issued. The fair value of Finders' Warrants is measured using the Black-Scholes option pricing model and the fair value of the Finders' Warrant Units is measured using the Geske compound option pricing model that both requires the use of certain assumptions regarding the risk-free market interest rate, expected volatility in the price of the underlying stock, and expected life of the instruments.

**Earnings (loss) per common share**

Basic earnings (loss) per common share is computed by dividing the net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period and the diluted loss per share assumes that the outstanding vested stock options and share purchase warrants had been exercised at the beginning of the year. Diluted earnings per share reflect the potential dilution that could share in the earnings of an entity. In the periods where a net loss is incurred, potentially dilutive common shares are excluded from the loss per share calculation as the effect would be anti-dilutive and basic and diluted loss per common share are the same. In a profit year, the weighted average number of common shares outstanding used for the calculation of diluted earnings per share assumes that the proceeds to be received on the exercise of dilutive stock options and warrants are used to repurchase the common shares at the average price per period.

**Foreign currency translation**

The Company's presentation currency is the Canadian dollar. The functional currency of the Company and its subsidiary is the Canadian dollar. Foreign currency transactions are translated into Canadian dollars using the exchange rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the rate of exchange in effect as of the financial position date. Gains and losses are recognized in profit or loss on a current basis.

**Income taxes**

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

Deferred income tax assets also result from unused loss carry forwards, resource related pools and other deductions. A deferred tax asset is recognized for unused tax losses, tax credits and deductible temporary differences to the extent that it is probable that future taxable profits will be available against which they can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

## 4. Critical accounting judgments and estimates

The preparation of consolidated financial statements requires management to make judgments and estimates that affect the amounts reported in the consolidated financial statements and notes. By their nature, these judgments and estimates are subject to change and the effect on the consolidated financial statements of changes in such judgments and estimates in future periods could be material. These judgments and estimates are based on historical experience, current and future economic conditions, and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Actual results could differ from these judgments and estimates.

Revisions to accounting estimates are recognized in the period in which the estimate is revised and may affect both the period of revision and future periods.

Information about critical accounting judgments in applying accounting policies that have the most significant risk of causing material adjustment to the carrying amounts of assets and liabilities recognized in the consolidated financial statements within the next financial year are discussed below:

**Share-based payment transactions and warrant liabilities**

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments on the date they are granted. Warrant liabilities are accounted for as derivative liabilities as the proceeds from exercise are not fixed given they are denominated in USD. Estimating fair value for share-based transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the instrument. This estimate also requires determining the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them.

The assumptions and models used for estimating fair value for share-based payment transactions and warrant liabilities are disclosed in Note 13.

**Classification of contract payments**

In concluding that contract payments are a non-current asset, management considered when future regulatory and clinical trial programs are anticipated to be completed. During the year ended December 31, 2022, management assessed that the future regulatory and clinical trial programs would not be completed within 12 months from period end and therefore reclassified contract payments as a non-current asset.

**Impairment of intangible assets**

Patents (obtained and pending) and licenses are reviewed for impairment at each financial reporting date. If, in the judgment of management, future economic benefits will not flow to the Company, then the Company will assess the recoverable value of the asset. If the carrying value is greater than the recoverable value, the asset will be impaired to the recoverable value.

**Determination of functional currency**

In concluding that the Canadian dollar is the functional currency of the Company and its subsidiary, management considered the currency that mainly influences the cost of providing goods and services in the primary economic environment in which each entity operates, or if there has been a change in events or conditions that determined the primary economic environment.

(Expressed in Canadian Dollars)

**4. Critical accounting judgments and estimates (Continued)**

**Treatment of research and development costs**

Costs to develop products are capitalized to the extent that the criteria for recognition as intangible assets in IAS 38 Intangible Assets are met. Those criteria require that the product is technically and economically feasible, the Company has the intention and ability to use the asset, and how the asset will generate future benefits. Management assessed the capitalization of development costs based on the attributes of the development project, perceived user needs, industry trends and expected future economic conditions. Management considers these factors in aggregate and applies significant judgment to determine whether the product is feasible. The Company has not capitalized any development costs as at December 31, 2022.

**Leases**

Value of right-of-use assets and lease obligations require judgement in determining lease terms such as extension options, determining whether a lease contract contains an identified asset to which the Company has the right to use substantially all of the economic benefits from the use of that asset and the incremental borrowing rate applied. The Company estimates the incremental borrowing rate based on the lease term, collateral assumptions and the economic environment in which the lease is denominated. Renewal options are only included if management is reasonably certain that the option will be renewed.

**Classification of pre-funded warrants**

Management applied judgment when determining the appropriate classification of pre-funded warrants included in unit offerings. Management considered the characteristics of derivative instruments and concluded that the pre-funded warrants should be classified as an equity instrument.

**Current and deferred taxes**

The measurement of income taxes payable and deferred income tax assets and liabilities requires management to make judgments in the interpretation and application of the relevant tax laws. Such differences may result in eventual tax payments differing from amounts accrued. Reported amounts for deferred tax assets and liabilities are based on management's expectation for the timing and amounts of future taxable income or loss, as well as future taxation rates. Changes to these underlying estimates may result in changes to the carrying value, if any, of deferred income tax assets and liabilities.

**5. Cash and cash equivalents**

The Company's cash and cash equivalents consist of cash held of $5,178,223 (2021 - $18,851,244) and redeemable interest-bearing deposits with the Company's bank totaling $8,947,299 (2021 - $nil). The current annual interest rate earned on these deposits is 3.90% (2021 - 0%).

**6. Prepaid expenses**

The Company's prepaid expenses relate to the following:

| | December 31, 2022<br>$ | December 31, 2021<br>$ |
|---|---|---|
| Research and development | — | 714,716 |
| Insurance | 322,842 | 441,388 |
| Investor relations conferences and services | 89,804 | 60,254 |
| Consulting | 16,667 | 50,000 |
| Administrative services | 84,847 | 4,198 |
| | 514,160 | 1,270,556 |

(Expressed in Canadian Dollars)

## 7. Contract payments

During the year ended December 31, 2020, the Company entered into an agreement with Prevail InfoWorks Inc. to provide regulatory and clinical trial services. As part of the agreement, the Company paid $1,606,320 through the issuance of units in the private placement (US$1,200,000) to be applied to future regulatory and clinical trial programs. The 977,318 units issued were measured by reference to their fair value on the issuance date, equal to $1.64 per unit in a concurrent private placement.

## 8. Intangible assets

| Cost | Total |
|---|---|
| | $ |
| Balance, December 31, 2020 | 325,182 |
| Additions | 39,809 |
| Balance, December 31, 2021 | 364,991 |
| Additions | 34,237 |
| **Balance, December 31, 2022** | **399,228** |

| Accumulated amortization | Total |
|---|---|
| | $ |
| Balance, December 31, 2020 | 90,866 |
| Amortization | 17,882 |
| Balance, December 31, 2021 | 108,748 |
| Amortization | 19,812 |
| **Balance, December 31, 2022** | **128,560** |

| Carrying values | Total |
|---|---|
| | $ |
| At December 31, 2021 | 256,243 |
| **At December 31, 2022** | **270,668** |

The Company has licensed intellectual property from various third parties. Annually costs incurred to prosecute patents related to the Company's intellectual property is also capitalized. The intangible assets are as described below:

**a)** The Company has licensed from a third party (the "Licensor"), under patent rights purchase agreement dated July 9, 2013 and amended April 15, 2014, certain patents relating to allopurinol for the treatment of hypertension. The Company paid a total of $42,460 (US$40,000) to the Licensor per the terms of the agreement.

The Company will also pay the Licensor royalties on the cumulative net revenues from the sale or sublicense of the product covered under the patent license until the later of (i) the expiration of the last patent right covering the product; and (ii) the expiration of ten years from the date of the first commercial sales of a product.

**b)** In December 2012, the Company entered into an agreement to license certain intellectual property relating to the use of all uric acid lowering agents to improve the treatment of metabolic syndrome. Under this patent rights purchase agreement, between the Company and Dr. Richard Johnson and Dr. Takahiko Nakagawa (the "Vendors"), the Company issued 143,100 common shares at $0.35 per common share for a total instalment price of $50,400. The Company also had the option to pay the Vendors an additional US$75,000 to purchase the patents which was set up as a provision in the year ended December 31, 2018.

(Expressed in Canadian Dollars)

**8. Intangible assets (continued)**

During the year ended December 31, 2020, the Company determined that it was no longer feasible to complete the purchase and as such, indicators of impairment existed leading to a test of recoverable amount of the license, which resulted in an impairment loss of $64,562. As this valuation technique requires management's judgment and estimates of the recoverable amount, it is classified within level 3 of the fair value hierarchy. During the year ended December 31, 2020, the purchase provision was reversed resulting in a gain of $95,490 on recovery of provision.

The Company will pay the Vendors a royalty based on the cumulative net revenues from the sale or sublicense of the product covered under the licensed intellectual property until the later of (i) the expiration of the last patent right covering the product; and (ii) the expiration of 10 years from the date of the first commercial sales of a product.

**c)** Pursuant to a license agreement dated October 9, 2012, as amended on June 23, 2014, between the Company and the University of Florida Research Foundation, Inc. ("UFRF"), the Company acquired the exclusive license to certain intellectual property related to the use of all uric acid lowering agents to treat insulin resistance. The Company has paid or is obligated to pay UFRF the following:

i) An annual license fee of US$1,000;

ii) Reimburse UFRF for United States and/or foreign costs associated with the maintenance of the licensed patents;

iii) The issuance to UFRF of 180,397 shares of common stock of the Company (160,783 have been issued to UFRF as at December 31, 2022. Remaining shares to be issued are included in obligation to issue shares);

iv) Milestone payments of US$500,000 upon receipt of FDA approval to market licensed product in the United States of America and US$100,000 upon receipt of regulatory approval to market each licensed product in each of the other jurisdictions;

v) Royalty payments of up to 1.5% of net sales of products covered by the license until the later of (i) the expiration of any patent claims; or (ii) 10 years from the date of the first commercial sale of any covered product in each country. Following commencement of commercial sales, the Company will be subject to certain annual minimum royalty payments that will increase annually to a maximum of US$100,000 per year; and

vi) UFRF is entitled to receive a royalty of 5% of amounts received from any sub-licensee that are not based directly on product sales, excluding payments received for research and development or purchases of the Company's securities at not less than fair market value.

UFRF may terminate the agreement if the Company fails to meet the above specified milestones.

**9. Right-of-use asset**

The Company entered into an office lease (note 12) during the year ended December 31, 2022 for which a right-of-use asset was recognized. The carrying value of the right-of-use asset is as follows:

| **Cost** | **Total** |
|---|---|
| | **$** |
| Balance, December 31, 2021 and 2020 | — |
| Additions | 155,206 |
| **Balance, December 31, 2022** | **155,206** |

| **Accumulated amortization** | **Total** |
|---|---|
| | **$** |
| Balance, December 31, 2021 and 2020 | — |
| Amortization | 51,735 |
| **Balance, December 31, 2022** | **51,735** |

| **Carrying values** | **Total** |
|---|---|
| | **$** |

| | |
|---|---|
| At December 31, 2021 and 2020 | — |
| **At December 31, 2022** | **103,471** |

## 10. Equipment

| Cost | Total<br>$ |
|---|---|
| Balance, December 31, 2021 | — |
| Additions | 25,779 |
| **Balance, December 31, 2022** | **25,779** |

| Accumulated amortization | Total<br>$ |
|---|---|
| Balance, December 31, 2021 and 2020 | — |
| Amortization | 3,721 |
| **Balance, December 31, 2022** | **3,721** |

| Carrying values | Total<br>$ |
|---|---|
| At December 31, 2021 and 2020 | — |
| **At December 31, 2022** | **22,058** |

(Expressed in Canadian Dollars)

## 11. Accounts payable and accrued liabilities

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| | $ | $ |
| Trade payables | 1,758,486 | 410,701 |
| Accrued liabilities | 202,259 | 290,298 |
| Total | 1,960,745 | 700,999 |

## 12. Lease obligation

The Company entered into an office lease during the year ended December 31, 2022. A reconciliation of the outstanding lease obligation as at December 31, 2022 is as follows:

| | $ |
|---|---|
| Balance, December 31, 2021 | — |
| Additions | 155,206 |
| Lease payments | (55,125) |
| Interest expense | 5,024 |
| **Balance, December 31, 2022** | **105,105** |
| | |
| Total lease obligations | 105,105 |
| Less: current portion | (89,517) |
| Non-current portion | 15,588 |

The office lease requires monthly payments of $7,875 and an end date of February 29, 2024. The right-of-use asset and lease obligation were measured at the present value of the lease payments and discounted using an incremental borrowing rate of 7.71%.

The following is a schedule of the Company's future minimum lease payments related to the office lease obligation:

| | $ |
|---|---|
| 2023 | 94,500 |
| 2024 | 15,750 |
| Total minimum lease payments | 110,250 |
| Less: imputed interest | (5,145) |
| Total present value of minimum lease payments | 105,105 |
| Less: current portion | (89,517) |
| Non-current portion | 15,588 |

## 13. Share capital and reserves

### a) Authorized and issued

Unlimited common shares with no par value – 15,030,687 issued as at December 31, 2022 (2021 - 12,989,687).

### b) Issuances

**Year ended December 31, 2022:**

On October 7, 2022, the Company closed a private placement of: (i) 1,400,000 common share units ("Common Share Units") at a price of US$1.00 per Common Share Unit, with each Common Share Unit consisting of one common share and one warrant ("Warrant") to purchase one common share; and (ii) 3,600,000 pre-funded warrant units ("Pre-Funded Units") at a price of US$0.9999 per Pre-Funded Unit, with each Pre-Funded Unit consisting of one pre-funded warrant ("Pre-Funded Warrant") to purchase one common share and one Warrant to purchase one common share. Aggregate gross proceeds amounted to $6,855,506 (US$4,999,640). The Pre-Funded Warrants have an exercise price of US$0.0001 per share, and will terminate once exercised in full. The Warrants are exercisable at an exercise price of US$1.22 per share expiring five years from the date of issuance.

The proceeds were allocated $5,093,593 to the derivative warrant liability (Note 13(g)) and the residual amounts of $493,474 and $1,268,439 were allocated to common shares and pre-funded warrants respectively.

In connection with the private placement, the Company incurred issuance costs of $1,438,127 and issued 250,000 finders' warrants with a fair value of $254,684. The costs were allocated between common shares and derivative warrant liability in proportion to their initial carrying amounts with $435,065 recorded as a reduction of equity and $1,257,746 recorded as transaction costs on derivative warrant liability and pre-funded warrants.

On December 29, 2022, the Company issued 641,000 common shares for the exercise of Pre-Funded Warrants at US$0.0001 per share in the amount of $87 (US$64). An amount of $225,842 was transferred from reserves to share capital as a result.

**Year ended December 31, 2021:**

On February 9, 2021, the Company closed a private placement with the issuance of 2,085,687 units at a subscription price of $2.935 per unit for gross proceeds of $6,121,572. Each unit comprised one common share 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 five years from the issuance of the units, provided, however, that, if, at any time following the expiry of the statutory four month hold period, the closing price of the common shares 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 were subject to typical anti-dilution provisions and a ratchet provision that provided 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 would be amended to match such lower price.

The proceeds were allocated $5,358,000 to the derivative warrant liability (Note 13(g)) and the residual $763,572 was allocated to common shares.

In connection with the private placement, the Company paid $171,347 in cash commissions, incurred additional issuance costs of $7,897 and issued 58,288 finders' warrants with a fair value of $150,000 (Note 13(e)). Each finders' 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. The costs were allocated between common shares and derivative warrant liability in proportion to their initial carrying amounts with $41,068 recorded as a reduction of equity and $287,946 recorded as transaction costs on derivative warrant liability.

**13. Share capital and reserves (continued)**

**b) Issuances (continued)**

On October 15, 2021, the Company listed its common shares on the Nasdaq Stock Market ("Nasdaq") under the symbol "XRTX" and closed an underwritten public offering of 2,906,000 units (the "US IPO Offering"), with each unit consisting of one common share, no par value, and one warrant to purchase one common share at a public offering price of US$4.13 per Unit, for gross proceeds of $14,851,850 (US$12,001,780). The proceeds were allocated $7,425,000 to the derivative warrant liability (Note 13(g)) and the residual $7,426,850 was allocated to common shares.

The warrants have an initial exercise price of US$4.77 per share and have a term of 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 IPO Offering price less the underwriting discounts. On October 15, 2021, the underwriter exercised its option to purchase additional warrants to purchase up to an additional 435,900 common shares.

On November 8, 2021, the underwriter partially exercised its 45-day option for 355,000 common shares at US$4.13 per share, resulting in additional gross proceeds to the Company of $1,825,159 (US$1,466,150) which increased the US IPO Offering to 3,261,000 common shares and 3,341,900 warrants.

In connection with the US IPO Offering, the Company incurred issuance costs of $2,300,549 and issued 145,300 finders' warrants with a fair value of $371,251. The costs were allocated between common shares and derivative warrant liability in proportion to their initial carrying amounts with $1,336,066 recorded as a reduction of equity and $1,335,734 recorded as transaction costs on derivative warrant liability.

The Company issued 51,106 common shares for the exercise of options in the amount of $84,000. A value of $65,172 was transferred from reserves to share capital as a result.

The Company issued 651,583 common shares for the exercise of warrants in the amount of $2,430,083. A value of $32,387 was transferred from reserves to share capital and a value of $425,900 was transferred from the derivative warrant liability to share capital as a result.

Pursuant to the terms of a consulting agreement, the Company issued 25,553 common shares with a fair value of $75,000 in exchange for services.

(Expressed in Canadian Dollars)

**13. Share capital and reserves (continued)**

**c) Common Share Purchase Warrants**

A summary of the changes in warrants for the years ended December 31, 2022 and 2021 is presented below:

| | Number of Warrants | Weighted Average Exercise price |
|---|---|---|
| Balance, December 31, 2020 | 1,555,317 | $ 2.94 |
| Granted – February 9, 2021 | 2,085,687 | $ 4.70 |
| Granted – October 15, 2021 | 2,431,900 | US$4.77 |
| Granted – October 15, 2021 | 910,000 | (1)US$1.17 |
| Exercised | (640,012) | $ 3.34 |
| Expired | (1,215,816) | $ 2.94 |
| Balance, December 31, 2021 | 5,127,076 | $ 5.58 |
| Granted – October 7, 2022 | 5,000,000 | US$1.22 |
| **Balance, December 31, 2022** | **10,127,076** | **$ 3.34** |

(1) On October 7, 2022, the Company entered into an agreement to reduce the exercise price of outstanding warrants to purchase up to 910,000 shares of common stock issued in the 2021 public offering and held by investors in this Offering from US$4.77 per share to US$1.17 per share.

At December 31, 2022, the weighted average contractual remaining life of the unexercised warrants was 4.15 years (2021 - 4.56 years).

The following table summarizes information on warrants outstanding at December 31, 2022:

| Exercise Price | Number Outstanding | Expiry date | Remaining Contractual Life |
|---|---|---|---|
| $4.70 | 1,785,176 | February 9, 2026 | 3.11 years |
| US$4.77 | 2,431,900 | October 15, 2026 | 3.79 years |
| US$1.17 | 910,000 | October 15, 2026 | 3.79 years |
| US$1.22 | 5,000,000 | October 7, 2027 | 4.77 years |

**d) Pre-Funded Warrants**

A summary of the changes in Pre-Funded Warrants for the years ended December 31, 2022 and 2021 is presented below:

| | Number of Warrants | Weighted Average Exercise price |
|---|---|---|
| Balance, December 31, 2020 and 2021 | — | — |
| Granted – October 7, 2022 | 3,600,000 | US$0.0001 |
| Exercised | (641,000) | US$0.0001 |
| **Balance, December 31, 2022** | **2,959,000** | **US$0.0001** |

The remaining 2,959,000 pre-funded warrants were exercised subsequent to year end.

(Expressed in Canadian Dollars)

**13. Share capital and reserves (continued)**

**e) Finders' Warrants**

A summary of the changes in finders' warrants for the years ended December 31, 2022 and 2021 is presented below:

| | Number of Warrants | | Weighted Average Exercise price |
|---|---|---|---|
| Balance, December 31, 2020 | 11,896 | $ | 1.64 |
| Granted – February 9, 2021 | 58,288 | $ | 4.70 |
| Granted – October 15, 2021 | 145,300 | | US$4.77 |
| Exercised | (11,571) | $ | 1.87 |
| Expired | (1,193) | $ | 1.64 |
| Balance, December 31, 2021 | 202,720 | $ | 5.66 |
| Granted – October 7, 2022 – finders' warrants | 250,000 | | US$1.22 |
| **Balance, December 31, 2022** | **452,720** | **$** | **3.58** |

At December 31, 2022, the weighted average contractual remaining life of the unexercised finders' warrant was 4.25 years (2021 - 4.60 years).

The following table summarizes information on finders' warrants outstanding at December 31, 2022:

| Exercise Price | Number Outstanding | Expiry date | Remaining Contractual Life |
|---|---|---|---|
| $4.70 | 57,420 | February 9, 2026 | 3.11 years |
| US$4.77 | 145,300 | October 15, 2026 | 3.79 years |
| US$1.22 | 250,000 | October 7, 2027 | 4.77 years |

The fair value of the finders' warrants issued on February 9, 2021 was estimated at $150,000 on the date of grant using the Black-Scholes option pricing model with the following assumptions: expected life of 5.0 years; expected volatility of 100%; risk free rate of 0.58%; and expected dividend yield of 0%.

The fair value of the finders' warrants issued on October 15, 2021 was estimated at $371,251 on the date of grant using the Black-Scholes option pricing model with the following assumptions: expected life of 5.0 years; expected volatility of 100%; risk free rate of 1.5%; and expected dividend yield of 0%.

The fair value of the finders' warrants issued on October 7, 2022 was estimated at $254,684 on the date of grant using the Black-Scholes option pricing model with the following assumptions: expected life of 5.0 years; expected volatility of 100%; risk free rate of 3.66%; and expected dividend yield of 0%.

The risk-free interest rate is the yield on zero-coupon Canadian Treasury Bills of a term consistent with the assumed option life. The expected life of the option is the average expected period to exercise.

Volatility is based on available historical volatility of the Company's share price or historical share price of comparable companies, excluding specific time frames in which volatility was affected by specific transactions that are not considered to be indicative of the Company's expected share price volatility. The Company has not declared dividends in the past.

(Expressed in Canadian Dollars)

**13. Share capital and reserves (continued)**

**f) Stock Options**

The Company has an incentive Stock Option Plan (the "Plan") for directors, officers, employees and consultants, under which the Company may issue stock options to purchase common shares of the Company provided that the amount of incentive stock options which may be granted and outstanding under the Plan at any time shall not exceed 10% of the then issued and outstanding common shares of the Company.

The fair value of stock options granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

| | 2022 | 2021 |
|---|---|---|
| Dividend yield | Nil | Nil |
| Annualized volatility | 100 % | 100 % |
| Risk-free interest rate | 1.44%-3.32 % | 0.36% - 1.19 % |
| Expected life | 5 years | 5 years |

The risk-free interest rate is the yield on zero-coupon Canadian Treasury Bills of a term consistent with the assumed option life. The expected life of the option is the average expected period to exercise.

Volatility is based on available historical volatility of the Company's share price or historical share price of comparable companies, excluding specific time frames in which volatility was affected by specific transactions that are not considered to be indicative of the Company's expected share price volatility. The Company has not declared dividends in the past.

The share-based payment expense recognized was $632,548 during the year ended December 31, 2022 (2021 - $499,158; 2020 - $293,493).

A summary of the changes in stock options for the years ended December 31, 2022 and 2021 is presented below:

| | Number of Options | Weighted Average Exercise price |
|---|---|---|
| Balance, December 31, 2020 | 464,207 | $ 3.29 |
| Granted – January 11, 2021 | 59,624 | $ 3.29 |
| Granted – May 12, 2021 | 42,588 | $ 1.88 |
| Granted – June 16, 2021 | 21,294 | $ 1.76 |
| Granted – July 14, 2021 | 63,882 | $ 2.41 |
| Granted – December 21, 2021 | 86,495 | $ 2.54 |
| Exercised | (51,106) | $ 1.64 |
| Expired | (80,917) | $ 3.40 |
| **Balance, December 31, 2021** | **606,067** | **$ 3.10** |
| Granted – January 12, 2022 | 127,500 | $ 2.54 |
| Granted – June 6, 2022 | 394,822 | $ 1.60 |
| Granted – November 25, 2022 | 70,000 | $ 1.38 |
| Expired | (44,070) | $ 3.19 |
| **Balance, December 31, 2022** | **1,154,319** | **$ 2.42** |
| **Vested and exercisable, December 31, 2022** | **872,055** | **$ 2.58** |

(Expressed in Canadian Dollars)

**13. Share capital and reserves (continued)**

**f) Stock Options (continued)**

The weighted average contractual remaining life of the unexercised options was 3.43 years (2021 - 3.42 years).

The following table summarizes information on stock options outstanding at December 31, 2022:

| Exercise Price | Number Outstanding | Number Exercisable | Expiry Date | Remaining Contractual Life |
|---|---|---|---|---|
| $5.87 | 114,984 | 114,984 | March 19, 2023 | 0.21 years |
| $5.87 | 21,294 | 21,294 | November 5, 2023 | 0.85 years |
| $1.64 | 170,354 | 150,479 | June 23, 2025 | 2.48 years |
| $2.82 | 12,776 | 12,776 | August 27, 2025 | 2.66 years |
| $3.29 | 59,624 | 59,624 | January 11, 2026 | 3.03 years |
| $1.88 | 21,294 | 21,294 | May 12, 2026 | 3.36 years |
| $1.76 | 21,294 | 21,294 | June 16, 2026 | 3.46 years |
| $2.41 | 63,882 | 30,166 | July 14, 2026 | 3.54 years |
| $2.54 | 86,495 | 86,495 | December 21, 2026 | 3.98 years |
| $2.54 | 117,500 | 35,902 | January 12, 2027 | 4.04 years |
| $1.60 | 394,822 | 315,803 | June 6, 2027 | 4.43 years |
| $1.38 | 70,000 | 1,944 | November 25, 2027 | 4.90 years |
| | **1,154,319** | **872,055** | | |

**g) Derivative warrant liability**

During the year ended December 31, 2022, the Company issued warrants which are recorded as a derivative financial liability as the exercise price is denominated in a currency other than the functional currency of the Company and therefore may be settled other than by the exchange of a fixed amount of cash. The fair value of the warrants was estimated at $5,093,593 on the date of grant using the Black-Scholes option pricing model with the following assumptions: share price on date of grant of US$1.01; exercise price of the warrant of US$1.22; expected life of 5.0 years; expected volatility of 100%; risk free rate of 3.66%; and expected dividend yield of 0%.

During the year ended December 31, 2021, the Company issued 2,085,687 warrants pursuant to a financing in February 2021 as described above. The warrants contained a ratchet provision that provides for an adjustment in the exercise price if shares or securities convertible to shares are sold at a price lower than the exercise price. Therefore, since the warrants (not including compensation warrants) may be settled other than by the exchange of a fixed amount of cash, they meet the definition of a derivative financial liability.

The fair value of the warrants was estimated at $5,358,000 on the date of grant using the Black-Scholes option pricing model with the following assumptions: share price on date of grant of $3.64; exercise price of the warrant of $4.70; expected life of 5.0 years; expected volatility of 100%; risk free rate of 0.58%; and expected dividend yield of 0%.

During the year ended December 31, 2021, 640,012 of these warrants were exercised and a value of $425,900 was transferred from the derivative warrant liability to share capital as a result. On October 15, 2021, the ratchet provision expired when the Company listed its common shares on the Nasdaq. As a result of the expiry, the warrants would now be settled by a fixed amount of cash and were reclassified as equity instruments. The fair value of the derivative warrant liability as of October 15, 2021 of $4,460,000 was reclassified to reserves.

During the year ended December 31, 2021, the Company issued warrants pursuant to the US IPO Offering discussed above. These warrants were recorded as a derivative financial liability as the exercise price of the warrants is denominated in a currency other than the functional currency of the

(Expressed in Canadian Dollars)

**13. Share capital and reserves (continued)**

**g) Derivative warrant liability (continued)**

Company and therefore may be settled other than by the exchange of a fixed amount of cash. The fair value of the warrants was estimated at $7,425,000 on the date of grant using the Black-Scholes option pricing model with the following assumptions: share price on date of grant of US$3.02; exercise price of the warrant of US$4.77; expected life of 5.0 years; expected volatility of 100%; risk free rate of 1.50%; and expected dividend yield of 0%.

**The balance of the derivative warrant liabilities (level 3) is as follows:**

| | | |
|---|---|---|
| **Balance at December 31, 2020** | **$** | **—** |
| Warrants issued February 9, 2021 | | 5,358,000 |
| Warrants exercised | | (425,900) |
| Fair value reclassified to reserves | | (4,460,000) |
| Warrants issued October 15, 2021 | | 7,425,000 |
| Fair value adjustment | | (3,299,768) |
| **Balance at December 31, 2021** | **$** | **4,597,332** |
| Warrants issued October 7, 2022 | | 5,093,593 |
| Fair value adjustment | | (4,470,276) |
| **Balance at December 31, 2022** | **$** | **5,220,649** |

Significant assumptions used in determining the fair value of the derivative warrant liabilities at December 31 2022 and 2021 are as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Share price | **$0.81** | **$2.05** |
| Risk-free interest rate | **3.55 %** | **1.23 %** |
| Dividend yield | **— %** | **— %** |
| Expected volatility | **100 %** | **100 %** |
| Remaining term (in years) | **3.8-4.8** | **4.8** |

The fair value is classified as level 3 as expected volatility is determined using historical volatility and is therefore not an observable input.

**14. Related party transactions**

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

During the year ended December 31, 2022, the Company incurred the following transactions with related parties:

a) Wages and benefits and professional fees were paid or accrued to Allen Davidoff, the Chief Executive Officer (“CEO”), Amar Keshri, the Chief Financial Officer (“CFO”), and David MacDonald, former Chief Technology Officer (“CTO”) of the Company in the amount of $775,259 (2021 - $311,840; 2020 - $196,097).

b) Professional fees were paid to 1282803 Ontario Inc., a company owned by Jim Fairbairn, a former CFO of the Company in the amount of $nil (2021 - $58,500; 2020 - $30,000).

c) Research and development fees were paid or accrued to Haworth Biopharmaceutical, a company owned by Stephen Haworth, the Chief Medical Officer (“CMO”) of the Company in the amount of $312,412 (2021 - $106,366; 2020 - $nil).

(Expressed in Canadian Dollars)

**14. Related party transactions (continued)**

d) Consulting fees were paid or accrued to Stacy Evans, the Chief Business Officer ("CBO") of the Company in the amount of $115,644 (2021 - $nil; 2020 - $nil).

e) Consulting fees were paid to Bruce Rowlands and Allan Williams, former directors of the Company in the amount of $nil (2021 - $54,950; 2020 - $36,000).

f) Consulting fees were paid to a private entity controlled by the spouse of the Company's CEO in the amount of $4,750 (2021 - $nil; 2020 - $nil).

g) Directors' fees were paid or accrued to the directors of the Company in the amount of $161,054 (2021 - $62,200). The amount includes director fees payment of $90,871 for the year ended December 31, 2022 (2021 - $nil) to Anthony Giovinazzo, Chairman of the Company.

h) As at December 31, 2022, $20,200 (2021 - $81,104) was payable to directors of the Company, $39,069 (2021 - $25,000) was accrued to the CEO of the Company, for CEO services, $14,769 (2021 - $nil) was accrued to the CFO of the Company, for CFO services, $67,720 (2021 - $47,543) was payable and accrued to the CMO of the Company, for consulting services, and $33,860 (2021 - $nil) was payable and accrued to the CBO of the Company, for consulting services. The balances are unsecured, non-interest bearing, and have no fixed terms of repayment.

i) Management compensation transactions for the years ended December 31, 2022, 2021 and 2020 are summarized as follows:

| | Short-term employee benefits | Directors' fees | Share-based payments | Total |
|---|---|---|---|---|
| | $ | $ | $ | $ |
| Year ended December 31, 2020 | | | | |
| Directors and officers | 226,097 | — | 217,816 | 443,913 |
| | | | | |
| Year ended December 31, 2021 | | | | |
| Directors and officers | 531,656 | 62,200 | 331,809 | 925,665 |
| | | | | |
| Year ended December 31, 2022 | | | | |
| Directors and officers | **1,153,439** | **161,054** | **519,741** | **1,840,103** |

**15. Income taxes**

The income taxes shown in the consolidated statements of comprehensive loss differ from the amounts obtained by applying statutory rates to the loss before income taxes due to the following:

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| | $ | $ | $ |
| Net loss for the year | (9,485,000) | (1,652,000) | (1,285,000) |
| Statutory tax rate | 27 % | 27 % | 27 % |
| Expected income tax recovery | (2,561,000) | (446,000) | (347,000) |
| Decrease to income tax recovery due to: | | | |
| Non-deductible permanent differences | 172,000 | 135,000 | 79,000 |
| Temporary differences | (361,000) | (516,000) | 6,000 |
| (Over) under provided in prior years | (722,000) | — | (278,000) |
| Change in tax assets not recognized | 3,472,000 | 827,000 | 540,000 |
| Income tax recovery | — | — | — |

(Expressed in Canadian Dollars)

**15. Income taxes (continued)**

The significant components of the Company's deferred tax assets are as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| | $ | $ |
| Share issuance costs | 700,000 | 529,000 |
| Cumulative eligible capital | 112,000 | 105,000 |
| Operating losses carried forward | 4,975,000 | 1,652,000 |
| Total deferred tax assets | 5,787,000 | 2,286,000 |
| Deferred tax assets not recognized | (5,787,000) | (2,286,000) |
| | — | — |

The realization of income tax benefits related to these deferred potential tax deductions is not probable. Accordingly, no deferred income tax assets have been recognized for accounting purposes. The Company has Canadian non-capital losses carried forward of approximately $18,427,000 that may be available for tax purposes. The losses expire as follows:

| Expiry date | $ |
|---|---|
| 2032 | 44,000 |
| 2033 | 748,000 |
| 2034 | 325,000 |
| 2035 | 286,000 |
| 2036 | 365,000 |
| 2037 | 618,000 |
| 2038 | 1,089,000 |
| 2039 | 554,000 |
| 2040 | 1,116,000 |
| 2041 | 3,648,000 |
| 2042 | 9,634,000 |
| Total | 18,427,000 |

**16. Financial instruments and risk management**

The Company's financial instruments consist of cash and cash equivalents, accounts payable and accrued liabilities, lease obligation, and derivative warrant liability. The fair values of cash and cash equivalents and accounts payable and accrued liabilities approximate their carrying values at December 31, 2022, due to their short-term nature. The lease liability is classified as level 2 in the fair value hierarchy as the fair value is determined based on market interest rates.

The following table presents the Company's financial instruments, measured at fair value on the consolidated statements of financial position as at December 31, 2022 and 2021 and categorized into levels of the fair value hierarchy:

| | | December 31, 2022 | | December 31, 2021 | |
|---|---|---|---|---|---|
| | Level | Carrying Value | Estimated Fair Value | Carrying Value | Estimated Fair Value |
| **FVTPL** | | $ | $ | $ | $ |
| Cash and cash equivalents | 1 | 14,125,522 | 14,125,522 | 18,851,244 | 18,851,244 |
| **Financial liabilities at amortized cost** | | | | | |
| Accounts payable and accrued liabilities | 1 | 1,960,745 | 1,960,745 | 700,999 | 700,999 |
| Lease liability | 2 | 105,105 | 105,105 | — | — |
| **FVTPL** | | | | | |
| Derivative warrant liability | 3 | 5,220,649 | 5,220,649 | 4,597,332 | 4,597,332 |

There were no transfers for levels of change in the fair value measurements of financial instruments for the years ended December 31, 2022 and 2021.

(Expressed in Canadian Dollars)

**16. Financial instruments and risk management (continued)**

Risk management is carried out by the Company's management team with guidance from the Board of Directors. The Company's risk exposures and their impact on the Company's financial instruments were as follows:

**a) Credit risk**

Credit risk is the risk of financial loss to the Company if a customer of counterparty to a financial instrument fails to meet its obligations. The Company's maximum exposure to credit risk at the financial position date under its financial instruments is summarized as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| | $ | $ |
| **Cash and cash equivalents** | 14,125,522 | 18,851,244 |

All of the Company's cash is held with major financial institutions in Canada and management believes the exposure to credit risk with such institutions is minimal. The Company considers the risk of material loss to be significantly mitigated due to the financial strength of the major financial institutions where cash is held. The Company has no exposure to the ongoing banking crisis. The Company's maximum exposure to credit risk as at December 31, 2022 and 2021 is the carrying value of its financial assets.

**b) Liquidity risk**

Liquidity risk is the risk that the Company will not be able to meet its obligations associated with financial liabilities. The Company has a planning and budgeting process in place by which it anticipates and determines the funds required to support normal operation requirements as well as the growth and development of its intellectual property portfolio.

The Company's financial assets are comprised of its cash and cash equivalents, and the financial liabilities are comprised of its accounts payable and accrued liabilities, lease liability and derivative warrant liability.

The contractual maturities of these financial liabilities as at December 31, 2022 and 2021 are summarized below:

| | Payments due by period as of December 31, 2022 | | | |
|---|---|---|---|---|
| | Total | Less than 3 months | Between 3 months and 1 year | 1-3 years |
| | $ | $ | $ | $ |
| Accounts payable and accrued liabilities | 1,960,745 | 1,960,745 | — | — |
| Lease liability | 105,105 | 22,379 | 67,138 | 15,588 |
| | 2,065,850 | 1,983,124 | 67,138 | 15,588 |

| | Payments due by period as of December 31, 2021 | | | |
|---|---|---|---|---|
| | Total | Less than 3 months | Between 3 months and 1 year | 1-3 years |
| | $ | $ | $ | $ |
| Accounts payable and accrued liabilities | 700,999 | 700,999 | — | — |
| | 700,999 | 700,999 | — | — |

**16. Financial instruments and risk management (continued)**

**b) Market risk**

i) Interest Rate Risk

Interest rate risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate due to changes in market interest rates. The Company's bank accounts bear interest. Management believes that the credit risk concentration with respect to financial instruments included in cash and cash equivalents is minimal.

ii) Foreign Currency Risk

As at December 31, 2022, the Company is exposed to currency risk on the following financial assets and liabilities denominated in US Dollars ("USD"), British Pounds ("GBP"), and European Euro ("EUR"). The sensitivity of the Company's net earnings due to changes in the exchange rate between the USD, GBP and EUR against the Canadian dollar is included in the table below in Canadian dollar equivalents:

| | USD | GBP amount | EUR | Total |
|---|---|---|---|---|
| | $ | $ | $ | $ |
| Cash | 12,907,255 | — | — | 12,907,255 |
| Accounts payable and accrued liabilities | (1,466,309) | (45,755) | (11,747) | (1,523,811) |
| **Net exposure** | 11,440,946 | (45,755) | (11,747) | 11,383,444 |
| | | | | |
| **Effect of +/- 10% change in currency** | 1,144,095 | (4,576) | (1,175) | |

The Company thoroughly examines the various financial instruments and risks to which it is exposed and assesses the impact and likelihood of those risks. These risks include foreign currency risk, interest rate risk, market risk, credit risk, and liquidity risk. Where material, these risks are reviewed and monitored by the Board of Directors

There have been no changes in any risk management policies since December 31, 2022.

**17. Capital management**

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

Since inception, the Company's objective in managing capital is to ensure sufficient liquidity to finance its research and development activities, general and administrative expenses, expenses associated with intellectual property protection and its overall capital expenditures. There were no changes during the year ended December 31, 2022. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

**18. Commitments**

The Company has long-term arrangements with commitments that are not recognized as liabilities as at December 31, 2022 and 2021 as follows:

**a) Employment Agreements**

(Expressed in Canadian Dollars)

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| | $ | $ |
| Management services – officers | 502,320 | 476,000 |

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

The CFO of the Company has a long-term employment agreement with the Company. The agreement has a termination clause whereby he is entitled to the equivalent of 12 times his then current monthly salary which as of December 31, 2022 and 2021, equated to an annual salary of $192,000.

**b) Payments**

In the normal course of business, the Company has committed to payments totaling $2,701,114 (2021 - $1,613,142) for activities related to its clinical trial, manufacturing, collaboration programs and other regular business activities which are expected to occur over the next two years.

**19. Segmented information**

The Company operates in one reportable operating segment, being the development and commercialization of therapies to treat progressive kidney disease. As the operations comprise a single reporting segment, amounts disclosed also represent segment amounts. All long-term assets of the Company are located in Canada.

**Exhibit 4.18**

# MASTER SERVICES AGREEMENT

(For All CRO Services)

This Master Services Agreement (this "Agreement") is made as of the 20th day of July, 2017 (the "Effective Date") by and between Cato Research Canada Inc., a Quebec corporation headquartered at 9900 Cavendish Boulevard, Suite 300, Saint-Laurent, Quebec, Canada H4M 2V2 ("CRC"), and XORTX Pharma Corp., a form of organization with offices located at 4000, 421 7th Avenue SW, Calgary, Alberta, Canada T2P 4K9 ("XORTX"). Each of CRC and XORTX may be referred to herein separately as a "Party" and collectively as the "Parties." As used in this Agreement, "Affiliate(s)" means any corporation, firm, partnership, or other entity which controls, is controlled by or is under common control with a Party. For the purpose of this definition, "control" shall mean the power to direct, or cause the direction of, the management and policies of an entity through the ownership, directly or indirectly, of at least fifty percent (50%) of the voting share capital of such entity or any other comparable equity, by contract, or by ownership interest.

**WHEREAS**, XORTX is engaged in the evaluation, development, commercialization or marketing of biologics, pharmaceutical agents, medical devices and/or other life sciences technologies (collectively, "Products"); and

**WHEREAS**, CRC is a contract research and development organization providing a broad range of services for the evaluation, development, commercialization or marketing of new biologics, pharmaceutical agents, medical devices and/or other life sciences technologies; and

**WHEREAS**, XORTX wishes to retain CRC, and CRC wishes to be retained by XORTX, to assist XORTX with certain aspects of the evaluation, development, commercialization or marketing of such Products or otherwise to provide certain consulting services as specified by XORTX from time to time; and

**NOW, THEREFORE**, in consideration of the foregoing premises and the promises, benefits, rights, and obligations set forth below, the Parties agree as follows:

1. **Work Orders for CRO Services**.

1.1 CRC shall provide services to XORTX, as requested by XORTX from time to time in accordance with the terms of this Agreement (the "CRO Services"). Requested CRO Services may include any area of services customarily undertaken by CRC, including without limitation the areas of clinical trials, clinical monitoring, site management, medical monitoring and pharmacovigilance or safety services.

1.2 If XORTX wants CRC to perform CRO Services and CRC wishes to perform such Services, the Parties shall prepare a Work Order in a form acceptable to both Parties, which Work Order shall contain, at a minimum, the CRO Services to be performed and the compensation therefore. It may also include any other requirements or obligations agreed upon by the Parties and not set forth herein. If CRC submits a proposal and such proposal is executed by both Parties with the intent that it be performed as a Work Order then it shall be deemed a Work Order. Each Work

Order shall be deemed a part of this Agreement and incorporated into it, but no Work Order shall be deemed part of another Work Order unless specifically so stated in the applicable Work Order.

1.3 CRC shall not be obligated to perform the CRO Services described in any proposal, draft work order or similar document until such time as the Work Order related to such CRO Services has been signed by both Parties.

1.4 If the terms of a Work Order conflict with those of this Agreement, then the terms of this Agreement shall control unless otherwise specifically stated in the Work Order. If either Party sends a purchase order, confirmation, or similar form, then the terms of this Agreement and not those in such additional document shall control; the Parties agree that any additional or different terms in such form, now or in the future, are void even if the form indicates that it shall control.

1.5 Unless a Work Order specifies to the contrary, CRC may subcontract some or all of its obligations under such Work Order to an Affiliate provided that such Affiliate is bound by confidentiality obligations at least as protective of XORTX's confidential information as those in this Agreement. CRC shall be equally responsible for the performance of such Affiliate as CRC would be if it performed such obligations itself.

1.6 If a Work Order is unclear, ambiguous, or permits different understandings of the CRO Services to be performed, the Parties shall use good faith efforts to resolve such ambiguity, it being understood that such resolution may result in an adjustment to the budgeted costs.

1.7 If the scope or definition of the CRO Services changes, including without limitation a change in the number of units of any CRO Services as specified in the budget for the applicable Work Order, and the additional cost of such additional CRO Services does not exceed ten percent (10%) of the budget for the CRO Services as set forth in the applicable Work Order, CRC will notify XORTX of the changes and, upon XORTX's written or email authorization, will commence performance of the additional CRO Services without a formal Work Order amendment. CRC will thereafter formalize the changes by providing to XORTX a formal amendment to the Work Order reflecting the authorized changes; XORTX shall timely sign such amendment, but shall nevertheless be obligated to pay for the additional CRO Services based on the previously-given authorization to proceed even if the Work Order amendment is never signed. The same process shall be followed with respect to changes requested in excess of ten percent (10%) of the applicable budget; provided however, CRC shall not be obligated to commence performance of the additional CRO Services without a prior written Work Order amendment signed by XORTX.

1.8 If any regulations to which the CRO Services are subject are modified, CRC is hereby authorized, without any action required on the part of XORTX, to immediately commence undertaking the CRO Services in compliance with the revised regulations without a formal amendment to the applicable Work Orders. To the extent that compliance with the revised regulations results in an increased cost of the CRO Services, CRC will thereafter formalize the changes by providing to XORTX a formal amendment to the Work Order reflecting the changes to the cost of the CRO Services reasonably and necessarily incurred as a result of the regulatory changes. XORTX shall timely sign such amendment, but shall nevertheless be obligated to pay for

necessary and reasonable additional CRO Services to address the regulatory changes, even if the Work Order amendment is never signed.

1.9 Unless specifically included in an applicable Work Order, CRC will not collect or report to XORTX any payments made which may be reportable under the Physicians Payment Sunshine Act. If collection and reporting obligations are specified in an applicable Work Order, CRC shall report the required information based no payments made by CRC, and CRC shall have no obligations with respect to any payments made by XORTX; XORTX shall aggregate its own information from all sources and make its report to the Centers for Medicare and Medicaid Services.

1.10 Subject to the terms of Section 1.7 or 1.8, a Work Order may only be amended in writing with the signature of both Parties.

2. **Performance of CRO Services**.

2.1 CRC shall use commercially reasonable efforts to perform the CRO Services in accordance with the specifications, instructions, and guidelines in each Work Order and this Agreement in all material respects. CRC shall use its own protocols in the performance of CRO Services unless specified to the contrary in the applicable Work Order.

2.2 All CRO Services performed by CRC shall be performed in conformity with all applicable international, federal, state and local laws and regulations, including without limitation, as applicable, current Good Laboratory Practices, Good Manufacturing Practices, Good Clinical Practices, ICH Guidelines, and all applicable FDA regulations.

**3. XORTX Obligations.** XORTX shall undertake the following obligations with respect to the performance of this Agreement, in addition to any other obligations outlined herein or in the applicable Work Order.

3.1 XORTX shall use commercially reasonable efforts to deliver all information and materials reasonably required for CRC's performance of CRO Services in accordance with mutually agreed upon timelines.

3.2 XORTX shall immediately inform CRC of any safety concerns or serious adverse events related to a Product ₹hat is the subject of the CRO Services.

3.3 XORTX shall use commercially reasonable efforts to not take any actions or participate in any activities that are intended to, or can be reasonably expected to, disrupt or interfere with CRC's obligations under this Agreement.

3.4 CRC believes all data, information and analysis provided and all reports generated as Deliverables (as defined below) will be accurate and reliable, but XORTX is ultimately and solely responsible for its use of the Deliverables or other matter or information produced or provided under this Agreement.

4. **Compensation**.

4.1 XORTX shall pay CRC for the CRO Services as specified in the Work Order governing such CRO Services. If travel time is not included in the applicable unit price on the Work Order, then it shall be billed as out of scope work time, with the understanding that, to the extent practical, travel time shall be used to perform CRO Services for XORTX.

4.2 Unless otherwise specified in the applicable Work Order, XORTX shall reimburse CRC for out-of-pocket expenses reasonably incurred in performance of the CRO Services under this Agreement including, but not limited to, third-party fees and expenses, pass-through expenses, telephone, facsimile, messenger, postage and other communication costs, document copying and retrieval, on-site and off-site storage fees, computer research fees and filing fees, reasonable transportation, lodging, and meal expenses for travel to sites away from CRC's office, and travel between CRC offices (collectively, "Expenses"); provided however, that advanced written approval is required from XORTX for any Expense which exceeds five hundred Canadian dollars (C$500). To the extent CRC pays fees to any third party on behalf of XORTX with respect to which payments a form of administrative fee is not specifically covered in the applicable Work Order, then a two percent (2%) administrative charge shall be assessed by CRC and paid with respect to each such payment by CRC.

4.3 Invoices for CRO Services and Expenses shall be in Canadian dollars unless the Work Order related to such CRO Services or Expenses specifies a different currency shall be sent monthly, and shall itemize the CRO Services performed and Expenses incurred. XORTX shall pay all invoices in the currency of the invoice within thirty (30) days of the date of the invoice via wire transfer, per wire instructions which shall be provided by CRC. In addition to paying the amount due with respect to CRO Services and Expenses, XORTX shall also make additional payments for any federal, state, county, local or governmental taxes, duties, excise taxes, now or hereafter applied including sales tax, value added tax, or any similar tax. No deduction shall be made from the amount due or paid as a result of any taxes or withholding that may occur by governments with respect to payments made to CRC from outside Canada or as a result of any taxes paid by XORTX. Except as specified in Section 4.4, payment shall be in the full amount specified on the invoice. Except as otherwise set forth below or in an applicable Work Order, any and all payments made hereunder are nonrefundable.

4.4 If XORTX disputes the amount due on any invoice, then XORTX must notify CRC of such dispute before the payment due date and pay such amount as is undisputed by the payment due date. Both Parties shall act in good faith to promptly resolve such dispute, and upon resolution of the dispute, any amount remaining due shall be paid within fifteen (15) days after the resolution.

4.5 If all or any undisputed portion of an invoice remains unpaid when due, then such unpaid portion shall accrue a finance charge of 1.25% per month from the date of the invoice until paid. For the avoidance of confusion, in calculating finance charges related to disputed invoices, an invoice (or portions thereof, as applicable) shall be deemed to have been due such that finance charges begin to accrue: (a) thirty (30) days after the date of the original invoice if the invoice is determined to have been correct; or (b) if the dispute relates to incomplete or incorrect work then fifteen (15) days after the date on which it is determined all obligations for payment of each

disputed amount were met under the Work Order such that payment of such amount should have been made. XORTX shall reimburse CRC on demand for all reasonable out-of-pocket costs and expenses CRC incurs in enforcing payment of an overdue invoice, including, without limitation, attorneys' fees and expenses. Payments received from XORTX by CRC on an overdue invoice shall be first applied to costs of collection, then to accrued interest, and then to the unpaid balance of the invoice. If XORTX has more than one overdue invoice, CRC may, in its discretion, allocate collection costs among the invoices and apply payments against the invoices.

4.6 Except as otherwise set forth herein, any and all payments made hereunder are nonrefundable.

5. **Term and Termination**.

5.1 The term of this Agreement shall be five (5) years from the Effective Date and it shall automatically renew for additional one (1) year terms unless, at least sixty (60) days before the expiration of any term, a Party gives written notice to the other Party that it does not want to renew this Agreement; provided however, that if the term of a Work Order extends beyond the term of this Agreement, then this Agreement will continue in effect as to that Work Order (only) until the completion or termination of such Work Order and all wind-down CRO Services related to such Work Order.

5.2 Either Party may terminate a Work Order upon the other Party's material default under this Agreement with respect to such Work Order, provided that the terminating Party has given the defaulting Party not less than thirty (30) days' prior written notice of such default and the defaulting Party has not cured such default by the end of the notice period. Termination of a Work Order based on an uncured default does not give rise to the right to terminate any other Work Order or this Agreement.

5.3 Except with respect to Work Orders for clinical trials, either Party may terminate a Work Order at any time upon no less than sixty (60) days' prior written notice to the other Party. With respect to Work Orders for clinical trials, only XORTX may terminate at any time upon no less than sixty (60) days' prior written notice to CRC.

5.4 Upon early termination of a Work Order, CRC shall invoice XORTX and XORTX shall pay CRC for all CRO Services rendered and Expenses incurred through the date of termination in accordance with Section 4 above. CRC's compensation under any Work Order being paid on a fixed-fee basis or on any payment schedule which is other than either time-and-materials or a unit-based budget, the Work Order shall be converted to a time-and-materials basis in accordance with CRC's current rates, and CRC shall be paid for all CRO Services performed and Expenses incurred through the date of termination.

5.5 If XORTX terminates a Work Order under Section 5.3 or CRC terminates a Work Order under Section 5.2, then, in addition to payments made under Section 5.4, XORTX shall (a) reimburse CRC for any and all non-cancelable obligations of CRC to third parties related to the terminated Work Order, and (b) XORTX shall also pay CRC (i) twenty-five percent (25%) of the estimated remaining unbilled amounts associated with the Work Order if the termination is due to

discontinuance of the clinical trial being performed by CRC under the Work Order as a result of adverse events or order of the FDA or other applicable regulatory authority, or (ii) forty percent (40%) of the estimated remaining unbilled amounts associated with the Work Order in all other circumstances. In calculating the termination fee with respect to any Work Order being paid on a fixed-fee basis CRC shall be entitled to the applicable percentage of the remaining fixed fee after deduction of the payments already made for CRO Services. CRC shall use its best efforts to mitigate any costs to XORTX and avoid incurring any non-cancelable obligations after its receipt of notice of termination,

5.6 Any termination fee paid pursuant to Section 5.5 shall provide XORTX with a "Termination Credit" in the amount paid. The Termination Credit will be applied, until used in full or its expiration, as payment for 50% of the Fees on any "New Work Order." As used in the preceding sentence, "New Work Order" shall mean any Work Order (a) for which the CRO Services commence not later than twelve (12) months after termination of the Work Order with respect to which the credit was created; and (b) which is for new CRO Services which are both (i) unrelated to the terminated Work Order and (ii) are not out-of-scope amendments for any Work Order already in effect. If no New Work Order is executed such that the CRO Services commence not later than twelve (12) months after termination of the Work Order with respect to which the credit was created, the Termination Credit shall expire.

5.7 Upon early termination of a Work Order, CRC shall inform XORTX of the extent to which it expects work in progress to be completed as of the termination date and CRC shall (unless otherwise instructed by XORTX) take steps to wind-down work in progress in an orderly fashion. In addition to all other amounts payable to CRC, XORTX shall pay CRC for such wind-down CRO Services on a time-and-materials basis at CRC's current rates for all reasonable and customary wind-down CRO Services performed and Expenses incurred by CRC. If XORTX instructs CRC not to complete such wind-down CRO Services, CRC shall, upon notification of the termination of the Work Order, promptly cease providing CRO Services and incurring costs to the extent practicable. In any such event, XORTX shall be deemed to have released CRC from all legal liability and to have covenanted not to sue CRC on any claims related to failure to perform and the failure to complete reasonable and customary wind-down CRO Services.

5.8 In addition to termination of this Agreement under Sections 5.1-5.3, at any time CRO Services under all Work Orders have been completed or terminated such that there is no request for CRO Services pending, either Party may terminate this Agreement by giving written notice of termination to the other Party.

5.9 The remedies set forth in this Section 5 are not meant to limit any additional remedies available to a Party for breach of this Agreement by the other Party.

6. **Suspension of CRO Services**.

6.1 If XORTX should, for any reason, suspend the CRO Services to be provided under any Work Order for a period of thirty (30) days, then at the end of such thirty (30) day period CRC may invoice XORTX and XORTX shall pay for all CRO Services which have been performed through the date of suspension which have not been invoiced previously. For any Work Order

being paid on a unit-based budget basis, payment shall be made for each partially completed unit on a time-and-materials basis related to the CRO Services undertaken for each such unit. For any Work Order being paid on a fixed-fee basis or on any payment schedule which is other than either time-and-materials or a unit-based budget, all CRO Services performed shall be converted to a time-and-materials basis in accordance with CRC's current rates and CRC shall be paid for all CRO Services performed and Expenses incurred through the date of suspension.

6.2 CRC may in its sole discretion suspend its performance of CRO Services if an undisputed invoice is sixty (60) days or more overdue, and CRC may refrain from resuming performance of CRO Services until all overdue undisputed invoices have been paid in full. If CRC should suspend the CRO Services pursuant to this Section 6.2, and in the further event that the suspension shall remain in place for a period of at least thirty (30) days, then at the end of such 30-day period, CRC may invoice XORTX and XORTX shall pay for all CRO Services which have been performed through the date of suspension which have not been invoiced previously in the same manner as set forth in Section 6.1.

6.3 Any CRO Services performed related to a Work Order, during a period when it is under suspension shall be invoiced on a time-and-materials basis at CRCS's then-current rates.

6.4 Upon suspension of CRO Services, CRC may reassign its personnel assigned to the suspended Work Order unless a retainer fee in an amount to be agreed upon by the Parties at such time is paid in advance of each month during which XORTX wishes to reserve the assigned personnel. Payment of such retainer will ensure CRC will not reassign the designated personnel such that they are unavailable to provide the CRO Services upon resumption of CRO Services.

6.5 If any suspension initiated continues for a period of ninety (90) days, then unless either a retainer is being paid pursuant to Section 6.4 or the Parties agree to the contrary, at the end of the 90-day period the Work Order shall be deemed terminated either by XORTX without cause or by CRC with cause, as applicable, such that the terms of Section 5.5 shall apply.

6.6 The resumption of CRO Services after any suspension shall be subject to any additional costs which may be incurred as a result of the Work Order having been suspended and then restarted, including without limitation the training of new personnel if the retainer has not been paid for personnel to remain with the project.

7. **Confidential Information**.

7.1 For purposes of this Section, the Party disclosing Confidential Information is known as "Disclosing Party" and the Party receiving information is known as "Receiving Party." As applied to CRC, each of these terms shall include CRC and any applicable Affiliates within the definition.

7.2 "Confidential Information" means: (i) all information furnished by the Disclosing Party to the Receiving Party in tangible, visible, electronic or verbal form or by observation or by any other means, including, but not limited to, business plans, protocols, processes, samples, formulae, chemical entities, compounds, mixtures, prospective and current products, clinical data and analyses, test results, toxicology and pharmacology information, study procedures and

manuals, pharmacy dispensing instructions, case report forms and their content, statistical reports, project management and staffing, manufacturing processes, nonpublished patent applications, financial data, forecasts and projections, proprietary software and database structures, research, "know-how," technology under development, marketing information, agreements with or proprietary information of third parties, licensors and licensees and strategic partners, regardless of whether such disclosures are marked or otherwise designated as "Confidential"; and (ii) the terms and conditions of this Agreement, all proposals and requests for proposals (including those submitted to the Receiving Party prior to the date of this Agreement and marked as Confidential at the time of delivery), and the existence of the discussions between the Parties to which this Agreement pertains.

7.3 No information shall be within the above definition of Confidential Information if it:

(a) is generally known to the public at the time the Disclosing Party discloses it to any Receiving Party;

(b) becomes generally known to the public subsequent to the time of the Disclosing Party's disclosure to any Receiving Party without any fault or disclosure on the part of such Receiving Party;

(c) was known to any Receiving Party prior to the disclosure by the Disclosing Party, free of any obligation of confidence, as evidenced by such Receiving Party's written records;

(d) is independently developed by such Receiving Party without reference to or reliance on the Confidential Information as evidenced by Receiving Party's written records;

(e) is, to such Receiving Party's knowledge, rightfully communicated to it free of any obligation of confidence by anyone who is not a Party to this Agreement; or

(f) is communicated by the Disclosing Party free of any obligation of confidence to anyone that is not a Party to this Agreement.

By way of example and not limitation, information is not generally known to the public if it is not available without considerable research or if it can be primarily located in cached memories of materials otherwise deleted from internet sources. Notwithstanding the foregoing, specific Confidential Information shall not be deemed to be within any of the foregoing exclusions merely because it is within the scope of more general information within one or more of the exclusions. Further, any combination of Confidential Information (whether or not combined with non-confidential information) shall not be deemed to be within the above exceptions merely because one or more individual items of Confidential Information are within the above exceptions. In furtherance but not limitation of the preceding sentence, any combination of items of Confidential Information shall not be deemed to fall within the foregoing exclusions merely because any or all of the items are published or otherwise in the rightful possession of the Receiving Party unless the combination itself and the principle of its use are published or otherwise in the rightful possession of the Receiving Party.

7.4 Receiving Party shall neither use nor reproduce Disclosing Party's Confidential Information except as necessary for: (a) negotiations, discussions and consultations with the personnel or authorized representatives of Disclosing Party; or (b) for the purpose of performing its obligations under this Agreement. Upon completion of the obligations under this Agreement that use the Confidential Information, or upon termination of this Agreement, Receiving Party shall, when requested by Disclosing Party in writing, promptly return to Disclosing Party all of the Confidential Information provided by Disclosing Party, except that Receiving Party may retain one (1) copy for recordkeeping purposes and Receiving Party shall not be required to remove or destroy any Confidential Information contained on backup media as a result of systematic backups of Receiving Party's computer system, provided that Receiving Party shall not access such backup media for the purpose of recovering the Confidential Information.

7.5 Receiving Party shall not disclose, without the prior written consent of Disclosing Party, any of Disclosing Party's Confidential Information to any third party other than Receiving Party's, and its Affiliates', directors, officers, employees, agents and consultants, hospital or institution authorities, Institutional Review Board members, clinical investigators, and others who are involved in fulfilling Receiving Party's obligations under this Agreement and who, in each case, (a) need to know such information for the purposes of performing such obligations and (b) are bound by obligations of confidentiality and non-use at least as restrictive as those set forth herein. With respect to the obligation in 7.5(b) it shall be deemed met as to disclosures by CRC of XORTX's confidential information if XORTX has in place a nondisclosure agreement with the third party related to XORTX's Confidential Information. Receiving Party shall take commercially reasonable steps to prevent the disclosure or use of any such Confidential Information by Receiving Party's, and its Affiliates', directors, officers, employees, agents or consultants except as provided in this Agreement.

7.6 If any Disclosing Party's Confidential Information is required to be disclosed by Receiving Party to any government or regulatory authority or court entitled by law to disclosure of the same, Receiving Party shall not, unless required by law, order, regulation or ruling, disclose Confidential Information until the Disclosing Party has first (a) received prompt written notice of such requirement to disclose and (b) had an adequate opportunity to obtain a protective order or other reliable assurance that confidential treatment will be accorded to the Confidential Information required to be disclosed. The Receiving Party shall, at the expense of the Disclosing Party, provide the Disclosing Party with any reasonable assistance requested, and shall not oppose reasonable actions by the Disclosing Party to assure confidential treatment. If the Disclosing Party is unable to obtain such protective order or other appropriate remedy, the Receiving Party and its Representatives will furnish only that portion of the Confidential Information which it is legally required to furnish. Any disclosure of Confidential Information pursuant to this Section 7.6 shall not affect or lessen the Receiving Party's obligations hereunder.

7.7 For purposes of this Agreement, the Parties hereby acknowledge and agree that, subject to the exceptions set forth in Section 7.3, this Agreement shall be considered XORTX's Confidential Information; provided however, that either Party may disclose the terms of this Agreement to advisors, investors and others on a need-to-know basis under circumstances that reasonably ensure the confidentiality, nondisclosure and nonuse thereof

7.8 Receiving Party's obligations under this Section 7 shall terminate with respect to any Confidential Information of Disclosing Party five (5) years after the date of disclosure.

**8. Protected Health information.** The Parties recognize that the Act Respecting the Protection of Personal Information in the Private Sector requires CRC to protect the privacy and security of protected health information that may be acquired in the course of performing this Agreement. The Parties agree to comply with this statute and other applicable laws and governmental regulations governing protected confidential health information.

9. **Ownership**.

9.1 Upon the creation of each Deliverable, XORTX is granted a license to use the Deliverable for the purpose contemplated by the Parties at the time of its creation. Such license shall terminate upon the earliest of the following: (a) payment of all amounts invoiced for the Deliverable, at which time XORTX shall own all right, title, and interest in and to all data, information, improvements, discoveries, inventions, printed materials, and other work product contained therein which is specific to the Deliverable; or (b) the passage of three (3) months after delivery of the applicable invoice without payment and without any notification from XORTX that there is a dispute about the invoice; or (c) the passage of one (1) year after delivery of a disputed invoice with no resolution, provided however, if at such time the invoice is in the process of formal dispute resolution in mediation, court or arbitration, then thirty (30) days after the date on which the amount due is finally determined by the finder of fact or by settlement. To the extent not covered by the preceding sentence, and except as limited by Section 9.2, all copyrights, patents, trade secrets, or other intellectual property rights associated with any ideas, concepts, techniques, inventions, processes, or works of authorship included in the Deliverable shall be treated in the same manner as the Deliverable and as specified in the preceding sentence. At such time as XORTX owns the Deliverable and all intellectual property rights related thereto, CRC irrevocably assigns and transfers to XORTX any and all right, title, or interest CRC may have in such Deliverable. Upon request of XORTX and at XORTX's expense, CRC shall take such further actions, including execution and delivery of instruments of conveyance necessary to obtain legal protection in the United States and foreign countries for such Deliverable and for the purpose of vesting title thereto in XORTX. As used herein, "Deliverable" shall mean reports, information or other matters which are physically delivered (whether in hard copy or electronically) to XORTX in accordance with the terms of the Work Order. To the extent the Work Order requires CRC to undertake general consulting services pursuant to which CRC provides generic explanations or information, only such part of any deliverable which contains XORTX-specific analysis shall be deemed a Deliverable subject to the terms of this Section 9.1. Notwithstanding any other provision of this Agreement to the contrary, (x) with respect to Deliverables relating to an invoice for which only a portion of amount due is disputed, if the disputed and unpaid amount is the lesser of (i) twenty-five thousand dollars ($25,000) or (ii) an amount not to exceed 20% of the amount invoiced for the Deliverable, and if XORTX has paid in full the undisputed amount, then upon such payment XORTX shall own all right, title, and interest in and to such Deliverable and (y) CRC may not transfer or place any liens or encumbrances on the applicable Deliverable until all disputes relating to the invoice for the Deliverable have been finally adjudicated in accordance with this Agreement.

9.2 Notwithstanding the foregoing Section 9.1, XORTX acknowledges that within the scope of the business practices of CRC and its Affiliates, they possess certain inventions, processes, know-how, trade secrets, improvements, other intellectual property and business assets, including forms, templates, analytical methods, protocols, procedures and techniques, computer technical expertise and software, independently developed or otherwise owned by CRC and its Affiliates and not specifically related to the Deliverables. In addition, during the course of performing or incidental to the CRO Services, CRC or its Affiliates may develop forms, templates, analytical methods, protocols, procedures and techniques, functions, computer code, database structures and other property that are not specific to the general functionality of the Deliverables, not specific to any Product unique to XORTX, and which does not in its generic form rely on or otherwise incorporate any Confidential Information of XORTX (collectively, the "Cato Property"). XORTX and CRC agree that any Cato Property used, improved or modified by CRC or its Affiliates under or during the term of this Agreement shall be deemed Cato Property and owned solely by CRC or its Affiliates. If any Cato Property is incorporated into the Deliverables, then CRC hereby grants to XORTX a fully paid-up, non-exclusive, perpetual worldwide license to use such Cato Property (without representation or warranty and without right to sublicense or otherwise transfer without the prior written consent of CRC), to the extent necessary to use such Deliverables as was anticipated by the Parties.

9.3 CRC and its Affiliates shall be free to use and employ the general skills, know-how, and expertise of their employees, and to use, disclose, and employ any generalized ideas, concepts, know-how, methods, techniques, or skills gained or learned by their employees and consultants during the course of any assignment, so long as they acquire and apply such information without disclosure of any Confidential Information of XORTX and without any unauthorized use or disclosure of any Deliverable.

10. **Representations and Warranties**.

10.1 CRC represents and warrants that CRC has the experience, capability, personnel and resources necessary to perform CRO Services under this Agreement and each Work Order in a commercially reasonable manner.

10.2 XORTX represents and warrants that it has the ability to comply with and perform all financial obligations under this Agreement. XORTX further represents and warrants that it owns or otherwise has all necessary rights in and to the Product and all intellectual property rights therein (including without limitation the patent rights in all Products) so as to permit use of the Product and such intellectual property by CRC as contemplated in each Work Order: no third party has any right to prevent or to claim a payment is due from CRC as a result of its use of any Product or of the intellectual property rights therein as contemplated in any Work Order.

10.3 Each Party represents and warrants that (a) it has the corporate power and authority to enter into and perform its obligations under this Agreement and any Work Order; and (b) entering into and performing this Agreement and any Work Order will not conflict with or result in a violation of any of the terms or provisions, or constitute a default under any of its organizational documents, any mortgage, indenture, lease, contract or other agreement or instrument binding upon it or by which any of its properties are bound, or any permit, concession,

franchise, license, judgment, order, decree, statute, law, ordinance, rule or regulation applicable to it or its properties.

10.4 Except as set forth in this Section 10, CRC makes no warranty, either express or implied, including without limitation the warranties of merchantability, fitness for a particular purpose, title and non-infringement as to any matter, and further including but not limited to the CRO Services, results of CRO Services, any Deliverables or any other matter or information produced or provided under this Agreement. Without limiting the foregoing, CRC does not warrant, guarantee, or make any warranty regarding the use, or the results of the use, of the Deliverable, reports, analyses, documents, memoranda or any other matter or information produced or provided under this Agreement.

11. **CRC Personnel**.

11.1 CRC shall be responsible for all aspects of the labor relations of the personnel undertaking the CRO Services including, but not limited to, wages, benefits, discipline, hiring, firing, promotions, pay raises, overtime, and job assignments. XORTX shall have no power or authority in these areas. CRC shall ensure the payment of all contributions and taxes imposed by any federal or state governmental authority with respect to or measured by wages, salaries, or other compensation paid to persons employed to undertake the CRO Services.

11.2 XORTX understands that the performance of CRO Services requires special skills, training and experience. XORTX further understands that CRC and its Affiliates have expended considerable sums to train their personnel to perform the CRO Services requested by XORTX from time to time under this Agreement, and CRC will give XORTX access to experienced and highly skilled practitioners. When CRC or its Affiliates lose personnel, CRC or its applicable Affiliate incurs significant expenses in hiring and training his or her replacement. Accordingly, during the term of this Agreement and for a period of one (1) year after the termination or expiration of the last Work Order to terminate or expire under this Agreement, XORTX agrees that it will not without CRC's written permission and payment of a fee, hire as an employee or independent contractor any employee or independent contractor of CRC or its Affiliates who has participated in the performance of CRO Services under this Agreement until after the date on which such person has ceased to be employed or retained by CRC or its applicable Affiliate for a period of not less than twelve (12) months. If permission is given, XORTX will pay CRC, or the applicable CRC Affiliate, a fee equal to the first year annual guaranteed salary (base and any guaranteed bonus) of the hired person to reimburse CRC for the estimated costs of hiring and training replacement personnel. Such fee shall be paid in cash no later than thirty (30) days after the date on which such employee begins employment or contractual work with XORTX. Each CRC Affiliate shall be a third party beneficiary for the purposes of being able to enforce this Section 11.2.

12. **Indemnification**.

12.1 XORTX shall indemnify, defend and hold harmless each CRC Indemnified Party from and against all Losses resulting from, related to or (as appropriate) alleging any CRC Indemnified Conditions. The foregoing indemnification obligations of XORTX under this Section

12.1 shall not include any Losses incurred by CRC when, and to the extent that, such Losses result from or are related to (a) the negligence, intentional misconduct or intentional omission of the CRC Indemnified Party, (b) the breach of this Agreement by CRC, an Affiliate of CRC or any other person for whose actions CRC is liable under this Agreement or applicable law, or (c) the violation by CRC, its directors, officers, employees or agents of any applicable law, regulation or other government requirement where such violation was caused by the conduct of the relevant CRC Indemnified Party and where CRC is seeking indemnification due to such breach.

12.2 CRC shall indemnify, defend and hold harmless each XORTX Indemnified Party from and against all Losses resulting from, related to or (as appropriate) alleging any XORTX Indemnified Conditions,. The foregoing indemnification obligations of CRC under this Section 12.2 shall not include any losses incurred by XORTX when, and to the extent that, such Losses result or are related to (a) the negligence, intentional misconduct or intentional omission of the XORTX Indemnified Party; (b) the breach of this Agreement by XORTX, an affiliate of XORTX, or any other person for whose actions XORTX is liable under this Agreement or applicable law; or (c) the violation by XORTX, its directors, officers, employees or agents, of any applicable law, regulation or other governmental requirement. Notwithstanding the foregoing, CRC shall not be liable for, and this Section 12.2 does not require CRC to provide indemnification with respect to, the actions or omissions of any third party which CRC hires (excluding Affiliates of CRC) at XORTX's request to provide services hereunder.

12.3 If an Indemnified Party receives notice of any claims for which the Indemnified Party wishes to seek indemnity under this Agreement, then the Indemnified Party shall promptly provide prompt written notice of the claim no later than thirty (30) calendar days following its notice of the claim to the Party required to provide indemnification by Section 12.1 or 12.2. The failure of an Indemnified Party to promptly provide such notice will not relieve the indemnifying Party of any indemnification responsibility under this Section 12, except to the extent, if any, that such failure materially prejudices the ability of the Indemnifying Party to defend such claims. The indemnifying Party shall have the right to control the defense or settlement of the claims with counsel of its own choosing provided that such counsel is reasonably acceptable to the Indemnified Party and provided further that the Indemnified Party will he entitled, at the Indemnified Party's expense, to participate with its own counsel in such defense and settlement. The Indemnified Party shall at all times cooperate in the investigation and defense of such claims and promptly deliver to the indemnifying Party (or its counsel) such information related to the basis for the claims as the indemnifying Party (or its counsel) may reasonably request. If the indemnifying Party declines to assume defense of any claim, and it is later determined by a court of competent jurisdiction that such claim was eligible for indemnification under Section 12.1 or 12.2, as applicable, then within thirty (30) calendar days following such determination, the Indemnifying Party shall reimburse the Indemnified Party in full for all judgments, costs and expenses (including reasonable attorneys' fees) incurred in connection with such claim. The indemnifying Party shall not settle any claim without the prior written consent of the Indemnified Party if such settlement: (a) materially diminishes any of the Indemnified Party's rights under this Agreement and/or the Work Order or seeks to impose additional obligations on the Indemnified Party; or (b) arises out of or is a part of any criminal action, suit or proceeding or contains a stipulation or admission or acknowledgement of any liability or wrongdoing (whether in contract, tort or otherwise) on the part of the Indemnified Party.

12.4 Definitions. The following definitions apply in this Section 12:

(a) "CRC Indemnified Party" means CRC and its Affiliates and the directors, officers, employees, consultants and agents of CRC and/or its Affiliates.

(b) "XORTX Indemnified Party" means XORTX and its Affiliates and the directors, officers, employees, consultants and agents of XORTX and/or its Affiliates.

(c) "Indemnified Party" means either a CRC Indemnified Party or an XORTX Indemnified Party.

(d) "Losses" mean all liability, loss, costs, claims, damages, expenses, judgments, awards, and settlements, including (without limitation) actual attorneys' fees and expenses, whether arising in tort or in contract, in law or in equity. arising from a claim brought by a third party, in response to any legal proceeding brought by a third party or occurring due to any contractual obligation to indemnify, defend and/or hold harmless any third party.

(e) "CRC Indemnified Conditions" means:

(i) the CRO Services;

(ii) the use of Deliverables;

(iii) any harm or bodily injury caused by any Product;

(iv) the infringement of or use of any intellectual property right or proprietary right in relation to XORTX's Products, programs, procedures, materials, data, or other information used by, or on behalf of, or furnished by or on behalf of, XORTX in connection with this Agreement or the provision of CRO Services under this Agreement;

(v) the material breach of this Agreement by XORTX or by any other person for whose actions XORTX is liable under this Agreement or applicable law;

(vi) the negligence, intentional misconduct or intentional omission of XORTX or of any employee, contractor, agent or representative of XORTX; or

(vii) any request for deposition, documents or other information legally compelled including, without limitation, by subpoena or by agreement made in lieu of subpoena, in connection with XORTX's litigation, arbitration or other proceeding with any third party where CRC and/or any of its Affiliates are not also a party or in any investigation of XORTX by any governmental authority.

(f) "XORTX Indemnified Conditions" means:

(i) the negligence, intentional misconduct or intentional omission of CRC or any employee, contractor, agent or representative of CRC;

(ii) the material breach of this Agreement by CRC or any other person for whose actions CRC is liable under applicable law or this Agreement;

(iii) the violation by CRC, its directors, officers, employees or agents, of applicable law, regulation or other governmental requirement;

13. **Insurance**.

13.1 XORTX shall maintain in full force and effect customary insurance coverage for all XORTX Products, clinical trials or other projects related to the CRO Services, including, without limitation, products liability, general liability, and related insurance coverage with policy limits in an amount XORTX's senior management reasonably determines to be sufficient to support XORTX's indemnification obligations hereunder, but as of such date as XORTX commences a clinical trial for which CRC or its Affiliates provide CRO Services, then in no event less than S5,000,000 per occurrence as it relates to clinical trials. Upon completing or otherwise terminating each clinical trial for which CRC provides CRO Services, XORTX shall purchase and maintain a tail policy to cover claims first made and/or reported after completion of such clinical trial.

13.2 XORTX's insurance policy(ies) covering any clinical trial shall name CRC and its respective officers, directors and employees as additional named insureds with a broad form additional insured endorsement (acceptable in form and content to CRC) and shall indicate that the policy will not be canceled or changed until thirty (30) days after written notice of such cancellation or change is delivered to CRC. At CRC's request, XORTX shall provide CRC with an additional insured certificate and a copy of the additional insured endorsement from XORTX's insurance carrier.

13.3 CRC shall maintain in full force and effect, at no cost to XORTX, customary insurance coverage for the CRO Services to be undertaken under each Work Order with policy limits in an amount CRC's senior management reasonably determines to be commercially reasonable under the circumstances.

14. **Limitation of Liability**.

14.1 XORTX agrees that, regardless of the form of any claim, XORTX's sole remedy and CRC's sole obligation with respect to any claims made related to or arising out of this Agreement shall be governed by this Section.

14.2 XORTX's remedies for defective performance by CRC under this Agreement shall be limited to, at CRC's option, either: (a) correction of the non-conforming CRO Services, or (b) reimbursements of payments (excluding payments for Expenses) made by XORTX to CRC for such nonconforming CRO Services under the applicable Work Order during the six (6) month period immediately preceding the event for which the claim is made.

14.3 CRC's obligations for any reason other than as set forth in Section 14.2 shall not exceed 50% of aggregate compensation paid to CRC for CRO Services actually performed during the rolling twelve (12) month period preceding the date on which notice of the claim is given under

the Work Order to which the claim pertains; provided however, with respect to delivery of any notice of claim during the initial twelve (12) months of the applicable Work Order, such limitation shall be equal to the actual aggregate compensation paid to CRC during the first six months of such Work Order; and provided, further, with respect to delivery of any notice of claim following termination or expiration of this Agreement, such limitation shall be equal to fifty percent (50%) of aggregate compensation paid to CRC during the final twelve (12) months of the applicable Work Order.

14.4 It is expressly agreed that in no event shall CRC, its Affiliates or anyone else who has been involved in the performance of this Agreement on behalf of CRC be liable for any indirect, consequential, incidental, special, punitive, or exemplary damages arising from any legal theory, even if such person had been apprised of the likelihood of such damages occurring. XORTX agrees that, notwithstanding the applicable statute of limitations, it may not bring any claim against CRC more than one (1) year after the cause of action arose.

15. **Investigator and Other Third-Party Payments**.

15.1 CRC shall, at XORTX's request in a Work Order, disburse payments to investigators, monitors, laboratories or other third parties contracted with XORTX to provide services with respect to a clinical study for which CRC is providing CRO Services to XORTX (each, a "Third-Party Contractor"). CRC will disburse all such payments (each, a "Third-Party Contractor Fee") in accordance with the provisions of the agreement between XORTX and the Third-Party Contractor (each, a "Third-Party Contractor Agreement"), a copy of which shall be provided to CRC prior to any payment being made. CRC will not unreasonably withhold any Third-Party Contractor Fee and will not impose additional restrictions on the terms of payment for the Third-Party Contractor Fee set forth in the Third-Party Contractor Agreement.

15.2 XORTX shall provide CRC with the funds to pay each Third-Party Contractor Fee, plus any related administrative fee, prior to the date on which CRC is scheduled to disburse such Third-Party Contractor Fee. To the extent payments to any Third-Party Contractors are to be made in a currency other than Canadian dollars, then contrary to the terms of Section 4.3 to make payment in Canadian dollars, funds for each such payment shall be made by XORTX in the currency in which the Third-Party Contractor Fee is to be paid. If XORTX does not provide the funds to CRC, then CRC will not disburse such Third-Party Contractor Fee until it receives the funds, including any administrative fee, from XORTX. In such event, XORTX shall be deemed to have released CRC from all legal liability, and to have covenanted to indemnify and not to sue CRC on any claims related to failure to disburse or otherwise pay the Third-Party Contractor Fee. XORTX agrees that CRC shall not have any liability to XORTX with respect to payments made to any Third-Party Contractor in accordance with the terms of the applicable Third-Party Contractor Agreement, even if XORTX would prefer such payment not be made unless XORTX shall have notified CRC prior to the time the payment is due not to make the payment. If XORTX notifies CRC not to make any payment, XORTX agrees to indemnify CRC with respect to any claims made against it by the Third-Party Contractor related to failure to disburse or otherwise pay the Third-Party Contractor Fee withheld in accordance with XORTX's instructions.

15.3 If XORTX provides CRC with funds in excess of the total Third-Party Contractor Fees disbursed by CRC (plus any administrative fee for Third-Party Contractor Fees actually paid), then CRC shall prepare and send a reconciliation of such funds to XORTX within ninety (90) days after the early termination or expiration of the Work Order under which such Fees were being disbursed. Any excess funds shall first be applied to undisputed amounts otherwise due to CRC hereunder, and then any remainder shall be refunded to XORTX.

16. **Transfer of Responsibilities and Obligations**.

16.1 If XORTX, pursuant to a Work Order, requests that CRC enter into agreements with investigators, monitors, laboratories, storage facilities, clinical material manufacturers or shippers, or other third parties to provide services with respect to a clinical study for which CRC is providing CRO Services to XORTX (each a "Third-Party Agreement"), then subject to CRC undertaking its obligations under each Third-Party Agreement (except as with respect to payment which is governed by Section 16.2), XORTX will assume all obligations and liabilities under such Third-Party Agreement, including but not limited to all regulatory and legal obligations, and indemnify CRC for any claims made against CRC for any liability incurred by it as a result of the execution and delivery by CRC of such Third-Party Agreement(s). Notwithstanding the foregoing, the Parties shall establish a process for review of Third-Party Agreements before execution, which process shall generally include an agreement on the base form, information provided by XORTX on parameters for changes, and consultation with XORTX on significant issues outside the parameters. If a Work Order terminates (for any reason) before completion of the CRO Services specified therein and pursuant to that Work Order, CRC has entered into any Third-Party Agreements, CRC shall be free to terminate such Third-Party Agreements and XORTX shalt pay all termination fees or other liabilities owed by CRC or its Affiliates due to such termination.

16.2 XORTX shall provide CRC with the funds to pay each Third-Party Agreement (the "Third- Party Fees"), plus any administrative fee, before the date on which CRC is scheduled to disburse each such Third-Party Fee. To the extent payments to Third Parties are to be made in a currency other than Canadian dollars, then contrary to the terms of Section 4.3, funds for each such payment shall be made by XORTX in the currency in which the Third-Party Fee is to be paid. If XORTX does not provide the funds to CRC before the scheduled payment date, then CRC will not disburse such Third-Party Fee until it receives the funds (including any administrative fee) from XORTX. CRC shall have no liability to XORTX with respect to payments made to any Third Party in accordance with the terms of a Third-Party Agreement, even if XORTX would prefer such payment not be made unless XORTX instructs CRC not to make the payment before CRC does so. If XORTX fails to provide the required funds on a timely basis or notifies CRC to withhold or otherwise not pay any Third-Party Fees required to be paid under an applicable Third-Party Agreement, then XORTX agrees to indemnify CRC with respect to any claims made against CRC by the Third Party for failure to make (or delay in making) the payment of the Third-Party Fees (including, but not limited to, charges for interest and late payment fees). If XORTX provides CRC with funds in excess of the total Third-Party Fees disbursed by CRC (plus the administrative fee), then CRC shall prepare and send a reconciliation of such funds to XORTX within ninety (90) days after the early termination or expiration of the Work Order under which such Third-Party Fees were being disbursed. Any excess Third-Party Fees shall first be applied to undisputed amounts otherwise due to CRC hereunder, and then any remainder shall be refunded to XORTX.

16.3 Transfer of sponsor obligations with respect to any clinical trial may only be made pursuant to a Work Order, a signed Transfer of Sponsor Obligation form, and otherwise in accordance with 21 CFR 312.52 and other applicable laws and regulations.

17. **Audits, Inspections and Site Visits**.

17.1 XORTX and/or XORTX's representative may, during normal business hours and upon no less than two (2) weeks' prior notice, meet with CRC or its applicable Affiliate(s) and their respective employees, consultants, and/or subcontractors engaged in the performance of CRO Services at CRC or at the location(s) of the facilities used to undertake the CRO Services to: (i) examine and inspect the facilities used for the performance of CRO Services, (ii) observe the progress of activities relating to the CRO Services; (iii) inspect and copy or have copied records, documents, information, data, and materials specifically relating to the CRO Services, and (iv) inspect and copy or have copied financial reports and other documents accounting for the fees, costs and expenses of the CRO Services.

17.2 CRC will, during regular business hours and on no less than two (2) weeks' notice, permit a regulatory auditor to have access to CRC's records pertaining to the CRO Services provided pursuant to this Agreement for the purpose of auditing and verifying such CRO Services.

17.3 CRC will, during regular business hours and on no less than two (2) weeks' notice, permit a financial auditor to have access to CRC's records pertaining to the CRO Services provided pursuant to this Agreement for the purpose of auditing and verifying the billing for such CRO Services.

17.4 At XORTX's reasonable request, CRC shall cooperate with any regulatory authorities and allow them to review and copy applicable records and data related to the CRO Services. If a request is made directly to CRC (or its applicable Affiliate(s)) by any regulatory authority to review records and data, or to contact, visit, or inspect CRC's (or its applicable Affiliate's or investigator's) records and data, relating to any CRO Services or CRC's (or its applicable Affiliate's or investigator's) performance of CRO Services, then CRC shall notify XORTX as soon as practicable (unless prohibited by law) after such regulatory authority issues or gives to CRC (or any such of its applicable Affiliate(s) or investigator) any notice of intent to inspect, notice of inspection, notice of inspectional observations, warning letter, or other written communication concerning any CRO Services, and CRC shall provide XORTX a copy thereof. To the extent permitted by law, prior to any submission to a regulatory authority of any response that may be required as a result of the inspection or visit, CRC (its applicable Affiliate(s) or investigator) shall provide XORTX with the opportunity to review and comment on the proposed response.

17.5 All persons sent by XORTX to undertake such visits, inspections or audits pursuant to Sections 17.1-17.3 shall be qualified by education, training, and experience, and shall be reasonably acceptable to CRC. The number, extent and frequency of such visits, inspections or audits shall be reasonable under the circumstances and normally shall not exceed one in every twelve (12) month rolling period. Unless such person is an employee of XORTX, he or she shall report to XORTX only those facts and conclusions determined as a result of the visit which are

directly related to XORTX's interests. All information obtained from an audit shall be Confidential Information except as otherwise set forth in Section 7.3, above. Unless the visits, inspections and/or audits set forth in Sections 17.1-17.4 are specifically included in a Work Order, XORTX shall, in addition to any other payment obligations under this Agreement, pay CRC, on a time-and-materials basis, at its current rates for the CRC or Affiliate personnel assigned to supervise or otherwise participate in or assist administratively with such audit, inspection or visit, including without limitation for any CRC or Affiliate personnel required to participate in it or meet with the regulatory inspectors.

18. **Force Majeure; Other Delays**.

18.1 if either Party is delayed in, hindered in, or prevented from the performance of any act required under this Agreement by reason of strike, lockout, labor problems, restrictions of government, judicial orders or decrees, riots, insurrection, terrorism, war, acts of God, inclement weather, or other causes that are beyond the reasonable control of such Party, then performance of such act shall be excused until the cause is remedied. The delayed Party shall use commercially reasonable efforts to resume performance as soon as possible. Notwithstanding the foregoing, this Section 18.1 shall not apply to or excuse any failure to make payments when due.

18.2 CRC will not be liable to XORTX nor be deemed to have breached this Agreement for errors, delays or other consequences arising from the failure of XORTX or any third party not under CRC's direct control to provide documents, materials or information in a timely manner or otherwise cooperate in order for CRC to perform its obligations, and any such failure by XORTX or any third party not under CRC's direct control shall automatically extend any timelines affected by such failure by at least the period of the delay (and such longer period as it may take as a result of the need to suspend and then wind up again), unless XORTX agrees in writing to pay any additional costs that would be required to meet the original timeline.

**19. Independent Contractor.** CRC shall perform CRO Services as an independent contractor. Neither Party has authority to make any statement, representation, or commitment of any kind nor to take any action binding on the other Party without the other Party's prior written consent.

**20. Use of XORTX's Name.** XORTX agrees that CRC may use XORTX's name as a reference for prospective clients or in literature relating to CRC's capabilities, provided that such use does not violate Section 7 above.

**21. Notification.** Any notices given hereunder shall be in writing and shall be deemed to have been given on the earlier of personal receipt by an authorized representative of the Party, or receipt at the Party's notice address. Notice may be given by the following means: registered mail/return receipt requested, overnight courier, or personal delivery. All notices shall be sent to a Party at its address set forth on the signature page of this Agreement, or to such other address as is given by notice to the other Party. Notices are deemed given on receipt or attempted delivery (if receipt is refused).

**22. Waiver.** No waiver of any right or remedy with respect to any occurrence or event shall be valid unless it is in writing and executed by the waiving Party. No such valid waiver shall be

deemed a waiver of such right or remedy with respect to such occurrence or event on a continuing basis or in the future unless the waiver states that it is intended to apply continuously or to future events. A waiver shall not excuse use a subsequent breach of the same term, unless the waiver so states.

**23. Severability.** If any provisions of this Agreement are determined to be invalid or unenforceable, those provisions shall be reformed to the extent necessary to comply with law and the Parties' intent, or struck if necessary, and the validity and effect of the other provisions of this Agreement shall not be affected.

24. **Contract Interpretation and Dispute Resolution**.

24.1 The official language of this Agreement and any interpretation of it is English. All contract interpretations, notices and dispute resolutions shall be in English. Any attachments or amendments to this Agreement shall be in English. Translation of any of these documents shall not be construed as official or original versions of the documents. *Les parties a cette convention ont expressement requis que cette convention et tout avis et autres documents y afferents soient rediges en longue anglaise et s'en deciarent satisfaits.*

24.2 This Agreement has been prepared following arm's-length negotiations in which each Party had the opportunity to consult with legal counsel regarding the provisions hereof. Every covenant, term and provision of this Agreement shall be construed according to its fair meaning and not strictly for or against any Party or Parties.

24.3 This Agreement shall be governed by, construed and interpreted in accordance with the laws of the laws of Canada and of the Province of Quebec, excluding the United Nations Convention on Contracts for the International Sale of Goods, and no conflict-of-laws provision shall be invoked to permit application of the laws of any other province, country or jurisdiction.

24.4 Any controversy, claim or dispute arising out of, in connection with or relating to this Agreement shall be first submitted to mediation, which mediation shall take place in Montreal, Quebec, unless another location shall be agreed upon by the Parties. In the event mediation is not successful, then the dispute shall be resolved in binding arbitration in accordance with the terms of Exhibit A.

24.5 Notwithstanding Section 24.4, (a) with respect to any uncollected invoice, if CRC shall have inquired as to whether there is a dispute as to whether payment is due as a result of issues in performance of the CRO Services and received no response or a response that there is no dispute, then CRC may bring a collection suit in a court resident in the Montreal Urban Community, and XORTX consents to the jurisdiction of such courts in such matter; and (b) if damages for a breach are not likely to be an adequate remedy, then either Party may commence injunction proceedings before a court of equity sitting in the Montreal Urban Community, and the Parties hereby consent to the jurisdiction of such court. Any arbitration award shall be homologated such that it can be put into compulsory execution in accordance with Articles 946 and following of the Quebec Code of Civil Procedure.

**25. Survival.** The representations and warranties of the Parties in Section I 0 shall survive the events to which they relate and survive the expiration or earlier termination of this Agreement and the rights and obligations of the Parties set forth in Sections 3.2, 4, 5, 7-17, 20, 24 and 25 shall survive expiration or earlier termination of this Agreement.

**26. Assignment.** This Agreement may not be assigned by either Party without the prior written consent of the other Party, which shall not be unreasonably withheld; provided however, that either Party may assign this Agreement in connection with a merger or the sale of all or substantially all of the assigning Party's assets or equity on the condition that such assignment shall be solely to the acquirer or purchaser of the assigning Party and such acquirer or purchaser must assume the assigning Party's obligations under this Agreement.

**27. Freedom to Contract.** Except with respect to CRO Services for which XORTX specifically hires CRC to perform under this Agreement, (a) XORTX is not required to use CRC for any specific work; (b) XORTX is free to retain others to perform the same or similar CRO Services as offered by CRC; (c) CRC is not required to provide any CRO Services to XORTX; and (d) CRC is free to provide CRO Services to other clients that are similar to CRO Services provided to XORTX.

28. **Entire Agreement.** Exhibit A to this Agreement and Work Orders are incorporated into and made a part of this Agreement. This Agreement, including the incorporated Exhibit A and Work Orders, constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all prior agreements, whether written or oral, relating to the subject matter hereof; provided however, that all prior confidentiality, nonuse and nondisclosure agreements shall remain in effect as to all matters not specifically covered by this Agreement. Except as otherwise authorized herein, changes, modifications, and amendments shall be valid only if made in writing and signed by both Parties. To be effective, any agreement between the Parties purporting to amend a term of this Agreement, including without limitation any Work Order, must specifically identify that term's Section number and state the Parties' specific intent to amend that term.

29. **Signatures**. This Agreement and any amendment or Work Order issued under it may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument. Facsimile signatures and signatures transmitted by email after having been scanned shall be accepted as originals for the purposes of this Agreement and nay Work Orders issued hereunder.

The Parties have executed this Agreement as of the date first written above.

**Cato Research Canada Inc.**

By: /s/ Daniel Cato
The signer certifies that he/she has the authority to execute this Master Services Agreement on behalf of Cato Research Canada Inc.

**XORTX Pharma Corp.**

By: /s/ Allen Davidoff
The signer certifies that he/she has the authority to execute this Master Services Agreement on behalf of XORTX Pharma Corp.

| | | | |
|---|---|---|---|
| Name: | Dan Cato | Name: | Allen Davidoff |
| Title: | Assistant Secretary | Title: | President & CEO |

## EXHIBIT A

## ARBITRATION PROCEDURES

The following rules shall apply to any arbitration of the parties under Section 24:

1. **Location and Language.** The location of the arbitration shall be in Canada, unless the Parties should agree to a different location. The arbitration shall be conducted in American English and any findings and/or decisions shall be rendered in American English.

2. **Number and Selection of Arbitrator.** The arbitration shall be conducted by one arbitrator who is independent and disinterested with respect to the Parties. this Agreement, and the outcome of the arbitration (a "neutral arbitrator"). If the Parties cannot agree on a neutral arbitrator, then each Party shall select an arbitrator it believes to be neutral, who together shall select a third neutral arbitrator to conduct the arbitration. The arbitrator will be selected with consideration given to his or her experience with disputes of the type being submitted (e.g., the nature of the claim and the technology involved). It is the intent of the Parties that the final arbitrator be selected within thirty (30) days after the arbitration demand is first made.

3. **Case Management.** Prompt resolution of any dispute is important to both Parties and the Parties agree that the arbitration of any dispute shall be conducted expeditiously. The arbitrator is instructed and directed to assume case management initiative and control over the arbitration process (including scheduling of events, pre-hearing discovery and activities, and the conduct of the hearing), in order to complete the arbitration as expeditiously as is reasonably practical to obtain a just resolution of the dispute.

4. **Remedies.** The arbitrator shall follow and apply the applicable law. The arbitrator shall grant such legal or equitable remedies and relief in compliance with applicable law that the arbitrator deems just and equitable, but only to the extent that such remedies or relief could be granted by a state or federal court and as otherwise limited by the terms in this Agreement. No punitive damages may be awarded by the arbitrator. The arbitrator may not award punitive damages and no court action may be maintained seeking punitive damages.

5. **Expenses.** The expenses of the arbitration, including the arbitrator's fees, expert witness fees, and attorney's fees, may be awarded to the prevailing Party, in the discretion of the arbitrator, or may be apportioned between the Parties in any manner deemed appropriate by the arbitrator. Unless and until the arbitrator decides that one Party is to pay for all (or a share) of such expenses, both Parties shall share equally in the payment of the arbitrator's fees as and when billed by the arbitrator.

6. **Confidentiality.** The Parties shall keep confidential the fact of the arbitration, the dispute being arbitrated, and the decision of the arbitrator. Notwithstanding the foregoing, (a) the Parties may disclose information about the arbitration to persons who have a need to know, such as directors, trustees. management employees, witnesses, experts, investors, attorneys, lenders, insurers, and others who may be directly affected; (b) if a Party has stock that is publicly traded, the Party may make such disclosures as are required by applicable securities laws or listing rules; and (c) if a Party is expressly asked by a Third Party about the dispute or the arbitration, the Party

may disclose and acknowledge in general and limited terms that there is a dispute with the other Party which is being (or has been) arbitrated.

**Exhibit 4.26**

**CONSULTING AGREEMENT**

This Consulting Agreement (together with the attached Exhibit A (the "**Business Terms Exhibit**"), collectively this "**Agreement**", is made as of September 1, 2022 (the "**Effective Date**") by and between XORTX Therapeutics Inc., a corporation incorporated in British Columbia and located at 3710, 33rd Street, N.W. Calgary, Alberta T2L 2M1 Canada ("**Company**"), and Stacy Evans, M.D., M.B.A. with an address of *** USA ("**Consultant**").

1. **Services**. Company retains Consultant, and Consultant agrees to provide, consulting and advisory services to Company as Company may from time to time reasonably request and as specified in the Business Terms Exhibit (the "**Consulting Services**"). Any changes to the Consulting Services must be agreed to in writing between Consultant and Company prior to implementation of any such changes. All Consulting Services are provided on a non-exclusive basis.

2. **Compensation and Expense Reimbursement**. As full consideration for Consulting Services provided under this Agreement, Company agrees to pay Consultant as described in the Business Terms Exhibit. Company shall pay all undisputed invoices within fifteen (15) days of its receipt of the invoice. Company shall notify Consultant promptly in writing if it disputes any fees and the parties shall work together in good faith to resolve such disputes within no more than fifteen (15) days of Company's notification of such dispute. Consultant shall continue to perform the Consulting Services during the pendency of any such invoice dispute.

   All reimbursable expenses over one-thousand US dollars ($1000 USD) must be approved by Company in writing, in advance. Consultant must pass through all reimbursable expenses at cost, without mark-up, and must provide receipts or documentation of all such expenses.

3. **Performance**. Consultant agrees to provide the Consulting Services to Company, or to its designee, in compliance with all applicable laws and regulations and in accordance with good biopharmaceutical industry professional standards.

4. **Compliance with Obligations Relating to Third Parties**. Consultant represents and warrants to Company that the terms of this Agreement and Consultant's performance of Consulting Services do not and will not conflict with any of Consultant's obligations to any third parties and vice versa. Consultant agrees not to use any trade secrets or other confidential information of any other person, firm, corporation, institution or other third party in connection with any of the Consulting Services. Consultant agrees not to make any use of any funds, space, personnel, facilities, equipment of a third party in performing the Consulting Services, nor take any other action that would result in a third party asserting ownership of, or other rights in, any Work Product (defined in Section 5), unless agreed upon in writing in advance by Company. Consultant also agrees not to make any use of any funds, space, personnel, facilities, equipment of the Company in performing any services for any third party. Notwithstanding the foregoing, Company acknowledges that Consultant may currently, and in the future potentially provide consulting services to other companies working in overlapping therapeutic disciplines as Company, provided that

Consultant fully complies with all confidentiality and other obligations set forth in this Agreement. The Consultant represents, warrants and covenants to and with the Company that Consultant is not currently working for any third party who is developing a therapeutic for the treatment of autosomal dominant polycystic kidney disease (ADPKD) and agrees not to intentionally do so within the term without the prior written consent of the Company, such consent not to be unreasonably withheld.

5. **Work Product**. Consultant will promptly and fully disclose in confidence to Company all inventions, discoveries, improvements, ideas, concepts, products, works of authorship, know-how, documentation, reports, research, or creations, arising from, or made in the performance of, the Consulting Services (whether or not patentable or subject to copyright or trade secret protection) (collectively, the "**Work Product**"). Consultant agrees to assign, at Company's request, all rights in the United States and throughout the world to Work Product. For purposes of the copyright laws of the United States, Work Product will constitute "works made for hire," except to the extent such Work Product cannot by law be "works made for hire". Consultant represents and warrants that Consultant has and will have the right to transfer and assign to Company all Work Product. Consultant will execute all documents and take any and all actions needed, at Company's sole expense, all without further consideration, in order to confirm Company' rights as outlined above. Notwithstanding the foregoing, Work Product shall not include information in the public domain or obtained by Consultant from proprietary databases.

6. **Confidentiality**.

6.1. Definition. "**Confidential Information**" means any non-public scientific, technical, business or financial information in whatever form (written, oral or visual) that is furnished or made available to Consultant by or on behalf of Company. Confidential Information is, and will remain, the sole property of Company.

6.2. Obligations. During the Term (as defined in Section 8) and for a period of five (5) years thereafter, Consultant agrees to (a) hold in strict confidence all Confidential Information, and not disclose Confidential Information without the prior written consent of Company; (b) use Confidential Information solely in connection with the Consulting Services; (c) treat Confidential Information with no less than a prudent and reasonable degree of care at least equal to how participants in the life sciences and biotech industry protect their own confidential information; (d) reproduce Confidential Information solely to the extent necessary to provide the Consulting Services, with all such reproductions being considered Confidential Information; and (e) notify Company of any unauthorized disclosure of Confidential Information promptly upon becoming aware of such disclosure. If Consultant is required by a governmental authority or by order of a court of competent jurisdiction to disclose any Confidential Information, Consultant will give Company prompt written notice thereof and Consultant will take all reasonable and lawful actions to avoid or minimize the degree of such disclosure. Consultant will cooperate reasonably with Company in any efforts to seek a protective order at Company's sole expense. In addition, Consultant shall continue to remain bound

by the terms of the separately executed mutual non-disclosure agreement dated July 11, 2022 (the "**CDA**"), provided however that if there is a conflict between the terms of the CDA and the term of Section 6 of this Agreement, this Agreement shall prevail.

6.3. Exceptions. Consultant's obligations of non-disclosure and non-use under this Agreement will not apply to any portion of Confidential Information that:

(a) is generally known to the public at the time of disclosure or becomes generally known through no wrongful act on the part of Consultant;

(b) is in Consultant's possession at the time of disclosure other than as a result of Consultant's breach of any legal obligation;

(c) becomes known to Consultant on a non-confidential basis through disclosure by sources other than Company having the legal right to disclose such Confidential Information; or

(d) is independently developed by Consultant without reference to or reliance upon Confidential Information.

7. **Publication; Publicity**. Consultant may not publish any Work Product, in whole or in part, without the prior express written consent of Company. Consultant will not use the Company's logo, trade name, or trademark, or any simulation, abbreviation, or adaptation of same, or the name of Company for publicity, promotion, or other uses without Company's prior written consent.

8. **Expiration/Termination**. The term of this Agreement will commence on the Effective Date and expire at the end of the period specified in the "Term of Engagement" Section of the Business Terms Exhibit, unless sooner terminated pursuant to the provisions of this Section 8 or extended by mutual written agreement of the parties (the "**Term**"). Company may terminate this Agreement at any time with or without cause upon not less than thirty (30) days' prior written notice to Consultant. Consultant may terminate this Agreement at any time with or without cause upon not less than thirty (30) days' prior written notice to Company. Any expiration or termination of this Agreement shall be without prejudice to any obligation of either party that has accrued prior to the effective date of expiration or termination. Upon expiration or termination of this Agreement, neither Consultant nor Company will have any further obligations under this Agreement, except that (a) Consultant will terminate all Consulting Services in progress in an orderly manner as soon as practicable and in accordance with a schedule agreed to by Company, unless Company specifies in the notice of termination that Consulting Services in progress should be completed; (b) Company will pay Consultant any accrued monies due and owing Consultant, up to the time of termination or expiration, for Consulting Services properly performed and all authorized expenses actually incurred; (c) unless this Agreement is terminated for cause by Company within sixty (60) days of the Effective Date, Company shall have a surviving obligation to pay Consultant the Transaction Bonus as outlined in the Business Terms Exhibit, irrespective of whether or not a Broker-Dealer was engaged

by Company, if a Transaction is consummated within 15 months of the expiration or termination date and this Agreement was not terminated by Company for cause; (d) upon Company's request, Consultant will promptly destroy all Confidential Information provided to Consultant under this Agreement with the exception of (i) one (1) copy of any such Confidential Information that shall be securely isolated by Consultant solely for the purposes of compliance with this Agreement and (ii) any ordinary course of business electronic archival back-up copies of such Confidential Information securely maintained by the Consultant; and (e) the terms, conditions and obligations under Sections 4, 5, 6, 7, 8, 9 will survive expiration or termination of this Agreement. For clarity, the last sentence of Section 4 will not survive expiration or termination of this Agreement.

9. **Miscellaneous**.

9.1. Independent Contractor. The parties understand and agree that Consultant is an independent contractor and not an agent or employee of Company. Consultant has no authority to obligate Company by contract or otherwise. Consultant will not be eligible for any employee benefits of Company and expressly waives any rights to any employee benefits. Except as otherwise required by law, Consultant will bear sole responsibility for paying and reporting Consultant's own applicable federal and state income taxes, social security taxes, unemployment insurance, workers' compensation, health or disability insurance, retirement benefits, and other welfare or pension benefits, as applicable.

9.2. Entire Agreement. This Agreement and the CDA contain the entire agreement of the parties with regard to its subject matter and supersedes all prior or contemporaneous written or oral representations, agreements and understandings between the parties relating to that subject matter. This Agreement may only be changed or amended in writing and signed by Consultant and an authorized representative of Company.

9.3. Assignment and Binding Effect. Consultant may not assign or transfer this Agreement or assign, transfer or subcontract any of Consultant's rights or obligations under this Agreement without Company's prior written consent. Company may transfer or assign this Agreement to a Company Affiliate, without the prior written consent of Consultant. For the purposes of such Company assignment, "**Affiliate**" means, with respect to Company, a firm, corporation or other entity which directly or indirectly owns or controls Company, or is owned or controlled by Company, or is under common ownership or control with Company. The word "control" means (i) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity, or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise. Any purported assignment or transfer in violation of this Section 9.3 is void. This Agreement will be binding upon and inure to the benefit of the parties and their respective legal representatives, heirs, successors and permitted assignees.

9.4. Notices. All notices required or permitted under this Agreement must be in writing and must be given by directing the notice to the address for the receiving party set forth in this Agreement or at such other address as the receiving party may specify in writing under this procedure. Notices to Company will be marked "Attention: Dr. Allen Davidoff, President and CEO". Notices to Consultant will be marked "Attention: Stacy Evans, MD, MBA". All notices must be given (a) by personal delivery, with receipt acknowledged; (b) by prepaid certified or registered mail, return receipt requested; (c) by prepaid next business day delivery service; or (d) via email with confirmed receipt from both parties. Notices will be effective upon receipt or at a later date stated in the notice.

9.5. Governing Law. This Agreement and any disputes relating to or arising out of this Agreement will be governed by, construed, and interpreted in accordance with the laws of the State of California applicable therein without regard to any choice of law principle that would require the application of the law of another jurisdiction.

9.6. Severability; Reformation. Each provision in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable because any other provision is found by a proper authority to be invalid or unenforceable in whole or in part. If any provision of this Agreement is found by such an authority to be invalid or unenforceable in whole or in part, such provision shall be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision and the intent of the parties, within the limits of applicable law.

9.7. Currency. All dollar amounts herein are stated in United States currency.

9.8. Broker-Dealer Status. The Consulting Services may include some or all services that are customarily rendered by a business and corporate strategy development and management consultant in the biotechnology and pharmaceutical industry, including without limitation evaluating the management, scientific and commercial capabilities of potential business partners for Company, evaluating the management, scientific and commercial capabilities of Company, evaluating development strategy and commercial potential for Company's pharmaceutical product candidates, helping Company develop and evaluate terms for a transaction between such potential business partners and Company, and advising Company's management, advisors, and Board of Directors in the area of Consultant's expertise. For clarity, Consultant is not engaged in the business of effecting or facilitating securities transactions and Consultant is not registered as a broker or dealer under the Securities Exchange Act of 1934, as amended, or the rules of any self-regulatory organization in the securities field, and therefore shall not participate materially in the solicitation, placement, negotiation or execution of a transaction to the extent involving the sale of securities for the account of Company, any of Company's securityholders, or any third party if such participation would require such registration.

9.9. No Strict Construction; Headings. This Agreement has been prepared jointly and will not be strictly construed against either party. The Section headings are included

solely for convenience of reference and will not control or affect the meaning or interpretation of any of the provisions of this Agreement.

9.10. Waivers. Any delay in enforcing a party's rights under this Agreement, or any waiver as to a particular default or other matter, will not constitute a waiver of such party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by Consultant or an authorized representative of the waiving party, as applicable.

9.11. Remedies. The parties agree that (a) either party may be irreparably injured by any willful or intentional uncured breach of this Agreement; (b) money damages may not be an adequate remedy for any such breach; (c) as a remedy for any such breach the non-breaching party will be entitled to seek equitable relief, including injunctive relief and specific performance, without being required by the breaching party to post a bond; and (d) such remedy may not be the exclusive remedy for any breach of this Agreement. Either party shall not be liable for any injuries or damages sustained by the other party unless resulting from the negligence, bad faith, willful misconduct or fraud on the part of the other party. Either party shall not be liable for any losses or any damage caused by the other party to a third party. Each party shall at all times indemnify and save harmless the other party, its officers, employees and agents from and against all actions, damages, claims, demands and losses (including legal expenses) incurred as a result of a breach by the other party of its covenants, representations and warranties under this Agreement or the other party's negligence, bad faith, willful misconduct or fraud.

9.12. Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. A facsimile or portable document format (".pdf") copy of this Agreement, including the signature pages, will be deemed an original.

**IN WITNESS WHEREOF**, the parties have executed this Agreement as of the Effective Date.

| **XORTX THERAPEUTICS, INC.** | **STACY EVANS, M.D., M.B.A.** |
|---|---|
| By: _____ | _____ |
| Name: _____ | _____ |
| Title: _____ | _____ |

**EXHIBIT A**
**BUSINESS TERMS EXHIBIT**

1. **Description of Consulting Services**. Consultant will provide consulting services in connection with a business development Transaction for Company ("**Consulting Services**"). "**Transaction**" means a license, option, co-development, other partnership or collaboration, equity investment, or other strategic transaction including a merger, acquisition, or sale of all or substantially all of Company's assets, in each case inclusive of the XRx-008 program, excluding any public financing or private placement through an investment dealer. It is expected that the Consulting Services shall include the following:

- Review past and ongoing business development interactions related to XRx-008 with pharmaceutical and biotech companies;
- Develop a proposed list of pharmaceutical and biotech companies with global or US presence for Transaction engagement, which may include companies that Company has previously engaged in XRx-008 business development discussions within the past six (6) months ("Company Lead") or companies that had not been engaged in XRx-008 business development discussions with Company within the past six (6) months ("Consultant Lead");
- Lead outreach and continued engagement with all Consultant Leads and Company Leads, respectively, that have been approved by Company (collectively, "Strategic Partners"). Company must authorize Consultant to contact all Strategic Partners on Company's behalf in writing (email is sufficient). All pharmaceutical and biotech companies listed in the business development tracker ("BD Tracker") will de facto be considered Strategic Partners;
- Maintain BD Tracker of all business development interactions and activity;
- Meet with Company on a weekly basis (or on a cadence as mutually agreed between Company and Consultant) to review the BD Tracker and align on next steps with each Strategic Partner;
- Develop discounted cashflow model for XRx-008 program
- Lead development of non-confidential and confidential slide decks with support from key Company individuals including R&D and other functional lines (tailored and updated, as needed, to specific Strategic Partners);
- Support ongoing Strategic Partner due diligence and data room management;
- Advise company regarding suitable deal construct(s) for a potential Transaction with a given Strategic Partner;
- Lead deal structuring, financial modeling, and negotiations of deal terms (term sheet and contract) in coordination with Company's transaction attorney, other relevant counsel, management team, and Board of Directors, as applicable, including identification of key contractual business issues as a result of the contemplated business development Transaction(s); and
- In the event of a competitive process, advise on process formalization including development of process letters and coordination of timelines amongst Strategic Partners of interest. Lead in-depth evaluation and comparison of offers based on financial modeling and strategic considerations and advise on competitive negotiation strategy.

Unless otherwise mutually agreed in writing by Consultant and Company, the focus of Consultant's consulting services will be to consummate a single Transaction for Company's proprietary program, XRx-008, for the treatment of progressive autosomal dominant polycystic kidney disease, that is global in scope or at a minimum includes the United States within the Transaction's territory. Accordingly, Consultant's services will focus on Strategic Partners with a relevant commercial presence, pipeline focus and/or strategic interest in the XRx-008 program within the United States or globally. For clarity, Consultant will not be responsible for engaging with potential partners that are interested in a regional Transaction which excludes the United States.

It is expected that Consultant will work closely and collaboratively with members of Company's executive management team, including Dr. Allen Davidoff, any relevant non-executive Company personnel as directed by the executive management team, as well as Company's external legal counsel, financial advisers and accountants in connection with the Consulting Services to be provided by Consultant. Consultant will not contact other Company personnel or discuss Transactions with other Company personnel without the prior written consent of Dr. Allen Davidoff (or such other member of the executive management team that Dr. Allen Davidoff may delegate the authority to provide such prior written consent).

2. **Term of Engagement**. Unless earlier terminated as provided in the Agreement, the term of the Agreement shall be twelve (12) months from the Effective Date (the "**Term**"). The Term may be extended upon written agreement of the parties.

3. **Compensation**. During the first ninety (90) days of the Term, Consultant shall be paid a fixed monthly fee of twenty thousand US dollars ($20,000 USD) for performance of the Consulting Services, and thereafter Consultant shall be paid a fixed monthly fee of twenty-five thousand US dollars ($25,000 USD); provided, however, that should Company formally engage an investment bank, broker, dealer or other financial advisor responsible for leading a Company sale process, merger, acquisition or other strategic transaction involving the equity or assets of the company which includes the XRx-008 program ("**Broker-Dealer**"), then Consultant will work in a supporting fashion with such Broker-Dealer to effectuate such a transaction and following the end of the calendar month of such Broker-Dealer formal engagement by Company, Consultant's fixed monthly retainer will be thereafter reduced to fifteen thousand US dollars ($15,000 USD) (the "**Retainer Fees**"). The Retainer Fees shall be paid monthly in arrears on payment terms as outlined in this Agreement.

In addition to the Retainer Fees, Consultant shall be eligible to receive a success fee following the consummation of a Transaction ("**Transaction Bonus**") as a component of Consultant's compensation for performance of Consulting Services. The Transaction Bonus shall be structured as follows:

- (i) 0.75% of Transaction Value for consummation of a Transaction with a Strategic Partner that originated as a Company Lead;
- (ii) 1.25% of Transaction Value for consummation of a Transaction with a Strategic Partner that originated as a Consultant Lead
- (iii) In the event that a Broker-Dealer is engaged by Company and such Broker-Dealer is entitled to a success fee, then (a) the Transaction Bonus will be 1.0% of the Transaction

Value if a Transaction is consummated with a Strategic Partner that originated as a Consultant Lead or (b) the Transaction Bonus will be 0.75% of the Transaction Value for any other consummated Transaction.

Provided in each case for a Transaction with a Strategic Partner that during the Term a non-confidential summary of the XRx-008 program has been shared with the Strategic Partner and the Strategic Partner was approved for outreach in writing (email is sufficient) by the Company.

"**Transaction Value**" means (a) any upfront consideration including upfront purchase price, licensing upfront fee, option upfront fee, option exercise fee, or upfront investment, (b) any payment over time that is neither a contingency nor tied to any success-based milestone event including a deferred upfront payment or maintenance fee, and (c) any contingent considerations including success-based development, regulatory or sales milestones, contingent value rights, royalties, or profit shares. In the event that the Transaction Value or any component thereof is provided in a non-cash consideration such as equity, options, or other securities, then the Transaction Bonus will be paid in the same form or in cash at fair market value of such non-cash consideration, at Company's sole discretion.

Notwithstanding the foregoing calculation of the Transaction Bonus in (i)-(iii) above, the total Transaction Bonus paid to Consultant shall not exceed four million US dollars ($4,000,000 USD) in the aggregate or the equivalent thereof based on fair market value for any non-cash considerations.

The Transaction Bonus will be due within fifteen (15) days of receipt by Company of any component of the Transaction Value. For clarity, for any payments to the Company over time or contingent considerations of the Transaction Value, payment of the related Transaction Bonus component will be due to Consultant only if and when the contingent component or future payment of the Transaction Value is achieved, earned and received (as applicable) by Company.

4. **Travel and Expenses**. It is not anticipated that any travel nor other out-of-pocket expenses will be required in Consultant's provision of Consulting Services.

**Exhibit 11.1**


# CODE OF BUSINESS CONDUCT AND ETHICS

This Code of Business Conduct and Ethics ("**Code**") represents standards of conduct for every director, officer, consultant and employee of XORTX Therapeutics Inc. (the "Company") and its subsidiaries.

The Company expects all of its directors, officers, consultants and employees to comply with the laws and regulations governing its conduct. The Company's business success is dependent on trusting relationships, which are built on this foundation of integrity. Our reputation is founded on the personal integrity of the Company's personnel and accordingly this Code is applicable to all of the Company's directors, officers, consultants and employees.

Each of us occupies a position of trust in our relations with our colleagues, fellow employees, customers, competitors, suppliers, government authorities, investors and the public. Whatever the area of activity, we should, of course, be honest and responsible in our relations with others.

If there are any doubts as to whether a course of action is proper, or about the application or interpretation of any legal requirement, discuss it with the Company's management and/or counsel.

**PLEASE REVIEW THE ATTACHED CODE CAREFULLY AND SIGN**
**THE ATTACHED FORM OF ACKNOWLEDGEMENT**
**AND RETURN IT TO THE CHIEF FINANCIAL OFFICER**

This Code applies, without exception, to all directors, officers, consultants and employees of the Company (and references to "employee" in this Code should be read to include directors, consultants and officers). It is the responsibility of each and every employee to live up to the standards outlined in the Code to build on the Company's foundation of goodwill. These standards are intended as a guide to making the right choice when faced with a complicated situation and adopting a higher standard of behaviour than simply what is 'legal'.

This is not a complete Code of Conduct. No statement can offer a complete guide to cover all possible situations that might be encountered. There are some areas, however, which because of their special importance, deserve particular attention and these are set out in what follows.

1. **Conflicts of Interest**

1.1 Disclosing and Avoiding of Conflicts

Each employee of the Company must avoid any conflict, or perception of conflict, between his or her personal interests and the interests of the Company in transacting the Company's business. A conflict situation can arise when an employee takes actions or has interests that may make it difficult or even appear to make it difficult to perform his or her work objectively and effectively.

Some examples of a conflict of interest might include:

(a) employment by a competitor or potential competitor, regardless of the nature of employment, while employed by the Company;

(b) acceptance of gifts, payment, or services from those seeking to do business with the Company;

(c) passing confidential information to competitors;

(d) investment activity using insider information;

(e) ownership of, or substantial interest in, a company which is a competitor or supplier of the Company; or

(f) acting as a consultant to a customer or supplier of the Company.

Employees should fully and promptly disclose to management of the Company ("Management") all circumstances that could be construed or perceived as a conflict of interest. Full disclosure creates an opportunity to resolve unclear situations and dispose of conflicting interests before any difficulty can arise. When an employee is in doubt as to whether or not a conflict of interest exists, he or she should consult Management.

1.2 Outside Business Activities / Other Employment

The Company should not be deprived of any employee's best efforts on the job because of excessive outside demands on his or her time, energy or attention. There are cases, however, where an employee may start his or her own outside businesses, or take on additional part-time work with organizations that are neither competitors, suppliers, nor customers. This in itself does not constitute a conflict of interest. It is every employee's responsibility to ensure that the second job does not conflict with the interests of the Company. This means, for example, ensuring that the two activities are strictly separated. This can be done by ensuring that:

(a) the other organization's work is not done on the Company's time;

(b) customers and colleagues from the outside activity do not contact an employee at the Company;

(c) the Company's equipment and supplies, or the time of any corporate personnel, are not used for outside work;

(d) the Company's products or services from the outside business are not promoted to other corporate employees during working hours; and

(e) products or services from outside work are not sold to the Company.

1.3 Gifts and Entertainment

Each employee must never use his or her position to obtain personal gain or become obligated to persons with whom the Company does business. Employees must not accept, directly or indirectly, gifts of value, including payments, services, fees, special privileges, pleasure trips, accommodations and loans from any person, organization, or group doing business or seeking to do business with the Company without obtaining the prior approval of Management.

If an employee has any doubt regarding the acceptance of such gift or benefit, he or she should discuss it with Management.

2. **Corporate Opportunities**

Employees are prohibited from (a) taking for themselves personally corporate opportunities that are discovered through the use of the Company's property, information or position; (b) using the Company's property, information or position for personal gain; and (c) competing with the Company. Employees owe a duty to the Company to advance its legitimate interests when the opportunity to do so arises.

**3. Fair Dealing**

Each employee should endeavour to deal fairly with the Company's shareholders, customers, suppliers, competitors and employees. None should take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts, or any other unfair dealing practice.

**4. Protection and Proper Use of the Company's Assets**

All employees should protect the Company's assets and ensure their efficient use. All of the Company's assets should be used for legitimate business purposes. Equipment, materials, supplies and services, including Internet access, that are purchased by the Company are the property of the Company and must be used only in the interest of the Company and must be protected from theft, misuse or damage.

5. **Compliance with Laws, Rules and Regulations (including Insider Trading Laws)**

The laws of the jurisdiction where the Company does business cover many aspects of the Company's business. The Company is committed to operating within the framework of these laws and regulations. Therefore, to ensure adherence to all applicable laws, all employees should take reasonable steps to familiarize themselves with the laws and regulations affecting their work and ensure that their conduct complies with those laws. Ignorance of the law is not a defence.

While striving to achieve challenging goals and objectives, all employees are expected to comply with the law and must not encourage other employees, contractors or suppliers to engage in any activities that are accomplished by breaking the law, or take part in any unethical business dealings.

The Company will proactively promote compliance with laws, rules and regulations, including, without limitation, all Canadian, U.S. and foreign laws prohibiting money laundering, bribery of public officials and improper payments and insider trading. The Company views insider trading as both unethical and illegal and will deal with it decisively. To this end, the Company has adopted a policy relating to trades in securities by "insiders" (the "Insider Trading Policy"), imposing trading restrictions and blackout periods. Employees should be knowledgeable of and comply with the Insider Trading Policy. Employees who do not have a copy of the Insider Trading Policy should contact the Corporate Secretary of the Company.

The Company's policy is full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with or submits to securities regulatory authorities and in all other publication communications made by the Company. Employees should not disclose corporate information, including material information relating to the business and affairs of the Company. Any employee who becomes aware of information that may be considered material should advise a member of the Audit Committee so that a proper determination can be made about whether the information should be publicly disclosed. Employees who are not authorized spokespersons must not respond under any circumstances to inquiries from the investment community or the media unless specifically asked to do so by an authorized spokesperson. All such inquiries shall be referred to the CEO. Furthermore, employees are prohibited from participating in Internet chat room or newsgroup discussions on matters pertaining to the Company's activities or its securities. Employees who encounter a discussion pertaining to the Company should advise Management immediately, so the discussion may be monitored.

The activities of all employees should withstand close scrutiny. If in doubt, employees should discuss the matter with Management.

6. **Confidentiality**

Employees will be required to maintain the confidentiality of information entrusted to them by the Company or its customers.

Any employee privy to confidential information is prohibited from communicating such information to anyone else, unless it is necessary to do so in the course of business. Efforts will be made to limit access to such confidential information to only those who need to know the information and such persons will be advised that the information is to be kept confidential.

Except as required by law, all information regarding the affairs of the Company must be considered confidential by all employees until it is available to the public. Confidential information includes all non-public types of corporate data, corporate records and information on individuals and information that might affect the Company's competitive position.

In order to prevent the misuse or inadvertent disclosure of material information, the procedures set forth below should be observed at all times:

(a) confidential matters should not be discussed in places where the discussion may be overheard, such as elevators, hallways, restaurants, airplanes or taxis;

(b) confidential documents should not be read in public places, left in unattended conference rooms, left behind when a meeting is over or discarded where they can be retrieved by others. Similarly, employees should not leave confidential information at their homes where it can be accessed by others;

(c) transmission of documents via electronic means, such as by fax or directly from one computer to another, should be made only where it is reasonable to believe that the transmission can be made and received under secure conditions;

(d) access to confidential electronic data should be restricted through the use of passwords;

(e) unnecessary copying of confidential documents should be avoided and extra copies of confidential documents should be shredded or otherwise destroyed;

(f) all proprietary information, including computer programs and other records, remain the property of the Company and may not be removed, disclosed, copied or otherwise used except in the normal course of employment or with the prior permission of Management; and

(g) documents and files containing confidential information should be kept in safe locations accessible to restricted individuals only.

Confidential information should not be destroyed or removed from the premises without the express consent of management or except as required by the terms of employment.

When leaving the employ of the Company, an employee must return all confidential information in any form and all copies which are, or may have been, in his or her possession. Employees are also expected not to divulge confidential information learned during the course of his or her employment.

If an employee has any doubt as to the confidentiality of specific information, he or she should discuss it with Management.

7. **Reporting any Illegal or Unethical Behaviour**

Employees should talk to supervisors, managers or other appropriate personnel when in doubt about the best course of action in a particular situation. Employees must report violations of laws, rules, regulations or the Code to their immediate supervisor, Management or the audit committee of the board of directors of the Company (the "Audit Committee") as soon as they become aware of such violations. Such reports may be made anonymously in accordance with the Company's Whistleblower Policy. All such reports will be dealt with in accordance with the Company's Whistleblower Policy.

8. **Harassment and Discrimination**

The Company supports the spirit and intent of applicable human rights and anti-discrimination laws. The Company will not tolerate any behaviour which conflicts with these principles and laws. Any employee whose actions are inconsistent with these principles will be disciplined, up to and including dismissal.

All employees of the Company should treat one another with courtesy, dignity and respect. Harassment, including sexual harassment, is a form of discrimination and will not be permitted at any level of the Company or in any part of the employment relationship. This includes areas such as recruitment, promotion, training opportunities, salary, benefits and terminations.

Forms of harassment include, but are not limited to, unwelcome verbal or physical advances and sexually, racially, or otherwise derogatory or discriminatory materials, statements or remarks.

All employees of the Company are entitled to harassment-free employment. Each employee has a responsibility to ensure that neither employees nor any external contacts are subjected to harassment.

Complaints will be treated with seriousness, sensitivity and in as discreet and confidential a manner as possible. If any employee believes he or she is being subjected to harassment or observes or knows of a colleague or group of employees who are being harassed, he or she should contact Management or any other senior officer of the Company for advice and assistance. There will be no retaliation for reporting harassment incidents.

9. **Disclosure**

If any employee may have breached the Code or observed a breach of the Code by another employee, he or she has a responsibility to report it immediately to Management or the Audit Committee. The Company will protect from retaliation any employee who, in good faith, reports actual or perceived breaches by another employee or problems with corporate policies, procedures or controls. The CEO will report to the Audit Committee on compliance with the Code. Breaches of the Code will be dealt with promptly and fairly and may, if appropriate, result in immediate disciplinary action, up to and including termination of employment.

The Audit Committee is the first source of information regarding the Code or when reporting an item of concern. However, if any employee feels unable to discuss an issue with the Audit Committee, he or she may make an anonymous report directly to the chairman of the Audit Committee by sending a letter, marked "Private and Confidential", to the chairman of the Audit Committee, c/o XORTX Therapeutics Inc., 4000, 421 – 7th Avenue SW, Calgary, Alberta, Canada T2P 4K9.

The board of directors of the Company (the "Board") may, if a conflict is disclosed fully and in advance, permit the conflict in certain limited instances.

10. **Waivers**

Any waiver of this Code for executive officers or directors of the Company may be made only by the Board or a committee of the Board. Amendments to and waivers of this Code will be publicly disclosed in accordance with applicable laws.

11. **Compliance**

New directors, officers, consultants and employees of the Company and its subsidiaries will be advised of this Code and its importance and this Code will be brought to the attention of all employees on a regular basis. The Board will review and, to the extent necessary, revise and update this Code on a regular basis.

Any employee who violates this Code may face disciplinary action up to and including termination of his or her employment with the Company. The violation of this Code may also violate certain laws. If the Company discovers that an employee has violated such laws, it may refer the matter to the appropriate legal authorities.

12. **No Rights Created**

This Code is a statement of certain fundamental principles, policies and procedures that govern the directors, officers, consultants and employees of the Company in the conduct of its business. It is not intended to and does not create any rights in any employee, director, client, customer, supplier, competitor, shareholder or any other person or entity.

13. **Effective Date**

This Code is dated and effective as of March 8, 2018.

**SCHEDULE A**

**CODE OF CONDUCT**

**ACKNOWLEDGEMENT**

I acknowledge that I:

have received a copy of the Code of Business Conduct and Ethics for the Company dated March 8, 2018;

(a) have read and understood the Company's Code of Business Conduct and Ethics; and

(b) am responsible for complying with the Company's Code of Business Conduct and Ethics and to report any instance of non-compliance with such Code.

_____
(Print Name)

_____
(Signature)

_____
(Date)

**Exhibit 12.1**

**CERTIFICATION**

**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Allen W. Davidoff, certify that:

1. I have reviewed this annual report on Form 20-F of XORTX Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the issuer as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)and 15d-15(f)) for the company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: April 28, 2023

/s/ Allen W. Davidoff

Name: Allen W. Davidoff
Title: Chief Executive Officer
(principal executive officer)

**Exhibit 12.2**

**CERTIFICATION**

**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Amar Keshri, certify that:

1. I have reviewed this annual report on Form 20-F of XORTX Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the issuer as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)and 15d-15(f)) for the company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: April 28, 2023

/s/ Amar Keshri

Name: Amar Keshri
Title: Chief Financial Officer
(principal financial officer)

**Exhibit 13.1**

**CERTIFICATION**

**PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The undersigned, as the Chief Executive Officer of XORTX Therapeutics Inc. certifies that, to the best of his knowledge and belief, the annual report on Form 20-F for the fiscal year ended December 31, 2022, which accompanies this certification, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and the information contained in the annual report on Form 20-F for the fiscal year ended December 31, 2021 fairly presents, in all material respects, the financial condition and results of operations of XORTX Therapeutics Inc. at the dates and for the periods indicated. The foregoing certification is made pursuant to § 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350) and shall not be relied upon for any other purpose. The undersigned expressly disclaims any obligation to update the foregoing certification except as required by law.

Date: April 28, 2023

/s/ Allen W. Davidoff

Allen W. Davidoff
Chief Executive Officer
(principal executive officer)

**Exhibit 13.2**

**CERTIFICATION**

**PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The undersigned, as the Chief Financial Officer of XORTX Therapeutics Inc. certifies that, to the best of his knowledge and belief, the annual report on Form 20-F for the fiscal year ended December 31, 2022, which accompanies this certification, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and the information contained in the annual report on Form 20-F for the fiscal year ended December 31, 2021 fairly presents, in all material respects, the financial condition and results of operations of XORTX Therapeutics Inc. at the dates and for the periods indicated. The foregoing certification is made pursuant to § 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350) and shall not be relied upon for any other purpose. The undersigned expressly disclaims any obligation to update the foregoing certification except as required by law.

Date: April 28, 2023

/s/ Amar Keshri

Amar Keshri
Chief Financial Officer
(principal executive officer)

**Exhibit 15.1**

# XORTX THERAPEUTICS INC.
## Management Discussion and Analysis
## For the year ended December 31, 2022

This management discussion and analysis of financial position and results of operations ("**MD&A**") is prepared as at March 30, 2023 and should be read in conjunction with the audited consolidated financial statements and related notes thereto of XORTX Therapeutics Inc. (the "**Company**" or "**XORTX**") for the year ended December 31, 2022, which have been prepared in accordance with International Financial Reporting Standards ("**IFRS**") as issued by the International Accounting Standards Board ("**IASB**') and interpretations of the International Financial Reporting Interpretations Committee ("**IFRIC**"). All dollar amounts included therein and in the following MD&A are expressed in Canadian dollars except where noted.

In this discussion, unless the context requires otherwise, references to "we" or "our" are references to XORTX Therapeutics Inc.

## CORPORATE INFORMATION

XORTX was incorporated under the laws of Alberta, Canada on August 24, 2012, under the name ReVasCor Inc. and continued under the Canada Business Corporations Act on February 27, 2013, under the name of XORTX Pharma Corp. Upon completion of a reverse take-over transaction on January 10, 2018, with APAC Resources Inc., a company incorporated under the laws of British Columbia, the Company changed its name to "XORTX Therapeutics Inc." and XORTX Pharma Corp. became a wholly-owned subsidiary. The Company's operations and mailing address is 3710 – 33rd Street NW, Calgary, Alberta, Canada T2L 2M1 and its registered address is located at 550 Burrard Street, Suite 2900, Vancouver, British Columbia, V6C 0A3. The Company's shares trade on the TSX Venture Exchange ("**TSXV**"), on the Nasdaq Stock Exchange ("**Nasdaq**") under the symbol "XRTX", and on the Börse Frankfurt under the symbol "ANU".

## FORWARD LOOKING STATEMENTS

This MD&A contains certain statements, other than statements of historical fact that are forward-looking statements, which reflect the current view of the Company with respect to future events including corporate developments, financial performance and general economic conditions which may affect the Company.

All statements other than statements of historical fact contained in this MD&A, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward- looking statements include, among other things, statements about:

- our ability to obtain additional financing;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- the success and timing of our preclinical studies and clinical trials;
- our ability to obtain and maintain regulatory approval of XORLO™, XORTX's proprietary formulation of oxypurinol, and any other product candidates we may develop, and the labeling under any approval we may obtain;
- regulatory approvals and other regulatory developments in the United States and other countries;
- the performance of third-party manufacturers and contract research organizations;
- our plans to develop and commercialize our product candidates;
- our plans to advance research in other kidney disease applications;

- our ability to obtain and maintain intellectual property protection for our product candidates;
- the successful development of our sales and marketing capabilities;
- the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available; and
- the loss of key scientific or management personnel.

XORTX relies on certain key expectations and assumptions in making the forecasts, projections, predictions or estimations set out in forward-looking information. These factors and assumptions are based on information available at the time that the forward-looking information is provided. These include, but are not limited to, expectations and assumptions concerning:

- the availability of capital on acceptable terms to fund planned expenditures;
- prevailing regulatory, tax and environmental laws and regulations; and
- the ability to secure necessary personnel, equipment and services.

Undue reliance should not be placed on forward-looking information because a number of risks and factors may cause actual results to differ materially from those set out in such forward-looking information. These include:

- incorrect assessments of the value of acquisitions, licenses and development programs;
- technical, manufacturing and processing problems;
- actions by governmental authorities, including increases in taxes;
- the availability of capital on acceptable terms;
- fluctuations in foreign exchange, currency, or interest rates and stock market volatility;
- failure to realize the anticipated benefits from licenses or acquisitions;
- the other factors specifically identified as risk factors in this MD&A; and
- potential labour unrest.

Readers are cautioned that the foregoing list of factors should not be construed as exhaustive. Further information relating to risks is included in this MD&A under Risks Related to the Business.

Except as may be required by applicable law or stock exchange regulation, XORTX undertakes no obligation to update publicly or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events. Accordingly, readers should not place undue reliance on forward-looking statements. If XORTX does update one or more forward-looking statements, no inference should be drawn that additional updates will be made with respect to those or other forward-looking statements. Additional information relating to the Company is available by accessing the SEDAR website at www.sedar.com.

## BUSINESS OVERVIEW

XORTX is a late stage clinical pharmaceutical company, focused on developing innovative and potentially commercializing innovative therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism in orphan (rare) disease indications such as autosomal dominant polycystic kidney disease ("**ADPKD**") and larger, more prevalent type 2 diabetic nephropathy ("**T2DN**") as well as acute kidney injury ("**AKI**") associated with respiratory virus infection.

Our focus is on developing three therapeutic products to:

1/ slow or reverse the progression of chronic kidney disease in patients at risk of end stage kidney failure;
2/ address the immediate need of individuals facing AKI associated with respiratory virus infection; and
3/ identify other opportunities where our existing and new intellectual property can be leveraged to address health issues.

We believe that our technology is underpinned by well-established research and insights into the underlying biology of aberrant purine metabolism, chronically high serum uric acid and its health consequences. Our aim is to advance novel proprietary formulations of oxypurinol, a uric acid lowering agent that works by effectively inhibiting xanthine oxidase. We are developing product candidates that include new or existing drugs that can be adapted to address different disease indications where aberrant purine metabolism and/or elevated uric acid is a common denominator, including polycystic kidney disease, pre-diabetes, insulin resistance, metabolic syndrome, diabetes, diabetic nephropathy, and infection. We are focused on building a pipeline of assets to address the unmet medical needs for patients with a variety of serious or life-threatening diseases using our innovative formulation of oxypurinol, and our proprietary pipeline-in-a-product strategy supported by our intellectual property, established exclusive manufacturing agreements, and proposed clinical trials with experienced clinicians,

Our three lead product candidates are XRx-008, for the treatment of ADPKD; XRx-101, to treat AKI associated with respiratory virus infection, AKI and associated health consequences; and XRx- 225, for the treatment of T2DN. At XORTX, we aim to redefine the treatment of kidney diseases by developing medications to improve the quality of life of patients with life threatening diseases by modulating aberrant purine and uric acid metabolism, including lowering elevated uric acid as a therapy.

## Our Proprietary Therapeutic Platforms

Our expertise and understanding of the pathological effects of aberrant purine metabolism combined with our understanding of uric acid lowering agent structure and function, has enabled the development of our proprietary therapeutic platforms. These are a complementary suite of therapeutic formulations and new chemical entities designed to provide unique solutions for acute and chronic disease. Our therapeutic platforms can be used alone, or in combination, with synergistic activity to develop a multifunctional tailored approach to a variety of indications that can address disease in multiple body systems through management of chronic or acute hyperuricemia, immune modulation, and metabolic disease. We continue to leverage these therapeutic platforms to expand our pipeline of novel and next generation drug-based product candidates that we believe could represent significant improvements to the standard of care in multiple acute and chronic cardiovascular diseases and specifically kidney disease.

We believe our in-house drug design and formulation capabilities confer a competitive advantage to our therapeutic platforms and are ultimately reflected in our programs. Some of these key advantages are:

**Highly Modular and Customizable**

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

**Fit-for-purpose**

Our platforms can also be utilized to engineer new chemical entities and formulations of those agents that have enhanced properties. For example, our XRx-225 product candidate program, some of the intellectual property for which we license from third parties, represents a potential new class of xanthine oxidase inhibitor(s) with a targeted design to enhance anti-inflammatory activity. The capability of tailoring the potential therapeutic benefit of this class of new agents permits us to identify targets and disease that we wish to exploit and then, through formulation design, optimize those small molecules and proprietary formulations to maximize potentially clinically meaningful therapeutic effect.

**Readily scalable and transferable**

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

Our team's expertise in uric acid lowering agents, specifically in the development and use of xanthine oxidase inhibitors, has enabled the development of our therapeutic product candidates to treat the symptoms of, and potentially delay the progression of ADPKD, AKI associated with respiratory virus infection, and T2DN. We note that there is no guarantee that the United States Food and Drug Administration ("**FDA**") will approve our proposed uric acid lowering agent product candidates for the treatment of kidney disease or the health consequences of diabetes.

## Product Candidate Pipeline

Our lead product candidates are XRx-008, XRx-101, and XRx-225. The XRx-008 program has reported topline results for the XRX-OXY-101 Bridging Pharmacokinetic Study of XORLO™ (the "**XRX-OXY-101 PK Clinical Trial**") in advance of initiating Phase 3 registration clinical trial testing, the last stage of clinical development before application for FDA approval. Our recently reported study XRX-OXY-101 supports both the XRx-008 and XRx-101 programs. Future late-stage clinical studies targeting attenuation or reversal of AKI in hospitalized individuals with respiratory virus infection are planned. XRx-225 is a non-clinical stage program advancing toward the clinical development stage.

**Products**

The Company's most advanced development program, XRx-008, is a late clinical stage program focused on demonstrating the potential of our novel product candidate for ADPKD. XRx-008 is the development name given to XORTX's therapeutics program and associated proprietary oral formulation of oxypurinol, XORLO™. XORLO™ has shown increased oral bioavailability compared to a control formulation and demonstrates the potential for an expanded use across a broad therapeutic range. XORTX is also developing a second oral formulation of oxypurinol, XRx-101, for use in treating patients with AKI associated with respiratory virus infection and/or associated co-morbidities including sepsis.

XORTX is currently evaluating novel XOI candidates for the XRx-225 program to potentially treat T2DN as well as developing new chemical entities to address other orphan and large market unmet medical need.

**Patents**

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

## OUR STRATEGY

The Company's goal is to apply our interdisciplinary expertise and pipeline-in-a-product strategy to further identify, develop and commercialize novel treatments in orphan indications, with an initial focus on renal and significant unmet medical needs.

Our ability to implement our business strategy is subject to numerous risks. These risks include, among others (see "Risks Related to the Business"):

- we have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future;
- we will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to alter, delay, scale back, or cease our product development programs or operations;
- we have not generated any revenue to date and may never be profitable;
- we have a limited number of product candidates, all of which are still in preclinical or clinical development, and we may fail to obtain regulatory approval or experience significant delays in doing so;
- our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approved, require them to be taken off the market, require them to include contraindications, warnings and precautions, limitations of use, or otherwise limit their sales;
- we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements, and the denial or delay of any such approval would delay commercialization of our product candidates, if approved, and adversely impact our potential to generate revenue, our business and our results of operations;
- security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation;
- the COVID-19 pandemic may materially and adversely affect our business and financial results;
- our existing strategic partnerships are important to our business, and future strategic partnerships may also be important to us; if we are unable to maintain any of these strategic partnerships, or if these strategic partnerships are not successful, we may not realize the anticipated benefits of our strategic partnerships and our business could be adversely affected;
- we rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates;
- our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties;
- our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged;
- if we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed; and
- if we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

### Funding Requirements

The Company has not generated any revenue from product sales to date and does not expect to do so until such time as XORTX obtains regulatory approval for and commercializes one or more of our product candidates. As the Company is currently in clinical and preclinical stages of development, it will be some time before we expect to achieve this, and it is uncertain that we ever will. We expect that we will continue to increase our operating expenses in connection with ongoing clinical trials and preclinical activities and the development of product candidates in our pipeline. We also expect to continue our strategic partnerships and we continue to seek additional collaboration opportunities. Further, we expect to continue our efforts to pursue additional grants and refundable tax credits from the Canadian government in order to further our research and development. Although it is difficult to predict our funding requirements, based upon our current operating plan, the Company anticipates that our existing cash and cash equivalents as

of December 31, 2022, combined with the net proceeds of future financings, will enable us to advance the clinical development of XRx-008 and XRx-101 product candidates. XORTX may also be eligible to receive certain research, development, and commercial milestone payments in the future. However, because successful development of our product candidates and the achievement of milestones by our strategic partners is uncertain, we are unable to estimate the actual funds we will require to complete the research, development, and commercialization of product candidates.

## RECENT DEVELOPMENTS

### Regulatory Advancements

On March 14, 2022, the Company announced the submission of its clinical trial application with Health Canada for the XRX-OXY-101 PK Clinical Trial, an important first clinical step in the Company's 505(b)2 clinical and regulatory plan for 2022 to support the XRx-008 program for ADPKD and an upcoming, planned phase 3 registration trial.

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

On March 31, 2022, the Company announced the filing of an Investigative New Drug ("**IND**") application with the FDA. This IND filing was in support of the Company's XRx-008 program for treatment of progressing kidney disease due to ADPKD and contained the protocol for the XRX-OXY-101 PK Clinical Trial.

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

On April 12, 2022, the Company announced receipt of a no objection letter from Health Canada regarding the Company's XRX-OXY-101 PK Clinical Trial. The XRX-OXY-101 PK Clinical Trial was designed with three important objectives: 1) to evaluate which of XORTX's novel formulations results in the best circulating oxypurinol concentrations; 2) to evaluate the effect of food on the bioavailability of this formulation; and 3) to evaluate the safety and pharmacokinetics of multiple doses of this selected formulation. Knowledge gained from the XRX-OXY-101 PK Clinical Trial will provide guidance regarding the future oral dosing of oxypurinol formulations in support of the Company's planned phase 3 registration trial in ADPKD. Additionally, the XRX-OXY-101 PK Clinical Trial will provide data to support future New Drug Application ("**NDA**") marketing submissions to the FDA and the European Medicines Agency ("**EMA**").

On April 20, 2022, the Company announced receipt of Small and Medium Enterprise ("**SME**") status for the European Union (the "**EU**"). This status is applicable for the EMA related interactions and confirmed by the SME office – Regulatory Science and Innovation Task Force. SME status provides reduced costs to the Company as it initiates discussions with EMA regarding the upcoming XRX-OXY-301 phase 3 registration trial for XRx-008 and other clinical programs.

On May 3, 2022, the Company announced that dosing of human subjects had been initiated in the XRX- OXY-101 PK Clinical Study. In addition, successful recruitment for part 1 of the three-part (now four-part) clinical trial was completed with 32 subjects receiving study drug. Following administration of the first dose of drug, blood sampling and bioanalytical evaluation was conducted to characterize the pharmacokinetics and bioavailability of the XRx-008 program's XORLO™ for future clinical trials development. Additionally, the XRX-OXY-101 PK Clinical Trial will provide fundamental information for the 505(b)2 marketing approval filing of the XRx-008 program.

On May 5, 2022, the Company announced receipt of official notification from the FDA that the Company's recent IND application had been reviewed and cleared. Accompanying this notification was a "Study May Proceed Letter" regarding the XRX-OXY-101 PK Clinical Trial. We plan to use data collected in the XRX-OXY-101 trial to support development of XRx-008 for treatment of progressing kidney disease due to ADPKD.

On July 7, 2022, following the successful regulatory filings with the FDA and Health Canada and commencement of the OXY-XRX-101 PK Clinical Study, the Company submitted a type B pre-Phase 3 meeting request with the FDA.

On July 13, 2022, the Company announced positive topline results from Part 1 of the three-part (now four part) XRX-OXY-101 PK Clinical Trial showing a substantial increase in oral bioavailability of two versions of XORTX's proprietary oxypurinol formulation compared to a control formulation. In addition to the substantial increase in bioavailability in part 1 of the XRX-OXY-101 PK Clinical Trial, XRx-008 was well-tolerated with a favorable pharmacologic profile. No drug related adverse or serious adverse events related to oral administration of oxypurinol were observed.

On July 19, 2022, the Company announced submission of a request for "scientific advice review" to the EMA and more specifically the Committee for Medical Products for Human Use (the "CHMP") regarding the XRx-008 program. This submission for CHMP/EMA review initiated discussions regarding the status of XORTX's XRx-008 program for ADPKD, plans for its global phase 3 registration trial, and included scientific advice pertaining to marketing approval in the EU.

On August 4, 2022, the Company announced that the pre-Phase 3 meeting request made to the FDA resulted in the grant of a virtual meeting scheduled on September 16, 2022. In advance of this meeting, XORTX submitted a "Pre-Phase-3 Briefing Package" to the FDA on July 28, 2022.

On August 22, 2022, the Company announced positive topline results from its XRX-OXY-101 PK Clinical Trial – Part 2 showing a substantial increase in oral bioavailability of XORLO™ provided with food compared to the fasted state. In addition to the substantial increase in bioavailability in part 2, XRx-008 was well-tolerated with a favorable pharmacologic profile. No drug related adverse or serious adverse events related to oral administration of oxypurinol were observed.

On September 19, 2022, the Company announced the completion of the Type B Pre-phase 3 meeting with the FDA held on September 16, 2022. In advance of this meeting, XORTX submitted a "Pre-Phase-3 Briefing Package" to the FDA on July 28, 2022 and received responses from, and responded to the FDA prior to the virtual meeting. The FDA provided guidance on the design of the planned Phase 3 clinical trial.

On October 26, 2022, the Company announced receipt of a further no objection letter from Health Canada regarding the Company's ongoing XRX-OXY-101 PK Clinical Trial. The XRX-OXY-101 PK Clinical Trial was originally designed as a three part study and a no objection letter was received by Health Canada in April 2022. The Company successfully completed parts 1 and 2 of the XRX-OXY-101 PK Clinical Trial, modified part 3 and added an additional part 4. The XRX-OXY-101 PK Clinical Trial was originally designed with three objectives: 1) to evaluate which of XORTX's novel formulations results in the best circulating oxypurinol concentrations; 2) to evaluate the effect of food on the bioavailability of this formulation; and 3) to evaluate the safety and pharmacokinetics of multiple doses of this selected formulation. After completion of parts 1 and 2, XORTX redesigned part 3 to include an additional characterization of food effect and added a fourth objective - part 4 - to characterize the proportion of oxypurinol absorbed with three increasing doses of XRx-008.

On November 3, 2022, the Company announced the presentation of a peer-reviewed abstract that was presented on November 4, 2022 at the American Society of Nephrology Annual Conference – Kidney week. The Abstract presented new discoveries in two species – mouse and rat models of polycystic kidney disease ("**PKD**") and reported original work showing the harmful consequences of chronically increased uric acid on both structure and function of kidneys. The Abstract "Raising Serum Uric Acid with a Uricase Inhibitor Worsens PKD in Rat and Mouse models" was presented during the Session Title: Genetic Diseases of the Kidneys, by Dr. Charles Edelstein of the University of Colorado and Dr. Allen Davidoff,

Chief Executive Officer ("**CEO**") of XORTX. This presentation reported for the first time, that XORTX's XRx008 formulation of XOI substantially and significantly blocked the increase in kidney size associated with high circulating uric acid in a rodent model of polycystic kidney disease.

On November 28, 2022, the Company announced the successful screening and enrollment of the last remaining subjects into the XRX-OXY-101 PK Clinical Trial, including initiation of dosing of all subjects enrolled in part 4 of the XRX-OXY-101 PK Clinical Trial.

On December 8, 2022, the Company announced new proof of concept data supporting, in a second study, the effectiveness of XOI produced by the Company's proprietary oral oxypurinol formulation, XORLO™, in a mouse model of ADPKD. This new experimental data reproduces the result reported at the American Society of Nephrology meeting held November 2022 and added further new evidence to support our belief that XOI produced by our proprietary formulation of oxypurinol at doses that would be considered moderate-to-low in man is effective at inhibiting the expansion of kidneys in ADPKD.

On December 19, 2022, the Company announced the completion of dosing in the XRX-OXY-101 PK Clinical Trial, in each of parts 1 through 4. Positive topline results from the XRX-OXY-101 PK Clinical Trial characterizing the pharmacokinetics of XORLO™ was announced on January 19, 2023. In the study, XORLO™ was well tolerated across the various dosing regimens. No safety issues were identified in any of the four parts of the XRX-Oxy-101 PK Clinical Trial on the 88 subjects who received drug.

On January 3, 2023, the Company announced the submission of a PCT patent application seeking international patent protection for the patent entitled "Compositions and Methods for Diagnosis, Treatment and Prevention of Kidney Disease".

On February 1, 2023, the Company announced it submitted an Orphan Drug Designation ("**ODD**") Request to the FDA for the XRx-008 program and specifically for XORLO™ for the treatment of ADPKD.

On March 14, 2023, the Company announced the submission of a Type D meeting request to the FDA and a response setting the date for a virtual meeting on May 1, 2023. A Type D meeting provides an opportunity to discuss with FDA a narrow set of issues on a shorter timeline than with other meeting types. Additionally, a revised clinical trial protocol for XRX-OXY-301 was submitted, a data update from the XRX-OXY-101 PK Clinical Trial as well as a description of future clinical development program plans for XORLO™ for the treatment of ADPKD. We believe our prior discussions with the FDA and existing agency guidance will permit application for accelerated approval based on specified validated endpoints such as total kidney volume in ADPKD. We believe submission of this revised clinical trial protocol, XRX-OXY-301 will provide the opportunity for XORTX's XRx-008 program to potentially achieve earlier completion of our planned registration trial and importantly to potentially accelerate our application to FDA for marketing approval.

### Private Placement

On October 7, 2022, the Company closed an underwritten public offering of: (i) 1,400,000 common share units ("**Common Share Units**"), with each Common Share Unit consisting of one common share, no par value, and one warrant ("**Warrant**") to purchase one common share at a public offering price of US$1.00 per Common Share Unit, and (ii) 3,600,000 pre-funded warrant units ("**Pre-Funded Units**" and together with the Common Share Units, the "**Units**"), with each Pre-Funded Unit consisting of one pre-funded warrant ("**Pre-Funded Warrant**") to purchase one common share and one Warrant to purchase one common share at a public offering price of US$0.9999 per Pre-Funded Unit, for aggregate gross proceeds of US$5 million, prior to deducting underwriting discounts and other offering expenses and excluding any exercise of the underwriters' option to purchase any additional securities as described herein (the "**Offering**"). The common shares and Warrants contained in the Common Share Units and the Pre-Funded Warrants and Warrants contained in the Pre-Funded Units were immediately separable upon issuance. The Warrants have an initial exercise price of US$1.22 per share, are immediately exercisable, and may be exercised for five years from the date of issuance. The Pre-Funded Warrants had an exercise price of US$0.0001 per share, were immediately exercisable, and terminated once exercised in full. As of the date of this MD&A, all 3,600,000 Pre-Funded Warrants have been exercised.

Further to an investment in connection with the Offering, the Company entered into an agreement, approved by the TSXV, to reduce the exercise price of outstanding warrants to purchase up to 910,000 shares of common stock issued in the 2021 public offering (the "**Prior Warrants**") and held by investors in the Offering from US$4.77 per share to US$1.17 per share, effective upon the closing of the Offering. All other terms of the Prior Warrants remained the same.

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

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

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

On November 16, 2022, the Company announced the appointment of Dr. Stacy Evans as Chief Business Officer ("**CBO**").

### Nasdaq Compliance

On November 25, 2022, the Company announced that it received notification from Nasdaq Listing Qualifications Department that it was not in compliance with the minimum bid price requirement set forth in Nasdaq Rule 5550(a)(2) since the closing bid price for the Company's common shares listed on Nasdaq was below US$1.00 for 30 consecutive business days. Nasdaq Rule 5550(a)(2) requires the shares to maintain a minimum bid price of US$1.00 per share, and Nasdaq Rule 5810(c)(3)(A) provides that failure to meet such a requirement exists when the bid price of the shares is below US$1.00 for a period of 30 consecutive business days. It was noted that these notifications do not impact the Company's listing on Nasdaq at this time. In accordance with Listing Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from the date of notification to regain compliance with the minimum bid price requirement, during which time the shares will continue to trade on the Nasdaq Capital Market. If at any time before the 180 calendar day period, the bid price of the shares closes at or above US$1.00 per share for a minimum of 10 consecutive business days, Nasdaq has the discretion to provide written notification that the Company has achieved compliance with the minimum bid price requirement and consider such deficiency matters closed.

## FUTURE PLANS AND OUTLOOK

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

In 2022, the Company made substantial progress advancing its strategic plan in key areas, including chemistry, manufacturing, formulation development, non-clinical studies using XORLO™ to attenuate PKD progression in animal models and completion of the first clinical study, the XRX-OXY-101 PK Clinical Trial, in support of the XRx-008 program for ADPKD. The Company advanced its intellectual property portfolio, characterized the XORLO™ formulation pharmacokinetics for dose modeling and dose selection in individuals with kidney disease. The XRX-OXY-101 PK Clinical Trial data gathered provides key data regarding dosing and safety of XORLO™ for communications with the FDA, EMA and Health Canada to advance the optimal design of XORTX's registration trial for ADPKD. We believe these communications will assist us in conducting more in-depth and meaningful partnering discussions in the near future.

In 2023, XORTX will be focused on advancing XORLO™ as part of the XRx-008 for ADPKD into Phase 3 clinical trial program, obtaining ODD, initiation of special protocol assessment ("**SPA**") discussions with the FDA and initiation of commercialization activities, if approved, for XORLO™ as well as advancing research in other kidney disease applications. To achieve these objectives, XORTX's action plan includes:

1. **Initiate the Phase 3 clinical trial, XRX-OXY-301, to support an application for "Accelerated Approval" of XORLO™ for individuals with ADPKD** (the "**XRX-OXY-301 Clinical Trial**")**.** The XRX-OXY-301 Clinical Trial is a Phase 3, Multi-Centre, Double-Blind, Placebo Controlled, Randomized Withdrawal Design Study to Evaluate the Efficacy and Safety of a Novel Oxypurinol Formulation in Patients with Progressing Stage 2-4 ADPKD and Coexistent Hyperuricemia. The XRX-OXY-301 Clinical Trial will provide data to support a future "Accelerated Approval" NDA submissions to the FDA and MAA to the EMA. The XRX-OXY-301 Clinical Trial is planned to start in the second half of 2023 and will enroll individuals with stage 2, 3 or 4 ADPKD and presenting with chronically high uric acid. The objective of the XRX-OXY-301 Clinical Trial is to evaluate the ability of XORLO™ to slow the expansion of total kidney volume over a 12-month treatment period.

2. **Orphan Drug Designation (ODD).** XORTX's ODD application was filed in January 2023, with anticipated feedback from the FDA ODD office within 90 days and ODD status during the first half 2023.

3. **Prepare and Communicate with the FDA and EMA regarding the XRX-OXY-302 Registration trial in ADPKD** (the "**XRX-OXY-302 Clinical Trial**")**.** The XRX-OXY-302 Clinical Trial is a Phase 3, Multi-Centre, Double-Blind, Placebo Controlled, Randomized Withdrawal Design Study to Evaluate the Efficacy and Safety of a Novel Oxypurinol Formulation in Patients with Progressing Stage 2-4 ADPKD and Coexistent Hyperuricemia with progressing stage 2, 3, or 4 kidney disease. The objective of the XRX-OXY-302 Clinical Trial is to evaluate the safety and effectiveness of XORLO™ for the XRx-008 program over a 24-month treatment period. The aim of the XRX-OXY-302 Clinical Trial is to characterize the ability of XOI to potentially decrease the rate of decline of glomerular filtration rate. An estimated 300 patients will be enrolled. The XRX-OXY-302 Clinical Trial is planned to start in the second half of 2024, subject to Special Protocol Assessment review by FDA.

4. **Ongoing CMC Work.** In parallel with the XRX-OXY-301 and XRX-OXY-302 Clinical Trials, XORTX will focus on scale-up, validation and stability testing of clinical drug product supplies of XORLO™ under the Company's granted IND, as well as future clinical and commercial supplies. All development will be performed according to current GMP methodology. This work will be ongoing throughout 2023.

5. **Activities Related to Potential Commercial Launch.** In preparation for a possible "Accelerated Approval" NDA filing in 2025 in the US for XORLO™ for XRx-008, XORTX will conduct commercialization studies to support in-depth analysis of pricing and/or reimbursement, as well as evaluate product brand name selection and prepare related filings, and conduct other launch preparation activities. This work will be ongoing from 2023 to 2025.

6. **Activities Related to European Registration.** XORTX will continue to work with and seek out guidance from the EMA to facilitate the path to potential approval of XORLO™ in the EU, including required clinical studies and reimbursement conditions. This work will be ongoing from 2023 through 2026, and will include a future request for orphan drug status.

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

## SUMMARY OF QUARTERLY RESULTS

The following table sets forth unaudited quarterly results prepared by management for the eight previous quarters to December 31, 2022:

| (unaudited) | 2022 Q4 | 2022 Q3 | 2022 Q2 | 2022 Q1 |
|---|---|---|---|---|
| Amortization of intangible and capital assets | 29,245 | 28,788 | 12,454 | 4,781 |
| Foreign exchange loss (gain) | 264,107 | (662,828) | (348,314) | 197,398 |
| Consulting | 24,834 | 145,606 | (153,266) | 291,982 |
| Directors' fees | 57,123 | 59,377 | 29,554 | 15,000 |
| General and administrative | 119,774 | 153,010 | 157,604 | 151,804 |
| Interest | (72,924) | (46,280) | (15,017) | (3,354) |
| Investor relations | 247,342 | 131,436 | 519,707 | 301,833 |
| Listing fees | 42,466 | 32,766 | 48,383 | 33,585 |
| Professional fees | 125,487 | 73,407 | 282,152 | 106,805 |
| Research and development | 2,583,769 | 1,922,287 | 1,861,216 | 2,440,720 |
| Share based payments (1) | 96,247 | 25,147 | 424,958 | 86,196 |
| Travel | 14,989 | 110 | 14,569 | – |
| Wages and benefits | 272,726 | 173,008 | 187,370 | 208,700 |
| Transaction costs on derivative warrant liability | 1,257,746 | – | – | – |
| (Gain) loss on derivative warrant liability | (2,144,722) | (473,360) | (1,440,006) | (412,188) |
| Total Comprehensive (loss) income | (2,918,209) | (1,562,474) | (1,581,364) | (3,423,262) |
| (Loss) earnings per share | (0.20) | (0.12) | (0.12) | (0.26) |

| (unaudited) | 2021 Q4 | 2021 Q3 | 2021 Q2 | 2021 Q1 |
|---|---|---|---|---|
| Amortization of intangible assets | 4,739 | 4,526 | 4,373 | 4,244 |
| Foreign exchange loss (gain) | (346,716) | 12,242 | 7,336 | 387 |
| Consulting | 368,662 | 109,269 | 94,480 | 151,861 |
| Directors' fees | 22,700 | 39,500 | – | – |
| General and administrative | 146,012 | 6,263 | 13,012 | 10,812 |
| Interest | 1,669 | 1,382 | 665 | 1,882 |
| Investor relations | 134,543 | 118,947 | 60,251 | 204,874 |
| Listing fees | 148,487 | 36,858 | 36,903 | 14,553 |
| Professional fees | 71,246 | (402,676) | 491,552 | 112,821 |
| Research and development | 430,948 | 381,967 | 26,423 | 13,786 |
| Share based payments (1) | 143,496 | 62,221 | 90,451 | 202,990 |
| Travel | 239 | – | – | 2,100 |
| Wages and benefits | 137,678 | 48,000 | 48,000 | 52,412 |
| Transaction costs on derivative warrant liability | 1,537,948 | – | – | 85,732 |
| (Gain) loss on derivative warrant liability | (11,895,882) | 7,936,114 | (655,000) | 1,315,000 |
| Total Comprehensive (loss) income | 9,094,231 | (8,354,613) | (218,446) | (2,173,454) |
| (Loss) earnings per share | 0.74 | (0.89) | (0.02) | (0.26) |

Notes:
(1) Share based payments relate to the vesting of options over the period.
(2) The loss during the three months ended December 31, 2022 relates mostly to the increase in research and development costs resulting from the commencement of various feasibility studies and clinical trial expenses as offset by gain on derivative warrant liability valuation and gain on foreign exchange.

**Three months ended December 31, 2022**

The Company incurred a comprehensive loss of $2,918,209 ($0.20 per share) for the three months ended December 31, 2022, compared to a comprehensive income of $9,094,231 ($0.74 per share) in the three months ended December 31, 2021.

Variances within the loss items are as follows:

***Foreign Exchange Loss*** **-** $264,107 (2021 – gain of $346,716) – Foreign exchange loss was $264,107 for the three months ended December 31, 2022 as compared to a gain of $346,716 in the prior year quarter primarily due to an unrealized translation loss on the US dollar denominated cash balance.

***Consulting*** - $24,834 (2021 - $368,662) – Consulting expenses decreased during the three months ended December 31, 2022, as fewer consultants were engaged during the interim period due to a decrease in Company activity with respect to corporate development.

***Directors' fees*** - $57,123 (2021 - $22,700) – Directors' fees expenses increased during the three months ended December 31, 2022 mainly due to monthly Director fee payment to Anthony Giovinazzo, Chairman of the Company.

***Investor relations*** - $247,342 (2021 - $134,543) – Investor relations expense increased during the three months ended December 31, 2022 as the Company entered into various engagements to provide information to investors.

***Listing fees*** - $42,466 (2021 - $148,487) – Listing fees decreased during the three months ended December 31, 2022 due to costs related to the Company's listings on the TSXV and Nasdaq stock exchanges in the prior year quarter.

***Research and development*** - $2,583,769 (2021 - $430,948) – Research and development expenses increased in the three months ended December 31, 2022 compared to the same period last year as detailed in the following table:

The table below presents combined research and development costs for XRx-008, XRx-101, and XRx-225 as the Company's projects are presently run concurrently and in combination.

| | Q4 2022 | Q4 2021 | Change $ | Change % |
|---|---|---|---|---|
| Clinical trials expense [1] | 1,399,798 | – | 1,399,798 | – |
| Manufacturing and related process expenses [2] | 560,940 | 115,295 | 445,645 | 387% |
| Intellectual property expenses [3] | 14,008 | 10,371 | 3,637 | 35% |
| Translational science expenses [4] | 216,117 | 196,633 | 19,484 | 10% |
| External consultants' expenses [5] | 392,906 | 108,649 | 284,257 | 262% |
| Total Research and development | $2,583,769 | $430,948 | $2,152,821 | 500% |

Notes:

(1) Clinical trials expenses include those costs associated with our clinical trial program which primarily included expenses related to the XRx-008 and XRx-101 projects. Included in clinical trials expenses are regulatory and consulting activities, contract research organization expenses, data management expenses, and other costs associated with our clinical trial program. In Q4 2022, clinical trials expense primarily related to the XRX-OXY-101 PK Clinical Trial increased during the current year quarter as a new expense.

(2) Manufacturing and related process expenses includes third party direct manufacturing costs, quality control testing and packaging costs. In Q4 2022, manufacturing costs primarily related to the Company's oxypurinol manufacturing, feasibility study and chemical compound studies. The increase in manufacturing and related process expenses in Q4 2022 as compared to Q4 2021 relates to the XRX-OXY-101 Clinical Trial and preparation of drug substance and drug product for the registration trial in ADPKD, while in Q4 2021, manufacturing costs primarily related to oxypurinol drug substance, stability and formulation development.

(3) Intellectual property expenses include legal and filing fees associated with our patent portfolio. No significant change in intellectual property expenses in Q4 2022 as compared to Q4 2021.

(4) Translational science expenses include various research studies conducted to expand our intellectual knowledge base related to oxypurinol and our proprietary formulations of oxypurinol, pharmacokinetic testing, non-clinical bioavailability studies, pharmacology and toxicology testing and identify potential licensing opportunities. The translational science expense in Q4 2022 related to new sponsored research at the University of Denver, Colorado whereas no comparable activity was undertaken in Q4 2021.
(5) External consultants' expenses include third party consultants engaged in the activities of research and development, including chemistry, manufacturing, drug product development, regulatory, non-clinical and clinical study execution. The increase in external consultants' expenses in Q4 2022 as compared to Q4 2021 was attributed to increased activity focused on the XRX-OXY-101 PK Clinical Trial and preparations for single registration trial associated with the XRx-008 program in individuals with ADPKD during 2023.

***Wages and benefits*** - $272,726 (2021 - $137,678) – The wages and benefits expense increased in the three months ended December 31, 2022, as the Company paid out year-end bonuses and accrued vacation payable.

***Gain on derivative warrant liability*** – $2,144,722 (2021 – $11,895,882). The gain recognized during the three months ended December 31, 2022 relates to the warrants included in the units issued under the October 2022 public offering and the IPO in the prior year, while the gain in 2021 relates to the warrants issued under the Private Placement and the IPO. The warrants issued under the Private Placement were classified as a derivative financial liability as they contained a ratchet provision that provided for an adjustment in the exercise price of the warrants if shares or securities convertible to shares were sold at a price lower than the exercise price. The public offering warrants have an exercise price in US dollars and have a derivative financial liability as the exercise price is in a different currency than the functional currency of the Company. The warrants are initially recognized at fair value and subsequently measured at fair value with changes recognized through profit or loss.

**Year ended December 31, 2022**

The Company incurred a comprehensive loss of 9,485,309 ($0.71 per share) for the year ended December 31, 2022, compared to $1,652,282 ($0.17 per share) in the year ended December 31, 2021.

Variances within the loss items are as follows:

***Foreign Exchange Gain*** - $549,637 (2021 – $326,751) – Foreign exchange gain of $549,639 for the year ended December 31, 2022 as compared to $326,751 in 2021 was primarily due to an unrealized translation gain on the US dollar denominated cash balance.

***Consulting*** - $309,156 (2021 - $724,272) – Consulting expenses decreased during the year ended December 31, 2022, as fewer consultants were engaged during the year due to a decrease in Company activity with respect to corporate development.

***Directors' fees*** - $161,054 (2021 - $62,200) – Directors' fees expenses increased during the year ended December 31, 2022, as the Company commenced paying directors' fees to its independent directors on July 1, 2021 and due to monthly Director fee paid to Anthony Giovinazzo, Chairman of the Company.

***General and administrative*** - $582,192 (2021 – $176,099) General and administrative costs increased significantly mostly due to an increase in the director and officer insurance premium as well as an increase in Company activity.

***Investor relations*** - $1,200,318 (2021 - $518,615) – Investor relations expense increased during the year ended December 31, 2022 as the Company entered into various engagements to provide information to investors.

***Professional fees*** - $587,851 (2021 - $272,943). Professional fees, which consists mainly of accounting, audit and legal fees, increased during the year ended December 31, 2022 as compared with the 2021 period, due to the Company's increased corporate activity.

***Research and development*** - $8,807,992 (2021 - $853,124) – Research and development expenses increased during the year ended December 31, 2022, compared to the same period last year as detailed in the table below.

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

| | 2022 | 2021 | Change $ | Change % |
|---|---|---|---|---|
| Clinical trials expense [1] | 3,872,967 | - | 3,872,967 | - |
| Manufacturing and related process expenses [2] | 2,285,278 | 392,619 | 1,892,659 | 482% |
| Intellectual property expenses [3] | 41,334 | 28,724 | 12,610 | 44% |
| Translational science expenses [4] | 1,104,359 | 210,605 | 893,754 | 424% |
| External consultants' expenses [5] | 1,504,054 | 201,090 | 1,302,964 | 648% |
| Other expenses | - | 20,086 | (20,086) | (100%) |
| Total Research and development | $8,807,992 | $853,124 | $7,954,868 | 932% |

Notes:

(1) Clinical trials expenses include those costs associated with our clinical trial program which primarily included expenses related to the XRx-008 and XRx-101 projects. Included in clinical trials expenses are regulatory and consulting activities, contract research organization expenses, data management expenses, and other costs associated with our clinical trial program. In 2022, the clinical trials expense related primarily to the XRX-OXY-101 PK Clinical Trial which contributed to the increase in the current year.

(2) Manufacturing and related process expenses include third party direct manufacturing costs, quality control testing and packaging costs. In 2022, the Company's manufacturing costs primarily related to oxypurinol manufacturing, feasibility study and chemical compound studies. The increase in manufacturing and related process expenses in 2022 as compared to 2021 is entirely attributable to increased activity geared towards the start of XRX-OXY-101 PK Clinical Trial and registration trial in ADKPD during 2023.

(3) Intellectual property expenses include legal and filing fees associated with our patent portfolio. The increase in intellectual property expenses in 2022 as compared to 2021 relates to additional patent filings as the Company expands its patent portfolio and legal filing fees with the EMA.

(4) Translational science expenses include various research studies conducted to expand our intellectual knowledge base related to oxypurinol, our proprietary formulations of oxypurinol, development of new chemical entities, pharmacokinetic testing, non-clinical bioavailability studies, pharmacology and toxicology testing and identification of potential licensing opportunities. The translational science expense in 2022 related to sponsored research work at the University of Denver, Colorado and animal studies. Very little activity was undertaken in 2021. We expect translational science expense in 2022 will increase as compared to 2021 as the Company expands its candidate formulation and new chemical entities testing.

(5) External consultants' expense includes third party consultants engaged in the activities of research and development, including chemistry, manufacturing, drug product development, regulatory, non-clinical and clinical study execution. The increase in external consultants' expenses in 2022 as compared to 2021 was attributed to increased activity focused on the initiation of the Company's XRX-OXY-101 PK Clinical Trial and thereafter a single registration trial associated with the XRx-008 program in individuals with ADKPD during 2023. We expect external consultants' expense in 2023 to increase as compared to 2022 as the Company initiates and conducts a registration trial in ADKPD.

***Wages and benefits*** - $841,804 (2021 - $286,090) – The wages and benefits expense increased in the year ended December 31, 2022, as the Company's Chief Financial Officer ("**CFO**"), Chief Technology Officer (**"CTO"**) (partial year), Chief Medical Officer ("**CMO**") and Chief Business Officer (**"CBO"**) were added to the payroll and vacation was accrued.

***Gain on derivative warrant liability*** – $4,470,276 (2021 – $3,299,768). The gain recognized during the year ended December 31, 2022 relates to the warrants included in the units issued under the IPO on October 15, 2021 and the warrants issued under the public offering in October 7, 2022. The gain recognized during the year ended December 31, 2021 relates to the warrants included in the units issued under the Private Placement on February 9, 2021 and the IPO on October 15, 2021. The Private Placement warrants were classified as a derivative financial liability as they contained a ratchet provision that provided for an adjustment in the exercise price of the warrants if shares or securities convertible to shares were sold at a price lower than the exercise price. The IPO warrants have an exercise price in US dollars and have a derivative financial liability as the exercise price is in a different currency than the functional currency of the entity. The warrants are initially recognized at fair value and subsequently measured at fair value with changes recognized through profit or loss.

## Selected Annual Financial Information

The financial information reported herein has been prepared in accordance with IFRS. The Company uses the Canadian dollar as its presentation currency. The following table represents selected financial information for the Company's fiscal years 2022, 2021, and 2020.

**Selected Statement of Operations Data**

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Revenue | $Nil | $Nil | $Nil |
| Comprehensive loss for the year | $9,485,309 | $1,652,282 | $1,284,602 |
| Weighted average shares outstanding | 13,319,226 | 9,847,641 | 6,664,025 |
| Loss per share, basic and diluted | $0.71 | $0.17 | $0.19 |

**Selected Statement of Financial Position Data**

| | Dec. 31, 2022 | Dec. 31, 2021 | Dec. 31, 2020 |
|---|---|---|---|
| Cash and cash equivalents | $14,125,522 | $18,851,244 | $171,271 |
| Net working capital | $12,700,150 | $19,472,340 | $1,021,928 |
| Total assets | $16,752,929 | $22,035,902 | $2,290,457 |
| Long-term liabilities | ($5,236,237) | ($4,597,332) | $Nil |

## Comparison of Operations for the 2022 and 2021 Financial Years

***Results of Operations***

| | 2022 | 2021 | Change $ | Change % |
|---|---|---|---|---|
| Amortization | 75,268 | 17,882 | 57,386 | 321% |
| Consulting | 309,156 | 724,272 | (415,116) | (57%) |
| Directors' fees | 161,054 | 62,200 | 98,854 | 159% |
| General and administrative | 582,192 | 176,099 | 406,093 | 231% |
| Investor relations | 1,200,318 | 518,615 | 681,703 | 131% |
| Listing fees | 157,200 | 236,801 | (79,601) | (34%) |
| Professional fees | 587,851 | 272,943 | 314,908 | 115% |
| Research and development | 8,807,992 | 853,124 | 7,954,868 | 932% |
| Share-based payments | 632,548 | 499,158 | 133,390 | 27% |
| Travel | 29,668 | 2,339 | 27,329 | 1168% |
| Wages and benefits | 841,804 | 286,090 | 555,714 | 194% |
| Foreign exchange (gain) | (549,637) | (326,751) | (222,888) | 68% |
| Gain on derivative warrant liability | (4,470,276) | (3,299,768) | (1,170,508) | 35% |
| Interest and other expenses | (137,575) | 5,598 | (143,173) | (2558%) |
| Transaction costs on derivative warrant liability | 1,257,746 | 1,623,680 | (365,934) | (23%) |
| Comprehensive Loss for the Year | 9,485,309 | 1,652,282 | 7,833,027 | 474% |
| Loss per Share | 0.71 | 0.17 | 0.54 | 318% |

### Comparison of cash flows for the years ended December 31, 2022 and 2021

The Company realized a net cash outflow of $4,725,722 for the year ended December 31, 2022, compared to a cash inflow of $18,679,973 for the year ended December 31, 2021. The variances in the cash flow for the year ended December 31, 2022, compared to December 31, 2021 were as follows:

***Operating activities –*** Cash used in operating activities for the year ended December 31, 2022, was $11,968,200 (2021 - $6,062,510). The cash used in operating activities was primarily due to the net loss during the year offset by the non-cash items.

***Investing activities –*** Cash used in investing activities for the year ended December 31, 2022, was $60,016 (2021 - $39,809). The cash used related to the acquisition of intangible and capital assets during the year.

***Financing activities –*** Cash provided by financing activities in the year ended December 31, 2022, was $6,430,858 (2021 – $24,456,551). The cash provided was related to the October 2022 public offering of 1,400,000 common share units to purchase one common share at a public offering price of US$1.00 per Common Share Unit and 3,600,000 pre-funded warrant units with each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one common share and one Warrant to purchase one common share at a public offering price of US$0.9999 per Pre-Funded Unit, for aggregate gross proceeds of $6,855,506 (US$4,999,640). In the prior year period, the cash provided was mostly related to the public offering that occurred when the shares of the Company were listed on Nasdaq of 2,906,000 units, with each unit consisting of one common share, no par value, and one warrant to purchase one common share at a public offering price of US$4.13 per Unit, for gross proceeds of $14,851,850 (US$12,001,780) as well as the private placement that took place in February 2021 raising gross proceeds of $6,121,572 through the issuance of 2,085,687 units at a subscription price of $2.935 per unit.

## LIQUIDITY AND CAPITAL RESOURCES

As at December 31, 2022, the Company had a cash balance of $14,125,522 and working capital of $12,700,150 as compared to a cash balance of $18,851,244 and working capital of $19,472,340 as at December 31, 2021. During the year ended December 31, 2022, the Company closed a public offering that consisted of 1,400,000 common share units and 3,600,000 pre-funded warrant units with each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one common share and one Warrant to purchase one common share at a public offering price of US$0.9999 per Pre-Funded Unit, for aggregate gross proceeds of $6,855,506 (US$4,999,640). During the year ended December 31, 2021, the Company closed a public offering that occurred when the shares of the Company were listed on Nasdaq. The offering consisted of 2,906,000 units, with each unit consisting of one common share, no par value, and one warrant to purchase one common share at a public offering price of US$4.13 per Unit, for gross proceeds of $14,851,850 (US$12,001,780) as well as the private placement that took place in February 2021 raising gross proceeds of $6,121,572 through the issuance of 2,085,687 units at a subscription price of $2.935 per unit. The Company's primary source of funding is by way of raising capital through the issuance of equity to third party investors.

Although there is no certainty, management is of the opinion that additional funding for its projects and operations can be raised as needed. The Company is subject to a number of risks associated with the successful development of new products and their marketing and the conduct of its clinical studies and their results. The Company will have to finance its research and development activities and its clinical studies. To achieve the objectives in its business plan, the Company plans to raise the necessary capital and to generate revenues. It is anticipated that the products developed by the Company will require approval from the FDA and equivalent organizations in other countries before their sale can be authorized. If the Company is unsuccessful in obtaining adequate financing in the future, corporate initiatives may be affected or postponed.

## USE OF FINANCING PROCEEDS

On October 7, 2022, the Company closed an underwritten public offering of: (i) 1,400,000 Common Share Units, with each Common Share Unit consisting of one common share, no par value, and one Warrant to purchase one common share at a public offering price of US$1.00 per Common Share Unit, and (ii) 3,600,000 Pre-Funded Units and together with the Common Share Units, the Units, with each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one common share and one Warrant to purchase one common share at a public offering price of US$0.9999 per Pre-Funded Unit, for aggregate gross proceeds of US$5 million, prior to deducting underwriting discounts and other offering expenses and excluding any exercise of the underwriters' option to purchase any additional securities as described herein (the "**Offering**"). The common shares and Warrants contained in the Common Share Units and the Pre-Funded Warrants and Warrants contained in the Pre-Funded Units were immediately separable upon issuance. The Warrants have an initial exercise price of US$1.22 per share, are immediately exercisable, and may be exercised for five years from the date of issuance. The Pre-Funded Warrants have an exercise price of US$0.0001 per share, are immediately exercisable, and will terminate once exercised in full. On December 29, 2022 and January 19, 2023, 641,000 and 2,959,000, Pre-Funded Warrants were exercised leaving a balance of Nil outstanding as at the date of this MD&A.

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

The Company has not fully used the net proceeds of the 2022 and 2021 US Offerings. The proceeds that the Company has used (approximately $11.9 million as of December 31, 2022) have been used for funding operations and general corporate purposes, which has included further research and development and manufacture of active pharmaceutical ingredients and drug product to support clinical trials. The Company intends to continue to use the remaining net proceeds of the offering, together with existing cash, for funding operations and general corporate purposes, which may include further research and development, clinical trials, manufacture of active pharmaceutical ingredients and drug product to support clinical trials and intends to use the proceeds in approximately the following proportions: XRx-008: 90%; XRx-101: 5%; XRx-225: 5%.

## COMMITMENTS

The Company had long-term arrangements with commitments as at December 31, 2022 and 2021 as follows:

**Employment Agreements**

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| | $ | $ |
| Management services – officers | 502,320 | 476,000 |

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

The CFO of the Company has a long-term employment agreement with the Company. The agreement has a termination clause whereby he is entitled to the equivalent of 12 times his then current monthly salary which as of December 31, 2022 and 2021, equated to an annual salary of $192,000.

**Payments**

In the normal course of business, the Company has committed to payments totaling $2,701,114 (2021 - $1,613,142) for activities related to its clinical trials, manufacturing, collaboration programs and other regular business activities which are expected to occur over the next two years.

## OFF BALANCE SHEET ARRANGEMENTS

The Company has no off-balance sheet arrangements.

## TRANSACTIONS WITH RELATED PARTIES

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

During the year ended December 31, 2022, the Company incurred the following transactions with related parties:

a) Wages and benefits were paid or accrued to Allen Davidoff, CEO, Amar Keshri, CFO, and David MacDonald, former CTO of the Company in the amount of $775,259 (2021 - $311,840).

b) Professional fees were paid or accrued to 1282803 Ontario Inc., a company owned by Jim Fairbairn, a former CFO of the Company in the amount of $nil (2021 - $58,500).

c) Research and development fees were paid or accrued to Haworth Biopharmaceutical, a company owned by Stephen Haworth, CMO of the Company in the amount of $312,412 (2021 - $106,366).

d) Consulting fees were paid or accrued to Stacy Evans, CBO of the Company in the amount of $61,018 (2021 - $nil).

e) Consulting fees were paid to Bruce Rowlands and Allan Williams, former directors of the Company in the amount of $nil (2021 - $54,950).

f) Consulting fees were paid to a private entity controlled by the spouse of the Company's CEO in the amount of $4,750 (2021 - $nil).

g) Directors' fees were paid or accrued to the directors of the Company in the amount of $166,923 (2021 - $62,200). The amount includes a director fee payment of $90,871 for the year ended December 31, 2022 (2021 - $nil) to Anthony Giovinazzo, Chairman of the Company.

h) As at December 31, 2022, $20,200 (2021 - $81,104) was payable to directors of the Company, $39,069 (2021 - $25,000) was accrued to the CEO of the Company for CEO services, $14,769 (2021 - $nil) was accrued to the CFO of the Company for CFO services, $67,720 (2021 - $47,543) was payable and accrued to the CMO of the Company for consulting services, and $33,860 (2021 - $nil) was payable and accrued to the CBO of the Company for consulting services. The balances are unsecured, non-interest bearing, and have no fixed terms of repayment.

i) Management compensation transactions for the years ended December 31, 2022 and 2021 are summarized as follows:

| | Short-term employee benefits | Directors' fees | Share-based payments | Total |
|---|---|---|---|---|
| | $ | $ | $ | $ |
| Year ended December 31, 2021 | | | | |
| Directors and officers | 531,656 | 62,200 | 331,809 | 925,665 |
| Year ended December 31, 2022 | | | | |
| Directors and officers | **1,153,439** | **166,923** | **519,741** | **1,840,103** |

## FINANCIAL AND CAPITAL RISK MANAGEMENT

The Company's financial instruments consist of cash and cash equivalents, accounts payable and accrued liabilities, lease obligation, derivative warrant liability, and warrants. The fair values of these financial instruments, other than derivative warrant liability and warrants, approximate their carrying values at December 31, 2022, due to their short-term nature.

The following table presents the Company's financial instruments, measured at fair value on the consolidated statements of financial position as at December 31, 2022 and 2021 and categorized into levels of the fair value hierarchy:

| | | December 31, 2022 | | December 31, 2021 | |
|---|---|---|---|---|---|
| | Level | Carrying Value | Estimated Fair Value * | Carrying Value | Estimated Fair Value * |
| | | $ | $ | $ | $ |
| **FVTPL** | | | | | |
| Cash | 1 | 14,125,522 | 14,125,522 | 18,851,244 | 18,851,244 |
| **Other financial liabilities** | | | | | |
| Accounts payable and accrued liabilities | 2 | 1,960,745 | 1,960,745 | 700,999 | 700,999 |
| **FVTPL** | | | | | |
| Derivative warrant liability | 3 | 5,220,649 | 5,220,649 | 4,597,332 | 4,597,332 |

* The Company has determined that the carrying values of its short-term financial assets and financial liabilities, including cash and accounts payable and accrued liabilities, approximate their fair value due to the short-term nature of the instruments. Information on the fair value of the derivative warrant liability is included in note 13(f) of the Financial Statements.

There were no transfers for levels of change in the fair value measurements of financial instruments for the years ended December 31, 2022 and 2021.

Risk management is carried out by the Company's management team with guidance from the Board of Directors. The Company's risk exposures and their impact on the Company's financial instruments were as follows:

**a) Credit risk**

Credit risk is the risk of financial loss to the Company if a customer of counterparty to a financial instrument fails to meet its obligations. The Company's maximum exposure to credit risk at the financial position date under its financial instruments is summarized as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| | $ | $ |
| **Cash** | 14,125,522 | 18,851,244 |

All of the Company's cash is held with major financial institutions in Canada and management believes the exposure to credit risk with such institutions is minimal. The Company considers the risk of material loss to be significantly mitigated due to the financial strength of the major financial institutions where cash is held. The Company has no current exposure to the ongoing banking crisis. The Company's maximum exposure to credit risk as at December 31, 2022 and 2021 is the carrying value of its financial assets.

**b) Liquidity risk**

Liquidity risk is the risk that the Company will not be able to meet its obligations associated with financial liabilities. The Company has a planning and budgeting process in place by which it anticipates and determines the funds required to support normal operation requirements as well as the growth and development of its intellectual property portfolio.

The Company's financial assets are comprised of its cash, and the financial liabilities are comprised of its accounts payable and accrued liabilities and derivative warrant liability.

The contractual maturities of these financial liabilities as at December 31, 2022 and 2021 are summarized below:

| | Payments due by period as of December 31, 2022 | | | |
|---|---|---|---|---|
| | Total | Less than 3 months | Between 3 months and 1 year | 1-3 years |
| | $ | $ | $ | $ |
| Accounts payable and accrued liabilities | 1,960,745 | 1,960,745 | - | - |
| | 1,960,745 | 1,960,745 | - | - |

| | Payments due by period as of December 31, 2021 | | | |
|---|---|---|---|---|
| | Total | Less than 3 months | Between 3 months and 1 year | 1-3 years |
| | $ | $ | $ | $ |
| Accounts payable and accrued liabilities | 700,999 | 700,999 | - | - |
| | 700,999 | 700,999 | - | - |

**b) Market risk**

i) Interest Rate Risk

Interest rate risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate due to changes in market interest rates. The Company's bank accounts bear interest. Management believes that the credit risk concentration with respect to financial instruments included in cash is minimal.

ii) Foreign Currency Risk

As at December 31, 2022, the Company is exposed to currency risk on the following financial assets and liabilities denominated in US Dollars ("**USD**"), British Pounds ("**GBP**"), and European Euro ("**EUR**"). The sensitivity of the Company's net earnings due to changes in the exchange rate between the USD, GBP and EUR against the Canadian dollar is included in the table below in Canadian dollar equivalents:

| | USD | GBP amount | EUR | Total |
|---|---|---|---|---|
| | $ | $ | $ | $ |
| Cash | 12,907,255 | - | - | 12,907,255 |
| Accounts payable and accrued liabilities | (1,466,309) | (45,755) | (11,747) | (1,523,811) |
| **Net exposure** | 11,440,946 | (45,755) | (11,747) | 11,383,444 |
| **Effect of +/- 10% change in currency** | 1,144,095 | (4,576) | (1,175) | |

Cash and cash equivalents are classified as a financial asset at FVTPL, accounts payable and accrued liabilities and lease obligation are classified as financial liabilities at amortized cost, and derivative warrant liability is classified as a financial liability at FVTPL.

The Company thoroughly examines the various financial instruments and risks to which it is exposed and assesses the impact and likelihood of those risks. These risks include foreign currency risk, interest rate risk, market risk, credit risk, and liquidity risk. Where material, these risks are reviewed and monitored by the Board of Directors

There have been no changes in any risk management policies since December 31, 2022.

## Capital Management

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

The Company includes the following items in its managed capital as at the following periods:

| **Equity is comprised of:** | **December 31 2022** | **December 31 2021** |
|---|---|---|
| | $ | $ |
| Share capital | 20,606,705 | 20,009,154 |
| Share-based payments, warrant reserve and other | 8,003,076 | 6,386,459 |
| Obligation to issue shares | 32,238 | 32,238 |
| Deficit | (19,175,589) | (9,690,280) |

Since inception, the Company's objective in managing capital is to ensure sufficient liquidity to finance its research and development activities, general and administrative expenses, expenses associated with intellectual property protection and its overall capital expenditures. There were no changes during the year ended December 31, 2022. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

## OUTSTANDING SHARE DATA

As at March 30, 2023, the Company had 17,989,687 common shares outstanding.

**Options Outstanding:**

The following table summarizes information on the 1,039,335 stock options outstanding as at March 30, 2023:

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

**Warrants Outstanding:**

The following table summarizes information on the 10,579,976 outstanding warrants as at March 30, 2023:

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

## RISKS RELATED TO THE BUSINESS

An investment in the Company is speculative and involves a high degree of risk. Accordingly, prospective investors should carefully consider the specific risk factors set out below, in addition to the other information contained in this MD&A, before making any decision to invest in the Company. The Directors consider the following risks and other factors to be the most significant for potential investors in the Company, but the risks listed do not necessarily comprise all those associated with an investment in the Company and are not set out in any particular order of priority. Additional risks and uncertainties not currently known to the Directors may also have an adverse effect on the Company's business. If any of the following risks actually occur, the Company's business, financial condition, capital resources, results or future operations could be materially adversely affected. In such a case, the price of the common shares could decline, and investors may lose all or part of their investment.

For additional discussion on XORTX's risks, refer to the "Risk Factors" section of the Company's Annual Information Form ("**AIF**") for the year ended December 31, 2022 and the "Forward Looking Statements" section of this MD&A.

**Speculative Nature of Investment Risk**

An investment in the common shares of the Company carries a high degree of risk and should be considered as a speculative investment by purchasers. The Company has limited cash reserves, a limited operating history, has not paid dividends, and is unlikely to pay dividends in the immediate or near future. The Company is in the development stage. Operations are not yet sufficiently established such that the Company can mitigate the risks associated with planned activities.

**Limited Operating History**

The Company has no present prospect of generating revenue from the sale of products. The Company is therefore subject to many of the risks common to early-stage enterprises, including under-capitalization, cash shortages, limitations with respect to personnel, financial, and other resources and lack of revenues. There is no assurance that the Company will be successful in achieving a return on shareholders' investment and the likelihood of success must be considered in light of the early stage of operations.

**Negative Cash Flow for the Foreseeable Future**

The Company has a no history of earnings or cash flow from operations. The Company does not expect to generate material revenue or achieve self-sustaining operations for several years, if at all. To the extent that the Company has negative cash flow in future periods, the Company may need to allocate a portion of its cash reserves to fund such negative cash flow.

**Reliance on Management**

The success of the Company is dependent upon the ability, expertise, judgment, discretion and good faith of its management. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on the Company's business, operating results or financial condition.

**Clinical trials for potential drug candidates will be expensive and time consuming, and their outcomes uncertain.**

Before the Company can obtain regulatory approval for the commercial sale of any drug candidate or attract major pharmaceutical companies with which to collaborate, it will be required to complete extensive clinical trials to demonstrate safety and efficacy. Clinical trials are expensive and are difficult to design and implement. The clinical trial process is also time-consuming and can often be subject to unexpected delays. The timing and completion of clinical trials may be subject to significant delays relating to various causes, including but not limited to: inability to manufacture or obtain sufficient quantities of materials for use in clinical trials; delays arising from collaborative partnerships; delays in obtaining regulatory approvals to commence a study, or government intervention to suspend or terminate a study; delays, suspensions or termination of clinical trials by the applicable institutional review board or independent ethics board responsible for overseeing the study to protect research subjects; delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites; slow rates of patient recruitment and enrollment; uncertain dosing issues; inability or unwillingness of medical investigators to follow clinical protocols; variability in the number and types of subjects available for each study and resulting difficulties in identifying and enrolling subjects who meet trial eligibility criteria; scheduling conflicts; difficulty in maintaining contact with subjects after treatment, resulting in incomplete data; unforeseen safety issues or side effects; lack of efficacy during clinical trials; reliance on clinical research organizations to efficiently and properly conduct clinical trials in accord with contracted arrangements and regulations, or other regulatory delays.

**Risks Related to Food and Drug Administration (FDA) Approval**

In the United States, the FDA regulates the approval of therapeutics and the FDA notification and approval process requires substantial time, effort and financial resources, and the Company cannot be certain that any approvals for its products will be granted on a timely basis, if at all. Foreign jurisdictions have similar government regulatory bodies and requirements that the Company must meet prior to selling products in those jurisdictions.

The Company must be considered in light of the risks, expenses, shifts, changes and difficulties frequently encountered with companies whose businesses are regulated by various federal, state and local governments. The health care, wellness, workers' compensation and similar companies are subject to a variety of regulatory requirements and the regulatory environment is ever changing particularly with recent legislation, the full impact of which is not yet understood as regulations have not been issued. Failure to follow applicable regulatory requirements will have a materially negative impact on the business of the Company. Furthermore, future changes in legislation cannot be predicted and could irreparably harm the business of the Company.

**Intellectual Property Rights**

The Company could be adversely affected if it does not adequately protect its intellectual property rights. The Company regards its marks, rights, and trade secrets and other intellectual property rights as critical to its success. To protect its investments and the Company's rights in these various intellectual properties, it may rely on a combination of patents, trademark and copyright law, trade secret protection and confidentiality agreements and other contractual arrangements with its employees, clients, strategic partners, acquisition targets and others to protect proprietary rights. There can be no assurance that the steps taken by the Company to protect proprietary rights will be adequate or that third parties will not infringe or misappropriate the Company's copyrights, trademarks and similar proprietary rights, or that the Company will be able to detect unauthorized use and take appropriate steps to enforce rights. In addition, although the Company believes that its proprietary rights do not infringe on the intellectual property rights of others, there can be no assurance that other parties will not assert infringement claims against the Company. Such claims, even if not meritorious, could result in the expenditure of significant financial and managerial resources.

The Company will rely on trade secrets to protect technology where it does not believe patent protection is appropriate or obtainable. Trade secrets are difficult to protect. While commercially reasonable efforts to protect trade secrets will be used, strategic partners, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose information to competitors.

If the Company is not able to defend patents or trade secrets, then it will not be able to exclude competitors from developing or marketing competing products, and the Company may not generate enough revenue from product sales to justify the cost of development of products and to achieve or maintain profitability.

**The results of preclinical studies or initial clinical trials are not necessarily predictive of future favorable results.**

Preclinical tests and initial clinical trials are primarily designed to test safety and to understand the side effects of drug candidates and to explore efficacy at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Favorable results in early trials may not be repeated in later ones.

**Difficulty to Forecast**

The Company must rely largely on its own market research to forecast sales as detailed forecasts are not generally obtainable from other sources at this early stage of the industry. A failure in the demand for its products to materialize as a result of competition, technological change or other factors could have a material adverse effect on the business, results of operations and financial condition of the Company.

**Litigation**

The Company may become party to litigation from time to time in the ordinary course of business which could adversely affect its business. Should any litigation in which the Company becomes involved be determined against the Company such a decision could adversely affect the Company's ability to continue operating and the market price for the Company's common shares. Even if the Company is involved in litigation and wins, litigation can redirect significant Company resources.

Commercial success of the Company will depend in part on not infringing upon the patents and proprietary rights of other parties and enforcing its own patents and proprietary rights against others. The research and development programs will be in highly competitive fields in which numerous third parties have issued patents and pending patent applications with claims closely related to the subject matter of the Company's programs. The Company is not currently aware of any litigation or other proceedings or claims by third parties that its technologies or methods infringe on their intellectual property.

While it is the practice of the Company to undertake pre-filing searches and analyses of developing technologies, it cannot guarantee that it has identified every patent or patent application that may be relevant to the research, development, or commercialization of its products. Moreover, it cannot assure that third parties will not assert valid, erroneous, or frivolous patent infringement claims.

**Uninsurable Risks**

The business of the Company may not be insurable or the insurance may not be purchased due to high cost. Should such liabilities arise, they could reduce or eliminate any future profitability and result in increasing costs and a decline in the value of the Company.

**The market price of the Company's common shares may be subject to wide price fluctuations.**

The market price of the Company's common shares may be subject to wide fluctuations in response to many factors, including variations in the operating results of the Company and its subsidiaries, divergence in financial results from analysts' expectations, changes in earnings estimates by stock market analysts, changes in the business prospects for the Company and its subsidiaries, general economic conditions, legislative changes, and other events and factors outside of the Company's control. In addition, stock markets have from time-to-time experienced extreme price and volume fluctuations, which, as well as general economic and political conditions, could adversely affect the market price for the Company's common shares.

**Dividends**

The Company has no earnings or dividend record and does not anticipate paying any dividends on the common shares in the foreseeable future.

**Dilution**

The financial risk of the Company's future activities will be borne to a significant degree by purchasers of the common shares. If the Company issues common shares from its treasury for financing purposes, control of the Company may change and purchasers may suffer additional dilution.

**Rapid Technological Change**

The business of the Company is subject to rapid technological changes. Failure to keep up with such changes may adversely affect the business of the Company. The Company is subject to the risks of companies operating in the medical and healthcare business. The market in which the Company competes is characterized by rapidly changing technology, evolving industry standards, frequent new service and product announcements, introductions and enhancements and changing customer demands. As a result, an investment in the stocks of the Company is highly speculative and is only suitable for investors who recognize the high risks involved and can afford a total loss of investment.

**Risks Associated with Acquisitions**

If appropriate opportunities present themselves, the Company may acquire businesses, technologies, services or products that the Company believes are strategic. The Company currently has no understandings, commitments or agreements with respect to any other material acquisition and no other material acquisition is currently being pursued. There can be no assurance that the Company will be able to identify, negotiate or finance future acquisitions successfully, or to integrate such acquisitions with its current business. The process of integrating an acquired business, technology, service or product into the Company may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of the Company's business. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to goodwill and other intangible assets, which could materially adversely affect the Company's business, results of operations and financial condition. Any such future acquisitions of other businesses, technologies, services or products might require the Company to obtain additional equity or debt financing, which might not be available on terms favorable to the Company, or at all, and such financing, if available, might be dilutive.

**Economic Environment**

The Company's operations could be affected by the economic context should the unemployment level, interest rates or inflation reach levels that influence consumer trends and consequently, impact the Company's future sales and profitability.

**Global Economy Risk**

The ongoing economic problems and downturn of global capital markets has generally made the raising of capital by equity or debt financing more difficult. Access to financing has been negatively impacted by the ongoing global economic risks. As such, the Company is subject to liquidity risks in meeting its development and future operating cost requirements in instances where cash positions are unable to be maintained or appropriate financing is unavailable. These factors may impact the Company's ability to raise equity or obtain loans and other credit facilities in the future and on terms favorable to the Company. If uncertain market conditions persist, the Company's ability to raise capital could be jeopardized, which could have an adverse impact on the Company's operations and the trading price of the Company's Shares on the stock exchange.

**International Conflict**

International conflict and other geopolitical tensions and events, including war, military action, terrorism, trade disputes and international responses thereto have historically led to, and may in the future lead to, uncertainty or volatility in financial markets and supply chains. Russia's invasion of Ukraine in early 2022 has led to sanctions being levied against Russia by the international community and may result in additional sanctions or other international action, any of which may have a destabilizing effect on supply chain disruptions which may adversely affect the Company's business, financial condition and results of operations. The extent and duration of the current Russia-Ukraine conflict and related international action cannot be accurately predicted at this time and the effects of such conflict may magnify the impact of the other risks identified in this document, including those relating to global financial conditions. The situation is rapidly changing and unforeseeable impacts, including on our shareholders and counterparties on which we rely and transact, may materialize and may have an adverse effect on the Company's business, results of operation and financial condition.

**Going-Concern Risk**

The Company's future operations are dependent upon the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that the Company will be successful in completing an equity or debt financing or in achieving profitability.

**Financial Risk Exposures**

The Company may have financial risk exposure to varying degrees relating to the currency of each of the countries where it operates and has financial risk exposure towards digital currencies. The level of the financial risk exposure related to a currency and exchange rate fluctuations will depend on the Company's ability to hedge such risk or use another protection mechanism.

**Attracting and keeping senior management and key scientific personnel**

The success of the Company depends on the continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel and to develop and maintain important relationships with leading academic institutions, companies, and thought leaders. Allen Davidoff, the Company's CEO, exercises significant control over the day-to-day affairs of the Company. The Company depends on Dr. Davidoff to engage with third parties and contractors to operate the business.

## SEGMENT REPORTING

We view our operations and manage our business in one segment, which is the development and commercialization of biopharmaceuticals, initially focused on the treatment of progressive kidney disease.

## TREND INFORMATION

Other than as disclosed elsewhere we are not aware of any trends, uncertainties, demands, commitments, or events that are reasonably likely to have a material effect on our net revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause reported financial information not necessarily to be indicative of future operating results or financial condition.

## MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL STATEMENTS

The Company's management is responsible for presentation and preparation of the financial statements and the MD&A. The MD&A have been prepared in accordance with the requirements of securities regulators, including National Instrument 51-102 of the Canadian Securities Administrators.

The financial statements and information in the MD&A necessarily include amounts based on informed judgments and estimates of the expected effects of current events and transactions with appropriate consideration to materiality. In addition, in preparing the financial information, we must interpret the requirements described above, make determinations as to the relevancy of information included, and make estimates and assumptions that affect reported information. The MD&A also includes information regarding the impact of current transactions and events, sources of liquidity and capital resources, operating trends, risks and uncertainties. Actual results in the future may differ materially from our present assessment of this information because future events and circumstances may not occur as anticipated.

## DISCLOSURE CONTROLS AND PROCEDURES

Disclosure controls and procedures are designed to provide reasonable assurance that material information required to be disclosed in the prescribed filings and reports filed with the Canadian securities regulatory authorities is recorded, processed, summarized and reported on a timely basis. Controls are also designed to provide reasonable assurance that information required to be disclosed is assimilated and communicated to senior management in a timely manner so that appropriate decisions can be made regarding public disclosure. The Company's CEO and CFO have evaluated the effectiveness of the Company's disclosure controls and procedures and concluded that they provide reasonable assurance that material information relating to the Company was made known to them and reported as required.

**Exhibit 15.2**

**CHARTER OF THE AUDIT COMMITTEE**

**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 Corporation's financial statements;

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

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

(d) the performance of the Corporation'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 Corporation;

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

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

(d) "Corporation" means XORTX Therapeutics Inc.

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

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

2.2 Interpretation

The provisions of this Charter are subject to the articles and by-laws of the Corporation and to the applicable provisions of the *British Columbia Business Corporations Act* (the "Act"), 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.* If a vacancy exists on the Committee, the remaining members shall exercise all of their powers so long as a quorum remains in office. If there is a vacancy of the Chair of the Committee, the members of the Committee shall appoint, by a majority vote of the remaining members, one of its members to fill the vacancy. The Board may appoint a member to fill a vacancy which occurs in the Committee between annual elections of Directors, including filling a vacancy in the Chair position of the Committee or confirming a new Chair of the Committee that has been appointed by the Committee.

(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 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 Corporation'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 Corporation 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 Corporation'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 Corporation (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 Communication with Auditors

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 Corporation 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 Corporation.

**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 Corporation'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 Corporation'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 Corporation's disclosure of financial information extracted or derived from the Corporation'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 Corporation's selection or application of accounting principles;

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

deficiencies;

(iii) analyses 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 Corporation of regulatory and accounting initiatives, as well as off-balance sheet transaction structures, obligations (including contingent obligations) and other relationships of the Corporation 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 Corporation;

(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 Corporation 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 Corporation'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 Corporation. 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 Corporation'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 Corporation'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, the Committee must 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 Corporation partners, employees and former partners and employees of the Corporation'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 Corporation to the Corporation (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 Corporation 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 Corporation is involved or which the Corporation 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 Corporation'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 Corporation regarding accounting, internal accounting controls or auditing matters; and

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

10.4 Code of Business Conduct and Ethics

The Committee shall receive and report any violations of the Code of Business Conduct and Ethics to the Chairman of the Board and will monitor compliance with the Code of Business Conduct and Ethics and recommend disclosures with respect thereto.

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 of Directors on October 28, 2021.**

**Exhibit 15.3**

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statement on Form F-1 (File No. 333-258741), the Registration Statement on Form F-1 (File No. 333-267328), the Registration on Form F-3 (File No. 333-269429), and the Registration Statement on Form S-8 (File No. 333-268034) of XORTX Therapeutics Inc. (the "Company") of our report dated March 29, 2023, relating to the consolidated financial statements of the Company for the years ended December 31, 2022, 2021 and 2020, appearing in the Company's Annual Report on Form 20-F for the year ended December 31, 2022, filed with the Securities and Exchange Commission.

/s/ Smythe LLP
Smythe LLP
Chartered Professional Accountants
Vancouver, Canada
April 28, 2023