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, 2021

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)

Suite 2400 - 745 Thurlow Street, Vancouver, British Columbia, Canada, V6E 0C5
(Address of Principal Executive Offices)

Amar Keshri, Chief Financial Officer
Telephone: 1-403-455-7727
E-mail: akeshri@xortx.com
Suite 2400 - 745 Thurlow Street, Vancouver, British Columbia, Canada, V6E 0C5
(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: 12,989,678

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. □

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

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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 has been prepared in accordance with IFRS as issued by the 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 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 make reference 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

This Annual Report contains forward-looking statements that are subject to risks and uncertainties. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions. The statements we make regarding the following matters are forward-looking by their nature and are based on certain of the assumptions noted below:

- the intentions, plans and future actions of the Company;
- statements relating to the business and future activities of the Company;
- anticipated developments in operations of the Company;
- market position, ability to compete and future financial or operating performance of the Company;
- the timing and amount of funding required to execute the Company's business plans;
- capital expenditures;
- the effect on the Company of any changes to existing or new legislation or policy or government regulation;
- the availability of labor;
- requirements for and availability to us of additional capital;
- goals, strategies and future growth;
- the adequacy of financial resources;
- expectations regarding revenues, expenses and anticipated cash needs;
- the impact of the COVID-19 pandemic on the business and operations of the Company; and
- general market conditions and macroeconomic trends driven by the COVID-19 pandemic and/or geopolitical conflicts, including supply chain disruptions, market volatility, inflation, and labor challenges, among other factors.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. The forward-looking statements are based on our beliefs, assumptions and expectations of future performance, taking into account the information currently available to us. These statements are only predictions based upon our current expectations and projections about future events. There are important factors that could cause our actual results, levels of activity, performance or achievements to differ materially from the results, levels of activity, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, those factors identified under the *Risk Factors* listed below in Item 3.D. of this Annual Report. Furthermore, unless otherwise stated, the forward-looking statements contained in this Annual Report are made as of the date hereof, and we have no intention and undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, changes or otherwise, except as required by law.

GLOSSARY

In this Annual Report, unless otherwise indicated or the context otherwise requires, the following terms shall have the indicated meanings. Words importing the singular include the plural and vice versa and words importing any gender include all genders. A reference to an agreement means the agreement as it may be amended, supplemented or restated from time to time.

"**ACA**" means the Patient Protection and Affordable Care Act;

"**ADPKD**" means autosomal dominant polycystic kidney disease;

"**AIA**" means the Leahy-Smith America Invents Act, also known as the America Invents Act;

"**AKI**" means acute kidney injury;

"**allowable capital loss**" means one-half of the amount of any capital loss;

"**ANDA**" means abbreviated new drug applications;

"**Annual Report**" means this Annual Report on Form 20-F;

"**APAC**" means APAC Resources Inc., a company incorporated under the laws of British Columbia;

"**articles**" means our articles of incorporation;

"**ASP**" means average sales price;

"**Audit Committee**" means the Audit Committee of the Company;

"**Audit Committee Charter**" means the Audit Committee Charter of the Audit Committee;

"**BCBCA**" means the Business Corporation Act (British Columbia);

"**Board of Directors**" or "**Board**" means the Board of Directors of the Company;

"**BPCA**" means the Best Pharmaceuticals for Children Act;

"**bylaws**" means our amended and restated bylaws;

"**Canadian Resident Holder**" means a Holder who, for the purposes of the Canadian Tax Act, is or is deemed to be a resident in Canada at all relevant times;

"**Cardiome**" means Cardiome Pharma Corp.;

"**CBCA**" means the *Canada Business Corporations Act* and the regulations made under that enactment, as amended;

"**CCPA**" means the California Consumer Privacy Act;

"**CEO**" means the Company's principal executive officer;

"**CFO**" means the Company's principal financial officer;

"Compensation Committee" means the Compensation Committee of the Company;

"**GCP**" means current good clinical practices;

"**cGMP**" means current Good Manufacturing Practices;

"**CHMP**" means Committee for Medicinal Products for Human Use;

"**CJEU**" means the Court of Justice of the European Union;

"**CMC**" means chemistry manufacturing and control;

"**CMOs**" means contract manufacturing organization;

"**CMS**" means Centers for Medicare & Medicaid Services;

"**CNS**" means central nervous system;

"**Code of Conduct**" means our Code of Business Conduct and Ethics;

"**Common Shares**" means common shares of the Company;

"**Company**", "**we**", "**us**", "**our**" or "**XORTX**" means XORTX Therapeutics Inc. and its subsidiaries.

"**CPRA**" means the California Privacy Rights Act;

"**CRA**" means the Canada Revenue Agency;

"**CREATES Act**" means the Creating and Restoring Equal Access to Equivalent Samples Act of 2019;

"**CRL**" means a complete response letter;

"**CROs**" means contract research organizations;

"**CRP**" means Creatinine Reactive Protein;

"**CSE**" means the Canadian Securities Exchange;

"**CTA**" means clinical trial application;

"**CTO**" means Chief Technology Officer;

"**Cures Act**" means the 21st Century Cures Act;

"**Davidoff Agreement**" means that certain Employment Agreement dated January 1, 2018, between the Company and Dr. Allen Davidoff;

"**DGCL**" means the Delaware General Corporation Law;

"**DHHS**" means the Department of Health and Human Services;

"**DSCSA**" means the Drug Supply Chain Security Act;

"**EMA**" means the European Medicines Agency;

"**ESRD**" means end stage renal disease;

"**ETASU**" means elements to assure safe use;

"**EU**" means the European Union;

"**EUA**" means the FDA Emergency Use Authorization;

"**EU Centralized Procedure**" means the procedure for the authorization of medicines, where there is a single application, a single evaluation and a single authorization throughout the European Union;

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended;

"**Fairbairn Consulting Agreement**" means the contract the Company entered into with 1282803 Ontario Inc., dated March 1, 2021, for consulting services to the Company to appoint James Fairbairn as the appointed consultant to act in the capacity as chief financial officer;

"**FCPA**" means the U.S. Foreign Corrupt Practices Act of 1977, as amended;

"**FDA**" means the U.S. Food and Drug Administration;

"**FDCA**" means the Federal Food, Drug, and Cosmetic Act;

"**GCPs**" means good clinical practices;

"**GDPR**" means the European Union General Data Protection Regulation;

"**GLPs**" means good laboratory practices;

"**Haworth Consulting Agreement**" means the contract the Company entered into with Haworth Biopharmaceutical Consulting Services Inc., dated July 1, 2021 and effective July 1, 2021, for consulting services to the Company to appoint Stephen Haworth as the appointed consultant to act in the capacity as chief medical officer;

"**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996, as amended;

"**HITECH**" means the Health Information Technology for Economic and Clinical Health Act.

"**Holder**" means a holder of the Company's shares;

"**IASB**" means International Accounting Standards Board;

"**ICU**" means intensive care units;

"**IFRS**" means International Financial Reporting Standards;

"**IL-6**" means interleukin-6;

"**IMM**" means irreversible morbidity or mortality;

"**IND**" means Investigational New Drug application;

"**IRB**" means institutional review board;

"**IRS**" means the Internal Revenue Service;

"**JAMA**" means the Journal of the American Medical Association;

"**JOBS Act**" means the Jumpstart Our Business Startups Act of 2012;

"**Keshri Consulting Agreement**" means the contract the Company entered into with Next Level Consultants Inc., dated July 1, 2021, for consulting services to the Company to appoint Amar Keshri as the appointed consultant to act in the capacity as chief financial officer;

"**MAA**" means marketing authorization application;

"**MRP**" means mutual recognition procedure;

"**MSI**" means MSI Methylation Sciences Inc., a clinical-stage pharmaceutical company;

"**Nasdaq**" means the Nasdaq Stock Market;

"**Nasdaq Rules**" means the Nasdaq Stock Market LLC Rules;

"**NDA**" means New Drug Application;

"**NIH**" means the United States National Institutes of Health;

"**ODD**" means orphan drug designation;

"**Orange Book**" means the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations;

"**Otsuka**" means Otsuka Pharmaceuticals Co., Ltd.;

"**PBMs**" means pharmaceutical benefit managers;

"**PCAOB**" means the Public Company Accounting Oversight Board;

"**PCT**" means Patent Cooperation Treaty;

"**PDMA**" means the Prescription Drug Marketing Act;

"**PPACA**" means the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (commonly referred to as the "**ACA**");

"**PREA**" means the Pediatric Research Equity Act;

"**pre-IND**" means pre-investigational new drug application;

"**Prevail**" means Prevail Partnerships LLC;

"**Prior FDA Review**" means the approvable letter for oxypurinol for allopurinol intolerant hyperuricemia that Cardiome announced it had received via a press release dated June 24, 2004;

"**Proposed Amendments**" means specific proposals to amend the Tax Act and Regulations publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof;

"**PSP**" means the Pediatric Study Plan;

"**R&D**" means research and development;

"**Regulations**" the regulations under the Tax Act;

"**REMS**" means risk evaluation and mitigation strategies;

"**RLD**" means reference listed drug;

"**Rowlands**" means William Bruce Rowlands, an individual;

"**Rowlands Consulting Agreement**" means the contract the Company entered into with W.B. Rowlands & Co. Ltd. for consulting services to the Company, dated March 1, 2018;

"**RTO**" means the reverse take-over transaction on January 10, 2018;

"**Sans Consulting Agreement**" means the contract the Company entered into with Mr. David Sans for consulting services to the Company in the capacity as executive adviser, dated February 1, 2021;

"**SEC**" means the U.S. Securities and Exchange Commission;

"**Section 404**" means Section 404 of the Sarbanes-Oxley Act of 2002;

"**Section 505(b)(2)**" or "**505(b)(2)**" means section 505(b)(2) of the FDCA;

"**Securities Act**" means the Securities Act of 1933, as amended;

"**SEDAR**" means the System for Electronic Document Analysis and Retrieval for Canadian public companies;

"**Share Consolidation**" means 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;

"**SPA**" means special protocol assessment;

"**SUA**" means a serum uric acid;

"**Tax Treaty**" means the Canada-U.S. Tax Convention (1980);

"**taxable capital gain**" means one-half of the amount of any capital gain;

"**T2DN**" means type 2 diabetic nephropathy;

"**Treaty**" means the Canada-United States Income Tax Convention (1980), as amended;

"**TSX**" means Toronto Stock Exchange;

"**TSXV**" means TSX Venture Exchange;

"**UK**" means United Kingdom;

"**UR**" means uric acid;

"**UFRF**" means the University of Florida Research Foundation, Inc.;

"**UFRF License Agreement**" means the amended and restated license agreement dated June 23, 2014, between the Company and the University of Florida Research Foundation, Inc;

"**United States Holders**" means a holder who, at all relevant times, (a) for the purposes of the Tax Act (i) is not resident, or deemed to be resident, in Canada, (ii) deals at "arm's length" with the Company, and is not "affiliated" with the Company (each as defined in the Tax Act), (iii) holds Common Shares as capital property, (iv) does not use or hold Common Shares in the course of carrying on, or otherwise in connection with, a business carried on or deemed to be carried on in Canada, and (v) is not an insurer that carries on an insurance business in Canada and elsewhere or "authorized foreign bank" (as defined in the Tax Act), or other holder of special status, and (b) for the purposes of the Tax Treaty, is a resident of the United States, has never been a resident of Canada, does not have and has not had, at any time, a "permanent establishment" (as defined in the Tax Treaty) of any kind in Canada, and otherwise qualifies for the full benefits of the Tax Treaty;

"**UofC**" means University of Colorado;

"**U.S.**" means United States;

"**US Offering**" means the Company's underwritten public offering of 2,906,000 units, with each unit consisting of one Common Share, no par value, and one warrant to purchase one Common Share at a public offering price of US$4.13 per unit, for aggregate gross proceeds of approximately US$12,000,000, prior to deducting underwriting discounts and other offering expenses;

"**USPTO**" means United States Patent and Trademark Office;

"**Vendors**" means Dr. Richard Johnson and Dr. Takahiko Nakagawa;

"**Vendors Agreement**" means an agreement, dated as of December 2012, between the Company, Dr. Richard Johnson and Dr. Takahiko Nakagawa;

"**WBR Consulting Agreement**" means the contract the Company entered into with W.B. Rowlands & Co. Ltd. and Rowlands for consulting services to the Company, dated December 20, 2021;

"**XRx-008**" means product candidate in development for ADPKD;

"**XRx-101**" means product candidate in development for AKI associated with COVID-19;

"**XRx-225**" means product candidate in development for diabetic nephropathy;

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not required.

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 of the Company to decline. If any of the following risks actually occur, the Company's business may be harmed and the Company's financial condition and results of operations may suffer significantly. Investors should carefully consider the risk factors set out below and consider all other information contained herein and in the Company's other public filings before making an investment decision. The risks set out below are not an exhaustive list and should not be taken as a complete summary or description of all the risks associated with the Company's business and the biotechnology business generally.

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a clinical-stage biotechnology company. We have incurred significant losses since our inception. Our net losses for the years ended December 31, 2020 and 2019 were $1.28 million and $1.65 million, respectively. As of December 31, 2021, our accumulated deficit was approximately $9.69 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

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

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

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development programs or operations.

We are currently advancing two of our product candidates through preclinical and clinical development as well as other potential product candidates through discovery. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials for each indication for each of our product candidates. We will continue to require additional funding to complete the development and commercialization of our product candidates and to continue to advance the development of our other product candidates and such funding may not be available on acceptable terms or at all. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we believe that the net proceeds from the US Offering, together with our existing cash and cash equivalents will enable us to advance the clinical development of XRx-008, XRx-101 and XRx-225 product candidates. However, because successful development of our product candidates and the achievement of milestones by our strategic partners is uncertain, we are unable to estimate the actual funds we will require to complete research and development and to commercialize our product candidates. Our future funding requirements will depend on many factors, including but not limited to:

● the number and characteristics of other product candidates that we pursue;
● the scope, progress, timing, cost and results of research, preclinical development, and clinical trials;
● the costs, timing, requirements and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
● the costs associated with manufacturing our product candidates and establishing sales, marketing and distribution capabilities;
● our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
● our need and ability to hire additional management, scientific and medical personnel;
● the effect of competing products that may limit market penetration of our product candidates;
● our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
● the economic and other terms, timing of and success of our existing strategic partnerships, and any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through a combination of public and private equity offerings. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our development programs or our business operations.

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

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

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

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

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

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

- timely completion of our preclinical studies and our current and future clinical trials, which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;

- our ability to complete IND-enabling studies and successfully submit INDs or comparable applications to allow us to initiate clinical trials for our current or any future product candidates;

- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;

- our ability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities the safety, efficacy, and acceptable risk-to-benefit profile of our product candidates or any future product candidates;

- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;

- the timely receipt of necessary marketing approvals from the FDA or similar foreign regulatory authorities;

- the willingness of physicians and patients to utilize or adopt any of our product candidates or future product candidates;

- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP requirements;

- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; and

- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates and our ability to obtain an Orphan Drug designation for certain products.

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

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

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

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

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

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

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

- successfully completing formulation and process development activities;
- completing 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.

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 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 associated with COVID-19 patients;
- failure of subjects to complete the clinical trial;
- the inability to enroll a sufficient number of subjects in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by clinical trial subjects, including possible deaths;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of subjects or clinical investigators to follow our clinical trial protocols;
- inability to monitor subjects adequately during or after treatment by us or our CROs;
- our CROs, clinical study sites or investigators failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing; and
- our clinical trials may be suspended or terminated upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future strategic partners that have responsibility for the clinical development of any of our product candidates.

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

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

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

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

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

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

The design or 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 labeling, 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 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 or prevent approval of our product candidates and jeopardize our ability, or our strategic partners' ability, to commence product sales and generate revenue in the future.

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

- delays in receiving approval from local or centralized regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees, 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 global outbreak of the Sars-CoV-2 coronavirus that causes COVID-19 infections continues to rapidly evolve. The extent to which the COVID-19 pandemic may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in Canada and other countries, business closures or business disruptions and the effectiveness of actions taken in Canada and other countries to contain and treat the disease.

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

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

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

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

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

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

Separately, in response to the global pandemic of COVID-19 and public health emergency declaration in the U.S., on March 10, 2020 the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products, and it subsequently postponed routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. As of May 2021, the FDA noted it was continuing to ensure timely reviews of applications for prescription drug products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission-critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. Utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus's trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, FDA is either continuing to, on a case-by-case basis, conduct only mission-critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace and delays or setbacks are possible in the future.

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

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

The Hatch-Waxman Amendments added section 505(b)(2) to the 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 development of 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 Orange Book, for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. An inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

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

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

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

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

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

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

We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

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

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

- our inability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authority that any of our product candidates are safe and effective for their proposed indications;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocols, trial designs or implementation of the trials;
- the FDA or similar foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or similar foreign regulatory authorities for marketing approval, or that regulatory agencies may require us to include a larger number of patients than we anticipated;

- upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate or may identify other GCP deficiencies related to the trials;

- the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies may fail to meet the requirements of the FDA or comparable foreign regulatory authorities;

- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates, including any potential companion diagnostics, may be insufficient or inadequate;

- the medical standard of care or the approval policies or regulations of the FDA or similar foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for marketing approval; or

- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a new drug application or other comparable marketing submissions in foreign jurisdictions or to obtain approval of our product candidates in the United States or elsewhere.

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

In addition, even if the trials are successfully completed, preclinical and clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or similar foreign regulatory authorities will interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or similar foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed or denied, 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, AKI associcated with COVID-19 infection and diabetes, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, as well as biologics that work by using next-generation antibody therapeutic platforms to address specific metabolic targets. In addition, other companies including Pfizer, Teijin, Takeda, Merck, are developing new treatments for cardiovascular, kidney disease or diabetes that may affect the progression of acute, intermittent or chronic kidney disease.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

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 products, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs 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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical and biologics industries. 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. There have been significant ongoing 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. The Trump administration issued executive orders which sought to reduce burdens associated with the Affordable Care Act and modified how it was implemented. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. 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 which heard oral arguments in the case in November 2020. 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, although the Biden administration has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law proposed to replace 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 and biologic 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.

Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our products, if approved. 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 any related third parties are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or any related third parties are not able to maintain regulatory compliance, our current or any future product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would materially affect our business, financial condition and results of operations.

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 associated with COVID-19 infections. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. If any of the foregoing estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

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

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

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

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

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

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

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters, adverse regulatory inspection findings, or holds on clinical trials;
- delay of approval or refusal by the FDA or another applicable regulatory authority to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- suspension or revocation of a product's regulatory approvals;
- product seizure or administrative detention of products, or refusal to permit the import or export of products; and
- operating restrictions, exclusion of eligibility from government contracts 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 any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products manufactured and distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive.

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

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

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

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

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure and that of any third-party billing and collections provider we may utilize, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such the federal privacy rules for health information promulgated under 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, 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 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 CCPA, which has been effective only since January 1, 2020, has already resulted in numerous class action lawsuits for companies suffering data breaches in which they are accused of failing to use reasonable security measures to protect the personal information of California residents. In addition, if we violate the CCPA and we are not able to cure the violation within thirty (30) days of notice, we may be subject to penalties ranging from US$2,500 for a non-intentional violation to US$7,500 for an intentional violation. Many other states are in the process of adopting similar laws, so we may potentially face litigation and penalties under the laws of other states as well.

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

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

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

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

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

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

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anticorruption 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 ongoing COVID-19 pandemic and the efforts to mitigate it may materially and adversely affect our business and financial results.

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

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

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

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

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

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

Risks Related to Our Securities

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

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

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

- failure of any of our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;
- general market conditions and market conditions for pharmaceutical stocks;
- overall fluctuations in U.S. equity markets; and
- other factors that may be unanticipated or out of our control.

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

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

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

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

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

In addition, while we are currently listed on the TSXV, Nasdaq and Frankfurt Borse exchanges, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and the related rules and regulations implemented by the SEC, the applicable Canadian securities regulators, or Nasdaq, will increase legal and financial compliance costs and will make some compliance activities more time consuming. We are currently evaluating these rules, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In connection with the US Offering, we increased our directors' and officers' insurance coverage which will increase our insurance cost. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board of Directors, particularly to serve on our Audit Committee and Compensation Committee, and qualified executive officers.

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

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

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

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

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

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

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

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

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

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

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

There is no public market for our convertible securities.

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

An active trading market for our Common Shares may never develop or be sustained.

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

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

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

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

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

- a limited availability of market quotations for our securities;
- a determination that our Common Shares is a "penny stock" which will require brokers trading in our Common Shares to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our Common Shares;
- a limited amount of news and analyst coverage for our Company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

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

We are governed by the BCBCA and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a U.S. jurisdiction, and may, together with our charter documents, have the effect of delaying, deferring or discouraging another party from acquiring control of our Company by means of a tender offer, a proxy contest or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the BCBCA and 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 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 was raised in an offering of Common Shares 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 may have been classified as a PFIC during the taxable year ended December 31, 2021. Based on current business plans and financial expectations, we may be a PFIC for our taxable year ending December 31, 2022, or future taxable years, and we cannot provide any assurances regarding our PFIC status for any current or future taxable years.

If we are a PFIC, a U.S. Holder would be subject to adverse U.S. federal income tax consequences, such as ineligibility for certain preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. A U.S. Holder may in certain circumstances mitigate adverse tax consequences of the PFIC rules by filing an election to treat the PFIC as a qualified electing fund, or QEF, or, if shares of the PFIC are "marketable stock" for purposes of the PFIC rules, by making a mark-to-market election with respect to the shares of the PFIC. U.S. Holders should be aware that, for each tax year, if any, that we are a PFIC, we can provide no assurances that we will satisfy the record keeping requirements of a PFIC, or that we will make available to U.S. Holders the information such U.S. Holders require to make a QEF election with respect to us, and as a result, a QEF election may not be available to U.S. Holders. Investors should consult your own tax advisors regarding the potential consequences to you if we were or were to become a PFIC, including the availability, and advisability, of, and procedure for making, QEF elections and mark-to-market elections.

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

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

Our forum selection provision seeks to reduce litigation costs and increase outcome predictability by requiring derivative actions and other matters relating to our affairs to be litigated in a single forum. While forum 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 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 Shares in the foreseeable future. The payment of dividends on our Common Shares 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, 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 may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any technology that we require may also materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

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

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

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

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

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

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

If we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed.

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

Moreover, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The issuance of a patent does not ensure that it is valid or enforceable. Third parties may challenge the validity, enforceability or scope of our issued patents, and such patents may be narrowed, invalidated, circumvented, or deemed unenforceable. In addition, changes in law may introduce uncertainty in the enforceability or scope of patents owned by pharmaceutical companies. If, our patents are narrowed, invalidated or held unenforceable, third parties may be able to commercialize our technology or product candidates and compete directly with us without payment to us. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or

enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the issuance, validity, enforceability, scope and commercial value of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product candidate and practicing our own patented technology.

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

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

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

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

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

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

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we or our strategic partners own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we obtain marketing approval for product candidates containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or vice versa, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

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

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

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

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

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

- we or our strategic partners may initiate litigation or other proceedings against third parties to enforce our patent and trade secret rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;
- third parties may initiate opposition or re-examination proceedings challenging the validity or scope of our patent rights, requiring us or our strategic partners and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being owned by or licensed to us;
- the USPTO may initiate an interference between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our strategic partners and/or licensors to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or
- third parties may seek approval to market small molecule drug versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

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

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

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

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

For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable or that afford meaningful trade secret protection.

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

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

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

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

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

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

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

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

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

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

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

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

Although we are not currently experiencing any claims challenging the inventorship or ownership of our patents, we may in the future be subject to claims that former employees, strategic partners or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. For example, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, or we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

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

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

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

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the 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 the 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 and unintentional 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 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.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. If we or they are unable to comply with these provisions, we may become subject to civil and criminal investigations and proceedings that could have a material adverse effect on our business, financial condition and prospects.

Our activities are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil False Claims Act, and laws and regulations pertaining to limitations on and reporting of healthcare provider payments (physician sunshine laws). These laws and regulations are interpreted and enforced by various federal, state and local authorities including CMS, the Office of Inspector General for the U.S. Department of Health and Human Services, the U.S. Department of Justice, individual U.S. Attorney offices within the Department of Justice, and state and local governments. These laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. 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 U.S. civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;
- U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal liability and amends provisions on the reporting, investigation, enforcement, and penalizing of civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. 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;

- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, 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 U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities;
- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; beginning in 2022, applicable manufacturers are required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and.
- the Foreign Corrupt Practices Act, or FCPA, prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business.

Violations of any of these laws or any other governmental regulations that may apply to us, may subject us to significant civil, criminal and administrative sanctions including penalties, damages, fines, imprisonment, and exclusion from government funded healthcare programs, such as Medicare and Medicaid, and/or adverse publicity. Moreover, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical and medical device companies for alleged false or misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical products.

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

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

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

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

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

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, such as the ongoing COVID-19 pandemic, 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

We were incorporated under the laws of Alberta, Canada on August 24, 2012 under the name ReVasCor Inc. and were continued under the Canada Business Corporations Act on February 27, 2013 under the name of XORTX Pharma Corp. Upon completion of the RTO with APAC, we changed our name to "XORTX Therapeutics Inc."

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

Since January 1, 2022, the Company, as a clinical-stage biotechnology company, has continued its focus of identifying, developing and commercializing therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism and uric acid metabolism in orphan (rare) disease indications such as:

- ADPKD;
- T2DN; and
- AKI associated with coronavirus infection.

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

For the balance of 2022, the Company anticipates a number of advancements and changes in its business. On January 31, 2022, XORTX announced that in 2022, XORTX is focused on advancing XRx-008 into a clinical trial, the submission of an Orphan Drug Designation, initiation of special protocol assessment discussions with the FDA and continuing formulation development for other kidney disease applications. To achieve these objectives, XORTX's action plan includes:

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

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

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

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

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

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

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

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

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

Three-Year History

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

2019

Letter of Intent with Teijin Pharma Limited

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

2020

Private Placement

On February 28, 2020, the Company closed a first tranche of a 3,066,439 unit private placement with the issuance of 1,555,317 units for gross proceeds of $900,000 in cash and $50,000 on the conversion of certain payables into units (while $1,606,320 in units were issued in exchange for services to be provided). Each unit was priced at $1.64 and comprised one Common Share and one Common Share Purchase Warrant exercisable at $2.94 for a period of one year from the issuance of the units, provided, however, that if, at any time following the expiry of the statutory four-month hold period, the closing price of the Common Shares on the TSXV was greater than $4.11 for 10 or more consecutive trading days, the Company could notify the holder, by way of news release, that the warrants would expire on the 20th business day following the date of such notice, unless exercised by the holder before such date. The objective of this funding round was to advance ADPKD program toward a phase 3 registration trial in ADPKD. Please note that the details above have been adjusted to reflect the Share Consolidation referenced below under “2021”.

COVID-19 Developments

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

On March 16, 2020, XORTX announced the filing of a provisional patent application and on March 15, 2021, a PCT application claiming priority to said provisional application covering the potential use of any uric acid lowering agent, and more specifically a xanthine oxidase inhibitor in the form of its XRx-101 product candidate to treat AKI in patients infected with COVID-19.

Appointment of LONZA Group as Manufacturer

On April 30, 2020, the Company announced the appointment of LONZA Group ("Lonza") as the manufacturer of GMP oxypurinol for the XRx-008 and XRx-101 clinical trial programs. Lonza is a leading global provider of integrated healthcare solutions. As of the date of this Form 20-F, Lonza's manufacturing work on behalf of XORTX has been completed.

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

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

December 2020 Notification from European Patent Office

On December 8, 2020, the Company received notification that the patent "Formulations of Xanthine Oxidase Inhibitors" will be granted by the European Patent Office. The patent covers compositions and methods of using XORTX's proprietary formulations of xanthine oxidase inhibitors for renal and other diseases where aberrant purine metabolism has been implicated in disease progression.

2021

Private Placement

On February 9, 2021, the Company issued 2,085,687 units in a private placement offering at a subscription price of $2.94 per unit for gross proceeds of $6,121,572. Each unit comprised one Common Share of the Company and one Common Share Purchase Warrant. Each warrant entitles the holder, on exercise, to purchase one additional Common Share in the capital of the Company, at a price of $4.70, for a period of 5 years from the issuance of the units provided, however, that, if, at any time following the expiry of the statutory four month hold period, the closing price of the Common Shares on the TSXV is greater than $14.09 for 10 or more consecutive trading days, the warrants will be accelerated upon notice and the warrants will expire on the 30th calendar day following the date of such notice. In addition, the warrants are also subject to typical anti-dilution provisions and were subject to 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 shall be amended to match such lower price. The ratchet provision was removed as the pricing of the US Offering was greater than the $2.94 unit price.

In connection with the February 9, 2021, private placement, the Company paid $171,085 in cash commissions and issued 58,291 finder's warrants. Each finder's warrant is exercisable into one Common Share at a price of $4.70 and having the same expiry, acceleration and anti-dilution provisions as the warrants included in the private placement.

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

United States Initial Public Offering

On October 15, 2021, the Company announced the closing of the US Offering. The warrants have an initial exercise price of US$4.77 per share, are immediately exercisable, and have a term of approximately five years. In addition, the Company granted the underwriters a 45-day option to purchase up to an additional 435,900 Common Shares and/or warrants to purchase up to an additional 435,900 Common Shares at the US Offering price less the underwriting discounts. On October 15, 2021, the underwriters exercised their option to purchase additional warrants to purchase up to an additional 435,900 Common Shares. On November 9, 2021, the Company announced that it had issued an additional 355,000 Common Shares at the US Offering price resulting in additional gross proceeds of approximately US$1.47 million pursuant to the partial exercise of the underwriters' over-allotment option, before deducting underwriting discounts and commissions.

In connection with the US Offering, the Company received conditional approval to list its Common Shares on the Nasdaq under the symbol "XRTX" on October 13, 2021. The Company's Common Shares began to trade on the Nasdaq on October 15, 2021. In order to qualify for listing on Nasdaq, the Company completed 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.

Significant Acquisitions During 2021

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 clinical-stage biotechnology company focused on identifying, developing and commercializing therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism in renal indications such as ADPKD, AKI due to coronavirus COVID-19 infection, and T2DN.

Our focus is on developing three therapeutic product candidates to slow or reverse the progression of kidney disease in patients at risk of end stage kidney failure, address the immediate need of individuals facing coronavirus COVID-19 infection-induced AKI, and the identification of other opportunities where our existing and new intellectual property can be leveraged to address health issues. We believe that our innovative technology is underpinned by well-established research and insights into the underlying biology of oxypurinol, a powerful uric acid lowering agent that works by effectively inhibiting xanthine oxidase.

While oxypurinol has not received final FDA marketing approval, we plan to leverage existing published studies and a prior FDA review for the indication of allopurinol intolerant gout under the 505(b)(2) development pathway so that we can combine the power of oxypurinol with our capacity to improve existing drugs that can be adapted for different disease indications where increased circulating uric acid is a common denominator, such as polycystic kidney disease, pre-diabetes, insulin resistance, metabolic syndrome, diabetes, diabetic nephropathy, and infections. Our formulations of oxypurinol, either combined with additional excipient ingredients, other uric acid lowering agents, and/or modified with other functional groups as new chemical entities, are being developed to address diseases associated with the renal system and the health consequences of diabetes, where evidence indicates a pathogenic role for acutely or chronically high serum uric acid. One of our product candidate formulations, specifically for AKI, combines a unique proprietary formulation of oxypurinol simultaneously with an existing approved drug for the purpose of rapidly decreasing serum uric acid in hospitalized patients and then maintaining low circulation concentrations of uric acid using the unique proprietary formulation of oxypurinol. Oxypurinol, and our proprietary pipeline-in-a-product strategy supported by our intellectual property, established exclusive manufacturing agreements, and our plan to conduct clinical trials with experienced clinicians, are focused on building a robust pipeline of assets to address the unmet medical needs for patients with ADPKD, AKI associated with COVID-19 infection, and T2DN. At this time, we have not developed product candidates to treat diseases beyond ADPKD, AKI associated with COVID-19 infection and T2DN.

Our three lead product candidates are XRx-008, a novel product candidate program for the treatment of ADPKD; XRx-101, a product candidate program for the treatment of AKI associated with COVID-19; and XRx-225, a product candidate program for the treatment of T2DN. At XORTX Therapeutics, we aim to redefine the treatment of kidney diseases by developing medications to improve the quality-of-life of patients and slow kidney disease progression by modulating aberrant purine metabolism and decreasing elevated uric acid as a therapy.

Overview of our Proprietary Pipeline-In-A-Product

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 pipeline-in-a-product strategy. This is a complementary suite of therapeutic product candidates designed to provide unique solutions for acute and chronic disease, and more specifically, kidney disease. We believe that our product candidates address a unique mechanism of injury and for this reason, in some renal diseases, can be used in a complementary way with existing therapies to develop tailored approaches to help address renal disease indications in multiple body systems through management of chronic or acute hyperuricemia, immune modulation, and metabolic disease. We plan to leverage these product candidates in the future to expand our pipeline of next generation drug-based therapies that we believe could represent significant improvements to the standard of care in kidney disease.

We believe our in-house product candidates' design and formulation capabilities confer significant competitive advantages to our pipeline. Some of these key advantages are:

Highly modular and customizable.

Our pipeline is based upon the use of unique proprietary formulations of oxypurinol with additional excipient ingredients, other uric acid lowering agents, and/or modified with other functional groups to address acute, intermittent or chronic disease progression such as ADPKD, AKI associated with COVID-19 infection, and T2DN. For example, our XRx-101 product candidate program for AKI associated with COVID-19 infection is designed to produce rapid suppression of hyperuricemia, then maintain purine metabolism. Our XRx-008 product candidate program is designed for longer term stable chronic oral dosing of xanthine oxidase inhibitors. We believe that our experience and capabilities related to formulation technology may allow us to manage the unique challenges of renal disease by modulating aberrant purine metabolism, slowing progression of kidney disease, and decreasing injury due to inflammatory and oxidative state.

Fit-for-purpose.

We believe our pipeline 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 represents a potential new class of xanthine oxidase inhibitor with a targeted design to enhance anti-inflammatory activity. The capability of tailoring the therapeutic benefit of this potential class of new agents may permit 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 the potential clinically meaningful therapeutic effect.

Readily scalable and transferable.

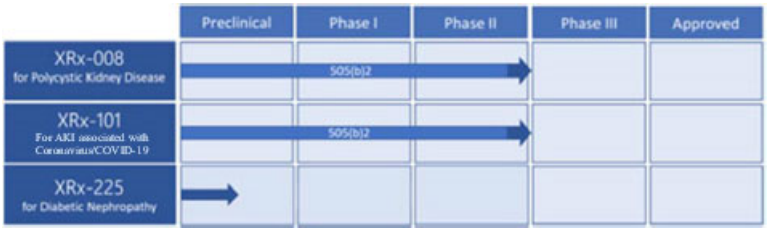
We believe our in-house small molecule and formulations design expertise is positioned to create a steady succession of product candidates that are scalable, efficient to manufacture (by a partner, contract manufacturing organizations or us), and produce high production and high purity active pharmaceutical product candidates. We believe this will provide a significant competitive advantage, new intellectual property, and an opportunity to provide novel uric acid lowering agent indication 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 pipeline to treat the symptoms of, and potentially delay the progression of, ADPKD, AKI associated with COVID-19 infection, and T2DN. We do note that there is no guarantee that the FDA will approve our proposed uric acid lowering agent products for the treatment of kidney disease or the health consequences of diabetes.

Product Candidates

Our lead product candidates are XRx-008, XRx-101 and XRx-225, and we intend to pursue FDA approval for each based upon the Prior FDA Review for the allopurinol intolerant gout indication and utilizing the development pathway established in 505(b)(2). In the future, one option available to XORTX is to use allopurinol as a reference drug under the 505(b)2 development path. However, there is no guarantee that the FDA will ultimately allow the use of the 505(b)(2) developmental pathway, that any trial will be positive, or that the FDA will view the results from any trial to be sufficient to grant marketing approval. XORTX has filed a pre-IND submission for XRx-008 and has received FDA guidance on steps necessary to advance this program through clinical trial and to filing of an NDA. In April 2022, XORTX submitted an IND to the FDA to advance the XRx-008 program in preparation for phase 3 protocol discussions, conduct of the announced clinical bridging pharmacokinetics study and planned registration phase 3 clinical trial. We have filed a pre-IND submission in our XRx-101 program, and the program is preparing for a "bridging" pharmacokinetic study in advance of a planned Phase 3 clinical trial to slow or reverse acute kidney disease in hospitalized individuals infected with COVID-19. The XRx-225 product candidate program is at the non-clinical stage.

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, 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.

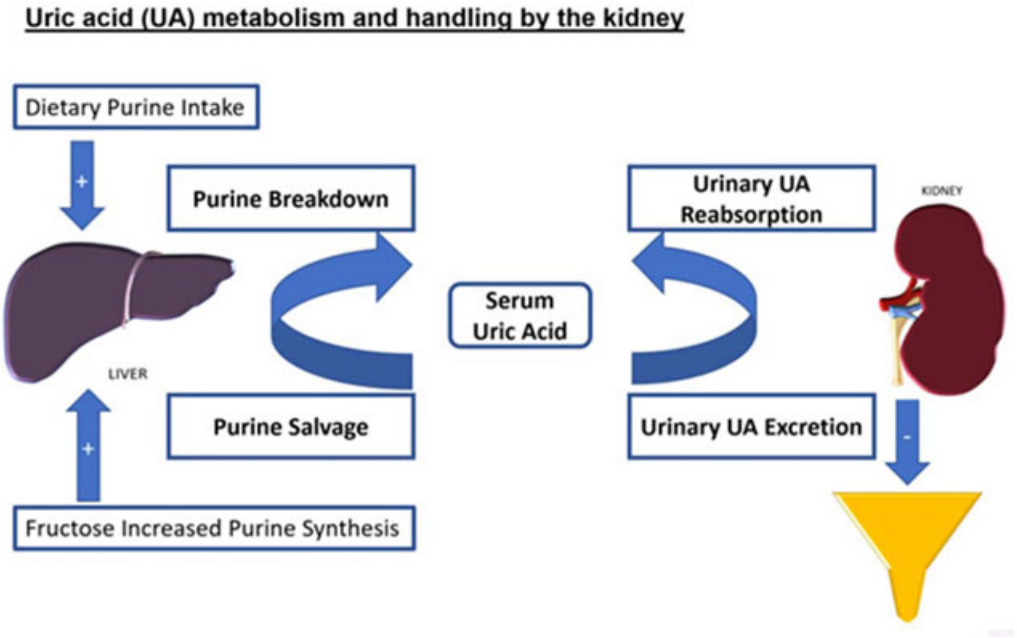


Figure 1: Dietary sources of purines such as yeast, shellfish, organ meats can lead to chronically increased nucleic acids and purines in the circulation. Both are broken down by the liver into uric acid for excretion. Fructose stimulates the liver to produce endogenous purines and can lead to increased 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 ESRD by the age of 60. Once a person has ESRD, 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 85% 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 140,000 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 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 COVID-19 infection & 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 lixivaptan, 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. In 2003, a third-party company Cardiome filed an NDA for the orphan indication of allopurinol intolerant gout. Cardiome announced via a press release 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 give final marketing approval for 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. More recently, another treatment, oxypurinol, has been developed as an alternative to allopurinol for gout patients who were intolerant of allopurinol. In one study conducted by third party Cardiome, 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.

Potential Advantages of XRx-008

XRx-008, 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, XRx-008, could become a significant treatment option for patients suffering from ADPKD. We believe XRx-008 can increase the bioavailability of oxypurinol. 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 is superior in terms of tolerability to allopurinol. The XRx-008 product 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 XRx-008 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's current cardiovascular and renal portfolio includes Entresto, Jynarque, and Samsca. While XRx-008 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 XRx-008 if approved.

Anticipated clinical development of XRx-008

Oxypurinol, a significant part of the XRx-008 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 final FDA marketing approval. We plan to rely on the prior research conducted and published in peer-reviewed journals and the Prior FDA Review for the FDA approval of XRx-008 as well as study results sponsored by XORTX. We have submitted a Pre-IND submission to the FDA for XRx-008. We believe XRx-008 may utilize the FDA 505(b)(2) developmental pathway supporting a reformulation of oxypurinol with increased bioavailability and superior tolerability compared to allopurinol. We are pursuing a regulatory pathway pursuant to Section 505(b)(2) of the FDCA and plan to pursue the hybrid application of the EU Centralized Procedure pursuant to article 10(3) of Directive 2001/83/EC, for the approval of this product candidate.

The Company has launched XRX-OXY-101 bridging pharmacokinetics study in support of the XRx-008 program to describe the bioavailability of the unique proprietary formulation and characterize the oral dosing form for the Company's Phase 3 clinical registration trial to slow or reverse progression of kidney disease in subjects with ADPKD. The bridging study will characterize the bioavailability and pharmacokinetics of oxypurinol formulation candidates for Phase 3 clinical testing. The Phase 3 registration trial's primary endpoint will characterize the benefit of uric acid lowering over a two year period on the rate of glomerular filtration rate decline. Secondary endpoints, will include change from total kidney volume, proteinuria, inflammatory markers.

XRx-101

Overview

Our second program, XRx-101, is being developed for the treatment of AKI in COVID-19 patients. 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 COVID-19 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 IL-6 and 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 JAMA, 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"). These drugs or therapies include remdesivir, beblelovibam, lagevrio, paxlovid, evusheld, acetemra, storovimab, propofol-lipuro, REGN-COV2, bamlanivimab, bamlanivimab in combination with etesevimab, casuvurumab plus imdevimab, COVID-19 convalescent plasma, regiocit, Fresenius kabi propoven and baricitinib, have been authorized for COVID-19 treatment under the FDA Emergency Use Authorization ("EUA"), and further drugs, such as dexamethasone and tocilizumab, have 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 COVID-19 in patients hospitalized and treated in ICU. 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 COVID 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 COVID-19 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 that in the Prior FDA Review, as well as study results to be sponsored by XORTX 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 our proprietary 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 COVID-19 infections. L-arginine has been shown to protect against kidney injury in the setting of ischemia reperfusion injury.

We are currently conducting a bridging pharmacokinetics study, and we are in the planning stages for the Phase 3 trial of XRx-101 at this time and have developed protocol synopses. However, lead investigators and FDA input will be required for final protocol details. The Company is in the process of evaluating and selecting a contract research organization. We expect our Phase 3 pivotal clinical trial will further demonstrate that XRx-101 could attenuate AKI in the setting of COVID-19 infection.

On October 8, 2020, we announced that we received a positive response from the FDA regarding our submission of a COVID-19 infection pre-IND meeting package, providing the Company with a clear development path forward for XRx-101. Our submission to the FDA summarized current data supporting the XRx-101 program. At the same time the FDA response provided clear feedback on the proposed plan and outlined the critical steps to test XRx-101 in patients with COVID-19 infection to treat AKI in a Phase 3 trial. To support preparation of the Phase 3 trial, we are preparing for a pharmacokinetic study to describe the bioavailability of this unique proprietary formulation of xanthine oxidase inhibitor and characterize the oral dosing for our Phase 3 clinical trial to slow or reverse acute kidney disease in hospitalized individuals with COVID-19. Similarly, we believe rapid decreased SUA concentration followed by sustained xanthine oxidase inhibition has the potential to improve cardiovascular and neurological outcomes as well. We believe a number of completed clinical studies support development of XRx-101 by XORTX.

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 (Diabeters 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 for this program. 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 provides oxypurinol, we may plan to rely on the prior research conducted and published in peer-reviewed journals and that in the prior FDA Review, 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. Lonza is a leading global provider of integrated healthcare solutions.

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 is an investigator-led study focused on evaluation of the more than 5,600 individuals with COVID-19 infection. Dr. Steven Coca, lead investigator and Associate Professor of Medicine at the Icahn School of Medicine at Mount Sinai observed a hypercatabolic phenotype in a significant proportion of patients with AKI, manifested by extremely high serum uric acid levels, along with hyperkalemia and hyperphosphatemia without overt evidence of rhabdomyolysis. A better understanding of the pathophysiologic causes of COVID-associated AKI is needed, including the potential effect of hyperuricemia on the severity of kidney injury and contribution to poor outcomes. The Company is advancing this investigator-led clinical study with Drs. Steven Coca and Jaime Uribarri and several other clinicians and investigators at the Icahn School of Medicine at Mount Sinai. This group 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.

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.

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 Patent Cooperation Treaty (PCT), application. XORTX-owned Patent Family Member No. 3 includes a pending Patent Cooperation Treaty (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 COVID19 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 or licenses oxypurinol, our technology is based upon proprietary formulations of oxypurinol that address unmet medical needs associated with kidney disease.

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 the Vendors Agreement between the Company and 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 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 (2020 fees– paid);

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:

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

- 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

- 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*: XRx-008 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 COVID-19 infection. Currently, only one drug, Remdesvir, has been approved by the FDA for treatment of COVID-19.

Additional drugs remdesivir, beblelovibam, lagevrio, paxlovid, evusheld, acetemra, storovimab, propofol-lipuro, REGN-COV2, bamlanivimab, bamlanivimab in combination with etesevimab, casuvurumab plus imdevimab, COVID-19 convalescent plasma, regiocit, Fresenius kabi propoven and baricitinib, have been authorized for COVID-19 treatment under the FDA EUA, and further drugs, such as dexamethasone and tocilizumab, have 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.

The FDA and corresponding regulatory authorities will ultimately review our clinical results and determine whether our product candidates are effective. No regulatory agency has made any such determination that any of our product candidates are effective for use by the general public for any indication.

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 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 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 signalled 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 a NDA, the FDA will issue a 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 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 Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as 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 PREA, 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 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 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 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. 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 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 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 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 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 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 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 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 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, or 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 a 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.

By way of example, the PPACA was enacted in March 2010 and has had a significant impact on the healthcare industry in the U.S. The ACA expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to biopharmaceutical products, the PPACA, among other things, addressed 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, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program. Additionally, in December 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on competition in the U.S. biopharmaceutical marketplace.

As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product's ASP to the DHHS beginning on January 1, 2022, subject to enforcement via civil money penalties.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the PPACA and we expect there will be additional challenges and amendments to the PPACA in the future. Members of the U.S. Congress have indicated that they may continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the PPACA. For example, the TCJA was enacted in 2017 and, among other things, removed penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, commonly referred to as the "individual mandate." In December 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate was a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA were invalid and the law in its entirety was unconstitutional. In December 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether other reforms enacted as part of the ACA but not specifically related to the individual mandate or health insurance could be severed from the rest of the ACA so as not to be declared invalid as well. In March 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and allocated one hour for oral arguments, which occurred on November 10, 2020 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.. Complying with any new legislation or reversing changes implemented under the PPACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA that affect healthcare expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which was signed into law on March 27, 2020 and 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 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. The 2021 Consolidated Appropriations Act was subsequently signed into law on December 27, 2020 and extended the CARES Act suspension period to March 31, 2021. The most recently enacted pandemic-relief legislation, the American Rescue Plan Act of 2021, which President Biden signed into law on March 11, 2021, also includes significant healthcare system reforms and programs intended to strengthen the insurance marketplace established under the PPACA, among others.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation 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. DHHS has solicited feedback on some of various measures intended to lower drug prices and reduce the out of pocket costs of drugs and implemented others under its existing authority. For example, in May 2019, DHHS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified a DHHS policy change that was effective January 1, 2019. Congress and the executive branch have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, making this area subject to ongoing uncertainty.

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 preempt the states' ability to regulate 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.

The FDA's and other regulatory authorities' policies also may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. For example, in December 2016, the Cures Act was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is uncertain. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug and device provisions that build on the Cures Act. In addition, the next cycle of Congressional reauthorization for FDA's prescription drug, biologic, and medical device user fee programs must be completed by mid-2022 and that periodic must-pass legislation is typically used as a vehicle to implement federal policy changes or other substantive amendments to the FDCA. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, once regulatory approval is obtained. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, including any future pharmaceutical products for which we secure marketing approval.

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 PPACA, 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 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 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

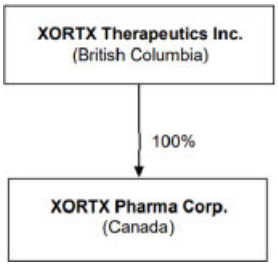
- State laws and foreign laws and regulations (particularly European Union laws regarding personal data relating to individuals based in Europe) that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating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

Moreover, in November 2020, the DHHS finalized significant changes to the regulations implementing the Anti-Kickback Statute, with the goal of offering the healthcare industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants.

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, 2021 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	61	President and Chief Executive Officer and Director	January 9, 2018	Current President and Chief Executive Officer of the Company since January 9, 2018 and its predecessor company, XORTX Pharma Corp. since July 2012; former Chief Scientific Officer and co-founder, Stem Cell Therapeutics Inc. (November 2004 to December 2011).
William Farley New York, United States	67	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.

Name, Province / State and Country of Residence	Age	Position with the Company	Date Became a Director / Officer	Principal Occupation Last Five Years
Stephen Haworth Pennsylvania, United Sates	71	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	43	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	55	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	68	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).

Name, Province / State and Country of Residence	Age	Position with the Company	Date Became a Director / Officer	Principal Occupation Last Five Years
David MacDonald British Columbia, Canada	59	Chief Technology Officer	January 20, 2022	Current Chief Technology Officer of the Company and current President, Mathylation Sciences Inc. since 2017 and former Chief Technology Officer (2008 through 2017); former Chief Technology Officer, ImmunoFlex (2020 to 2021).
Raymond Pratt Michigan, United States	71	Director	December 20, 2021	Former Chief Development Officer and Chief Medical Officer, Rockwell Medical, Inc. (2012 to 2022).
Paul Van Damme[(1)] Ontario, Canada	72	Director and Chair	January 25, 2018	Former director of 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); former Chief Financial Officer, Structural Genomics Consortium (May 2012 to June 2019); former Chief Financial Officer, Bradmer Pharmaceuticals Inc. (September 2007 to July 2018).

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 CNS, oncology and anti-infectives. Mr. Farley currently serves on the board of directors of SOMA and as a consultant to various executive management teams, and also advises several boards of directors on the commercialization of assets. He received his Bachelor of Science degree in Chemistry from State University of New York, Oswego and has taken graduate courses at Rutgers and University of California, Irvine.

Dr. Stephen Haworth, MB BS, MRCP

Dr. Stephen Haworth joined XORTX as the Chief Medical Officer effective July 1, 2021. Dr. Haworth holds a medical degree from University College Hospital Medical School, University of London having graduated with Honors. Dr. Haworth brings to XORTX more than 25 years of successful global drug development and leadership in both start up and Fortune 500 pharmaceutical firms in both the United States and Europe. Dr. Haworth has a broad clinical and regulatory experience that ranges from infectious disease through nephrology, cardiovascular disease and most recently on programs for treatment and prevention of SARSCoV infection. He has held key roles in numerous FDA and EMA submissions and has been involved in several licensing and M&A transactions. Since 2011, Dr. Haworth has served as the principal consultant for Haworth Biopharmaceutical Consulting Services. In addition, from 2016 to 2018, Dr. Haworth served as the Executive Director Medical Science for Cormedix, Inc. a biopharmaceutical company.

Amar Keshri, CA, CPA

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

Ian Klassen, B.A.

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

Jacqueline Le Saux, BScL, MBA, LLB

Jacqueline Le Saux is a seasoned Canadian health care legal executive who has held senior positions at large and small public and private life science companies. Jacqueline's legal experience is focused on securities, pharmaceutical regulatory and intellectual property law. As a Vice President, Legal in both public and private companies Ms. Le Saux has led multiple financings, mergers and acquisitions and product licensing transactions, mitigating risk and executing strategies in the Canadian healthcare industry. Her broad industry experience spans big pharma to early and late-stage research and development, as well as consumer products and pharmaceutical manufacturing. Prior to entering the health care industry, she was a partner at a top tier Canadian law firm, specializing in securities and corporate law. From 2009 to 2018, Ms. Le Saux served as Vice-President, Legal and Compliance for Purdue Pharma (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. David MacDonald, PhD

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

Dr. Raymond Pratt, MD FACP

Dr. Pratt is an accomplished Physician Executive with 40 years' experience in both clinical medicine and Nephrology. In his 25 years in the pharmaceutical industry, he has led global clinical trials, clinical pharmacology, drug safety and regulatory affairs in both large and small companies. His leadership has led to the approval of drugs for renal, hematology and CNS patients in the US and other global markets. Until March 2022, Dr. Pratt was the Chief Development Officer and former Chief Medical Officer, Rockwell Medical, Inc. since 2012, the former Vice President, Strategic Drug Development, Quintiles Transnational and former Vice President, R&D and Scientific Leader and various other senior management positions with Shire Pharmaceutical Development.

Paul Van Damme, B Comm, CPA, MBA

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

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, 2021 include our principal executive officer and our principal accounting officer.

Overview

Compensation Philosophy

The goal of our compensation program is to attract, retain and motivate our employees and executives. The Board of Directors and our Compensation Committee are responsible for setting our executive compensation and establishing corporate performance objectives. 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 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 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 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

During the period ended December 31, 2021, the non-executive directors of the Company received an annual fee of $12,000 and for each meeting exceeding 30 minutes, each committee chair received a fee of $700 and each member of a committee received a fee of $300 for director services.

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, 2021, 2020 and 2019 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*	2021	221,840	25,000	Nil	63,072	Nil	246,840
	2020	196,097	Nil	Nil	63,072	Nil	259,169
	2019	192,000	Nil	Nil	17,137	Nil	209,137
Amar Keshri[(1)] *CFO*	2021	85,000	N/A	N/A	17,446	Nil	102,446
	2020	N/A	N/A	N/A	N/A	N/A	N/A
	2019	N/A	N/A	N/A	N/A	N/A	N/A
James Fairbairn[(1)] *Former CFO*	2021	58,500	Nil	Nil	Nil	Nil	58,500
	2020	30,000	Nil	Nil	15,635	Nil	45,635
	2018	30,000	Nil	Nil	12,510	Nil	42,510
William Farley[(2)] *Director*	2021	6,000	Nil	1,200	55,963	N/A	63,163
	2020	N/A	N/A	N/A	N/A	N/A	N/A
	2019	N/A	N/A	N/A	N/A	N/A	N/A
Ian Klassen[(3)] *Director*	2021	6,000	Nil	2,200	86,728	Nil	94,928
	2020	Nil	Nil	Nil	30,988	Nil	30,988
	2019	Nil	Nil	Nil	Nil	Nil	Nil
Jacqueline Le Saux [(2)] *Director*	2021	6,000	Nil	2,300	54,463	N/A	62,763
	2020	N/A	N/A	N/A	N/A	N/A	N/A
	2019	N/A	N/A	N/A	N/A	N/A	N/A
Raymond Pratt [(4)] *Director*	2021	Nil	Nil	300	57,922	N/A	58,222

	2020	N/A	N/A	N/A	N/A	N/A	N/A
	2019	N/A	N/A	N/A	N/A	N/A	N/A
Bruce Rowlands[5] *Former Director*	2021	40,950	Nil	2,600	Nil	Nil	43,550
	2020	36,000	Nil	Nil	41,348	Nil	77,348
	2019	Nil	Nil	Nil	Nil	Nil	Nil
Paul Van Damme *Director*	2021	6,000	Nil	3,600	41,841	Nil	51,441
	2020	Nil	Nil	Nil	33,387	Nil	33,387
	2019	Nil	Nil	Nil	Nil	Nil	Nil
Allan Williams[6] *Former Director*	2021	20,000	Nil	Nil	Nil	Nil	20,000
	2020	Nil	Nil	Nil	33,387	Nil	33,387
	2019	Nil	Nil	Nil	Nil	Nil	Nil

Outstanding Equity Awards at 2021 Fiscal Year End

The following table lists all outstanding equity awards held by our named executive officers and non-executive directors as of December 31, 2021 after giving effect to the Share Consolidation.

Compensation Securities							
Name and Position	**Type of Compen-sation Security**	**Number of Compensation Securities, Number of Underlying Securities and Percentage of Class (1)**	**Date of Issue or Grant**	**Issue, Conver-sion or Exercise Price ($) (1)**	**Closing Price of Security or Underlying Security on Date of Grant ($) (1)**	**Closing Price of Security or Underlying Security at Year End ($)**	**Expiry Date**
Allen Davidoff(2) *CEO*	N/A	Nil	N/A	N/A	N/A	N/A	N/A
Amar Keshri(3) *CFO*	Stock Option	21,294 *3.5%*	Jul 14, 2021	$2.41	$2.41		Jul 14, 2026
James Fairbairn *Former CFO*	N/A	Nil	N/A	N/A	N/A	N/A	N/A
William Farley(4) *Director*	Stock Option	21,294 13,706 *5.8%*	May 12, 2021 Dec 21, 2021	$1.88 $2.54	$1.88 $2.54	$2.50	May 12, 2026 Dec 21, 2026
Ian Klassen(5) *Director*	Stock Option	29,812 7,412 *6.1%*	Jan 11, 2021 Dec 21, 2021	$3.29 $2.54	$3.29 $2.54	$2.50	Jan 11, 2026 Dec 21, 2026
Jacqueline Le Saux(6) *Director*	Stock Option	21,294 13,706 *5.8%*	Jun 16, 2021 Dec 21, 2021	$1.76 $2.54	$1.76 $2.54	$2.50	Jun 16, 2026 Dec 21, 2026
Raymond Pratt(7) *Director*	Stock Option	30,000 *4.9%*	Dec 21, 2021	$2.54	$2.54	$2.50	
Bruce Rowlands *Former Director*	N/A	Nil	N/A	N/A	N/A	N/A	N/A
Paul Van Damme(8) *Director*	Stock Option	21,671 *3.6%*	Dec 21, 2021	$2.54	$2.54	$2.50	Dec 21, 2026
Allan Williams *Former Director*	N/A	Nil	N/A	N/A	N/A	N/A	N/A

Notes:

(1) Adjusted to reflect consolidation of 1:11.74 that occurred September 24, 2021.
(2) Allen Davidoff holds 105,178 options, 42,589 exercisable at $5.87, 42,589 exercisable at $1.64 and 20,000 exercisable at $2.54, expiring March 19, 2023, June 23, 2025 and January 12, 2027, respectively.
(3) Amar Keshri holds 31,294 options, 21,294 exercisable at $2.41 expiring July 14, 2026 and 10,000 options exercisable at $2.54 expiring January 12, 2027.
(4) William Farley holds 35,000 options, 21,294 exercisable at $1.88 expiring May 12, 2026 and 13,706 options exercisable at $2.54 expiring December 21, 2026.
(5) Ian Klassen holds 50,000 options, 12,776 exercisable at $2.82, 29,812 exercisable at $3.29 and 7,412 exercisable at $2.54, expiring August 27, 2025, January 11, 2026 and December 21, 2026, respectively.
(6) Jacqueline Le Saux holds 35,000 options, 21,294 exercisable at $1.76 expiring June 16, 2026 and 13,706 exercisable at $$2.54 expiring December 21, 2026.
(7) Raymond Pratt holds 30,000 options exercisable at $2.54 expiring December 21, 2026.
(8) Paul Van Damme holds 60,000 options, 12,776 exercisable at $5.87, 25,553 exercisable at $1.64 and 21,671 exercisable at $2.54, expiring March 19, 2023, June 23, 2025 and December 21, 2026, respectively.

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 BCBA.

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 CEO at an annual salary of US$300,000, pursuant to 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, 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 entered into the Keshri Consulting Agreement, pursuant to which Next Level Consultants Inc. is entitled to compensation for the provision of such services of base fees of $16,000 per month, with a discretionary bonus of up to 30% of the total value of the contract, subject to the discretion of the Company's Compensation Committee. This agreement may be terminated at any time and for any reason by either party with 30 days' notice.

On November 1, 2022, the Company entered into an employment agreement with Amar Keshri as the Company's Chief Financial Officer at an annual salary of Cdn.$192,000 (the "Keshri Agreement") with a discretionary bonus up to 30% of the annual salary. The Keshri Agreement 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 the Haworth Consulting Agreement, as amended by the Consulting Amending Agreement, dated as of January 27, 2022, by and between the Company and Stephen Haworth, pursuant to which Haworth Biopharmaceutical Consulting Services Inc. is entitled to compensation for the provision of such services of base

fees of US$18,750 per month, with a discretionary bonus of up to 30% of the total value of the contract, subject to the discretion of the Company's 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 an employment agreement with David MacDonald as the Company's Chief Technology Officer at an annual salary of $188,000, effective January 10, 2022 (the "MacDonald Agreement"). Pursuant to the MacDonald Agreement, David Macdonald receives an annual salary of $188,000. The MacDonald Agreement contains standard confidentiality and non-compete clauses and has an indefinite term. The MacDonald Agreement can be terminated by Dr. MacDonald or the Company by providing 30 days' notice. In the case of the Company providing termination notice, Dr. MacDonald 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. MacDonald is entitled to a lump sum payment of 12 times his then current monthly salary. In the case of a change of control, the Macdonald Agreement provides for a lump sum payment equal to 12 times his monthly base salary amount in effect at the time.

In addition to the arrangements for our executive officers as set forth above, the Company entered into the Sans Consulting Agreement, pursuant to which Mr. Sans is entitled to compensation for the provision of such services of a base fee of US$11,700 per month, with a one-time bonus of US$144,000 on completion of an offering of at least US$10,000,000 of the Company's shares on a U.S. securities exchange. The agreement generally requires that we indemnify and hold Mr. Sans harmless for liabilities arising out of the Mr. Sans' service, unless the liability resulted from the gross negligence or willful misconduct of any person seeking indemnification for such claim. This agreement may be terminated at any time and for any reason by either party with 30 days' notice.

The Company entered into 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 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. This agreement has been replaced with the 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.

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) – Mr. 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, 2021 were pre-approved by our Audit Committee. It is our policy that all audit and non-audit services performed by our auditors will continue to be pre-approved by our Audit Committee.

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, B COMM, CPA, MBA. 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 Paul Van Damme, B COMM, CPA, MBA. 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, 2021, we had two (Allen Davidoff and Amar Keshri) full-time employees and 12 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 employees to be good.

6.E. Share Ownership

The following table indicates information as of April 1, 2022, 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 1, 2022, 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 1, 2022, we had 32 record holders of our Common Shares, with 18 record holders in Canada, representing 78.6% of our outstanding Common Shares, and 13 record holders in the United States, representing 20.8% of our outstanding Common Shares.

Except as otherwise indicated, the address of each of the persons in this table is Suite 4000, 421 – 7th Avenue SW, Calgary, Alberta, Canada T2P 4K9.

Name and Address of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% and Greater Shareholders:		
Prevail Partnerships LLC (1)	977,318	7.5%
Directors and Named Executive Officers:		
Davidoff, Allen (2)	511,454	3.9%
Farley, William (3)	35,000	*%
Haworth, Stephen (4)	7,026	*%
Keshri, Amar (5)	15,526	*%
Klassen, Ian (6)	92,759	*%
Le Saux, Jacqueline (7)	35,000	*%
MacDonald, David (8)	22,777	*%
May, Charlotte (9)	22,676	*%
Pratt, Raymond (10)	30,000	*%
Van Damme, Paul (11)	123,993	*%
All executive officers and directors as a group (10 persons)	896,126	6.9%

* Indicates beneficial ownership of less than 1%.
(1) Consists of 977,318 Common Shares held by Prevail Partners LLC.
(2) Consists of 430,917 Common Shares, warrants exercisable for 8,517 Common Shares, and options exercisable for 72,020 Common Shares within 60 days of April 1, 2022, held personally by Mr. Davidoff.
(3) Consists of options exercisable for 35,000 Common Shares within 60 days of April 1, 2022, held personally by Mr. Farley.
(4) Consists of options exercisable for 7,026 Common Shares within 60 days of April 1, 2022, held personally by Mr. Haworth.
(5) Consists of 8,500 Common Shares and options exercisable for 7,026 Common Shares within 60 days of April 1, 2022, held personally by Mr. Keshri.
(6) Consists of 42,759 Common Shares, and options exercisable for 50,000 Common Shares within 60 days of April 1, 2022, held personally by Mr. Klassen.
(7) Consists of options exercisable for 35,000 Common Shares within 60 days of April 1, 2022, held personally by Ms. Le Saux.
(8) Consists of 20,000 Common Shares and options exercisable for 2,777 Common Shares within 60 days of April 1, 2022, held personally by Mr. MacDonald.
(9) Consists of options exercisable for 22,676 Common Shares within 60 days of April 1, 2022, held personally by Ms. May.
(10) Consists of options exercisable for 30,000 Common Shares within 60 days of April 1, 2022, held personally by Mr. Pratt.
(11) Consists of 63,993 Common Shares and options exercisable for 60,000 Common Shares within 60 days of April 1, 2022, held personally by Mr. Van Damme.

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 12,989,687 Common Shares of the Company issued and outstanding, and therefore the current 10% threshold is 1,298,969 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 4.16 to this Annual Report.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

7.A. Major Shareholders

See Item 6.E. above.

7.B. Related Party Transactions

Since January 1, 2019, no director or executive officer of the Company or any person or company who beneficially owns, or controls or directs, directly or indirectly more than 10% of the outstanding Common Shares or any known associate or affiliate of such persons, has or has had any material interest direct or indirect, in any transaction or in any proposed transaction that has materially affected or is reasonably expected to material affect the Company except for Prevail, which owns 977,318 Common Shares, currently representing approximately 7.5% of the issued and outstanding Common Shares of the Company. Prevail acquired the 977,318 Common Shares as part of the private placement that closed on February 28, 2020, in connection with an agreement between the Company and Prevail wherein the Company paid a deposit of $1,606,320 (US$1,200,000 at the exchange rate on the date of the transaction) to Prevail to support two clinical trials on behalf of the Company. Prevail, a clinical research organization, is a key partner in XORTX Therapeutics future clinical plans and is anticipated to participate in clinical trials to support XRx-008, XRx101 and XRx-225 programs in the future.

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), more than 10% of any class or series of our outstanding voting securities, or any associate or affiliate of any of the foregoing persons, in any transaction within the three years before the date hereof that has materially affected or is reasonably expected to materially affect us or any of our subsidiaries.

7.C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

The audited consolidated financial statements for the years ended December 31, 2021 and 2020 can be found under “Item 17. Financial Statements”.

8.B. Significant Changes

We are not aware of any significant change that has occurred since December 31, 2021, 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 12,989,687 are issued and outstanding. In addition, we have 733,567 Common Shares issuable pursuant to outstanding stock options, 5,329,796 Common Shares issuable upon the exercise of outstanding Common Share purchase warrants. We had approximately 23 holders of record and approximately 1,237 beneficial owners of our Common Shares as of December 31, 2021.

   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;
      a. decrease the par value of those shares; or
      b. 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:

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

(ii) 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:

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

(i) state the general nature of the special business; and
(ii) 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:

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

B. 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 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.

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 associated with 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 Cdn.$190,000.00 which amount was increased to US$300,000 effective November 1, 2021;

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. Consulting Agreement, dated effective February 1, 2021, by and between the Company and David Sans, Ph.D., pursuant to which the Company retained David Sans, Ph.D. as the executive advisor for the purpose of establishing collaborations or clinical trials to study the effect of the Company's products;

5. Consulting Agreement, dated effective March 1, 2021, by and between the Company and 1282803 Ontario Inc., pursuant to which the Company retained James Fairbairn as the appointed consultant to act as Chief Financial Officer;

6. 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;

7. 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;

8. 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;

9. Consulting Agreement, dated effective July 1, 2021, by and between the Company and Next Level Consultants Inc., pursuant to which the Company retained Amar Keshri as Chief Financial Officer for Cdn.$8,000 per month for the period of July 2021, Cdn.$15,000 per month for the period of August 1, 2021, bonus eligibility and 250,000 options based on the discretion of the Management and Board of Directors, at current market pricing at the time of the grant, which Consulting Agreement has been amended to annual compensation of Cdn.$192,000 effective November 1, 2021;

10. 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;

11. Consulting Agreement, dated effective July 1, 2021, by and between the Company and Haworth Biopharmaceutical Consulting Services Inc., as amended by a Consulting Amending Agreement, dated as of January 27, 2022, by and between the Company and Stephen Haworth, pursuant to which the Company has retained Stephen Haworth as Chief Medical Officer for USD$18,750 per month, bonus eligibility and options based on the discretion of the Management and Board Directors;

12. 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;

13. 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;

14. 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;

15. 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;

16. 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;

17. 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;

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

19. Sponsored Research Agreement between the Regents of the 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;

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; and

26. Agreement, dated as of November 1, 2021, by and between the Company and Amar Keshri, pursuant to which the Company retained Amar Keshri as Chief Financial Officer for an annual salary for Cdn.$192,000.

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 Canadian Federal Income Tax Considerations

The following is, as of the date of this Annual Report, a general summary of the principal Canadian federal income tax considerations under the Income Tax Act (Canada) (the "Canadian Tax Act"), generally applicable to a beneficial owner of common shares and/or warrants and who, for the purposes of the Canadian Tax Act and at all relevant times, deals at arm's length with the Company and the underwriters, is not affiliated with the Company and who acquires and holds the common shares and/or warrants, as capital property (each a "Holder"). Generally, the common shares and warrants will be considered to be capital property to a Holder thereof provided that the Holder does not use the Common Shares in the course of carrying on a business of trading or dealing in securities and such Holder has not acquired them in one or more transactions considered to be an adventure or concern in the nature of trade.

This summary does not apply to a Holder (i) that is a "financial institution" for the purposes of the mark-to-market rules contained in the Canadian Tax Act; (ii) that is a "specified financial institution" as defined in the Canadian Tax Act; (iii) if an interest in such a Holder is a "tax shelter" or a "tax shelter investment," each as defined in the Canadian Tax Act; (iv) a holder that reports its "Canadian tax results," as defined in the Canadian Tax Act, in a currency other than Canadian currency; or (v) that has or will enter into a "derivative forward agreement" or a "synthetic disposition arrangement", as those terms are defined in the Canadian Tax Act, with respect to the common shares and warrants. **Such Holders should consult their own tax advisors with respect to the consequences of acquiring and holding common shares and/or warrants**.

Additional considerations, not discussed herein, may be applicable to a Holder that (i) is a corporation resident in Canada and (ii) is (or does not deal at arm's length for the purposes of the Canadian Tax Act with a corporation resident in Canada that is), or becomes as part of a transaction or event or series of transactions or events that includes the acquisition of common shares and/or warrants, controlled by a corporation that is not resident in Canada for purposes of the "foreign affiliate dumping" rules in section 212.3 of the Canadian Tax Act. **Such Holders should consult their own tax advisors with respect to the consequences of acquiring common share units.**

This summary is based upon the current provisions of the Canadian Tax Act and the regulations thereunder (the "Regulations"), in force as of the date hereof and the Company's understanding of the current published administrative and assessing practices of the Canada Revenue Agency (the "CRA"). This summary takes into account all specific proposals to amend the Canadian Tax Act and the Regulations publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof (the "Tax Proposals"), and assumes that the Tax Proposals will be enacted in the form proposed, although no assurance can be given that the Tax Proposals will be enacted in their current form or at all. This summary does not otherwise take into account any changes in law or in the administrative policies or assessing practices of the CRA, whether by legislative, governmental or judicial decision or action. Except as set out in "*Material U.S. Federal Income Tax Considerations for U.S. Holders*" below, this summary also does not take into account or consider any provincial, territorial or foreign income tax considerations, which considerations may differ significantly from the Canadian federal income tax considerations discussed in this summary.

This summary is of a general nature only, is not exhaustive of all possible Canadian federal income tax considerations and is not intended to be, nor should it be construed to be, legal or tax advice to any particular Holder. This summary does not address the deductibility of interest expense incurred or paid by a Holder that has borrowed money in connection with the acquisition of common shares and/or warrants. **Holders should consult their own tax advisors with respect to their particular circumstances.**

All amounts in a currency other than the Canadian dollar relevant in computing a Holder's liability under the Canadian Tax Act with respect to the acquisition, holding or disposition of common shares and warrants must generally be converted into Canadian dollars using the single daily exchange rate quoted by the Bank of Canada for the day on which the amount arose or such other rate of exchange that is acceptable to the CRA.

Residents of Canada

The following section of this summary applies to a Holder who, for the purposes of the Canadian Tax Act, is or is deemed to be resident in Canada at all relevant times, or a Canadian Resident Holder. Certain Canadian Resident Holders whose Common Shares might not constitute capital property may in certain circumstances make an irrevocable election in accordance with subsection 39(4) of the Canadian Tax Act to deem the Common Shares, and every other "Canadian security" as defined in the Canadian Tax Act, held by such Canadian Resident Holder, in the taxation year of the election and each subsequent taxation year to be capital property. Such an election will not be applicable to a warrant. Canadian Resident Holders should consult their own tax advisors regarding this election.

Dividends

Dividends received or deemed to be received on the Common Shares will be included in computing a Canadian Resident Holder's income. In the case of an individual (other than certain trusts), such dividends will be subject to the gross-up and dividend tax credit rules normally applicable in respect of "taxable dividends" received from "taxable Canadian corporations" (each as defined in the Canadian Tax Act). An enhanced dividend tax credit will be available to individuals in respect of "eligible dividends" designated by the Company to the Canadian Resident Holder in accordance with the provisions of the Canadian Tax Act.

Dividends received or deemed to be received by a corporation that is a Canadian Resident Holder on the common shares must be included in computing its income but generally will be deductible in computing its taxable income. In certain circumstances, subsection 55(2) of the Canadian Tax Act will treat a taxable dividend received by a Canadian Resident Holder that is a corporation as proceeds of disposition or a capital gain. A Canadian Resident Holder that is a corporation should consult its own tax advisors having regard to its own circumstances. A Canadian Resident Holder that is a "private corporation" as defined in the Canadian Tax Act and certain other corporations controlled, by or for the benefit of an individual (other than a trust) or a related group of individuals (other than trusts) generally will be liable to pay a 38 1/3% refundable tax under Part IV of the Canadian Tax Act on dividends received or deemed to be received on the Common Shares to the extent such dividends are deductible in computing taxable income. Such refundable tax will generally be refunded to a corporate Canadian Resident Holder at the rate of 38 1/3% of taxable dividends paid while it is a private corporation.

Expiry of Warrants

In the event of the expiry of an unexercised warrant, a Canadian Resident Holder will be considered to have disposed of such warrant for nil proceeds and will accordingly realize a capital loss equal to the Canadian Resident Holder's adjusted cost base of such warrant immediately before that time. For a description of the tax treatment of capital losses, see "*Capital Gains and Capital Losses*", below.

Exercise of Warrants

No gain or loss will be realized by a Canadian Resident Holder on the exercise of a warrant to acquire common shares. When a warrant is exercised, the Canadian Resident Holder's cost of the common shares acquired thereby will be equal to the adjusted cost base of the warrant to the Canadian Resident Holder, immediately before that time, plus the amount paid on the exercise of the warrant. For the purpose of computing the adjusted cost base of each Common Share acquired on the exercise of a warrant, the cost of such common share must be averaged with the adjusted cost base to the Canadian Resident Holder of all other common shares held as capital property immediately before the exercise of the warrant.

Dispositions of Common Shares or Warrants

Upon a disposition (or a deemed disposition) of a common share, a Canadian Resident Holder generally will realize a capital gain (or a capital loss) equal to the amount by which the proceeds of disposition of such common share or warrant, net of any reasonable costs of disposition, are greater (or are less) than the adjusted cost base of such common share to the Canadian Resident Holder. The Canadian federal tax treatment of capital gains and capital losses is discussed in greater detail below under the subheading "*Capital Gains and Capital Losses*."

The adjusted cost base to a Canadian Resident Holder of a common share will be averaged with the adjusted cost base of any other of the Company's Common Shares held by such Canadian Resident Holder as capital property for the purposes of determining the Canadian Resident Holder's adjusted cost base of each common share.

Capital Gains and Capital Losses

Generally, a Canadian Resident Holder is required to include in computing its income for a taxation year taxable capital gain realized in the year. Subject to and in accordance with the provisions of the Canadian Tax Act, a Canadian Resident Holder is required to deduct an allowable capital loss realized in a taxation year from taxable capital gains realized in the year by such Canadian Resident Holder. Allowable capital losses in excess of taxable capital gains may be carried back and deducted in any of the three preceding taxation years or carried forward and deducted in any following taxation year against taxable capital gains realized in such year to the extent and under the circumstances described in the Canadian Tax Act.

The amount of any capital loss realized on the disposition or deemed disposition of Common Shares by a Canadian Resident Holder that is a corporation may be reduced by the amount of dividends received or deemed to have been received by it on such shares or shares substituted for such shares to the extent and in the circumstances specified by the Canadian Tax Act. Similar rules may apply where a Canadian Resident Holder that is a corporation is a member of a partnership or beneficiary of a trust that owns such shares or that itself is a member of a partnership of a beneficiary of a trust that owns such shares. Canadian Resident Holders to whom these rules may be relevant should consult their own tax advisors.

A Canadian Resident Holder that is throughout the relevant taxation year a "Canadian-controlled private corporation" as defined in the Canadian Tax Act may also be liable to pay an additional refundable tax on its "aggregate investment income" for the year which will include taxable capital gains. The rate of the refundable tax is 10 2/3% for taxation years beginning after 2015. Such refundable tax will generally be refunded to a corporate Canadian Resident Holder at the rate of 38 1/3% of taxable dividends paid while it is a private corporation.

Minimum Tax

Capital gains realized and dividends received by a Canadian Resident Holder that is an individual or a trust, other than certain specified trusts, may give rise to minimum tax under the Canadian Tax Act. Such Canadian Resident Holders should consult their own advisors with respect to the application of minimum tax.

Non-Residents of Canada

The following section of this summary is generally applicable to a Holder who, for the purposes of the Canadian Tax Act, and at all relevant times: (i) has not been and will not be deemed to be resident in Canada; and (ii) does not use or hold the common shares or warrants in, or in the course of, carrying on a business, or part of a business, in Canada, each a Non-Canadian Holder. Special rules, which are not discussed in this summary, may apply to a Non-Canadian Holder that is an insurer carrying on business in Canada and elsewhere or that is an "authorized foreign bank" as defined in the Canadian Tax Act. Such a Non-Canadian Holder should consult its own tax advisors.

Dividends

Dividends on the Common Shares paid or credited or deemed to be paid or credited to a Non-Canadian Holder will be subject to Canadian withholding tax at the rate of 25% on the gross amount of the dividend unless such rate is reduced by the terms of an applicable tax treaty. Under the *Canada-United States Income Tax Convention* (1980) (the "Treaty"), as amended, the rate of withholding tax on dividends paid or credited to a Non-Canadian Holder who is resident in the U.S. for purposes of the Treaty, is entitled to the full benefits under the Treaty and beneficially owns the dividend (a "U.S. Holder"), is generally limited to 15% of the gross amount of the dividend (or 5% in the case of a U.S. Holder that is a corporation beneficially owning at least 10% of the Company's voting shares). Not all persons who are residents of the U.S. for purposes of the Treaty will qualify for the benefits of the Treaty. Non-Canadian Holders that are resident in the U.S. are advised to consult their tax advisors in this regard. The rate of withholding tax on dividends is also reduced under other bilateral income tax treaties or conventions to which Canada is a signatory.

Expiry of Warrants

In the event of the expiry of an unexercised warrant, a Non-Canadian Holder will be considered to have disposed of such Warrant for nil proceeds and will accordingly realize a capital loss equal to the Non-Canadian Holder's adjusted cost base of such Warrant immediately before that time. For a description of the tax treatment of capital losses, see the discussion under "*Non-Residents of Canada - Disposition of Common Shares and Warrants*", below.

Exercise of Warrants

No gain or loss will be realized by a Non-Canadian Holder on the exercise of a warrant. When a warrant is exercised, the Non-Canadian Holder's cost of the Common Shares acquired thereby will be equal to the adjusted cost base of the warrant, immediately before that time, plus the amount paid on the exercise of the warrant. For the purpose of computing the adjusted cost base of each common share acquired on the exercise of a warrant, the cost of such Common Share must be averaged with the adjusted cost base to the Non-Canadian Holder of all other common shares held as capital property immediately before the exercise of the warrant.

Dispositions of Common Shares and Warrants

A Non-Canadian Holder generally will not be subject to tax under the Canadian Tax Act in respect of a capital gain realized on the disposition or deemed disposition of a common share or warrant nor will capital losses arising therefrom be recognized under the Canadian Tax Act, unless the common share or warrant constitutes "taxable Canadian property" to the Non-Canadian Holder thereof for purposes of the Canadian Tax Act, and the gain is not exempt from Canadian federal income tax pursuant to the terms of an applicable tax treaty.

Generally the common shares will not be "taxable Canadian property" to a Non-Canadian Holder if the Common Shares are listed on a "designated stock exchange", as defined in the Canadian Tax Act (which currently includes the Nasdaq) at the time of disposition, unless at any time during the 60 month period immediately preceding the disposition the following two conditions are met concurrently: (i) the Non-Canadian Holder, persons with whom the Non-Canadian Holder did not deal at arm's length, partnerships in which the Non-Canadian Holder or persons with whom the Non-Canadian Holder did not deal at arm's length held a membership interest (either directly or indirectly through one or more partnerships), or the Non-Canadian Holder together with all such persons, owned 25% or more of the Company's issued shares of any class or series of the Company's shares; and (ii) more than 50% of the fair market value of such shares was derived directly or indirectly from one, or any combination of, real or immovable property situated in Canada, "Canadian resource properties" (as defined in the Canadian Tax Act), "timber resource properties" (as defined in the Canadian Tax Act) or an option, an interest or right in such property, whether or not such property exists. A warrant would generally be a "taxable Canadian property" to a Non-Canadian Holder at a particular time if, at any time in the previous 60-month period: (a) the Non-Canadian Holder held warrants that provided such Non-Canadian Holder with the right to acquire 25% or more of the outstanding common shares of the Company or the Non-Canadian Holder and other persons and/or partnerships held shares of the Company at that time that satisfy the requirement in paragraph (i) above; and (b) the requirement in paragraph (ii) is satisfied at that time. Notwithstanding the foregoing, a Common Share may otherwise be deemed to be taxable Canadian property to a Non-Canadian Holder for purposes of the Canadian Tax Act.

A Non-Canadian Holder's capital gain (or capital loss) in respect of common shares or warrants that constitute or are deemed to constitute taxable Canadian property (and are not "treaty-protected property" as defined in the Canadian Tax Act) will generally be computed and included in income in the manner described above under the subheadings "*Residents of Canada—Dispositions of Common Shares or Warrants*" and "*Residents of Canada—Capital Gains and Capital Losses*".

Non-Canadian Holders whose Common Shares may be taxable Canadian property should consult their own tax advisors.

SHAREHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE CANADIAN OR OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON SHARES AND WARRANTS, INCLUDING, IN PARTICULAR, THE EFFECT OF ANY NON-U.S., STATE OR LOCAL TAXES.

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 that we may have been classified as a PFIC for the tax year ended December 31, 2021. Based on current business plans and financial expectations, we anticipate that we may be a PFIC for the current tax year and future tax 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.

U.S. Holders should be aware that, for each tax year, if any, that we are a PFIC, we can provide no assurances that we will satisfy the record keeping requirements of a PFIC, or that we will make available to U.S. Holders the information such U.S. Holders require to make a QEF Election with respect to us or any Subsidiary PFIC, and as a result, a QEF Election may not be available to U.S. Holders. U.S. Holders should consult with their own tax advisors regarding the potential application of the PFIC rules to the ownership and disposition of the Common Shares, and the availability of certain U.S. tax elections under the PFIC rules.

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

Not applicable.

10.G. Statement by Experts

Not applicable.

10.H. Documents on Display

Documents concerning our Company referred to in this Annual Report may be viewed by appointment during normal business hours at our registered and records office at Suite 4000, 421 – 7th Avenue SW, Calgary, Alberta, Canada T2P 4K9 .

10.I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed in varying degrees to a variety of financial instrument related risks. The Board approves and monitors the risk management processes, inclusive of controlling and reporting structures. The type of risk exposure and the way in which such exposure is managed is provided as follows:

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, 2021, the Company is exposed to currency risk on the following financial assets and liabilities denominated in US Dollars and British Pounds ("**GBP**"). The sensitivity of the Company's net earnings due to changes in the exchange rate between the USD and GBP against the Canadian dollar is included in the table below in Canadian dollar equivalents:

	USD amount	GBP amount	Total
	$	$	$
Cash	13,813,058	-	13,813,058
Accounts payable and accrued liabilities	(76,178)	(143,900)	(220,078)
Net exposure	13,736,880	(143,900)	13,592,980
Effect of +/- 10% change in currency	1,373,688	(14,390)	

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

Not applicable.

14.E. Use of Proceeds

The effective date of the registration statement on Form F-1 (File No. 333-258741) for the Company's initial underwritten public offering of securities in the United States was October 12, 2021 (defined herein as the "US Offering"). The offering of 2,906,000 units ("Units"), with each 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$4.13 per Unit closed on October 15, 2021 for gross proceeds of approximately CAD$14,851,850 (US$12,001,780), before deducting underwriting discounts and offering expenses of approximately CAD$2,300,549 and issued 145,300 finders' warrants with a fair value of CAD$371,251. The total net proceeds to the Company from the offering of CAD$12,551,301. 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 Common Share Purchase Warrants. None of the net proceeds of the US 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.

The Company has not fully used the net proceeds of the US Offering. The proceeds that the Company has used (approximately CAD$3,000,000 as of December 31, 2021) 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 to ensure that (i) information required to be disclosed in reports that the Company files or submits to regulatory authorities is recorded, processed, summarized and reported within the time periods specified by regulation, and (ii) is accumulated and communicated to management, including the Company's CEO and CFO, to allow timely decisions regarding required disclosure.

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

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2021, 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, attached as an exhibit hereto, 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, 2021 and 2020:

	Year Ended December 31,	
Services	**2021**	**2020**
Audit Fees[1]	$49,000	$18,750
Audit-Related Fees[2]	397	--
Tax Fees[3]	2,500	--
Other Fees[4]	16,000	--
Total	$67,897	$18.750

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 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.

PART III

ITEM 17: FINANCIAL STATEMENTS

Financial Statements Filed as Part of this Annual Report:

Consolidated Financial Statements for the Years Ended December 31, 2021, 2020 and 2019:

Independent Auditor's Report of Smythe LLP (PCAOB ID: 00995), dated April 7, 2022;

Consolidated Statements of Financial Position for the years ended December 31, 2021 and 2020;

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2021, 2020 and 2019;

Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2021, 2020 and 2019;

Consolidated Statements of Cash Flows for the years ended December 31, 2021, 2020 and 2019;

Notes to the Consolidated Financial Statements.

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019

(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, 2021 and 2020, and the related consolidated statements of comprehensive loss, changes in shareholders' equity and cash flows for the years ended December 31, 2021, 2020 and 2019, 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, 2021 and 2020, and the results of its operations and its cash flows for the years ended December 31, 2021, 2020 and 2019, 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. We determined that there are no critical audit matters.

/s/ Smythe LLP, Chartered Professional Accountants

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

Vancouver, Canada
April 7, 2022

XORTX THERAPEUTICS INC.

Consolidated Statements of Financial Position
(Expressed in Canadian Dollars)

	Note	December 31, 2021	December 31, 2020
		$	$
Assets			
Current			
Cash		18,851,244	171,271
Accounts receivable		51,539	14,351
Contract payments	**5**	–	1,606,320
Prepaid expenses	**6**	1,270,556	264,199
		20,173,339	2,056,141
Non-current			
Contract payments	**5**	1,606,320	–
Intangible assets	**7**	256,243	234,316
Total Assets		**22,035,902**	**2,290,457**
Liabilities			
Current			
Accounts payable and accrued liabilities	**8,10**	700,999	1,034,213
		700,999	1,034,213
Non-current			
Derivative warrant liability	**9(g)**	4,597,332	–
Total Liabilities		**5,298,331**	1,034,213
Shareholders' Equity			
Share capital	**9**	20,009,154	8,258,395
Share-based payments, warrant reserve and other	**9**	6,386,459	1,003,609
Obligation to issue shares	**7(c)**	32,238	32,238
Deficit		(9,690,280)	(8,037,998)
Total Shareholders' Equity		16,737,571	1,256,244
Total Liabilities and Shareholders' Equity		**22,035,902**	**2,290,457**

Nature of Operations (Note 1)
Commitments (Note 14)

/s/ "Allen Davidoff"
Director

/s/ "Paul Van Damme"
Director

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

XORTX THERAPEUTICS INC.

Consolidated Statements of Comprehensive Loss
For the years ended December 31, 2021, 2020 and 2019
(Expressed in Canadian Dollars)

	Note	2021	2020	2019
		$	$	$
Expenses				
Amortization	**7**	17,882	20,439	19,900
Consulting	**10**	724,272	102,880	46,561
Directors' fees	**10**	62,200	-	-
General and administrative		176,099	9,516	17,344
Investor relations		518,615	241,177	34,782
Listing fees		236,801	52,138	42,495
Professional fees	**10**	272,943	162,580	108,427
Research and development	**10**	853,124	277,455	39,897
Share-based payments	**9(f),10**	499,158	293,443	26,317
Travel		2,339	8,460	36,076
Wages and benefits	**10**	286,090	227,905	194,166
Loss before other items		(3,649,523)	(1,395,993)	(565,965)
Accretion		-	(846)	(1,638)
Transaction costs on derivative warrant liability	**9(b)**	(1,623,680)	-	-
Fair value adjustment on derivative warrant liability	**9(g)**	3,299,768	-	-
Foreign exchange gain (loss)		326,751	2,961	(26,397)
Impairment of intangible assets	**7**	-	(64,562)	-
Interest and other expenses		(5,598)	(12,666)	(35,576)
Forgiveness of debt		-	91,014	-
Recovery of provision for patent acquisition	**7(b)**	-	95,490	-
Net loss and comprehensive loss for the year		(1,652,282)	(1,284,602)	(629,576)
Basic and diluted loss per common share		(0.17)	(0.19)	(0.12)
Weighted average number of common shares outstanding				
Basic and diluted		9,847,641	6,664,025	5,359,444

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

XORTX THERAPEUTICS INC.

Consolidated Statements of Changes in Shareholders' Equity
For the years ended December 31, 2021, 2020 and 2019
(Expressed in Canadian Dollars)

	Note	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, 2018		5,359,444	5,863,872	581,486	–	–	5,202	(6,129,022)	321,538
Share-based payments		–	–	26,317	–	–	–	–	26,317
Share subscriptions received in advance		–	–	–	–	70,000	–	–	70,000
Net loss for the year		–	–	–	–	–	–	(629,576)	(629,576)
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	**9(b)**	1,555,314	2,465,023	91,297	–	(70,000)	–	–	2,486,320
Share issuance costs	**9(b)**	–	(70,500)	11,066	–	–	–	–	(59,434)
Convertible loan debt forgiveness		–	–	–	–	–	(5,202)	5,202	–
Obligation to issue shares	**7(c)**	–	–	–	32,238	–	–	–	32,238
Share-based payments	**9(f)**	–	–	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 placements	**9(b)**	2,085,687	763,572	–	–	–	–	–	763,572
Shares issued pursuant to IPO	**9(b)**	3,261,000	9,252,009	–	–	–	–	–	9,252,009
Reclassification of derivative warrant liability	**9**	–	–	4,460,000	–	–	–	–	4,460,000
Share issuance costs	**9(b)**	–	(1,377,364)	521,251	–	–	–	–	(856,113)
Options exercised	**9(b)**	51,106	149,172	(65,172)	–	–	–	–	84,000
Warrants exercised	**9(b)**	651,583	2,888,370	(32,387)	–	–	–	–	2,855,983
Shares issued for services	**9(b)**	25,553	75,000	–	–	–	–	–	75,000
Share-based payments	**9(f)**	–	–	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**

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, 2021, 2020 and 2019
(Expressed in Canadian Dollars)

	2021	2020	2019
	$	$	$
Cash provided by (used in):			
Operating activities			
Net loss for the year	(1,652,282)	(1,284,602)	(629,576)
Items not affecting cash:			
Accretion expense	–	846	1,638
Amortization	17,882	20,439	19,900
Forgiveness of debt	–	(91,014)	–
Impairment of intangible assets	–	64,562	–
Fair value adjustment on derivative warrant liability	(3,299,768)	–	–
Share-based payments	499,158	293,443	26,317
Shares issued for services	75,000	–	
Unrealized foreign exchange (gain) loss	(325,741)	1,201	34,064
Recovery of provision for patent acquisition	–	(95,490)	–
Changes in non-cash operating assets and liabilities:			
Fund held in trust	–	–	(70,000)
Accounts receivable	(37,188)	–	14,788
Prepaid expenses	(1,006,357)	(42,998)	–
Accounts payable and accrued liabilities	(333,214)	405,212	353,289
	(6,062,510)	(728,401)	(249,580)
Investing activity			
Acquisition of intangible assets	(39,809)	(14,350)	(7,037)
Financing activities			
Proceeds from issuance of shares	22,798,581	900,000	–
Cash share issuance costs	(856,113)	(44,592)	–
Options exercised	84,000	–	–
Warrants exercised	2,430,083	–	–
Deferred share issuance costs	–	–	(14,788)
Share subscription received in advance	–	–	70,000
	24,456,551	855,408	55,212
Effect of foreign exchange on cash	325,741	–	–
Increase in cash	18,679,973	112,657	(201,405)
Cash, beginning of year	171,271	58,614	260,019
Cash, end of year	18,851,244	171,271	58,614
Supplemental Cash Flow and Non-Cash Investing and Financing Activities Disclosure			
Recognition of derivative warrant liabilities	12,783,000	–	–
Derivative warrant liability reclassified to reserves	4,460,000	–	–
Derivative warrant liability reclassified to share capital on exercise of warrants	425,900	–	–
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 Cato deposit against payable	–	436,240	–

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

1. Nature of operations

XORTX Therapeutics Inc. (the "Company" or "XORTX") 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. Upon completion of the reverse take-over ("RTO") transaction on January 10, 2018 with APAC Resources Inc. ("APAC"), a company incorporated under the laws of British Columbia, the Company changed its name to "XORTX Therapeutics Inc." and XORTX Pharma Corp. became a wholly-owned subsidiary.

On September 23, 2021, the Company completed a share consolidation of the common shares on a basis of 1 post-consolidation common share for 11.74 pre-consolidation common shares (the "Consolidation"). As required by IAS 33, Earnings per Share, all information with respect to the number of common shares and issuance prices for time periods prior to the Consolidation have been restated to reflect the Consolidation.

XORTX is a public company listed on the TSX Venture Exchange (the "TSXV"), on the Nasdaq Stock Market ("Nasdaq") under the symbol "XRTX", and on the Börse Frankfurt under the symbol "ANU". The Company's operations and mailing address is Suite 4000, 421 - 7th Avenue SW, Calgary, Alberta, T2P 4K9 and its head office and registered address is located at Suite 2400, 745 Thurlow Street, Vancouver, British Columbia, V6E 0C5.

XORTX is a bio-pharmaceutical company, dedicated to the development and commercialization of therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism in orphan disease indications such as autosomal dominant polycystic kidney disease, larger market type 2 diabetic nephropathy, and fatty liver disease. 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, which has continued to spread, and any related adverse public health developments, have adversely affected workforces, economies, and financial markets globally, potentially leading to an economic downturn. It is not possible for the Company to predict the duration or magnitude of the adverse results of the outbreak and its effects on the Company's business or results of operations at this time. To date, COVID-19 has had little impact on the Company's operations but may impact the Company's ability to obtain additional financing to support future research projects.

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.

2. Basis of preparation (continued)

Basis of Measurement and Presentation (continued)

In the opinion of management, all adjustments (including normal recurring accruals) considered necessary for a fair presentation have been included. The accounting policies set out below have been applied consistently to all years presented in these consolidated financial statements.

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 April 7, 2022.

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, 2021:

	Classification
Cash	FVTPL
Accounts payable and accrued liabilities	amortized cost
Derivative warrant liability	FVTPL

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).

3. Accounting policies (continued)

Financial Instruments (continued)

b) Measurement (continued)

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.

c) 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.

d) 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 the consolidated statements of comprehensive 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.

3. Accounting policies (continued)

d) Derecognition (continued)

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.

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 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. Compound financial instruments represent financial instruments that include equities and derivatives, which 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 (Share Capital) 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 pricing model to estimate fair value at each period end date. The key assumptions used in the model are described in Note 9(g).

3. Accounting policies (continued)

d) Derecognition (continued)

Share-based payments
The Company has a stock option plan that is described in Note 9 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.

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, 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; both require 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.

General provisions
A provision is a liability of uncertain timing or amount of a future expenditure when the Company has a present obligation as a result of a past event, it is probable that an outflow of resources will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. The present value of expected future cash outflows is recognized as a liability and the increase to the liability due to the passage of time is recorded as a finance expense. The Company uses a credit adjusted discount rate that reflects current market assessments of the time value of money and the risk specific to the liability.

3. Accounting policies (continued)

d) Derecognition (continued)

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.

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.

Foreign currency translation
The Company's functional and 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.

Convertible loans
Convertible loans are separated into their liability and equity components on the statement of financial position. The liability component is initially recognized at fair value, calculated as the net present value of a similar liability without an associated equity conversion feature and accounted for at amortized cost using the effective interest rate method. The effective interest rate used is the estimated rate for debt with similar terms at the time of issue. The fair value of the equity component (conversion feature) is determined at the time of issue as the difference between the face value of the exchangeable note and the fair value of the liability component.

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.

4. Critical accounting judgments and estimates (Continued)

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 at the date at which they are granted. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. 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.

Warrant liabilities are accounted for as derivative liabilities as exercise price is not fixed. The assumptions and models used for estimating fair value for share-based payment transactions and warrant liabilities are disclosed in Note 9.

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, 2021, management assessed that the future regulatory and clinical trial programs would not be completed within 12 months from year 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.

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, 2021.

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.

(Expressed in Canadian Dollars)

5. Contract payments

During the year ended December 31, 2020, the Company entered into an agreement with Prevail InfoWorks Inc. As part of the agreement, the Company paid $1,606,320 through the issuance of units in the private placement (US$1,200,000 at the exchange rate on the date of the transaction) 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, which is equal to $1.
64 per unit in the concurrent private placement. The deposit was reclassified as a non-current asset during the year ended December 31, 2021 as it has been determined to be long-tern in nature.

6. Prepaid expenses

The Company's prepaid expenses relate to the following:

	December 31 2021	December 31 2020
	$	$
Research and development	714,716	220,084
Insurance	441,388	—
Investor relations conferences and services	60,254	44,115
Consulting	50,000	—
Administrative services	4,198	—
	1,270,556	264,199

During 2018, the Company entered into an agreement with Cato Research Canada Inc. ("Cato") to manage a planned clinical study. As part of this agreement, the Company made a payment of US$505,331 and has committed to utilize Cato for this clinical study, subject to certain conditions. During the year ended December 31, 2020, Cato agreed to apply $436,240 of the payments against the accounts payable balance owing to Cato and forgive interest on these balances of $36,234.

(Expressed in Canadian Dollars)

7. Intangible assets

Cost	Total
	$
Balance, December 31, 2019	378,814
Additions	46,588
Impairment	(100,220)
Balance, December 31, 2020	325,182
Additions	39,809
Balance, December 31, 2021	**364,991**

Accumulated amortization	Total
	$
Balance, December 31, 2019	106,426
Amortization	20,098
Impairment	(35,658)
Balance, December 31, 2020	90,866
Amortization	17,882
Balance, December 31, 2021	**108,748**

Carrying values	Total
	$
At December 31, 2020	234,316
At December 31, 2021	**256,243**

The Company has licensed intellectual property from various third parties. The intangible assets relate solely to licensed intellectual property and there are no other classes of intangible assets. 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.

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.

(Expressed in Canadian Dollars)

7. Intangible assets (continued)

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 considerations:

i) An annual license fee of US$1,000 (2021 fees - paid);
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, 2021. 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 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.

8. Accounts payable and accrued liabilities

	December 31 2021	December 31 2020
	$	$
Trade payables	410,701	389,982
Accrued liabilities	290,298	644,231
Total	700,999	1,034,213

9. Share capital and reserves

a) Authorized and issued

Unlimited common shares – 12,989,687 issued at December 31, 2021 (2020 - 6,914,758).

b) Issuances

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 will also be 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.

The proceeds were allocated $5,358,000 to the derivative warrant liability (Note 9(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 9(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.

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 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.

The proceeds were allocated $7,425,000 to the derivative warrant liability (Note 9(g)) and the residual $7,426,850 was allocated to common shares.

9. Share capital and reserves (continued)

b) Issuances (continued)

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.

Year ended December 31, 2020:

On February 28, 2020, the Company closed a private placement, through the issuance of 1,555,314 units for gross proceeds of $2,556,320, of which $900,000 was received in cash, $50,000 represented the conversion of certain outstanding payables into units and $1,606,320 (US$1,200,000 at the then current exchange ratio) was issued to Prevail Partners LLC, who have agreed to provide certain services to the Company in exchange for units.

The 977,318 units issued to Prevail Partners LLC were measured by reference to their fair value on the issuance date, which is equal to $1.64 per unit in the concurrent private placement.

Each unit 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. However, if at any time following the expiry of the statutory four-month hold period, the closing price of the common shares is greater than $4.11 for 10 or more consecutive trading days, the Company may notify the holder, by way of a 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 warrants were assigned a value of $91,297 using the residual method.

The Company paid $59,434 in cash share issuance costs and issued 11,896 finders' warrant units valued at $11,066, with each finder's warrant unit being exercisable at $1.64 for a period of 12 months from the closing of the private placement. Each finders' warrant unit comprised one common share and one common share purchase warrant exercisable at $2.94 for a period of one year from the closing date of the private placement. The warrants are subject to the same acceleration provision as the warrants issued in the private placement.

As at December 31, 2019, $70,000 of the cash proceeds were received and held in trust by the Company's lawyer and recorded as share subscriptions received in advance. The amount was reclassified to share capital during the year ended December 31, 2020, upon closing of the private placement.

c) Escrow Shares

Following the closing of the RTO, the Company had an aggregate of 441,946 common shares held in escrow pursuant to an escrow agreement dated January 9, 2018. The shares are subject to a 10% release on January 25, 2018, with the remaining escrowed securities being released in 15% tranches every 6 months thereafter. As at December 31, 2021, there were nil shares (2020 - 66,292) remaining in escrow.

(Expressed in Canadian Dollars)

9. Share capital and reserves (continued)

d) Common Share Purchase Warrants

A summary of the changes in warrants for the years ended December 31, 2021 and 2020 is presented below:

	Number of Warrants		Exercise price
Balance, December 31, 2019	341,119	$	9.39
Granted – February 28, 2020	1,555,317	$	2.94
Expired – January 10, 2020	(341,119)	$	9.39
Balance, December 31, 2020	1,555,317	$	2.94
Granted – February 9, 2021	2,085,687	$	4.70
Granted – October 15, 2021	3,341,900		*US$4.77
Exercised	(640,012)	$	3.34
Expired	(1,215,816)	$	2.94
Balance, December 31, 2021	**5,127,076**	**$**	**5.58**

*$6.05 as at December 31, 2021

The weighted average contractual remaining life of the unexercised warrants was 4.56 years (2020 - 0.16 years).

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

Exercise Price	Number Outstanding	Expiry date	Average Remaining Contractual Life
$4.70	1,785,176	February 9, 2026	4.11 years
US$4.77	3,341,900	October 15, 2026	4.79 years

e) Finders' Warrants

A summary of the changes in finders' warrants for the years ended December 31, 2021 and 2020 is presented below:

	Number of Warrants		Exercise price
Balance, December 31, 2019	—		—
Granted – February 28, 2020 – finders' warrants	11,896	$	1.64
Balance, December 31, 2020	11,896	$	1.64
Granted – February 9, 2021 – finders' warrants	58,288	$	4.70
Granted – October 15, 2021 – finders' warrants	145,300		US$4.77
Exercised	(11,571)	$	1.87
Expired	(1,193)	$	1.64
Balance, December 31, 2021	**202,720**	**$**	**5.66**

*$6.05 as at December 31, 2021

The weighted average contractual remaining life of the unexercised finders' warrant was 4.60 years (2020 - 0.16 years).

(Expressed in Canadian Dollars)

9. Share capital and reserves (continued)

e) Finders' Warrants (continued)

The following table summarizes information on finders' warrants outstanding at December 31, 2021:

Exercise Price	Number Outstanding	Expiry date	Average Remaining Contractual Life
$4.70	57,420	February 9, 2026	4.11 years
US$4.77	145,300	October 15, 2026	4.79 years

The fair value of finders' warrant units issued on February 28, 2020 was estimated at $11,066 on the date of grant using Black-Scholes. The exercise price of the unit of $1.64; expected life of 1.0 years; expected volatility of 99.76%; risk free rate of 1.37%; and expected dividend yield of 0%.

The fair value of the finders' warrants issued on February 9, 2021 was estimated at $150,000 on the date of grant using Black-Scholes. The exercise price of the unit 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%.

The fair value of the finders' warrants issued on October 15, 2021 was estimated at $371,251 on the date of grant using Black-Scholes. The exercise price of the unit of US$4.77; expected life of 5.0 years; expected volatility of 100%; risk free rate of 1.5%; and expected dividend yield of 0%.

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 model with the following data and assumptions:

	2021	2020
Dividend yield	Nil	Nil
Annualized volatility	100%	151.64% - 152.24%
Risk-free interest rate	0.36% - 1.19%	0.33%
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 $499,158 during the year ended December 31, 2021 (2020 - $293,443; 2019 - $26,317).

(Expressed in Canadian Dollars)

9. Share capital and reserves (continued)

f) Stock Options (continued)

A summary of the changes in stock options for the years ended December 31, 2021 and 2020 is presented below:

	Number of Options		Exercise price
Balance, December 31, 2019	183,124	$	5.87
Granted – June 23, 2020	268,307	$	1.64
Granted – August 25, 2020	12,776	$	2.82
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**	**$**	**3.10**
Vested and exercisable, December 31, 2021	**482,683**	**$**	**3.38**

The weighted average contractual remaining life of the unexercised options was 3.42 years (2020 - 3.64 years).

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

Exercise Price	Number Outstanding	Number Exercisable	Average remaining Contractual Life
$5.87	127,760	127,760	1.21 years
$5.87	21,294	21,294	1.85 years
$1.64	170,354	114,991	3.48 years
$2.82	12,776	12,776	3.66 years
$3.29	59,624	59,624	4.03 years
$1.88	42,588	27,801	4.36 years
$1.76	21,294	21,294	4.46 years
$2.41	63,882	10,648	4.54 years
$2.54	86,495	86,495	4.98 years
	606,067	482,683	

g) Derivative Warrant Liability

Private Placement Warrants

During the year ended December 31, 2021, the Company issued 2,085,687 warrants for the Company's common shares pursuant to a financing in February 2021 as described above.

The warrants issued as part of the unit contain 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.

(Expressed in Canadian Dollars)

9. Share capital and reserves (continued)

g) Derivative warrant liability (continued)

Private Placement Warrants (continued)

The fair value of the warrants was estimated at $5,358,000 on the date of grant using the Black-Scholes 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 an equity instrument. The fair value of the derivative warrant liability as of October 15, 2021 of $4,460,000 reclassified to reserves.

During the year ended December 31, 2021, the Company issued warrants for the Company's common shares pursuant to the US IPO Offering discussed above. These warrants were recorded as a derivative financial liability as the exercise price of the units 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 $7,425,000 on the date of grant using the Black-Scholes 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:

		December 31 2021
Balance at December 31, 2019 and 2020	**$**	—
Warrants issued February 9, 2021		5,358,000
Warrants exercised		(425,900)
Fair value adjustment		(472,100)
Fair value reclassified to reserves		(4,460,000)
Warrants issued October 15, 2021		7,425,000
Fair value adjustment		(2,827,668)
Balance at December 31, 2021	**$**	**4,597,332**

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

		December 31, 2021
Share price	**$**	**2.05**
Risk-free interest rate		**1.23%**
Dividend yield		**0%**
Expected volatility		**100%**
Remaining term (in years)		**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.

9. Share capital and reserves (continued)

h) Share Consolidation

On September 23, 2021, the Company completed a share consolidation of the common shares on a basis of 1 post-consolidation common share for 11.74 pre-consolidation common shares (the "Consolidation"). As required by IAS 33, Earnings per Share, all information with respect to the number of common shares and issuance prices for time periods prior to the Consolidation have been restated to reflect the Consolidation.

10. 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, 2021, the Company incurred the following transactions with related parties:

a) Wages and benefits were paid or accrued to officers of the Company in the amount of $278,840 (2020 - $196,097; 2019 - $194,166).

b) Professional fees were paid or accrued to a former officer of the Company in the amount of $58,500 (2020 - $30,000; 2019 - $30,000).

c) Professional fees were paid or accrued to an officer of the Company in the amount of $53,000 (2020 -$Nil; 2019 - $Nil).

d) Research and development fees were paid or accrued to an officer of the Company in the amount of $106,366 (2020 - $Nil; 2019 - $Nil).

e) Consulting fees were accrued to directors of the Company in the amount of $34,950 (2020 - $36,000; 2019 - $Nil) and directors fees were accrued to the directors of the Company in the amount of $62,200 (2020 - $Nil; 2019 - $Nil).

f) 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.

(Expressed in Canadian Dollars)

10. Related party transactions (continued)

g) Management compensation transactions for the years ended December 31, 2021, 2020 and 2019 are summarized as follows:

	Short-term employee benefits	Share-based payments	Total
	$	$	$
Year ended December 31, 2019			
Directors and officers	224,166	29,646	253,812
Year ended December 31, 2020			
Directors and officers	262,097	217,816	479,913
Year ended December 31, 2021			
Directors and officers	**593,856**	**331,809**	**925,665**

11. 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:

	2021	2020	2019
	$	$	$
Net loss for the year	(1,652,000)	(1,285,000)	(630,000)
Statutory tax rate	27%	27%	27%
Expected income tax recovery	(446,000)	(347,000)	(170,000)
Decrease to income tax recovery due to:			
Non-deductible permanent differences	135,000	79,000	16,000
Temporary differences	(516,000)	6,000	—
(Over) under provided in prior years	—	(278,000)	13,000
Change in tax assets not recognized	827,000	540,000	141,000
Income tax recovery	—	—	—

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

	December 31, 2021	December 31, 2020
	$	$
Share issuance costs	529,000	18,000
Cumulative eligible capital	105,000	100,000
Operating losses carried forward	1,652,000	1,341,000
Total deferred tax assets	2,286,000	1,459,000
Deferred tax assets not recognized	(2,286,000)	(1,459,000)
	—	—

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 $6,119,000 that may be available for tax purposes. The losses expire as follows:

(Expressed in Canadian Dollars)

11. Income taxes (continued)

Expiry date	$
2032	135,000
2033	748,000
2034	325,000
2035	287,000
2036	364,000
2037	618,000
2038	1,089,000
2039	553,000
2040	847,000
2041	1,153,000
Total	6,119,000

12. Financial instruments and risk management

The Company's financial instruments consist of cash, accounts payable and accrued liabilities, and derivative warrant liability. The fair values of these financial instruments, other than derivative warrant liability, approximate their carrying values at December 31, 2021, 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, 2021 and 2020 and categorized into levels of the fair value hierarchy:

		December 31, 2021		December 31, 2020	
	Level	Carrying Value	Estimated Fair Value *	Carrying Value	Estimated Fair Value *
		$	$	$	$
FVTPL					
Cash	1	18,851,244	18,851,244	171,271	171,271
Other financial liabilities					
Accounts payable and accrued liabilities	2	700,999	700,999	1,034,213	1,034,213
FVTPL					
Derivative warrant liability	3	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 9(g).

There were no transfers for levels of change in the fair value measurements of financial instruments for the years ended December 31, 2021 and 2020.

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:

(Expressed in Canadian Dollars)

12. Financial instruments and risk management (continued)

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, 2021	December 31, 2020
	$	$
Cash	18,851,244	171,271

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, 2021 and 2020 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, 2021 and 2020 are summarized below:

	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	—	—

	Payments due by period as of December 31, 2020			
	Total	Less than 3 months	Between 3 months and 1 year	1-3 years
	$	$	$	$
Accounts payable and accrued liabilities	1,034,213	1,034,213	—	—
	1,034,213	1,034,213	—	—

12. Financial instruments and risk management (continued)

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, 2021, the Company is exposed to currency risk on the following financial assets and liabilities denominated in US Dollars ("USD") and British Pounds ("GBP"). The sensitivity of the Company's net earnings due to changes in the exchange rate between the USD and GBP against the Canadian dollar is included in the table below in Canadian dollar equivalents:

	USD amount	GBP amount	Total
	$	$	$
Cash	13,813,058	—	13,813,058
Accounts payable and accrued liabilities	(76,178)	(143,900)	(220,078)
Net exposure	13,736,880	(143,900)	13,592,980
Effect of +/- 10% change in currency	1,373,688	(14,390)	

iii) Other price risk

Other price risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices, other than those arising from interest rate risk or foreign currency risk. The Company's derivative warrant liability is subject to price risks associated with the Company's share price in the future. A 10% increase in the Company's share price would have decreased the Company's net loss and comprehensive loss by $116,000 due to the impact of the share price on the fair value of the financial instrument.

13. 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, 2021. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

(Expressed in Canadian Dollars)

14. Commitments

The Company has long-term arrangements with commitments that are not recognized as liabilities as at December 31, 2021 and 2020 as follows:

a) Employment Agreement

	December 31 2021	December 31 2020
	$	$
Management services – officers	380,000	192,000

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, 2021, equated to US$300,000.

b) Payments

In the normal course of business, the Company has committed to payments totaling $1,613,142 (2020 - $Nil) 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.

15. 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.

ITEM 18: FINANCIAL STATEMENTS

Refer to Item 17. 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*	Specimen common share certificate
2.2	Form of 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 pre-funded warrant (incorporated by reference to Exhibit 4.2 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021)
2.4*	Form of Underwriter's Warrant Agreement
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#%	Consulting Agreement, dated February 1, 2021, by and between the Company and David Sans (incorporated by reference to Exhibit 10.4 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021)
4.5#	Consulting Agreement, dated March 1, 2021, by and between the Company and 1282803 Ontario Inc. (incorporated by reference to Exhibit 10.5 to the Company's Amendment No. 2 to the Registration Statement on Form F-1 filed on October 4, 2021)
4.6%	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)
4.7%	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)
4.8%	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)
4.9#	Consulting Agreement, dated July 1, 2021, by and between the Company and Next Level Consultants Inc. (incorporated by reference to Exhibit 10.10 to the Company's Amendment No. 1 to the Draft Registration Statement on Form F-1 filed on July 21, 2021)
4.10%	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)
4.11#	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)
4.12%	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)
4.13	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)

4.14	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)
4.15*#	Consulting Services Agreement, dated effective December 20, 2021, by and between the Company, W.B. Rowlands & Co. Ltd., and William Bruce Rowlands
4.16#	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.)
4.17*%	Patent Rights Purchase Agreement dated effective May 26, 2014 between Dr. Richard Johnson, Dr. Takahiko Nakagawa and the Company
4.18*%	Equity Agreement dated effective June 23, 2014 between the Company and the University of Florida Research Foundation, Inc.
4.19*%	Sponsored Research Agreement dated May 27, 2021 between the Regents of the University of Colorado and the Company
4.20*%	Combined Master Services Agreement made on July 19, 2021 between the Company and Quotient Sciences Limited
4.21*	Development and Clinical Manufacturing Services Agreement dated effective August 17, 2021 between the Company and Lonza Ltd.
4.22*	Global Master Services Agreement between Altasciences Company Inc., (a contract research organization) and the Company dated effective December 22, 2021
4.23*	Proposal for XORTX Therapeutics Inc., dated February 21, 2022, by and between the Company and Covar Pharmaceuticals Inc.
4.24*	Proposal for XORTX Therapeutics Inc., dated December 6, 2021, by and between the Company and Covar Pharmaceuticals Inc.
4.25*%	Proposal, dated as of March 29, 2022, by and between the Company and Curia Spain, S.A.U.
4.26*#	Consulting Amending Agreement, dated as of January 27, 2022, by and between the Company and Stephen Haworth
4.27*#	Agreement, dated as of November 1, 2021, by and between the Company and Amar Keshri
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, 2021
15.2*	Audit Committee Charter
15.3*	Consent of independent registered public accounting firm (Smyth LLP)
101	The following materials from the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2021, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Financial Statements for the Years Ended December 31, 2021,2020 and 2019; (ii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2021, 2020 and 2019; (iii) Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2021, 2020 and 2019; (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2021, 2020 and 2019; and (v) Notes to Consolidated Financial Statements for the Years Ended December 31, 2021, 2020 and 2019
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.
% Portions of this exhibit (indicated by asterisks) have been omitted as the Company has determined that (1) the omitted information is not material and (2) the omitted information would likely cause competitive harm to the Company if publicly disclosed.

SIGNATURES

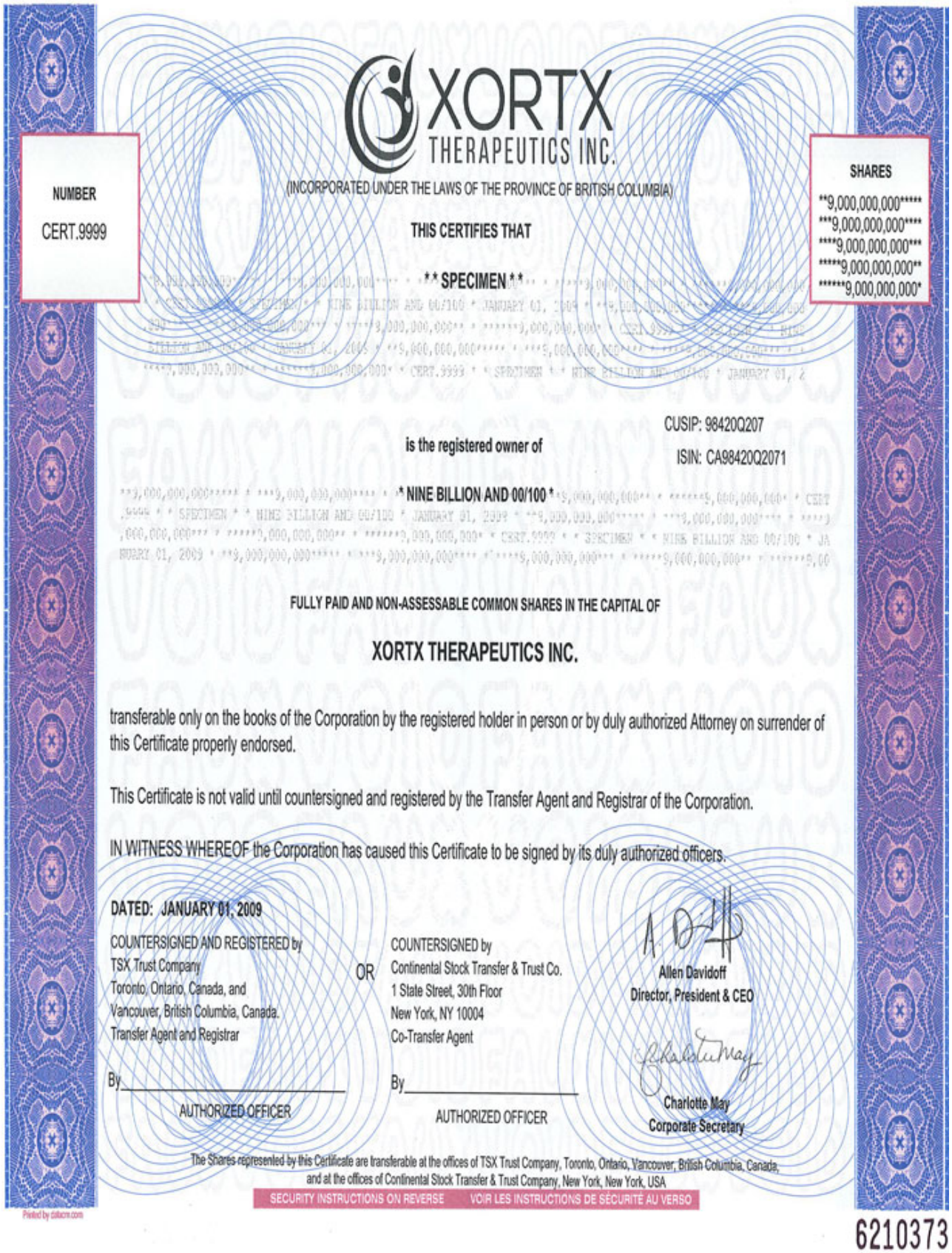
The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

XORTX THERAPEUTICS INC.

/s/ Amar Keshri

By: Amar Keshri
Title: Chief Financial Officer

Date: May 3, 2022



XORTX THERAPEUTICS INC.

(INCORPORATED UNDER THE LAWS OF THE PROVINCE OF BRITISH COLUMBIA)

NUMBER

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SHARES

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THIS CERTIFIES THAT

** SPECIMEN **

CUSIP: 98420Q207

ISIN: CA98420Q2071

is the registered owner of

* NINE BILLION AND 00/100 *

FULLY PAID AND NON-ASSESSABLE COMMON SHARES IN THE CAPITAL OF

XORTX THERAPEUTICS INC.

transferable only on the books of the Corporation by the registered holder in person or by duly authorized Attorney on surrender of this Certificate properly endorsed.

This Certificate is not valid until countersigned and registered by the Transfer Agent and Registrar of the Corporation.

IN WITNESS WHEREOF the Corporation has caused this Certificate to be signed by its duly authorized officers.

DATED: JANUARY 01, 2009

COUNTERSIGNED AND REGISTERED by
TSX Trust Company
Toronto, Ontario, Canada, and
Vancouver, British Columbia, Canada.
Transfer Agent and Registrar

By_____
AUTHORIZED OFFICER

OR

COUNTERSIGNED by
Continental Stock Transfer & Trust Co.
1 State Street, 30th Floor
New York, NY 10004
Co-Transfer Agent

By_____
AUTHORIZED OFFICER

Allen Davidoff
Director, President & CEO

Charlotte May
Corporate Secretary

The Shares represented by this Certificate are transferable at the offices of TSX Trust Company, Toronto, Ontario, Vancouver, British Columbia, Canada, and at the offices of Continental Stock Transfer & Trust Company, New York, New York, USA

SECURITY INSTRUCTIONS ON REVERSE VOIR LES INSTRUCTIONS DE SÉCURITÉ AU VERSO

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6210373

FOR VALUE RECEIVED, _____ hereby sell, assign and transfer unto

(PLEASE INSERT SOCIAL INSURANCE NUMBER OF TRANSFEREE)

			-				-			

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS OF ASSIGNEE)

_____

_____ Shares

of the Capital Stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney

to transfer the said Stock on the Books of the within named Corporation, with full power of substitution in the premises.

Dated: _____

Signature: _____

NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE, IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT, OR ANY CHANGE WHATSOEVER, AND MUST BE GUARANTEED BY A SCHEDULE 1 CANADIAN CHARTERED BANK OR AN ELIGIBLE GUARANTOR INSTITUTION

Guaranteed by: _____

999999

ACCT9999

TIR5405

CERT.9999

RESTRICTIONS

SECURITY INSTRUCTIONS - INSTRUCTIONS DE SÉCURITÉ

THIS IS WATERMARKED PAPER. DO NOT ACCEPT WITHOUT NOTING WATERMARK. HOLD TO LIGHT TO VERIFY WATERMARK.

PAPIER FILIGRANÉ. NE PAS ACCEPTER SANS VÉRIFIER LA PRÉSENCE DU FILIGRANE. POUR CE FAIRE, PLACER À LA LUMIÈRE.

Exhibit 2.4

Execution Version

Form of Underwriter's Warrant Agreement

THE REGISTERED HOLDER OF THIS PURCHASE WARRANT BY ITS ACCEPTANCE HEREOF, AGREES THAT IT WILL NOT SELL, TRANSFER OR ASSIGN THIS PURCHASE WARRANT EXCEPT AS HEREIN PROVIDED AND THE REGISTERED HOLDER OF THIS PURCHASE WARRANT AGREES THAT IT WILL NOT SELL, TRANSFER, ASSIGN, PLEDGE OR HYPOTHECATE THIS PURCHASE WARRANT FOR A PERIOD OF ONE HUNDRED EIGHTY DAYS FOLLOWING THE EFFECTIVE DATE (DEFINED BELOW) TO ANYONE OTHER THAN (I) A.G.P./ALLIANCE GLOBAL PARTNERS OR AN UNDERWRITER OR A SELECTED DEALER IN CONNECTION WITH THE OFFERING, OR (II) A BONA FIDE OFFICER OR PARTNER OF A.G.P./ALLIANCE GLOBAL PARTNERS OR OF ANY SUCH UNDERWRITER OR SELECTED DEALER.

THIS PURCHASE WARRANT IS EXERCISABLE ON APRIL 12, 2022. VOID AFTER 5:00 P.M., EASTERN TIME, OCTOBER 12, 2026.

COMMON SHARE PURCHASE WARRANT

For the Purchase of [_____] Common Shares

of

XORTX THERAPEUTICS, INC.

1. Purchase Warrant. THIS CERTIFIES THAT, in consideration of funds duly paid by or on behalf of A.G.P./Alliance Global Partners ("**Holder**"), as registered owner of this Purchase Warrant, to Xortx Therapeutics, Inc., a company organized under the laws of British Columbia (the "**Company**"), Holder is entitled, at any time or from time to time from April 12, 2022 (the "**Commencement Date**"), and at or before 5:00 p.m., Eastern time, October 12, 2026 (the "**Expiration Date**"), being the date that is five (5) years following October 12, 2021 (the "**Effective Date**")), but not thereafter, to subscribe for, purchase and receive, in whole or in part, up to [__] common shares (the "**Shares**") of the Company, no par value per share (the "**Common Shares**"), subject to adjustment as provided in Section 6 hereof. If the Expiration Date is a day on which banking institutions are authorized by law to close, then this Purchase Warrant may be exercised on the next succeeding day which is not such a day in accordance with the terms herein. During the period ending on the Expiration Date, the Company agrees not to take any action that would terminate this Purchase Warrant. This Purchase Warrant is initially exercisable at $4.77 per Share; provided, however, that upon the occurrence of any of the events specified in Section 6 hereof, the rights granted by this Purchase Warrant, including the exercise price per Share and the number of Shares to be received upon such exercise, shall be adjusted as therein specified. The term "**Exercise Price**" shall mean the initial exercise price or the adjusted exercise price, depending on the context. For the avoidance of doubt, this Purchase Warrant will be exercisable at any time, and from time to time, in whole or in part, from the Commencement Date (as defined in the Underwriting Agreement (as defined below)), which period shall not extend further than five (5) years from the Effective Date in compliance with FINRA Rule 5110(f)(2)(G)(i).

2. Exercise.

2.1 Exercise Form. In order to exercise this Purchase Warrant, the exercise form attached hereto must be duly executed and completed and delivered to the Company, together with this Purchase Warrant and payment of the Exercise Price for the Shares being purchased payable in cash by wire transfer of immediately available funds to an account designated by the Company or by certified check or official bank check. If the subscription rights represented hereby shall not be exercised at or before 5:00 p.m., Eastern time, on the Expiration Date, this Purchase Warrant shall become and be void without further force or effect, and all rights represented hereby shall cease and expire.

2.2 Cashless Exercise. If at any time after the Commencement Date there is no effective registration statement registering, or no current prospectus available for, the resale of the Shares by the Holder, then in lieu of exercising this Purchase Warrant at such time, by payment of cash or check payable to the order of the Company pursuant to Section 2.1 above, Holder may elect to receive the number of Shares equal to the value of this Purchase Warrant (or the portion thereof being exercised), by surrender of this Purchase Warrant to the Company, together with the exercise form attached hereto, in which event the Company shall issue Shares to Holder in accordance with the following formula:

X = Y(A-B)/A

Where,

X = The number of Shares to be issued to Holder;
Y = The number of Shares for which the Purchase Warrant is being exercised;
A = The fair market value of one Share; and
B = The Exercise Price.

For purposes of this Section 2.2, the fair market value of a Share is defined as follows:

(i) if the Company's common shares are traded on a securities exchange, the value shall be deemed to be the closing price on such exchange prior to the exercise form being submitted in connection with the exercise of the Purchase Warrant; or
(ii) if the Company's common shares are actively traded over-the-counter, the value shall be deemed to be the closing bid prior to the exercise form being submitted in connection with the exercise of the Purchase Warrant; if there is no active public market, the value shall be the fair market value thereof, as determined in good faith by the Company's Board of Directors.

If Warrant Shares are issued in such a "cashless exercise," the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act of 1933, as amended (the "**Securities Act**"), the Warrant Shares shall take on the registered characteristics of the Warrants being exercised, and the holding period of the Warrants being exercised may be tacked on to the holding period of the Warrant Shares. The Company agrees not to take any position contrary to this Section 2.2.

2.3 Legend. Each certificate for the securities purchased under this Purchase Warrant shall bear a legend as follows unless such securities have been registered under the Securities Act:

"The securities represented by this certificate have not been registered under the Securities Act of 1933, as amended (the "**Securities Act**"), or applicable state law. Neither the securities nor any interest therein may be offered for sale, sold or otherwise transferred except pursuant to an effective registration statement under the Securities Act, or pursuant to an exemption from registration under the Securities Act and applicable state law which, in the opinion of counsel to the Company, is available."

2.4 Cash Payment. For the avoidance of doubt, the Company shall not be required to make any cash payments or net cash settlement to any registered holder in lieu of issuance of Shares.

3. Transfer.

3.1 General Restrictions. The registered Holder of this Purchase Warrant agrees by his, her or its acceptance hereof, that this Purchase Warrant and the securities issuable hereunder shall not be sold during the Offering, or sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of this Purchase Warrant or the securities issuable hereunder by any person for a period of one hundred eighty (180) days immediately following the Effective Date (as defined in the Underwriting Agreement (as defined below)), except as provided for in FINRA Rule 5110(g)(2). On and after 180 days after the Effective Date, transfers to others may be made subject to compliance with or exemptions from applicable securities laws. In order to make any permitted assignment, the Holder must deliver to the Company the assignment form attached hereto duly executed and completed, together with the Purchase Warrant and payment of all transfer taxes, if any, payable in connection therewith. The Company shall within five (5) Business Days transfer this Purchase Warrant on the books of the Company and shall execute and deliver a new Purchase Warrant or Purchase Warrants of like tenor to the appropriate assignee(s) expressly evidencing the right to purchase the aggregate number of Shares purchasable hereunder or such portion of such number as shall be contemplated by any such assignment.

3.2 Restrictions Imposed by the Securities Act. The securities evidenced by this Purchase Warrant shall not be transferred unless and until: (i) the Company has received the opinion of counsel for the Holder that the securities may be transferred pursuant to an exemption from registration under the Securities Act and applicable state securities laws, the availability of which is established to the reasonable satisfaction of the Company (the Company hereby agreeing that the opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. shall be deemed satisfactory evidence of the availability of an exemption), or (ii) a registration statement or a post-effective amendment to the registration statement relating to the offer and sale of such securities has been filed by the Company and declared effective by the U.S. Securities and Exchange Commission (the "**Commission**") and compliance with applicable state securities law has been established.

4. Registration Rights.

4.1 Demand Registration.

4.1.1 Grant of Right. The Company, upon written demand (a "**Demand Notice**") of the Holder(s) of at least 51% of the Purchase Warrants and/or the underlying Shares ("**Majority Holders**"), agrees to register, on one occasion, all or any portion of the Shares underlying the Purchase Warrants (collectively, the "**Registrable Securities**"). On such occasion, the Company will file a registration statement with the Commission covering the Registrable Securities within thirty (30) days after receipt of a Demand Notice and use its commercially reasonable efforts to have the registration statement declared effective as promptly as practicable thereafter, subject to compliance with review by the Commission; provided, however, that if the Demand Notice is issued within 50 days prior to the beginning of the Company's fiscal year, the 30 day period shall be extended until 80 days after the last day of the prior fiscal year; and provided further that the Company shall not be required to comply with a Demand Notice if the Company has filed a registration statement with respect to which the Holder is entitled to piggyback registration rights pursuant to Section 4.2 hereof and the Holder has elected to participate in the offering covered by such registration statement. The demand for registration may be made at any time during a period of five (5) years beginning on the Commencement Date. The Company covenants and agrees to give written notice of its receipt of any Demand Notice by any Holder(s) to all other registered Holders of the Purchase Warrants and/or the Registrable Securities within ten (10) days after the date of the receipt of any such Demand Notice.

4.1.2 Terms. The Company shall bear all fees and expenses attendant to the registration of the Registrable Securities pursuant to Section 4.1.1, but the Holders shall pay any and all underwriting commissions and the expenses of any legal counsel selected by the Holders to represent them in connection with the sale of the Registrable Securities. The Company agrees to use its commercially reasonable efforts to cause the filing required herein to become effective as promptly as practicable and to qualify or register the Registrable Securities in such States as are reasonably requested by the Holder(s); provided, however, that in no event shall the Company be required to register the Registrable Securities in a State in which such registration would cause: (i) the Company to be obligated to register or license to do business in such State or submit to general service of process in such State, or (ii) the principal shareholders of the Company to be obligated to escrow their shares of the Company. The Company shall use its commercially reasonable efforts to cause any registration statement filed pursuant to the demand right granted under Section 4.1.1 to remain effective for a period of at least twelve (12) consecutive months after the date that the Holders of the Registrable Securities covered by such registration statement are first given the opportunity to sell all of such securities. The Holders shall only use the prospectuses provided by the Company to sell the shares covered by such registration statement, and will immediately cease to use any prospectus furnished by the Company if the Company advises the Holder that such prospectus may no longer be used due to a material misstatement or omission, or if the Company determines in good faith that such suspension of use is necessary to delay the disclosure of material non-public information concerning the Company, the disclosure of which at the time is not, in the good faith opinion of the Company, in the best interests of the Company. Notwithstanding the provisions of this Section 4.1.2, the Holder shall be entitled to a demand registration under this Section 4.1.2 on only one (1) occasion and such demand registration right shall terminate on the fifth anniversary of the effectiveness of the registration statement in accordance with FINRA Rule 5110(f)(2)(H)(iv).

4.2 "Piggy-Back" Registration.

4.2.1 Grant of Right. In addition to the demand right of registration described in Section 4.1 hereof, the Holder shall have the right, for a period of no more than seven (7) years from the date of effectiveness of the registration statement in accordance with FINRA Rule 5110(f)(2)(G)(v), to include the Shares underlying the Purchase Warrant (collectively, the "**Registrable Securities**") as part of any other registration of securities filed by the Company (other than in connection with a transaction contemplated by Rule 145(a) promulgated under the Securities Act or pursuant to Form S-8 or any equivalent form); provided, however, that if, solely in connection with any primary underwritten public offering for the account of the Company, the managing underwriter(s) thereof shall, in its reasonable discretion, impose a limitation on the number of Common Shares which may be included in the registration statement because, in such underwriter(s)' judgment, marketing or other factors dictate such limitation is necessary to facilitate public distribution, then the Company shall be obligated to include in such registration statement only such limited portion of the Registrable Securities with respect to which the Holder requested inclusion hereunder as the underwriter shall reasonably permit. Any exclusion of Registrable Securities shall be made pro rata among the Holders seeking to include Registrable Securities in proportion to the number of Registrable Securities sought to be included by such Holders; provided, however, that the Company shall not exclude any Registrable Securities unless the Company has first excluded all outstanding securities, the holders of which are not entitled to inclusion of such securities in such registration statement or are not entitled to pro rata inclusion with the Registrable Securities.

4.2.2 Terms. The Company shall bear all fees and expenses attendant to registering the Registrable Securities pursuant to Section 4.2.1 hereof, but the Holders shall pay any and all underwriting commissions and the expenses of any legal counsel selected by the Holders to represent them in connection with the sale of the Registrable Securities. In the event of such a proposed registration, the Company shall furnish the then Holders of outstanding Registrable Securities with not less than thirty (30) days written notice prior to the proposed date of filing of such registration statement. Such notice to the Holders shall continue to be given for each registration statement filed by the Company until such time as all of the Registrable Securities have been sold by the Holder. The holders of the Registrable Securities shall exercise the "piggy-back" rights provided for herein by giving written notice within ten (10) days of the receipt of the Company's notice of its intention to file a registration statement. Except as otherwise provided in this Purchase Warrant, there shall be no limit on the number of times the Holder may request registration under this Section 4.2.2; provided, however, that such registration rights shall terminate on the sixth anniversary of the Commencement Date.

4.3 General Terms.

4.3.1 Indemnification. The Company shall indemnify the Holder(s) of the Registrable Securities to be sold pursuant to any registration statement hereunder and each person, if any, who controls such Holders within the meaning of Section 15 of the Securities Act or Section 20 (a) of the Securities Exchange Act of 1934, as amended ("**Exchange Act**"), against all loss, claim, damage, expense or liability (including all reasonable attorneys' fees and other expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which any of them may become subject under the Securities Act, the Exchange Act or otherwise, arising from such registration statement but only to the same extent and with the same effect as the provisions pursuant to which the Company has agreed to indemnify the Underwriters contained in Section 9(a) of the Underwriting Agreement between the Underwriters and the Company, dated as of October 12, 2021 (the "**Underwriting Agreement**"). The Holder(s) of the Registrable Securities to be sold pursuant to such registration statement, and their successors and assigns, shall severally, and not jointly, indemnify the Company, against all loss, claim, damage, expense or liability (including all reasonable attorneys' fees and other expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which they may become subject under the Securities Act, the Exchange Act or otherwise, arising from information furnished by or on behalf of such Holders, or their successors or assigns, in writing, for specific inclusion in such registration statement to the same extent and with the same effect as the provisions contained in Section 9(b) of the Underwriting Agreement pursuant to which the Underwriters have agreed to indemnify the Company.

4.3.2 Exercise of Purchase Warrants. Nothing contained in this Purchase Warrant shall be construed as requiring the Holder(s) to exercise their Purchase Warrants prior to or after the initial filing of any registration statement or the effectiveness thereof.

4.3.3 Documents Delivered to Holders. The Company shall furnish upon written request to each Holder participating in any of the foregoing offerings and to each underwriter of any such offering, if any, a signed counterpart, addressed to such Holder or underwriter, of: (i) an opinion of counsel to the Company, dated the effective date of such registration statement (and, if such registration includes an underwritten public offering, an opinion dated the date of the closing under any underwriting agreement related thereto), and (ii) a "cold comfort" letter dated the effective date of such registration statement (and, if such registration includes an underwritten public offering, a letter dated the date of the closing under the underwriting agreement) signed by the independent registered public accounting firm which has issued a report on the Company's financial statements included in such registration statement, in each case covering substantially the same matters with respect to such registration statement (and the prospectus included therein) and, in the case of such accountants' letter, with respect to events subsequent to the date of such financial statements, as are customarily covered in opinions of issuer's counsel and in accountants' letters delivered to underwriters in underwritten public offerings of securities. The Company shall also deliver promptly to each Holder participating in the offering requesting the correspondence and memoranda described below and to the managing underwriter, if any, copies of all correspondence between the Commission and the Company, its counsel or auditors and all memoranda relating to discussions with the Commission or its staff with respect to the registration statement and permit each Holder and underwriter to do such investigation, upon reasonable advance notice, with respect to information contained in or omitted from the registration statement as it deems reasonably necessary to comply with applicable securities laws or rules of FINRA. Such investigation shall include access to books, records and properties and opportunities to discuss the business of the Company with its officers and independent auditors, all to such reasonable extent and at such reasonable times as any such Holder shall reasonably request.

4.3.4 Underwriting Agreement. The Company shall enter into an underwriting agreement with the managing underwriter(s), if any, selected by any Holders whose Registrable Securities are being registered pursuant to this Section 4, which managing underwriter shall be reasonably satisfactory to the Company. Such agreement shall be reasonably satisfactory in form and substance to the Company, each Holder and such managing underwriters, and shall contain such representations, warranties and covenants by the Company and such other terms as are customarily contained in agreements of that type used by the managing underwriter. The Holders shall be parties to any underwriting agreement relating to an underwritten sale of their Registrable Securities and may, at their option, require that any or all the representations, warranties and covenants of the Company to or for the benefit of such underwriters shall also be made to and for the benefit of such Holders. Such Holders shall not be required to make any representations or warranties to or agreements with the Company or the underwriters except as they may relate to such Holders, their Shares and their intended methods of distribution.

4.3.5 Documents to be Delivered by Holder(s). Each of the Holder(s) participating in any of the foregoing offerings shall furnish to the Company a completed and executed questionnaire provided by the Company requesting information customarily sought of selling security holders.

4.3.6 Damages. Should the registration or the effectiveness thereof required by Sections 4.1 and 4.2 hereof be delayed by the Company or the Company otherwise fails to comply in any material respect with such provisions, the Holder(s) shall, in addition to any other legal or other relief available to the Holder(s), be entitled to obtain specific performance or other equitable (including injunctive) relief against the threatened breach of such provisions or the continuation of any such breach, without the necessity of proving actual damages and without the necessity of posting bond or other security.

5. New Purchase Warrants to be Issued.

5.1 Partial Exercise or Transfer. Subject to the restrictions in Section 3 hereof, this Purchase Warrant may be exercised or assigned in whole or in part. In the event of the exercise or assignment hereof in part only, upon surrender of this Purchase Warrant for cancellation, together with the duly executed exercise or assignment form and funds sufficient to pay any Exercise Price and/or transfer tax if exercised pursuant to Section 2.1 hereto, the Company shall cause to be delivered to the Holder without charge a new Purchase Warrant of like tenor to this Purchase Warrant in the name of the Holder evidencing the right of the Holder to purchase the number of Shares purchasable hereunder as to which this Purchase Warrant has not been exercised or assigned.

5.2 Lost Certificate. Upon receipt by the Company of evidence satisfactory to it of the loss, theft, destruction or mutilation of this Purchase Warrant and of reasonably satisfactory indemnification or the posting of a bond, the Company shall execute and deliver a new Purchase Warrant of like tenor and date. Any such new Purchase Warrant executed and delivered as a result of such loss, theft, mutilation or destruction shall constitute a substitute contractual obligation on the part of the Company.

6. Adjustments.

6.1 Adjustments to Exercise Price and Number of Securities. The Exercise Price and the number of Shares underlying the Purchase Warrant shall be subject to adjustment from time to time as hereinafter set forth:

6.1.1 Share Dividends; Split Ups. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Common Shares is increased by a share dividend payable in Shares or by a split up of Common Shares or other similar event, then, on the effective day thereof, the number of Shares purchasable hereunder shall be increased in proportion to such increase in outstanding Common Shares, and the Exercise Price shall be proportionately decreased.

6.1.2 Aggregation of Shares. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Common Shares is decreased by a consolidation, combination or reclassification of Common Shares or other similar event, then, on the effective date thereof, the number of Shares purchasable hereunder shall be decreased in proportion to such decrease in outstanding Common Shares, and the Exercise Price shall be proportionately increased.

6.1.3 Replacement of Securities upon Reorganization, etc. In case of any reclassification or reorganization of the outstanding Common Shares other than a change covered by Section 6.1.1 or 6.1.2 hereof or that solely affects the par value of such Common Shares, or in the case of any share reconstruction or amalgamation or consolidation of the Company with or into another corporation (other than a consolidation or share reconstruction or amalgamation in which the Company is the continuing corporation and that does not result in any reclassification or reorganization of the outstanding Common Shares), or in the case of any sale or conveyance to another corporation or entity of the property of the Company as an entirety or substantially as an entirety in connection with which the Company is dissolved, the Holder of this Purchase Warrant shall have the right thereafter (until the expiration of the right of exercise of this Purchase Warrant) to receive upon the exercise hereof, for the same aggregate Exercise Price payable hereunder immediately prior to such event, the kind and amount of Common Shares or other securities or property (including cash) receivable upon such reclassification, reorganization, share reconstruction or amalgamation, or consolidation, or upon a dissolution following any such sale or transfer, by a Holder of the number of Shares of the Company obtainable upon exercise of this Purchase Warrant immediately prior to such event; and if any reclassification also results in a change in Shares covered by Section 6.1.1 or 6.1.2, then such adjustment shall be made pursuant to Sections 6.1.1, 6.1.2 and this Section 6.1.3. The provisions of this Section 6.1.3 shall similarly apply to successive reclassifications, reorganizations, share reconstructions or amalgamations, or consolidations, sales or other transfers.

6.1.4 Changes in Form of Purchase Warrant. This form of Purchase Warrant need not be changed because of any change pursuant to this Section 6.1, and Purchase Warrants issued after such change may state the same Exercise Price and the same number of Shares as are stated in the Purchase Warrants initially issued pursuant to this Agreement. The acceptance by any Holder of the issuance of new Purchase Warrants reflecting a required or permissive change shall not be deemed to waive any rights to an adjustment occurring after the Commencement Date or the computation thereof.

6.2 Substitute Purchase Warrant. In case of any consolidation of the Company with, or share reconstruction or amalgamation of the Company with or into, another corporation (other than a consolidation or share reconstruction or amalgamation which does not result in any reclassification or change of the outstanding Common Shares), the corporation formed by such consolidation or share reconstruction or amalgamation shall execute and deliver to the Holder a supplemental Purchase Warrant providing that the holder of each Purchase Warrant then outstanding or to be outstanding shall have the right thereafter (until the stated expiration of such Purchase Warrant) to receive, upon exercise of such Purchase Warrant, the kind and amount of shares and other securities and property receivable upon such consolidation or share reconstruction or amalgamation, by a holder of the number of Shares of the Company for which such Purchase Warrant might have been exercised immediately prior to such consolidation, share reconstruction or amalgamation, sale or transfer. Such supplemental Purchase Warrant shall provide for adjustments which shall be identical to the adjustments provided for in this Section 6. The above provision of this Section shall similarly apply to successive consolidations or share reconstructions or amalgamations.

6.3 Elimination of Fractional Interests. The Company shall not be required to issue certificates representing fractions of Shares upon the exercise of the Purchase Warrant, nor shall it be required to issue scrip or pay cash in lieu of any fractional interests, it being the intent of the parties that all fractional interests shall be eliminated by rounding any fraction up or down, as the case may be, to the nearest whole number of Shares or other securities, properties or rights.

7. Reservation and Listing. The Company shall at all times reserve and keep available out of its authorized Common Shares, solely for the purpose of issuance upon exercise of the Purchase Warrants, such number of Shares or other securities, properties or rights as shall be issuable upon the exercise thereof. The Company covenants and agrees that, upon exercise of the Purchase Warrants and payment of the Exercise Price therefor, in accordance with the terms hereby, all Shares and other securities issuable upon such exercise shall be duly and validly issued, fully paid and non- assessable and not subject to preemptive rights of any shareholder. The Company further covenants and agrees that upon exercise of the Purchase Warrants and payment of the exercise price therefor, all Shares and other securities issuable upon such exercise shall be duly and validly issued, fully paid and non-assessable and not subject to preemptive rights of any shareholder. As long as the Purchase Warrants shall be outstanding, the Company shall use its commercially reasonable efforts to cause all Shares issuable upon exercise of the Purchase Warrants to be listed (subject to official notice of issuance) on all national securities exchanges (or, if applicable, on the OTC Bulletin Board or any successor trading market) on which the Shares issued to the public in the Offering may then be listed and/or quoted.

8. Certain Notice Requirements.

8.1 Holder's Right to Receive Notice. Nothing herein shall be construed as conferring upon the Holders the right to vote or consent or to receive notice as a shareholder for the election of directors or any other matter, or as having any rights whatsoever as a shareholder of the Company. If, however, at any time prior to the expiration of the Purchase Warrants and their exercise, any of the events described in Section 8.2 shall occur, then, in one or more of said events, the Company shall give written notice of such event at least fifteen days prior to the date fixed as a record date or the date of closing the transfer books for the determination of the shareholders entitled to such dividend, distribution, conversion or exchange of securities or subscription rights, or entitled to vote on such proposed dissolution, liquidation, winding up or sale. Such notice shall specify such record date or the date of the closing of the transfer books, as the case may be. Notwithstanding the foregoing, the Company shall deliver to each Holder a copy of each notice given to the other shareholders of the Company at the same time and in the same manner that such notice is given to the shareholders.

8.2 Events Requiring Notice. The Company shall be required to give the notice described in this Section 8 upon one or more of the following events: (i) if the Company shall take a record of the holders of its Shares for the purpose of entitling them to receive a dividend or distribution payable otherwise than in cash, or a cash dividend or distribution payable otherwise than out of retained earnings, as indicated by the accounting treatment of such dividend or distribution on the books of the Company, (ii) the Company shall offer to all the holders of its Shares any additional shares of the Company or securities convertible into or exchangeable for shares of the Company, or any option, right or warrant to subscribe therefor, or (iii) a dissolution, liquidation or winding up of the Company (other than in connection with a consolidation or share reconstruction or amalgamation) or a sale of all or substantially all of its property, assets and business shall be proposed.

8.3 Notice of Change in Exercise Price. The Company shall, promptly after an event requiring a change in the Exercise Price pursuant to Section 6 hereof, send notice to the Holders of such event and change ("**Price Notice**"). The Price Notice shall describe the event causing the change and the method of calculating same and shall be certified as being true and accurate by the Company's Chief Financial Officer.

8.4 Transmittal of Notices. All notices, requests, consents and other communications under this Purchase Warrant shall be in writing and shall be deemed to have been duly made when hand delivered, or mailed by express mail or private courier service: (i) if to the registered Holder of the Purchase Warrant, to the address of such Holder as shown on the books of the Company, or (ii) if to the Company, to following address or to such other address as the Company may designate by notice to the Holders:

If to the Holder:

A.G.P./Alliance Global Partners ("**A.G.P.**")
590 Madison Avenue, 36th Floor
New York, New York 10022
Attn: Chris Pravecek
Fax No.: (203) 662-9771

with a copy (which shall not constitute notice) to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C.
666 Third Avenue
New York, New York 10017
Attention: Ivan K. Blumenthal
E-mail: IKBlumenthal@mintz.com

If to the Company:

XORTX Therapeutics, Inc.
Suite 2400 – 745 Thurlow Street
Vancouver, British Columbia
Canada V6E 0C5
Attention: Allen Davidoff, Ph.D., Chief Executive Officer
Telephone number: (403) 607-2621
Email address: adavidoff@xortx.com

with a copy (which shall not constitute notice) to:

Dorsey & Whitney LLP
111 S. Main Street, Suite 2100, Salt Lake City, UT 84111-2176
Attention: Anthony Marsico and Anthony Epps
Email: marsico.anthony@dorsey.com and epps.anthony@dorsey.com

9. Miscellaneous.

9.1 Amendments. The Company and A.G.P. may from time to time supplement or amend this Purchase Warrant without the approval of any of the Holders in order to cure any ambiguity, to correct or supplement any provision contained herein that may be defective or inconsistent with any other provisions herein, or to make any other provisions in regard to matters or questions arising hereunder that the Company and A.G.P. may deem necessary or desirable and that the Company and A.G.P. deem shall not adversely affect the interest of the Holders. All other modifications or amendments shall require the written consent of and be signed by the party against whom enforcement of the modification or amendment is sought.

9.2 Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Purchase Warrant.

9.3 Entire Agreement. This Purchase Warrant (together with the other agreements and documents being delivered pursuant to or in connection with this Purchase Warrant) constitutes the entire agreement of the parties hereto with respect to the subject matter hereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof.

9.4 Binding Effect. This Purchase Warrant shall inure solely to the benefit of and shall be binding upon, the Holder and the Company and their permitted assignees, respective successors, legal representative and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Purchase Warrant or any provisions herein contained.

9.5 Governing Law; Submission to Jurisdiction; Trial by Jury. This Purchase Warrant shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Purchase Warrant shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 8 hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. The Company and the Holder agree that the prevailing party(ies) in any such action shall be entitled to recover from the other party(ies) all of its reasonable attorneys' fees and expenses relating to such action or proceeding and/or incurred in connection with the preparation therefor. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its shareholders and affiliates) and the Holder hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

9.6 Waiver, etc. The failure of the Company or the Holder to at any time enforce any of the provisions of this Purchase Warrant shall not be deemed or construed to be a waiver of any such provision, nor to in any way affect the validity of this Purchase Warrant or any provision hereof or the right of the Company or any Holder to thereafter enforce each and every provision of this Purchase Warrant. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Purchase Warrant shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non- fulfillment.

9.7 Execution in Counterparts. This Purchase Warrant may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same agreement, and shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Such counterparts may be delivered by facsimile transmission or other electronic transmission.

9.8 Exchange Agreement. As a condition of the Holder's receipt and acceptance of this Purchase Warrant, Holder agrees that, at any time prior to the complete exercise of this Purchase Warrant by Holder, if the Company and A.G.P. enter into an agreement ("**Exchange Agreement**") pursuant to which they agree that all outstanding Purchase Warrants will be exchanged for securities or cash or a combination of both, then Holder shall agree to such exchange and become a party to the Exchange Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused this Purchase Warrant to be signed by its duly authorized officer as of the 15th day of October, 2021.

XORTX THERAPEUTICS, INC.

By: _____
Name:
Title:

[Form to be used to exercise Purchase Warrant]

Date: _____, 20__

The undersigned hereby elects irrevocably to exercise the Purchase Warrant for_____ common shares, no par value per share (the "**Shares**"), of Xortx Therapeutics, Inc., a company organized under the laws of British Columbia (the "**Company**"), and hereby makes payment of $____ (at the rate of $____ per Share) in payment of the Exercise Price pursuant thereto. Please issue the Shares as to which this Purchase Warrant is exercised in accordance with the instructions given below and, if applicable, a new Purchase Warrant representing the number of Shares for which this Purchase Warrant has not been exercised.

or

The undersigned hereby elects irrevocably to convert its right to purchase Shares of the Company under the Purchase Warrant for ___ Shares, as determined in accordance with the following formula:

$$X = \frac{Y\,(A-B)}{A}$$

Where,

X = The number of Shares to be issued to Holder;
Y = The number of Shares for which the Purchase Warrant is being exercised;
A = The fair market value of one Share which is equal to $___; and
B = The Exercise Price which is equal to $___ per share

The undersigned agrees and acknowledges that the calculation set forth above is subject to confirmation by the Company and any disagreement with respect to the calculation shall be resolved by the Company in its sole discretion.

Please issue the Shares as to which this Purchase Warrant is exercised in accordance with the instructions given below and, if applicable, a new Purchase Warrant representing the number of Shares for which this Purchase Warrant has not been converted.

Signature_____

Signature Guaranteed_____

INSTRUCTIONS FOR REGISTRATION OF SECURITIES

Name _____
(Print in Block Letters)

Address _____
_____
_____

NOTICE: The signature to this form must correspond with the name as written upon the face of the Purchase Warrant without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank, other than a savings bank, or by a trust company or by a firm having membership on a registered national securities exchange.

[Form to be used to assign Purchase Warrant]

ASSIGNMENT

(To be executed by the registered Holder to effect a transfer of the within Purchase Warrant):

FOR VALUE RECEIVED, _____ does hereby sell, assign and transfer unto the right to purchase common shares, no par value per share, of Xortx Therapeutics, Inc., a company organized under the laws of British Columbia (the "**Company**"), evidenced by the Purchase Warrant and does hereby authorize the Company to transfer such right on the books of the Company.

Dated: _____, 20__

Signature_____

Signature Guaranteed _____

NOTICE: The signature to this form must correspond with the name as written upon the face of the within Purchase Warrant without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank, other than a savings bank, or by a trust company or by a firm having membership on a registered national securities exchange.

CONSULTING SERVICES AGREEMENT

THIS CONSULTING SERVICES AGREEMENT (the "**Agreement**") is dated effective the 20th day of December, 2021.

BETWEEN:

XORTX THERAPEUTICS INC., a corporation incorporated under the laws of the province of British Columbia and having its head office at 4000, 421 – 7th Avenue SW, Calgary, Alberta, Canada T2P 4K9 (hereinafter referred to as the "**Company**")

OF THE FIRST PART

- AND -

W.B. ROWLANDS & CO. LTD., a corporation incorporated under the laws of the province of Ontario and having its head office at 201 Bain Avenue, Toronto, Ontario, Canada M4K 1E9 (hereinafter referred to as the "**WBR**")

OF THE SECOND PART

- AND -

WILLIAM BRUCE ROWLANDS, an individual having his residential address at 201 Bain Avenue, Toronto, Ontario, Canada M4K 1E9 (hereinafter referred to as the "**Rowlands**")

OF THE THIRD PART

WHEREAS:

A. Rowlands, President of WBR, has been a director of the Company since 2013 and due to this history, he has intimate knowledge of the business of the Company;

B. The Compensation Committee of the Company has made a recommendation that WBR be paid a one-time cash fee of $50,000 plus HST to acknowledge and to compensate Rowlands for his past service to the Company and in respect of the services contemplated hereunder;

C. Rowlands holds 51,106 stock options issued under the Company's stock option plan ("the "**Plan**"), 12,776 of which are exercisable at $5.87 and 38,330 of which are exercisable at $1.64 (the "**Options**");

NOW THEREFORE in consideration of the premises and of the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by each of the parties hereto (individually, a "**Party**" and together, the "**Parties**"), the Parties agree as follows:

1. ENGAGEMENT, TERM AND SERVICES

1.1 Engagement

The Company hereby engages WBR to provide support and advice, as may be requested by the Chief Executive Officer of the Company in respect of outstanding or new matters that relate to the Company that may arise from time to time (the "**Services**").

1.2 Term

During the Term, Rowlands, on behalf of WBR, will provide the Services for an eighteen (18) month period, commencing December 20, 2021 (the "**Effective Date**") through June 20, 2023 (the "**Termination Date**").

1.3 Services

During the Term, Rowlands, on behalf of WBR, will personally provide the Services to the Company and will report to the Company's Chief Executive Officer, provided that the total number of hours of Services shall not exceed 200.

2. RELATIONSHIP

In entering into this Agreement and providing the Services hereunder, WBR will have the status of an independent contractor and nothing in this Agreement will constitute that WBR or Rowlands is an employee or officer or director of the Company for any purpose and Neither WBR nor Rowlands will be deemed to be an employee of the Company. Neither WBR nor Rowlands shall be entitled to bind the Company in any way or make any representation on behalf of the Company.

3. COMPENSATION

3.1 Incentive Stock Options

In lieu of any additional cash compensation, WBR and Rowlands agree that the Options currently granted to Rowlands, being 12,776 exercisable at $5.87 and 38,330 exercisable at $1.64, and having current expiry dates of March 19, 2023 and June 23, 2025, respectively, will remain outstanding in accordance with the Plan for the term of this Agreement. The Options will be further subject to the terms and conditions of the Plan.

3.2 Expenses

Upon submission of complete and detailed invoices or other evidence of payment, the Company will reimburse WBR for all reasonable out-of-pocket expenses actually and properly incurred by WBR in connection with providing the Services under this Agreement. Any single expense in excess of $200 will require pre-approval by the Company. The Company agrees to pay the amounts due within thirty (30) days of the receipt of such invoices or other evidence of payment.

4. CONFIDENTIALITY

4.1 Access to Confidential Information

WBR and Rowlands acknowledge that in the course of carrying out, performing and fulfilling the Services, it may have access to confidential information and to undisclosed information concerning the Company ("**Confidential Information**"), and that disclosure of Confidential Information will be highly detrimental to the best interests and business of the Company and may be a breach of applicable securities laws.

4.2 Use and Disclosure

Except as may be specifically required in the course of carrying out the Services or as may be required by law, WBR and Rowlands will not, during the Term or at any time thereafter:

- disclose any Confidential Information to any person or entity; or
- use or exploit, directly or indirectly, the Confidential Information for any purpose other than the purposes of the Company.

5. TERMINATION

WBR and the Company agree that the engagement of WBR pursuant to this Agreement is scheduled to terminate on the Termination Date and may be terminated prior to the Termination Date by either Party, for cause, at any time upon written notice in the event of a failure by the other Party to comply with any of the material provisions hereunder, or, in the case of termination by the Company, a persistent failure by the WBR to follow the lawful directions and policies of the Company, or any act of gross negligence or wilful misconduct by the WBR.

6. SEVERABILITY

In the event that any provision or part of this Agreement is deemed void or invalid by a court of competent jurisdiction, the remaining provisions or parts will be and remain in full force and effect.

7. GOVERNING LAW

This Agreement will be construed in accordance with and governed by the laws of Alberta, Canada.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF the Parties have executed this Agreement as of the day and year first above written. The terms of this Agreement are hereby acknowledged and consented to by:

XORTX THERAPEUTICS, INC.

Per: /s/ Allen Davidoff
Allen Davidoff
President and Chief Executive Officer

W.B. ROWLANDS & CO. LTD.

Per: /s/ W. Bruce Rowlands
W. Bruce Rowlands
President and Chief Executive Officer

The undersigned acknowledges and agrees with the foregoing.

/s/ W. Bruce Rowlands
W. Bruce Rowlands

/s/ Charlotte May
Witness

Exhibit 4.17

CERTAIN INFORMATION (INDICATED BY [***]) 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 REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

PATENT RIGHTS PURCHASE AGREEMENT

THIS PATENT RIGHTS PURCHASE AGREEMENT ("Agreement") is made and entered into effective as of May 26, 2014 (the "Effective Date"):

BETWEEN:

DR. RICHARD JOHNSON, having an address, at:

***

("**Johnson**")

DR. TAKAHIKO NAKAGAWA, having an address at

***

("**Nakagawa**", and collectively, with Johnson, the "**Vendors**")

AND:

XORTX PHARMA CORP., having a place of business at ***

(the "**Purchaser**")

(each a "Party," or collectively as the "**Parties**")

WHEREAS:

A. The Vendors have an ownership interest in certain patent and patent applications covering certain inventions relating to the treatment of cardiovascular diseases; and

B. The Purchaser wishes to purchase such patent and patent applications from the Vendors on the terms and conditions contained in this Agreement.

NOW THEREFORE, in consideration of the premises and the mutual covenants, terms, conditions and agreements contained herein, and other good and valuable consideration, the sufficiency of which are hereby acknowledged by the Parties, the Parties agree as follows.

ARTICLE 1 INTERPRETATION

1.1 Definitions

In this Agreement, unless something in the subject matter or context is inconsistent therewith:

"**Abandoned Patents**" means the abandoned, lapsed, expired, withdrawn, or dead Patents as listed in Schedule A attached hereto.

"**Affiliate**" of a Party means any other entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such first Party. For purposes of this definition only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" will mean the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance.

"**Applicable Law**" means the applicable laws, rules, and regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities that may be in effect from time to time.

"**Business Day**" means any day, other than Saturday, Sunday or any statutory holiday in Canada or the United States of America.

"**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

"**Calendar Quarter**" means each three (3) month period commencing January 1, April 1, July 1 and October 1 of each Calendar Year.

"**Claims**" means all losses, damages, fines, penalties, expenses, liabilities (whether accrued, actual, contingent, latent or otherwise), claims and demands of whatever nature or kind including all legal fees and costs on a solicitor and client basis.

"**Commercialize**" means to Use and otherwise exploit worldwide in any manner whatsoever and grant sublicenses (and permit the granting of sublicenses) in accordance with Section 2.2 to do any or all of the foregoing.

"**Combination Product**" means the Products which are sold in combination with a Third Party product or service.

"Confidential Information" means all information and know-how and any tangible embodiments thereof provided by or on behalf of one Party to the other Party either in connection with the discussions and, negotiations pertaining to this Agreement or in the course of performing this Agreement, which may include data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. For clarity, the Patent Rights (to the extent they are not publicly available) are the Confidential Information of the Purchaser.

Notwithstanding the foregoing, information or know-how of a Party will not be deemed Confidential Information of such Party for purposes of this Agreement if such information or know-how:

(a) was already known to the receiving Party, other than under an obligation of confidentiality or non-use, at the time of disclosure to such receiving Party;

(b) was generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or was otherwise part of the public domain, at the time of its disclosure to such receiving Party;

(c) became generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or otherwise became part of the public domain, after its disclosure to such receiving Party through no fault of the receiving Party;

(d) was disclosed to such receiving Party, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the disclosing Party not to disclose such information or know-how to others; or

(e) was independently discovered or developed by such receiving Party, as evidenced by their written records, without the use of Confidential Information belonging to the disclosing Party and prior to any subsequent disclosure by the receiving Party.

"**Control**" means, with respect to any Patent or other Intellectual Property Right, possession of the right (whether by ownership, license or otherwise), to assign, or grant a license, sublicense or other right to or under, such Patent or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party or incurring any additional financial or other obligation to a Third Party.

"**Covered**" means, with respect to a Patent Rights, that, but for a license granted by the Purchaser under a Valid Claim included in such Patent Rights, the practice of the subject matter claimed in such Patent Rights would infringe such Valid Claim.

"**Effective Sale Date**" means the date the Vendors secure the NIH Waiver.

"**Encumbrances**" means pledges, liens, charges, security interests, leases, title retention agreements, mortgages, restrictions, development or similar agreements, easements, rights-of-way, title defects, options or adverse claims or encumbrances of any kind or character whatsoever.

"**Executory**" as used in relation to Vendors' rights in Patent Rights means the Vendors, as inventors of Patent Rights, have requested for and are awaiting assignment of the Patent Rights from the NIH per NIH policies and procedures.

"**First Commercial Sale**" means, with respect to a Product, the first bona fide sale of such Product to a Third Party by or on behalf of the Purchaser, its Affiliates or licensees in a country after Regulatory Approval has been achieved for such Product in such country. For greater certainty, sales for test marketing, sampling and promotional uses, clinical trial purposes or compassionate or similar use will not be considered to constitute a First Commercial Sale.

"**Intellectual Property Rights**" mean any and all proprietary rights provided under (a) patent law, (h) copyright law, (c) trade-mark law, (d) design patent or industrial design law, (e) semi-conductor chip or mask work law, or (0 any other applicable statutory provision or common law principle, including trade secret law, that may provide a right in ideas, formulae, algorithms, concepts, inventions, or know-how, or the expression or use thereof.

"**Know-How**" means to the extent Controlled by the Vendors or any Affiliate of the Vendors, as the case may be, whether existing as of Effective Date or acquired or developed by the Vendors or their Affiliates thereafter, and necessary or useful for the development, making, having made, use, sale, offering to sell, having sold or importing of the Product, all know-how, inventions, discoveries, data, results, information, trade secrets, ideas, concepts, formulas, techniques, methods, processes, developments, materials or compositions of matter of any type or kind. expertise, formulas, technology, stability data, research, pre-clinical and clinical data, regulatory information, manufacturing process, scale-up and other technical data, reports, documentation and samples, whether or not patented or patentable, pertaining to the inventions and technology described in the Patent Rights, including, without limitation, the Abandoned Patents, and all Patents in the same family for which Dr. Richard Johnson is identified as an inventor.

"**Net Revenues**" means all revenues to the Purchaser derived from any combination of Net Sales, Sublicensing Royalty Revenue, and Sublicensing Revenue, but specifically will exclude (i) equity purchases of the Purchaser's securities, or (ii) milestones amounts paid by licensees or other collaborators or hinders for contract research and development activities.

"**Net Sales**" means the total invoiced sales price for Products sold by Purchaser (or an Affiliate or licensee) less the following deductions:

(a) sales taxes or other taxes separately stated in the invoice;

(b) shipping and insurance charges actually paid and separately stated on the invoice;

(c) actual allowances, rebates, credits and refunds for returned or defective goods;

(d) chargeback payments and rebates (or the equivalent thereof) granted to managed health care organizations or to federal, state/provincial, local and other governments, including their agencies, purchasers, and/or reimburses, or to trade customers;

(e) normal and customary trade and quantity discounts, retroactive price reductions, or other allowances actually allowed or granted from the billed amount and taken; and

(f) any import or export duties, tariffs, or similar charges incurred with respect to the import or export of Product into or out of a country.

For purposes of this Agreement, a distributor will not be deemed a licensee and sales by the Purchaser, its Affiliates or licensees to a distributor will be considered as Net Sales. Notwithstanding the foregoing, Net Sales will not include, and will be deemed zero with respect to, (i) the distribution of reasonable quantities of promotional samples of Products, (ii) amounts received by the Purchaser, its Affiliates or licensees for the sale of Products among the Purchaser, its Affiliates or licensees whether for their internal use or for resale or other disposition; and (iii) amounts received by the Purchaser, its Affiliates or licensees for Products provided for clinical trials, research purposes, or charitable or compassionate use purposes.

"**NIH Waiver**" means an approval from the National Institutes of Health for Vendors to transfer ownership of the Patent Rights to Purchaser.

"**Patents**" will include (i) all patents and patent applications, (ii) any substitutions, divisions, continuations, continuations-in-part (but only to the extent that they cover the same invention claimed in the foregoing), revisions, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates, patent term extensions, patent term adjustments, and the like, and any provisional applications, of any such patents or patent applications, and (iii) any foreign or international equivalent of any of the foregoing.

"**Patent Rights**" means the Patents listed in Schedule A.

"**Product**" means any method, process, device, product or service, that, in whole or in part is developed, made, used, sold, distributed, imported or exported by utilizing or incorporating, in any way, directly or indirectly any subject matter Covered by a Valid Claim in any Patent Rights.

"**QuestMed**" means QUESTMED, LLC, a limited liability company formed under the laws of the State of Florida.

"**Regulatory Approval**" means approval by a Regulatory Authority to allow marketing of a Product.

"**Regulatory Authority**" means any applicable government entities regulating or otherwise exercising authority with respect to the development and commercialization of the Product.

"**Royalty Due Dates**" means March 31, June 30, September 30 and December 31 of each and every year during which this Agreement remains in full force and effect.

"**Sublicensing Revenue**" means any consideration actually received by Purchaser or an Affiliate from a Third Party as consideration for the grant of rights to Products (net of any tax or similar withholding obligations imposed by any tax or other government authorities that are not reasonably recoverable by Purchaser). Sublicensing Revenue includes, but is not limited to, upfront fees, license maintenance fees, and milestone payments received by Purchaser in consideration for any rights granted to Products under a sublicense agreement, and excludes (i) Sublicensing Royalty Revenue, (ii) purchases of equity or debt of Purchaser or any Affiliate, (iii) fair market value payments made in connection with research and development agreements, joint ventures, partnerships or collaboration agreements where Purchaser or an Affiliate is obligated to perform research and development of any Product(s), (iv) the grant to Purchaser of Intellectual Property Rights related to the Patent Rights; and (v) other payments made by a licensee as consideration for Purchaser's or an Affiliate's performance of services or provision of goods, provided such services or goods are not Products or, if such services or goods are Products, (a) the provision of such services or goods results in Net Sales pursuant to which a royalty is payable or (b) the provision of such services or goods constitutes one or more of the following: (1) the distribution of reasonable quantities of promotional samples of Products or (2) the provision of Products for clinical trials, research purposes, or charitable or compassionate use purposes.

"**Sublicensing Royalty Revenue**" means sales-based royalties, sales milestone payments, other payments calculated on the basis of sales, and minimum sales royalties actually received by Purchaser or its Affiliate from a Third Party as consideration for the grant of rights to Products (net of any tax or similar withholding obligations imposed by any tax or other government authorities that are not reasonably recoverable by Purchaser).

"**Technology**" means the Patent Rights and the IV tow-How.

"**Third Party**" means any party other than the Vendors or the Purchaser or their respective Affiliates.

"**Use**" means to use, operate, make, have made, manufacture, sell, offer to sell, license, assign, transfer, market, distribute, sub-license, import, export, reproduce, modify, adapt, create derivative works, support, translate, port, practice any method or process claimed in any patent, benefit from or exploit any Intellectual Property Rights or have done any of such things above by any means and any forms.

"**Valid Claim**" means a claim of any issued, unexpired patent which has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

"**Withholding Taxes**" has the meaning set forth in Section 4.8.

1.2 Headings.

The division of this Agreement into Articles and Sections and the insertion of headings are for convenience of reference only and shall not affect the construction or interpretation of this Agreement. The terms "this Agreement", "hereof", "hereunder" and similar expressions refer to this Agreement and not to any particular Article, Section or other portion hereof and include any agreement supplemental hereto. Unless something in the subject matter or context is inconsistent therewith, references herein to Articles and Sections are to Articles and Sections of this Agreement.

1.3 Extended Meanings.

In this Agreement words importing the singular number only shall include the plural and *vice versa,* words importing the masculine gender shall include the feminine and neuter genders and *vice versa and wads* importing pet sons shall include individuals, partnerships, associations, trusts, unincorporated organizations and corporations.

1.4 Accounting Principles.

Wherever in this Agreement reference is made to a calculation to be made in accordance with generally accepted accounting principles, such reference shall be deemed to be to the generally accepted accounting principles from time to time approved by the Canadian Institute of Chartered Accountants, or any successor institute, applicable as at the date on which such calculation is made or required to be made in accordance with generally accepted accounting principles.

1.5 Knowledge.

In this Agreement, the phrase "to the knowledge, information and belief" of any person will be interpreted as follows:

(a) A person who is an individual will he deemed to have knowledge, information and/or belief of a particular fact or other matter if such individual is actually aware of such fact cr other matter, or a prudent individual could be expected to discover or otherwise become aware of such fact or other matter in the course of conducting a reasonably comprehensive investigation concerning the existence of such fact or other matter.

(b) A person, other than an individual, will be deemed to have knowledge, information and/or belief of a particular fact or other matter if any individual who is serving, or who has at any time served, as a director, officer, partner, executor, or trustee of such person (or in any similar capacity) has, or at any time had, knowledge, information and/or belief of such fact or other matter.

ARTICLE 2 - LICENSE AND NIH WAIVER

2.1 NTH Waiver

The Vendors will use best efforts to promptly secure the NIH Waiver from the National Institutes of Health.

2.2 License.

As of the Effective Date, prior to the Vendors securing the NIH Waiver, the Vendors hereby grant to the Purchaser an exclusive, assignable (in accordance with Section 11.1), and sublicensable license, including under all of the Vendors' present and future Intellectual Property Rights in and to the Technology, to Commercialize the Technology worldwide in any manner whatsoever, including, without limitation, the Commercialization of any Products (the "License") for the issuance of shares in the Purchaser in accordance with Section 4.1.

2.3 Vendors' Rights.

The Parties acknowledge and agree that the Vendors may use the Technology for their own internal research, teaching and educational purposes, including treatment of patients with cardiovascular diseases at patient care facilities operated or controlled by the University of Colorado (the "**Colorado Patient Care**") provided that such use shall not (i) contravene the Vendors' confidentiality obligations under Article 9, (ii) be subject to any Intellectual Property Rights granted to any commercial Third Party; or (iii) include any human use or clinical administration without prior written approval from the Purchaser (other than with respect to the Colorado Care), such approval not to be unreasonably withheld. The Purchaser shall also retain the rights to make, use and provide the Technology to other academic and non-profit research institutions collaborating with the Vendors for their own internal research, teaching and educational purposes relating to such collaboration, provided that such academic and non-profit research institutions are bound by confidentiality obligations to protect the Technology that are commensurate with those under this Agreement, and the Vendors shall require such Third Parties that the use of such Technology shall not (i) be subject to any Intellectual Property Rights granted to any commercial Third Party nor (ii) include any human use or clinical administration without prior written approval from the Purchaser, such approval not to be unreasonably withheld.

2.4 Prosecution of Patents.

(a) Upon the Purchaser's request and direction, prior to the Effective Sale Date, the Vendors will promptly do all things necessary or desirable to prepare, file, register, prosecute or maintain the Patent Rights as the Purchaser may stipulate in writing from time to time in each jurisdiction designated by the Purchaser, and the Purchaser will bear the cost of all reasonable and pre-approved expenses incurred after the Effective Date, continuing until the Effective Sale Date, and associated with the preparation, filing, registration, issuance and maintenance of all Patents included in the Patent Rights (collectively, the "**Prosecution and Maintenance Fees**") for which applicable invoices have been provided to the Purchaser and approved by the Purchaser. The Purchaser has the right to (a) select and stipulate legal and patent counsel; (b) stipulate and restrict the jurisdiction(s) for filing, registration, prosecution, and maintenance of the Patent Rights; and (c) all matters relating to the prosecution of the Patent Rights. The Vendors will provide copies of all applicable invoices specifying the Prosecution and Maintenance Fees, and, the Purchaser will pay to the Vendors all undisputed Prosecution and Maintenance Fees within thirty (30) days after receipt of the applicable invoice. In the event the Vendors elect not to file, register, prosecute or maintain the Patent Rights in specified jurisdictions, the Vendors will provide written notice to the Purchaser, in advance of any filing or response to deadline or fee due. The foregoing will not be construed to restrict the right of the Vendors from making such filings, registrations, prosecution, and maintenance, at the Vendors' expense, as the Vendors may deem appropriate.

(b) **Cooperation**. Prior to the Effective Sale Date, each Party will cooperate reasonably in the preparation, filing, registration, prosecution, and maintenance of the Patent Rights. Such cooperation includes (a) promptly executing all papers and instruments and requiring employees to execute such papers and instruments as reasonable and appropriate so as to enable such other Party, to prepare, file, register, prosecute, and maintain such Patents in any country; and (b) promptly informing such other Party of matters that may affect the preparation, filing, prosecution, registration, or maintenance of any such Patents. The Party responsible for filing, prosecuting, registering, and maintaining the Patent Rights will provide the non-prosecuting Party with sufficient opportunity to comment on any document that the prosecuting Party intends to file or to cause to be filed with the relevant intellectual property or patent office, and after such filing, provide such filed documents to the other Party. Each Party will promptly inform the other as to all matters that come to its attention that may affect the filing, prosecution, registration, and maintenance of any of the Patent Rights and wilt permit the other Party to provide comments and suggestions with respect to such activities, which comments and suggestions will be reasonably considered by the other Party.

ARTICLE 3 - PURCHASE AND SALE

3.1 Purchase and Sale

Subject to the terms and conditions hereof, the Vendors securing the NIH Waver, the Vendors hereby sell, assign and transfer to Purchaser as of the Effective Date, free and clear of all Encumbrances, the Patent Rights, and the Purchaser hereby purchases from the Vendors the Patent Rights, for the amounts payable in accordance with Section 4.2 hereof (the “Purchase Price”).

3.2 Transfer of Possession

This Agreement shall operate, without further act or formality, as a transfer to the Purchaser for all purposes as at the Effective Sale Date of all right, title and interest in and to the Patent Rights, including all worldwide rights in and to the Patent Rights. The Vendors shall forthwith and from time to time hereafter execute and deliver to the Purchaser all deeds, transfers, assignments and other instruments in writing and further assurances as the Purchaser or its counsel shall reasonably require to effect such acquisition and transfer; and, for greater certainty, to the extent that any of the Patent Rights shall not have been effectively transferred to the Purchaser pursuant to this Agreement, the Vendors shall hold all of the same in trust for and as the property of the Purchaser, pending the effective transfer thereof.

3.3 License Rights

Notwithstanding the purchase and sale of the Patent Rights contemplated in Section 3.1, upon the assignment of the Patent Rights, the Purchaser hereby grants to the Vendors a non-exclusive, personal, revocable, and royalty-free license to: (a) use the Patent Rights for their own internal research, teaching and educational purposes, including the Colorado Patient Care provided that such use shah not (i) contravene the Vendors' confidentiality obligations under Article 9, (ii) be subject to any Intellectual Property Rights granted to any commercial Third Party; or (iii) include any human use or clinical administration without prior written approval from the Purchaser (other than with respect to the Colorado Care), such approval not to be unreasonably withheld; and (b) make, use and provide the Patent Rights to other academic and non-profit research institutions collaborating with the Vendors for their own internal research, teaching and educational purposes relating to such collaboration, provided that such academic and non-profit research institutions are bound by confidentiality obligations to protect the Patent Rights that are commensurate with those under this Agreement, and the Vendors shall require such Third parties that the use of such Patent Rights shall not (i) be subject to any Intellectual Property Rights granted to any commercial Third party nor (ii) include any human use or clinical administration without prior written approval from the Purchaser, such approval not to be unreasonably withheld.

ARTICLE 4 – FINANCIAL PROVISIONS

4.1 Payment by the Purchaser for the License

In consideration of granting the License pursuant to Section 2.2 under this Agreement, subject to applicable securities laws and the constating documents of the Purchaser, the Purchaser shall issue to: (i) Johnson *** common shares of the Purchaser, (ii) QuestMed *** common shares of the Purchaser, (collectively "Initial Shares"), and (iii) Nakagawa *** common shares of the Purchaser representing in the aggregate 7.99% of the Purchaser's issued and outstanding shares ass of the Effective Date. In addition to issuing the Initial Shares, as of the Effective Date, Purchaser will issue to: (i) Johnson *** common shares of the Purchaser, (ii) QuestMed *** common shares of the Purchaser, and (iii) Nakagawa *** common shares of the Purchaser Vendor (the "Second Shares"), which represent a total of *** shares additional to Initial Shares.

4.2 Payment by the Purchaser for the Assignment of Patent Rights.

In consideration of the assignment of the Patent Rights as of the Effective Sale Date pursuant to Section 3.1 under this Agreement, the Purchaser shall pay to *** to each of the Vendors and QuestMed.

4.3 Royalty

(a) After the Effective Sale Date, the Purchaser shall pay to the Vendors a royalty equal to 1.5% on the cumulative Net Revenues from the sale or sublicense of the Product until the later of (a) the expiration of the last Patent Right covering a Product, and (b) the expiration of ten (10) years from the date of First Commercial Sale of a Product. In the event that a Third Party or an Affiliate of the Purchaser wishes to acquire any of the Purchased Patent Rights, Purchaser shall make as a condition of such acquisition that the Third Party of Affiliate acquirer agree to the obligations under this Section 4.3(a) and agree that for any future acquisition of the Purchased Patent Rights, a condition of the future acquisition shall include that the future acquirer assuming the obligations under this Section 4.3(a), such that these obligations shall carry forward in perpetuity to any future Third Party acquirers until termination of the payment of royalties as contemplated in the foregoing.

(b) **In the event that research and development expenditures of Purchaser or Third-Party acquirer for all research and development purposes (including without limitation the development of products) are less than 15% of that company's total expenditures for all purposes in the calendar year, the component of the above-referenced royalty that is directed to Sublicensing Royalty Revenue shall be tripled for that year from 1.5% to 4.5%. The Purchaser will not be obligated to meet the Project Commitment as contemplated in the foregoing of this Section 4.3(b) upon the First Commercial Sale.**

4.4 Combination Product

If a Product is a Combination Product, Net Sales for the Combination Products will be calculated by multiplying Net Sales for such Combination Products by the fraction (A/A+B) where A is the invoice price of the Products when sold separately, and B is the aggregate invoice price of the Third Party products in the Combination Product (the **"Third Party Subproducts")** when such Combination Product is sold separately. If either of the Product or the Third Party Subproduct is not at the time sold separately, then the allocation of Net Sales will be commercially reasonable and determined by good faith negotiation between the Vendors and the Purchaser, based on the relative value of the Product and Third Party Subproducts, consistent with the formula provided above.

4.5 Third Party Royalties.

In the event the Purchaser is required to pay royalties to Third Party as part of its sale of Products (the **"Third Party Royalties"),** the Purchaser may deduct an amount equal to fifty percent (50%) of any Third Party Royalties from any royalty amount due to the Vendors hereunder, provided that in no event will the royalties otherwise due to the Venders be less than fifty (50%) of the royalties that would be payable to the Vendors absent the effects of this Section 4.5.

4.6 Tinting of Payments.

The royalties from the Purchaser to the Vendors set forth in Section 4.3 will be paid by the Purchaser on a quarterly basis and, will become due and payable within forty-five (45) clays after each respective Royalty Due Date and will be calculated based on the Net Revenues in the three (3) month period immediately preceding the applicable Royalty Due Date. Provided the Purchaser has acted reasonably in a commercially reasonable fashion in extending credit to its customers and has had diligent efforts to collect its accounts receivable respecting Products sold, then the Purchaser may claim a credit against the royalties otherwise owing respecting royalties paid where the revenues from the sales have not been collected by the Purchaser within one hundred and twenty (120) days of the sale of such Product, provided that in the event of ultimate collection by the Purchaser, the Royalties payable will thereupon be submitted to the Vendors.

4.7 Payment Method.

Any amounts due to the Vendors under this Agreement will be paid in United States dollars, by wire transfer in immediately available funds to an account designated by the Vendors. Any payments or portions thereof due hereunder which are not paid on the date such payments are due under this Agreement will bear simple interest at a rate equal to the lesser of the prime rate as published in *The Globe and Mail,* on the first day of each Calendar Quarter in which such payments are overdue, plus two percent (2%), or the maximum rate permitted by law, whichever is lower, calculated on the number of days such payment is delinquent.

4.8 Currency; Foreign Payments.

Net Sales of Product made in currency other than United States dollars will be converted to United States dollars using the average exchange rates for the applicable foreign currency published in *The Globe and Mail* for the applicable Calendar Quarter. If at any time legal restrictions prevent the prompt remittance of any payments in any jurisdiction, the Purchaser may notify the Vendors and make such payments by depositing the amount thereof in local currency in a bank account or other depository in such country in the name of the Vendors Or its designee, and the Purchaser will have no further obligations under this Agreement with respect thereto.

4.9 Taxes.

The Purchaser may deduct from any amounts it is required to pay to the Vendors pursuant to this Agreement an amount equal to that withheld for or due on account of any taxes (other than taxes imposed on or measured by net income) or similar governmental charge imposed by a jurisdiction based on such payments to the Vendors ("**Withholding Taxes**"). The Purchaser will provide the Vendors a certificate evidencing payment of any Withholding Taxes hereunder within thirty (30) days of such payment (or when available from the applicable foreign tax authority) and will reasonably assist the Vendors, at the Vendors' expense, to obtain the benefit of any applicable tax treaty.

4.10 Reports; Records Retention; Audit.

(a) **Sales Reports**. Within forty-five (45) days after each respective Royalty Due Date, the Purchaser will furnish to the Vendors a written report showing in reasonably specific detail, on a country-by-country and Product-by-Product basis, (a) the gross sales of Products sold by the Purchaser, its Affiliates and licensees during the applicable calendar quarter, the calculation of Net Sales from such gross sales and the calculation of Net Revenues; (b) the calculation of the royalties which will have accrued based upon such Net Revenues; (c) the Withholding Taxes, if any, required by law to be deducted with respect to such Net Revenues; and (d) the exchange rates, if any, used in determining the amount of U.S. dollars.

(b) **Record Retention**. The Purchaser will maintain (and will ensure that its licensees will maintain) complete and accurate books, records and accounts that fairly reflect Net Revenues with respect to the Product, in each case in sufficient detail to confirm the accuracy of any payments required hereunder, which books, records and accounts will he retained by the Purchaser until the later of (i) 3 years after the end of the period to which such books, records and accounts pertain, and (ii) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

(c) **Audit**. The Vendors will have the right to have an independent certified public accounting firm of nationally recognized standing, reasonably acceptable to the Purchaser, have access during normal business hours, and upon reasonable prior written notice, to the Purchaser' records (and its licensees) as may be reasonably necessary to verify the accuracy of Net Revenues for any Calendar Quarter ending not more than twenty-four (24) months prior to the date of such request; *provided, however, that* the Vendors will not have the right to conduct more than one such audit in any Calendar Year except as provided below or more than one such audit covering any given time period. The Vendors will bear the cost of such audit unless the audit reveals an underpayment to the Vendors of more than 5% for the audited period, in which case the Purchaser will bear the cost of the audit.

(d) **Payment of Additional Amounts**. If, based on the results of such audit, additional payments are owed by the Purchaser under this Agreement; the Purchaser will make such additional payments, with interest as set forth in Section 4.7, within thirty (30) days after the date on which such accounting firm's written report is delivered to such Party.

(e) **Confidentiality**. The Vendors will treat the financial information subject to review under this Section 4.10(e), any information contained in the Sales Reports under Section 4.10(a) as Confidential Information of the Purchaser in accordance with the confidentiality provisions of Article 9.

ARTICLE 5 - REPRESENTATIONS AND WARRANTIES

5.1 Representations and Warranties of the Vendors

The Vendors represent, warrant and acknowledge to Purchaser, as of the Effective Date and the Effective Sale Date, and acknowledge and confirm that Purchaser is relying upon the representations and warranties in connection with the purchase by Purchaser of the Patent Rights that:

General

(a) they have the power, authority and right to enter into and deliver this Agreement and to complete all transactions to be completed by them contemplated hereunder and without limiting the generality of the foregoing to transfer the legal and beneficial title and ownership of the Patent Rights to Purchaser free and clear of all Encumbrances;

(b) this Agreement and all other agreements, documents and instruments to be executed by either of the Vendors pursuant hereto have been validly executed and delivered by each of the Vendors, as applicable, and are valid and enforceable against the Vendors in accordance with their terms, subject to applicable bankruptcy and insolvency laws and to equitable remedies being always in the discretion of a court;

(c) there is no contract, option or any other right of another binding upon or which at any time in the future may become binding upon either of the Vendors to sell, transfer, assign, pledge, charge, mortgage, create any Encumbrance or in any other way dispose of or encumber any of the Patent Rights other than pursuant to the provisions of this Agreement;

(d) neither the entering into nor the delivery of this Agreement nor the completion of the transactions contemplated hereby by Vendors will result in the violation of:

(i) any agreement or other instrument to which either of the Vendors is a party; or

(ii) any Applicable Law; and

(e) no distress, execution or other process been levied against the Vendors or action taken to repossess goods in the possession of the Vendors. No steps have been taken for the appointment of an administrator or receiver of any part of the property of the Vendors. The Vendors have not made or proposed any arrangement or composition with its creditors or any class of the Vendors' creditors. The Vendors have not been party to a transaction pursuant to or as a result of which an asset owned, purportedly owned or otherwise held by the Vendors are liable to be transferred or are transferred to another person or which gives or may give rise to a right of compensation or other payment in favour of another person under the provisions of any applicable bankruptcy or insolvency legislation. The Vendors are not undischarged bankrupts and will not, by reason of the sale of the Patent Rights to Purchaser hereunder, be rendered insolvent or be rendered unable to pay their debts when they become due.

Patent Rights

(f) the Vendors have an Executory interest in the Patent Rights as of the Effective Date, and, upon receiving the N1H Waiver, will be the owner of all rights, title, and interests in and to the Patent Rights, and upon becoming the owner of such rights, title, and interests, the Vendors will have good and marketable title to the Patent Rights, free and clear of all Encumbrances and any other rights of others;

(g) other than with respect to the rights of the N1H and the United States government in and to the Patent, the Vendors have the exclusive right to use the Patent Rights and no Third Party has any right, title or interest (including, without limitation, by way of license) to any of the Patent Rights;

(h) other than with respect to the Abandoned Patents, the Patent Rights are valid, subsisting and, to the knowledge, information, and belief of each of the Vendors, enforceable, and in good standing and have been duly registered, issued, or granted or applications to register the same have been filed with the patent granting authorities identified in Schedule A in all appropriate offices to preserve the rights therein and of the Vendors thereto;

(i) other than with respect to the Abandoned Patents, all maintenance and renewal fees for or in respect of all Patent Rights, and owing and/or due prior to or within ninety (90) days of the Effective Sale Date, have been paid, and there are no responses to office actions, submissions, or any other outstanding action or steps required to be taken and/or made in respect of any of the Patent Rights prior to or within ninety (90) days of the Effective Sale Date, [except as noted in Schedule *Al;*

(j) the Vendors have received no notice of any Claims made against either of the Vendors asserting the invalidity or unenforceability of the Patent Rights (including, without limitation, any re-examinations, interference actions, derivation proceedings, or conflict proceedings) or the misuse of the Patent Rights, and neither of the Vendors is aware of any basis for any of the same;

(k) neither of the Vendors has received notice of any Third Party challenge to either of the Vendor's right to use any of the Patent Rights;

(l) at no time have the Vendors infringed, misused, misappropriated or jeopardized the Intellectual Property Rights of any Third Party, and to the knowledge, information and belief of each of the Vendors, Use of the Patent Rights and Commercialization of the Technology do not infringe upon or violate any Third Party Intellectual Property Right. Neither of the Vendors has entered into any agreement to indemnify any other person against any charge or claim that the Patent Rights infringe Third Party Intellectual Property Rights. There is no and has not been any unauthorized use, infringement or misappropriation of any of the Patent Rights by any employee, former employee, contractor, consultant, customer, or potential customer to whom the Patent Rights have been provided or made accessible on a pilot basis, and, to the knowledge, information and belief of each of the Vendors, there is no and has not been any unauthorized use, infringement or misappropriation of any of the Patent Rights by any other person or Third Party;

(m) neither of the Vendors is a party to or bound by any contract or commitment to pay any royalty, license or other fee with respect to the Patent Rights; and

(n) the Vendors have received no notice of any actions, suits or proceedings or Claims pending or threatened against either of the Vendors or the Patent Rights purchased and sold hereunder, or before or by any governmental authorities, whether or not insured, and which might involve the possibility of any Encumbrance, or any other right of another against any of the Patent Rights.

5.2 Survival of Vendor Representations, Warranties and Covenants

(a) The representations and warranties of the Vendors set forth in Section 5.1 shall survive the completion of the sale and purchase of the Patent Rights herein provided for and shall continue in hill force and effect for the benefit of Purchaser.

(b) The covenants of the Vendors set forth in this Agreement shall survive the completion of the sale and purchase of the Patent Rights herein provided for and, notwithstanding such completion, shall continue in full force and effect for the benefit of Purchaser in accordance with the terms thereof.

5.3 Purchaser's Representations and Warranties

Purchaser represents and warrants to the Vendors, as of the Effective Date and the Effective Sale Date, and acknowledges and confirms that the Vendors are relying upon the representations and warranties in connection with the purchase by Purchaser of the Patent Rights, that•

(a) Purchaser is a corporation duly incorporated, organized and subsisting under the laws of the Province of Alberta, Canada;

(b) Purchaser has the power, authority and right to enter into and deliver this Agreement and to complete all transactions **to** be completed by Purchaser contemplated hereunder, and the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated under this Agreement have been duly and validly authorized and approved by all necessary corporate action on the part of Purchaser;

(c) this Agreement and all other agreements, documents and instruments to be executed by Purchaser pursuant hereto have been validly executed and delivered by Purchaser, and are valid and enforceable against Purchaser in accordance with their teens, subject to applicable bankruptcy and insolvency laws and to equitable remedies being always in the discretion of a court**;**

(d) Neither the entering into nor the delivery of this Agreement nor the completion of the transactions contemplated hereby by Purchaser will result in the violation of:

(i) any of the provisions of the constating documents or by-laws of Purchaser;

(ii) any agreement or other instrument to Purchaser is a party or by which Purchaser is bound; or

(iii) any Applicable Law; and

(e) no order has been made or petition presented or resolution passed for the winding up of Purchaser nor has any distress execution or other process been levied against Purchaser or action taken to repossess goods in the possession of Purchaser. No steps have been taken for the appointment of an administrator or receiver of any part of the property of Purchaser. No floating charge created by Purchaser has crystallised and there are no circumstances likely to cause such floating charge to crystallise. Purchaser has not been party to any transaction that could be avoided in a winding up. Purchaser has not made or proposed any arrangement or composition with its creditors or any class of its creditors. Purchaser has not been party to a transaction pursuant to or as a result of which an asset owned, purportedly owned or otherwise held by it is liable to be transferred or re-transferred to another person or which gives or may give rise to a right of compensation or other payment in favour of another person under the provisions of the *Bankruptcy Insolvency Act* (Canada).

5.4 Survival of Purchaser's Representations, Warranties arid Covenants

(1) The representations and warranties of Purchaser set forth in Section 5.2 shall survive the completion of the sale and purchase of the Patent Rights herein provided for and, notwithstanding such completion, shall continue in full force and effect for the benefit of the Vendors.

(2) The covenants of Purchaser set forth in this Agreement shall survive the completion of the sale and purchase of the Patent Rights herein provided for and, notwithstanding such completion, shall continue in full force and effect for the benefit of the Vendors in accordance with the terms thereof.

ARTICLE 6 - COVENANTS

6.1 Covenants of the Vendors

The Vendors shall indemnify and save harmless Purchaser and the directors, officers, employees and agents of Purchaser from and against any and all Claims directly or indirectly suffered by any of the same resulting from:

(a) any breach by either of the Vendors of, or inaccuracy or misrepresentation contained in, any representation or warranty set forth in:

(i) this Agreement;

(ii) any other agreement to be entered into in connection with the transactions contemplated hereby; and

(b) any Claim in respect of action taken or omitted to be taken by either of the Vendors in relation to the Patent Rights prior to the Effective Sale Date.

6.2 Covenants of Purchaser

Purchaser shall indemnify and save harmless the Vendors and the directors, officers, employees and agents of the Vendors from and against any and all Claims directly or indirectly suffered by either of the Vendors resulting from any breach by Purchaser of, or inaccuracy or misrepresentation contained in, any representation or warranty set forth in:

(i) this Agreement; and

(ii) any other agreement to he entered into in connection with the transactions contemplated hereby.

6.3 Indemnification Procedure

Each Party's agreement to indemnify and hold the other harmless is conditioned upon the indemnified Party (i) providing written notice to the indemnifying Party of any Claim, arising out of the indemnified activities within thirty (30) days after the indemnified Party has knowledge of such Claim, (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such Claim, (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation of and defense of any such Claim; and (iv) not compromising or settling such claim or demand without the indemnifying Party's prior written consent; provided that if the Party entitled to indemnification fails to promptly notify the indemnifying Party pursuant to the foregoing clause (i), the indemnifying Party will only be relieved of its indemnification obligation to the extent prejudiced by such failure.

6.4 Limitation of Liability

Except with respect to breaches of the obligations under Article 9, in no event shall either Party be liable for special, indirect or consequential damages, losses, costs, charges, claims, demands, fees or expenses of any nature or kind.

ARTICLE 7 - TECHNOLOGY TRANSFER

7.1 Technology Transfer

As of the Effective Sale Date, the Vendors and Purchaser will cooperate in the filing and execution of any and all documents necessary to effect the assignment to Purchaser of the Patent Rights, including the filing of assignments or other transfer of title covenants with the U.S. Patent and Trademark Office and foreign patent offices as applicable to the Patent Rights. Within thirty (30) days from the Effective Sale Date, the Vendors will notify all lawyers, patent agents, patent attorneys, and other patent professionals handling the prosecution of the Patent Rights to contact the Purchaser to provide an immediate status update on the Patent Rights and to prepare the documents necessary to transfer the Patent Rights to Purchaser. The cost of recording assignments of the Patent Rights will be borne by Purchaser. Within forty-five (45) days from the Effective Sale Date, the Vendors and their counsel will use their reasonable best efforts to transfer all files and supporting documents relating to the Patent Rights to Purchaser, including but not limited to, all initial invention disclosure documents, all documents sent to the U.S. Patent and Trademark Office and other patent granting authorities regarding inventions and claims, copies of all draft patent applications, copies of all filing or prosecution documents submitted to the patent offices, and all file wrappers. Conception notebooks and all other documents in the possession or under the control of either of the Vendors or their counsel relating to conception and/or reduction to practice, such as scientist notebooks shall be retained by the Vendors and made available to Purchaser upon Purchaser's reasonable request. All documents to be provided to Purchaser hereunder are to be sent by expedited delivery service.

ARTICLE 8 - PATENT MAINTENANCE AND PROSECUTION RESPONSIBILITIES

8.1 Patent Maintenance

On and after the Effective Sale Date, Purchaser will take responsibility for any action or proceeding involving the Patent Rights. The cost of recording the assignment of Patent Rights shall be borne solely by Purchaser. If Purchaser elects not to take such responsibility involving Patent Right(s) in a particular country then Purchaser will notify the Vendors thirty (30) days before the time the future action is due, and thereafter the Vendors may undertake **such** responsibility. If the Vendors elect to do so, Purchaser will grant any necessary authority to the Vendors. If the Vendors determine to take such responsibility, it shall do so at its own expense.

8.2 Notice of Infringement

Purchaser shall promptly notify the Vendors in writing of any infringement of any assigned Patent Right(s) of which it becomes aware.

8.3 Enforcement of Patents

Except as otherwise set forth in this Section, Purchaser may, but shall not be required to, prosecute any alleged infringement or threatened infringement of any assigned Patent Right(s) of which it is aware or which is brought to its attention. Purchaser shall act in its own name and at its own expense. If Purchaser has failed to prosecute under the first sentence of this Section with respect to alleged or threatened infringement relating to any Patent Right(s) (i) two (2) months after it has been notified in writing of such alleged infringement, or (ii) one (1) month before the time limit, if any, set forth in the Applicable Laws for the filing of such actions, whichever conies first, the Vendors may, but shall not be required to, prosecute any such alleged infringement or threatened infringement of any such Patent Rights. In any such event, the Vendors will be free to act in its own name and at its own expense. Upon Vendors prosecuting any such alleged infringement or threatened infringement, Purchaser agrees to cooperate in Vendors' efforts, including but not limited to acting as a named party in any litigation and/or transferring rights to Vendors only to the extent necessary to act as a valid party with standing for such litigation.

ARTICLE 9 - CONFIDENTIALITY

9.1 Disclosure and Use Restriction.

(3) Except as expressly provided herein, the Parties agree that each Party will keep completely confidential and will not publish, submit for publication or otherwise disclose, and will not use for any purpose except for the purposes contemplated by this Agreement, any Confidential Information received from the other Party. Notwithstanding the foregoing, the Purchaser may publish or disclose at the Purchaser's discretion technical or research data or results that are the Vendors' Confidential Information and that are customary to disclose in the life sciences industry for scientific or business reasons, provided that the data or results disclosed do not compromise the Vendors' Intellectual Property Rights, including trade secrets.

9.2 Authorized Disclosure.

(a) Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

(i) made in response to a valid order of a court of competent jurisdiction; provided, however, that such Party will first have given notice to such other Party and given such other Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order, as determined in good faith by counsel to the Party that is obligated to disclose Confidential Information pursuant to such order,

(ii) otherwise required by law or regulation; provided, however, that the Party that is so required will provide such other Party with notice of such disclosure in advance thereof to the extent practicable;

(iii) made by such Party to the Regulatory Authorities as necessary for the development or commercialization of a Product in a country, as required in connection with any filing, application or request for Regulatory Approval or as required by applicable securities laws and regulations; provided, however, that reasonable measures will be taken to assure confidential treatment of such information;

(iv) made by such Party, in connection with the performance of this Agreement, to such Party's Affiliates, or to directors, officers, employees, consultants, representatives or agents of such Party or its Affiliates, in each case on a need to know basis and solely for use of such information as permitted in this Agreement, and provided that each of the foregoing recipients prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9; or

(v) made by such Party to existing or potential acquirers; investment hankers; existing or potential investors, merger candidates, venture capital firms or other financial institutions or investors for purposes of obtaining financing; in each case on a need to know basis, and provided that each of the foregoing recipients prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9.

(b) In addition, the Purchaser may disclose Confidential Information of the Vendors to the extent that such disclosure is made to the Purchaser's existing or potential sublicensees, licensors, or potential collaborators or bona tide strategic partners, in each case on a need to know basis and solely for *use* of such information as permitted in this Agreement, and provided that the Purchaser causes each of the foregoing recipients must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9.

9.3 Press Releases.

Press releases or other similar public communication by either Party relating to this Agreement will be approved in advance by the other Party, which approval will not be unreasonably withheld or delayed. The Parties agree in advance that no financial terms related to this transaction will be disclosed in any press release related to or describing the transaction. Notwithstanding the foregoing, communications required by Applicable Law, and disclosures of information for which consent has previously been obtained will not require advance approval, but will be provided to the other Party as soon as practicable after the release or communication thereof.

ARTICLE 10 - GENERAL

10.1 Further Assurances

Each of the Vendors and Purchaser shall from time to time execute and deliver all such further documents and instruments and do all acts and things as the other Party may, either before or after the Effective Date, reasonably require to effectively carry out or better evidence or perfect the full intent and meaning of this Agreement, including, without limitation, the execution and delivery to Purchaser of one or more assignments. Without limiting the generality of the foregoing, this Agreement shall operate, without further act or formality, as a transfer to Purchaser for all purposes as at the Effective Sale Date of all the property and rights transferred and acquired hereunder. The Vendors shall forthwith and from time to time hereafter execute and deliver or cause to be executed and delivered to Purchaser all deeds, transfers, assignments and other instruments in writing and further assurances as Purchaser or its counsel shall reasonably require from any of them to effectuate such acquisition and transfer; and, for greater certainty, the Vendors shall hold all of the property and rights transferred and acquired hereunder, to the extent that the same shall not have been effectually transferred to or pursuant to this Agreement, in trust for and as the property of Purchaser pending effective transfer thereof. Purchaser proposes a reverse takeover of *** that will result in Purchaser shareholders controlling approximately *** of all *** shares, while not contemplated in the agreement, the Vendor agrees, and confirms approval of this transaction resulting in the merger of the two companies and change of business to a pharmaceutical research and development company.

ARTICLE 11 - MISCELLANEOUS

11.1 Assignment.

Without the prior written consent of the other Party hereto, neither Party will sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that. either Party hereto may assign or transfer this Agreement or any of its rights or obligations hereunder without the consent of the other Party to any Affiliate or to any Third Party successor in interest with which it has merged, consolidated, amalgamated, or combined, including by plan of arrangement, or to which it has transferred all or substantially all of its assets or stock to which this Agreement relates, if in any such event the assignee or surviving entity assumes in writing all of the assigning Party's obligations under this Agreement. Any purported assignment or transfer in violation of this Section 11.1 will be void ab initio and of no force or effect.

11.2 Severability.

If any provision of this Agreement is held to be illegal, invalid or unenforceable by a court of competent jurisdiction, such adjudication will not affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions will remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

11.3 Governing Law.

This Agreement will be governed by and construed in accordance with the laws of province of Alberta and the federal laws of Canada applicable therein without reference to any rules of conflicts of laws. The United Nations Convention on Contracts for the International Sale of Goods and any implementation of such Convention will not apply in any way to this Agreement or to the transactions contemplated by this Agreement or otherwise to create any rights or to impose any duties or obligations on any Party to this Agreement.

11.4 Dispute Resolution.

The Parties agree that, in the event of any dispute under this Agreement, the Parties shall first seek to resolve such dispute in good faith. If such dispute cannot be resolved despite the Parties' good faith efforts within a ninety (90) day period and a Party wishes to pursue the matter further, each such dispute, controversy or claim will be finally resolved by binding arbitration in accordance with and under the rules of the American Arbitration Association, and judgment on the arbitration award may be entered in any court having jurisdiction thereof The arbitration will be conducted by a panel of three persons experienced in the life sciences business. Within thirty (30) days after initiation of arbitration, each Party will select one person to act as arbitrator and the two Party- selected arbitrators will select a third arbitrator within thirty (30) days of their appointment. No individual will be appointed to arbitrate a dispute pursuant to this Agreement unless he or she agrees in writing to be bound by the provisions of this Section 11.4. The place of arbitration will be Orlando, Florida, or such other location as agreed by the Parties in writing. Either Party may apply to the arbitrators or to a court for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved.

11.5 Notices.

All notices or other communications that are required or permitted hereunder will be in writing and delivered personally with acknowledgement of receipt, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier as provided herein), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to the Purchaser, to:

Xortx Pharma Corp.
****

Attention: President & CEO
Facsimile:●
Email: ●

If to the Vendors, to:

Dr. Richard Johnson
***

or to such other address *as* the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication will be deemed to have been given (i) when delivered, if personally delivered or sent by facsimile or other means of electronic communication on a Business Day; (ii) on the Business Day after dispatch, if sent by nationally-recognized overnight courier, and (iii) on the fifth (5^{1h}) Business Day following the date of mailing, if sent by mail. Tt is understood and agreed that this Section 11.5 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of ibis Agreement.

11.6 Entire Agreement; Modifications.

This Agreement sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge will be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

11.7 Relationship of the Parties.

It is expressly agreed that the Parties will be independent contractors of one another and that the relationship between the Parties will not constitute a partnership, joint venture or agency.

11.8 Waiver.

Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. Any such waiver will not be deemed a waiver of any other right or breach hereunder.

11.9 Counterparts and Delivery.

This Agreement may be executed in two (2) 01 more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Delivery of an executed signature page to this Agreement by any Party by electronic transmission will be as effective as delivery of a manually executed copy of this Agreement by such Party.

11.10 No Benefit to Third Parties.

The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other parties.

11.11 Further Assurance.

Both Parties will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary to carry out the provisions and purposes of this Agreement.

11.12 Remedies not Exclusive.

The remedies provided to the Parties under this Agreement are cumulative and not exclusive to each other, and any such remedy will not be deemed or construed to affect any right which any of the Parties is entitled to seek at law, in equity or by statute.

11.13 Force Majeure.

The failure or delay of any Party to this Agreement to perform any obligation under this Agreement solely by reason of acts of God, acts of civil or military authority, civil disturbance, war, strikes or other labour disputes or disturbances, fire, transportation contingencies, shortage of facilities, fuel, energy, labour or materials, or laws, regulations, acts or orders of any governmental agency or official, other catastrophes, or any other circumstance beyond its reasonable control ("Force Majeure") will be deemed not to be a breach of this Agreement so long as the Party so prevented from complying with this Agreement has not contributed to such Force Majeure, has used reasonable efforts to avoid such Force Majeure or to ameliorate its effects, and continues to take all actions within its power to comply as fully as possible with the terns of this Agreement. In the event of any such Force Majeure, performance of the obligations will be deferred until the Force Majeure ceases. This Section will not apply to excuse a failure to make any payment when due.

11.14 Number and Gender.

Unless the context of this Agreement otherwise requires, to the extent necessary so that each clause will be given the most reasonable interpretation, the singular number will include the plural and vice versa, the verb will be construed as agreeing with the word so substituted, words importing the masculine gender will include the feminine and neuter genders, words importing persons will include firms and corporations and words importing firms and corporations will include individuals.

11.15 Headings and Captions.

The headings and captions of sections and paragraphs contained in this Agreement arc all inserted for convenience of reference only and are not to be considered when interpreting this Agreement.

11.16 Enurement.

Subject to the restrictions on transfer contained in this Agreement, this Agreement will enure to the benefit of and he binding on the Parties and their respective successors and permitted assigns.

11.17 Currency.

Unless otherwise indicated, all references to currency herein are to U.S. dollars.

IN WITNESS WHEREOF the Parties have executed this Agreement.

DR. RICHARD JOHNSON

per:

/s/ Dr. Richard Johnson

XORTX PHARMA CORP.

per:

/s/ Allen Davidoff

Name: Dr. Allen Davidoff
Title: President and CEO

[DR. TAKAHIKO NAKAGAWA]

per:

/s/ Dr. Takahiko Nakagawa

SCHEDULE A

PATENT RIGHTS

***

CERTAIN INFORMATION (INDICATED BY [***]) 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 REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Appendix E - Equity Agreement

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THIS EQUITY AGREEMENT (the "Agreement") is made effective the 23rd day of June, 2014 by and between the University of Florida Research Foundation, Inc. (hereinafter called "UFRF"), a non-stock, nonprofit Florida corporation, and XORTX Pharma Corp (hereinafter called "Licensee" or the "Company"), a corporation organized and existing under the laws of Canada.

WHEREAS, UFRF and Licensee have entered into certain License Agreements with respect to certain inventions owned by UFRF or in which UFRF has a joint, undivided interest;

WHEREAS, as an accommodation to Licensee, UFRF is willing to accept shares of common stock of Licensee in lieu of charging Licensee certain fees under the License Agreements.

NOW THEREFORE, in consideration of the mutual covenants and agreements set forth below, the parties covenant and agree as follows:

Section 1. Definitions

For the purpose of this Agreement, the Exhibit A definitions shall apply. Capitalized terms used and not otherwise defined herein shall have the meanings assigned thereto in the License Agreements.

Section 2. Issuance of Shares to UFRF: Closing Deliveries

2.1 Issuance of Shares***

2.1.1 Licensee will issue to UFRF, as of the Effective Date, *** shares of common stock of Licensee (collectively, the "First Shares"). License represents and warrants that the First shares equal *** of the total number of issued and outstanding shares of common stock of License on the Effective Date calculated on a Fully Diluted Basis.

2.1.2 License will issue to UFRF, as of the Effective Date, an additional *** shares of common stock of License (collectively, the "Second Shares"). Licensee represents and warrants that the Second Shares shall be equal to at least *** of the total number of shares of common stock of that are expected to be issued to meet the minimum in the Proposed Financing.

2.1.3 UFRF and Licensee agree that if the Proposed Financing is not completed on or before January 31, 2015, then License shall redeem, and UFRF shall set to License, all of the Second Shares for total consideration of ***. If, however, the Proposed Financing is completed on or before January 31, 2015, then Licensee shall not have the right pursuant to this Section 2.1.3 to redeem the Second Shares.

2.1.4 If, at any time after the Effective Date and before completion of the Proposed Financing or before License receives a total of *** cash in exchange for the issuance of Licensee's Equity Securities, Licensee issues any Equity Securities directly or through this Proposed Financing other than pursuant to the Proposed Financing, then License shall issue additional shares of common stock to UFRF such that immediately after such issuance to UFRF the total number of shares issued to UFRF under this Section constitutes *** of the total number of issued and outstanding shares of License calculated on a Fully Diluted Basis. License shall delver, or cause to be delivered, to UFRF a stock certificate, duly signed by appropriate officers of License and issued in UFRF's name, representing all of the Shares required to be issued to UFRF.

2.1.5 All Shares shall be fully-paid and non-assessable upon their issuance to UFRF. UFRF's execution of this Agreement and the License Agreements shall be deemed full consideration for the issuance of the Shares, and no additional consideration for such Shares shall be due from UFRF. No Shares shall be subject any restrictions on their transfer other than the restrictions specified in Exhibit C hereto.

2.1.6 If UFRF owns *** or less of the outstanding shares of common stock of Licensee, or will own *** or less as a result of an initial public offering by Licensee, but subject to the provisions of Section 6, UFRF's shares will not be subject to any lock-up requirement or other restriction on selling such shares, other than as required by law, in connection with the initial public offering or any public offering by License thereafter.

2.1.7 If prior to completion of the Proposed Financing Licensee, at any time while UFRF owns Shares, shall issue any shares of Licensee's common stock ("Additional Shares"), at a price per share less than the Investment Price (as defined below), then the number of Shares owned by UFRF shall be increased upon each such issuance by that amount (rounded to the nearest whole Share) determined by multiplying the number of Shares then owned by UFRF by a fraction:

(a) the numerator of which shall be equal to the number of shares of common stock outstanding immediately after the issuance of Additional Shares, and

(b) the denominator of which shall be equal to the sum of (A) the number of shares of common stock outstanding immediately prior to the issuance of Additional Shares plus (B) the number of shares of common stock (rounded to the nearest whole share) which the aggregate consideration for the total number of Additional Shares so issued would purchase at the Investment Price.

For purposes of this Section 2.1.5, "Investment Price" means the price per share paid by purchasers acquiring equity securities of the Licensee in a transaction for aggregate consideration of at least ***. The issuance of securities that are convertible into or exercisable or exchangeable for shares of Licensee's common stock shall be deemed an issuance of Additional Shares at such time if the consideration per share received by Licensee for the issuance of such convertible, exchangeable or exercisable security, plus the consideration per share payable to Licensee upon exercise, exchange or conversion thereof, is less than the Investment Price. In the event of a subdivision or combination of the outstanding common stock of Licensee, the Investment Price shall be increased or decreased proportionately.

No adjustment shall be made under this Section 2.1.5 with respect to the issuance of shares (a) to employees, consultants, officers or directors of Licensee pursuant to any bona fide stock option plan of Licensee approved by the Board of Directors, (b) upon any stock split or stock dividend, or (c) issued for fair value (as determined in good faith by the Board of Directors) pursuant to the acquisition of any other company by Licensee by merger or purchase of substantially all of the assets or other reorganization.

2.2 Closing Deliveries

2.2.1 On the Effective Date, Licensee shall deliver to UFRF a certificate from Licensee, dated as of the Effective Date and signed by the Secretary or an Assistant Secretary of Licensee, certifying that the attached copies of the Certificate of Incorporation, Bylaws of Licensee, and resolutions of the Board of Directors of Licensee approving the License Agreements, this Agreement and the transactions contemplated thereby, are all true, complete and correct and that such resolutions remain unamended and in full force and effect; and

2.2.2 Within 30 days of the Effective Date, Licensee must deliver to UFRF stock certificates representing each of the First Shares and the Second Shares, registered in the name of UFRF.

Section 3. Representations and Warranties

3.1 Representations and Warranties by License

Licensee represents and warrants to UFRF that:

3.1.1 Licensee is a duly organized and validly existing corporation under the laws of the Province of Alberta with adequate power and authority to conduct the business in which it is now engaged or currently proposed to be engaged. and Licensee is duly qualified to do business as a foreign corporation and is in good standing in such other states or jurisdictions as is necessary to enable it to carry on its business or own its properties.

3.1.2 There are no actions, suits, or proceedings pending or threatened against or affecting Licensee, its officers or directors in their capacity as such, its properties, or its patents in any court or before any governmental or administrative agency, which can have any material adverse effect on the business as now conducted or as currently proposed to be conducted, on the properties, the financial condition, or income of Licensee, or the transactions contemplated by this Agreement or the License Agreements and Licensee is not in default under any order or judgment of any court or governmental or administrative agency.

3.1.3 Licensee is not a party to any agreement or instrument, or subject to any charter, bylaw, or other corporate restrictions materially adversely affecting its business and operations, present or prospective, or its property, assets, or condition, financial or otherwise.

3.1.4 Licensee is not in default or breach in the performance, observance, or fulfillment of any of the obligations, covenants, or conditions contained in any bond, debenture. note, or other evidence of indebtedness or any contract or other agreement of Licensee.

3.1.5 This Agreement has been duly authorized, executed, and delivered on behalf of Licensee and constitutes the valid and binding agreement of Licensee, enforceable in accordance with its terms, and Licensee has full power and lawful authority to issue, sell, and repurchase the Shares on the terms and conditions herein set forth.

3.1.6 Consummation of the transactions contemplated by this Agreement in compliance with provisions of this Agreement will not result in any breach of any of the terms, conditions, or provisions of, or constitute a default under, or result in the creation of any lien, charge, or encumbrance on, any property or assets of Licensee pursuant to any indenture, mortgage, deed of trust, agreement, corporate charter, bylaws, contract, or other instrument to which Licensee is a party or by which Licensee may be bound or any law, rule, regulation, qualification, license, order or judgment applicable to Licensee or any of its property.

3.1.7 Licensee is in compliance with all federal, state and local environmental laws and there are no conditions currently existing or contemplated which are likely to subject Licensee to damages, penalties, injunctive relief. removal costs, remedial costs or cleanup costs under any such laws or assertions thereof.

3.1.8 Attached hereto as Exhibit B and hereby made a part hereof are the Articles of Incorporation (including any amendments thereto) Bylaws (including any amendments thereto) of Licensee in effect on the date hereof.***

3.1.9 Pursuant to its Articles of Incorporation wens e is authorized to issue unlimited shares of Common Stock, of which approximately *** shares are issued and outstanding. All issued and outstanding shares are, and the Shares issuable to UFRF will be, validly issued, fully paid and nonassessable, and are not subject to any preemptive rights. There are no other authorized or outstanding Equity Securities of any class, kind, or character, and there are no outstanding subscriptions, options, warrants, or other agreements, or commitments obligating Licensee to issue any additional shares of its capital stock of any class, or any options or rights with respect thereto, or any securities convertible into any shares of stock of any class. No person has any preemptive rights, rights of first refusal, “tag along” rights, rights of co-sale or any similar rights with respect to the issuance of the Shares contemplated hereby.

3.1.10 Attached hereto as Exhibit C and hereby made a part hereof is a list of all restrictions on the transfer of any Shares or other securities of Licensee and all agreements between any shareholders or convertible debt holders of Licensee regarding the valuation, voting or transfer of any Shares or other securities of Licensee.

3.1.11 Attached hereto as Exhibit D and hereby made a part hereof are the unaudited Financial Statements of Licensee for the year ended December 31, 2013. These financial statements are true and complete and are in accordance with the books and records of Licensee. As of the date of the most recent financial statements provided to UFRF under this Agreement, Licensee has no material liabilities, absolute or contingent, that are not reflected in such financial statements except obligations incurred in the ordinary course of business and the License Agreements.

3.1.12 Since the date of the most recent financial statements provided to UFRF under this Agreement, there has been no: (a) material adverse change in the condition, financial or otherwise, of Licensee other than changes in the ordinary course of business; (b) damage or loss, whether or not covered by insurance, materially and adversely affecting Licensee's properties or business taken as a whole; and (c) declaration or setting aside, or payment of any dividend or other distribution in respect of the stock of Licensee or any direct or indirect redemption, purchase or other acquisition of such shares.

3.1.13 Licensee has timely filed all tax returns and reports required to be filed by it. Licensee has timely paid all taxes, interest and penalties required to be paid pursuant to said returns or otherwise required to be paid by it.

3.1.14 Attached hereto as Exhibit E is a true and complete record of (i) issued and outstanding shares of Common Stock as of the Effective Date and the holders thereof, and (ii) shares issuable under options, warrants or other convertible equity or debt instruments outstanding as of the Effective Date, whether vested or non-vested, restricted or unrestricted, the holders thereof, the exercise price or conversion price thereof and an outline of all other material terms with respect thereto.

3.2 Representations and Warranties by UFRF

UFRF represents and warrants to Licensee that:

3.2.1 UFRF is acquiring the Shares for investment for its own account and not with a view to resale or distribution within the meaning of the Securities Act, and UFRF does not intend to divide its participation with other or to resell or otherwise dispose of all or any part of the Shares without registration under the Securities Act, except to Licensee or unless and until it determines at some future date that changed circumstances, not now in its contemplation, make such disposition advisable.

3.2.2 This Agreement has been duly authorized, executed, and delivered on behalf of UFRF and constitutes the valid and binding agreement of UFRF, enforceable in accordance with its terms, and UFRF has full power and lawful authority to acquire the Shares on the terms and conditions herein set forth.

3.3 Survival and Timing of Warranties

The warranties and representation made in this Section 3 shall survive the closing of any issuance of the Shares to UFRF. The warranties and representations made in this Section 3 shall be true and correct as of the date of this Agreement and as of the date the Shares are issued to UFRF.

Section 4. Miscellaneous Covenants

4.1 Financial Statements and Other Information

As long as UFRF owns any Equity Securities, Licensee shall promptly provide to UFRF such Financial Agreements, amendments to or restatements of its Articles of Incorporation or Bylaws, stock transfer restrictions and agreements among shareholders with respect to the valuation, transfer or voting of Shares and amendments thereto as may be effected from time to time, and such other information respecting the business, affairs, and financial condition of Licensee as UFRF may reasonably request, in each case as and when such information is provided to Licensee's other shareholders.

Until such time as the Proposed Financing is completed and Licensee through its merger with African Queen becomes a publicly reporting company, Financial Statements shall be provided to UFRF within the time that such Financial Statements are required to be provided to holders of preferred stock of Licensee and UFRF's representatives may visit and inspect any of the properties, books and information of Licensee, upon reasonable notice, during business hours and in a manner not disruptive to the business of the Licensee. If subsequent to the Proposed Financing being completed and Licensee becoming publicly reporting company through its merger with African Queen, Licensee is no longer a publicly reporting company, then UFRFs rights pursuant to this paragraph shall be reinstated.

4.2 Preemptive Rights

4.2.1 In addition to its other rights under this Agreement, but only until the Proposed Financing is completed, UFRF shall have a preemptive right to acquire such shares of Common Stock or other Equity Securities that may be issued, from time to time, by Licensee while UFRF remains the owner of Equity Securities. Such preemptive right shall apply with respect to all Equity Securities issued by Licensee after the Effective Date, whether such additional Equity Securities constitute a part of the Equity Securities presently or subsequently authorized or constitute Equity Securities held in the treasury of Licensee, and regardless of whether such Equity Securities are to be issued for cash, property (other than cash) or services. Such preemptive right shall not apply to (i) Equity Securities issued pursuant to the acquisition of another corporation or business entity by Licensee or one or more of its wholly owned subsidiaries by merger, consolidation, share exchange, purchase of substantially all the assets or other reorganization whereby the shareholders of Licensee immediately prior to the transaction owns in the aggregate more than *** of the voting power of Licensee or other surviving entity after the transaction; (ii) Equity Securities issued to employees, consultants or directors of Licensee pursuant to any incentive agreement or arrangement approved by the Board of Directors of Licensee in an amount up to *** of Licensee's then outstanding shares; (iii) Equity securities issued pursuant to any stock dividend, stock split, combination or other reclassification by Licensee of any of its capital stock; (iv) Equity Securities issued in connection with real or personal property leases or loans or lines of credit from financial institutions. UFRF may transfer all or part of the preemptive right described in this Section 4.2.1 to any entity to which UFRF has assigned its preemptive rights; or (v) the Proposed Financing.

4.2.2 In furtherance of the preemptive rights hereby granted UFRF, Licensee agrees to provide UFRF with not less than sixty (60) days prior written notice (an "Equity Security Issuance Notice") of its intent to issue any Equity Securities to which the preemptive rights in this Section 4.2 apply. Such notice should specify in reasonable detail the Equity Securities to be issued, including class, total number of shares and the applicable rights and preferences associated therewith, including, if applicable, conversion rights into Shares, and the purchase price for the Equity Securities UFRF may purchase pursuant to its preemptive rights hereby granted. UFRF shall have the right to acquire Equity Securities of the type being issued in an amount equal to UFRF's Proportionate Share Percentage of the aggregate Equity Securities of that type that are to be issued to all persons or entities pursuant to that issuance. The terms and conditions of UFRF's exercise of its preemptive rights, including the consideration to be paid for such Equity Securities, shall be no less favorable to UFRF than the most favorable price, terms and conditions offered to any other shareholder or prospective shareholder with respect to the Equity Securities then being issued.

4.2.3 In order to exercise UFRF's preemptive rights, UFRF shall deliver written notice thereof to Licensee within sixty (60) days following its receipt of the Equity Security Issuance Notice to which such exercise relates, accompanied by full payment of the purchase price for the Equity Securities to be purchased by UFRF in connection with the exercise of such preemptive rights. UFRF may, at its option, exercise such preemptive rights to some or all of the Equity Securities to which it has preemptive rights under this Section 4.2. In the event that any Equity Securities are to be issued by Licensee in return for property (other than cash) or services, in calculating the purchase price of the Equity Securities with respect to which UFRF has preemptive rights pursuant to this Section 4.2, the purchase price shall be equal to the fair market value of such property or services as determined in good faith by the Board of Directors of Licensee.

4.3 Issuance of Shares/Options to Affiliates/Founders

Licensee shall not issue any Equity Securities (including shares of Common Stock) to any of the shareholders of Licensee listed on Exhibit A attached hereto (the "Founders"), Affiliate thereof or Affiliate of Licensee for less than the fair market value of that security. Licensee shall have the burden of proving that the consideration to be paid for any such Equity Securities equals the fair market value of such Equity Securities issued.

4.4 Piggyback Registration Rights

4.4.1 As soon as practicable after a written request from UFRF to effect a registration with respect to all or part of the Shares owned by UFRF, Licensee will use its diligent best efforts to effect such Registration, cause it to become effective promptly and maintain it as effective for at least thirty six (36) months (or less if all the Shares included therein are sooner sold), provided, however, that no such request may be made until the six (6) month anniversary of the date that a Registration Statement covering an initial public offering of shares of Common Stock is declared effective by the Commission (the "Trigger Date"), except that this six-month period shall be extended to up to another six months if required by the underwriter for the initial public offering. if so requested by UFRF, Licensee shall enter into an underwriting agreement in customary form with any underwriter selected by UFRF with respect to such Registration. The provisions of this Section 4.4.1 shall terminate once the Shares owned by UFRF become eligible for sale in the United Sates without restriction pursuant to Rule 144 (the "Termination Date").

4.4.2 If, after the Trigger Date but prior to the Termination Date, the Licensee proposes to register the sale any of its securities with the Commission either for its own account or the account of a security holder or holders, other than a registration on any form which does not permit secondary sales, Licensee will promptly give UFRF written notice thereof and include in such Registration (and any related qualification under Blue Sky laws or other applicable laws), and in any underwriting involved therewith, all of the Shares specified in a written request made by UFRF within twenty (20) days after Licensee's written notice to UFRF.

4.4.3 All expenses incurred by Licensee and UFRF in connection with any Registration hereunder, including reasonable fees and disbursements of accountants and counsel for UFRF, but excluding underwriting discounts and commissions and transfer taxes, shall be borne solely by Licensee.

4.4.4 To the extent permitted by law, Licensee will indemnify UFRF and each of its officers, directors, and control persons ("UFRF indemnified parties") against all claims, losses, damages and liabilities ("Claims") arising out of on any untrue statement (or alleged untrue statement) of a material fact contained in any prospectus or other document incident to any such Registration, or any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading (to the extent not made in reliance upon written information furnished by UFRF specifically for use in such Registration) or any violation by Licensee of the Securities Act or the Exchange Act, and will reimburse each UFRF indemnified party for any legal and other expenses reasonably incurred in connection with investigating and defending or settling any such Claim.

4.5 Rule 144 Reporting

With a view to making available to UFRF the benefits of certain rules and regulations of the Commission which may permit UFRF to sell securities of Licensee to the public without registration, Licensee agrees to:

4.5.1 Make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act, at all times following the effective date of the first registration under the Securities Act filed by Licensee with the Commission for an offering of its securities to the general public;

4.5.2 Use its best efforts to file with the Commission in a timely manner all reports and other documents required of Licensee under the Securities Act and the Exchange Act at any time following registration of any of its securities under the Securities Act or Exchange Act; and

4.5.3 So long as UFRF owns any Shares, furnish to UFRF forthwith upon request a written statement by Licensee as to its compliance with the reporting requirements of Rule 144 (at any time following the effective date of the first registration statement filed by Licensee with the Commission for an offering of its securities to the general public), and of the Securities Act and the Exchange Act following registration of any of its securities under the Securities Act or Exchange Act, a copy of the most recent annual or quarterly report of Licensee, and such other reports and documents so filed as UFRF may reasonably request in availing itself of any rule or regulation of the Commission allowing UFRF to sell any such securities without registration.

4.6 Transfer or Assignment of Registration Rights

The rights to cause Licensee to register the securities granted to UFRF hereunder may be transferred or assigned by UFRF to a transferee or assignee of any of UFRF's Shares; provided, however, that such transfer or assignment of Shares was permitted under this Agreement.

Section 5. Tag-Along Rights

5.1 If at any time prior to an initial public offering, or Licensee becoming publicly traded through the Proposed Financing, any of the shareholders set forth on Exhibit E (the "Disposing Shareholders") propose to sell, in any one or more private transactions, capital stock of Licensee which, in the aggregate, represents more than fifty percent (50%) of the outstanding capital stock of Licensee on a fully-diluted basis to any one or more third parties (a "Third Party"), then UFRF shall have the right to participate (a "Tag-along Right") in such sale with respect to the Shares, on a pro rata basis for the same consideration per share and otherwise on the same terms as the Disposing Shareholders. If circumstances occur which give rise to the Tag-along Right, then the Disposing Shareholders shall give written notice to UFRF, providing the particulars of the proposed sale to the Third Party and advising UFRF of its Tag-along Rights. UFRF may exercise its Tag-along Right by written notice to the Company and the Disposing Shareholders within twenty-five (25) days of the date of mailing of the Disposing Shareholders' notice stating the number of shares that UFRF wishes to sell, up to the maximum permitted herein. If UFRF gives written notice indicating that it wishes to sell, UFRF shall be obligated to sell that number of Shares specified in its written acceptance notice upon the same terms and conditions as the Disposing Shareholders are selling to the Third Party and shall not be subject to the requirements of Section 8. For purposes of this Section 5, "pro rata" means the percentage derived by dividing the aggregate Shares then owned by UFRF by the aggregate Shares then owned by UFRF and the Disposing Shareholders. The Company agrees to cause its shareholders, including those persons who become shareholders, from time to time in the future, to enter into an agreement to carry out the provisions of this Section 5.1.

5.2 Upon receipt of such notice, Licensee shall tender the specified number of Shares, if any, at the same price applicable to the Transferring Shareholders in the transaction. In each case, tender shall be made upon the same terms and conditions applicable to the Transferring Shareholders in the transaction or, in the discretion of the acquirer or successor to Licensee, upon payment of the purchase price to the Shareholder in immediately available funds.

Section 6. Termination

6.1 Unless terminated sooner by either party as provided below, this Agreement shall terminate on the date that UFRF, after having been issued Shares hereunder, no longer owns any Equity Securities. If this Agreement terminates automatically as provided in this Section 7, the License Agreements shall remain in effect according to the terms specified therein.

6.2 If Licensee at any time fails to timely issue Shares to UFRF on a timely basis, or otherwise commits a material breach of this Agreement, or if any of the representations or warranties made by Licensee are untrue in any material respect as of any date on which they are required to be true and correct, and Licensee fails to remedy any such breach or default within thirty (30) days after written notice thereof by UFRF, UFRF may, at its option, terminate either this Agreement, the License Agreements, or all of them.

Section 7. Assignability

Except as set forth in Section 4.6, neither party may assign its rights or obligations under this Agreement, except that Licensee may assign this Agreement in connection with the sale of all or substantially all of the assets or stock of the Licensee, whether by merger, acquisition or otherwise, if the successor assumes all of the Licensee's obligations hereunder.

Section 8. Miscellaneous

This Agreement shall be construed exclusively in accordance with the internal laws of the State of Florida.

Section 9. Notices

Any notice required to be given pursuant to the provisions of this Agreement shall be in writing and shall be deemed to have been given at the earlier of the time when actually received as a consequence of any effective method of delivery, including but not limited to hand delivery, transmission by telecopier, or delivery by a professional courier service or the time when sent by certified or registered mail addressed to the party for whom intended at the address below or at such changed address as the party shall have specified by written notice, provided that any notice of change of address shall be effective only upon actual receipt:

to UFRF:

University of Florida Research Foundation, Inc.
204 Tigert Hall
PO Box 113100
Gainesville, Florida 32611-0001
Attention: President

with a copy to:

Office of Technology Licensing
University of Florida
Attention: Director
747 SW Second Avenue
PO Box 115575
Gainesville, Florida 32611-5575
Attention: Director

to Licensee:

with a copy to:

***

Section 10. Integration

This Agreement constitutes the full understanding between the parties with reference to the subject matter hereof, and no statements or agreements by or between the parties, whether orally or in writing, except as provided for elsewhere in this 10, made prior to or at the signing with respect to the subject matter hereof, shall vary or modify the written terms of this Agreement. Neither party shall claim any amendment, modification, or release from any provisions of this Agreement by mutual agreement, acknowledgment or otherwise, unless such mutual agreement is in writing, signed by the other party, and specifically states that it is an amendment to this Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement on the dates indicated below.

UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INC.

/s/ David L. Day Date: June 26, 2014

David L. Day
Director of Technology Licensing

XORTX Pharma Corp.

By: /s/ Allen Davidoff Date: June 23, 2014

Name and Office: Allen Davidoff, President & CEO

Reviewed by UFRF's Attorney:

(name typed)
(Attorney shall not be deemed a signatory to this Agreement.)

Exhibit A - Definitions In Equity Agreement

(1) "Common Stock" shall mean shares of Licensee's common stock, $0.50 par value per share.

(2) "Dollars" as used in this Agreement shall mean Canadian dollars.

(3) "License Agreements" shall mean the license agreements entered into between UFRF and Licensee of even date herewith pertaining to each Licensed Patent Group, as such term is defined in each License Agreement.

(4) "Affiliate" shall mean any person who is related by blood or marriage to any person or entity who owns more than twenty percent of the issued and outstanding shares of Licensee or to any officer, director, or employee of Licensee or any entity in which any such person has a direct or indirect beneficial ownership interest or for which any such person serves as a director, officer or employee.

(5) "Financial Statements" shall mean a balance sheet, and the related statements of earnings, stockholders' equity and cash flow as of the end of the last fiscal year that has been completed when the statements are to be provided to UFRF and a balance sheet and income statement as of the end of the last fiscal quarter, which financial statements shall be in the form and delivered at the time that such financial statements are delivered to holders of preferred stock of Licensee. Financial Statements shall be true and complete and prepared in accordance with the books and records of Licensee and with generally accepted accounting principles.

(6) "Equity Securities" shall mean the shares of Common Stock, any other capital stock of Licensee (including preferred shares), and any securities of Licensee that are convertible into capital stock of Licensee or that carry a right to subscribe to or acquire capital stock of Licensee.

(7) "Register," "Registered," and "Registration" shall refer to a registration for the sale of securities effected by preparing and filing with the Commission a Registration Statement in compliance with the Securities Act, and the declaration or ordering of the effectiveness of such Registration Statement by the Commission.

(8) "Registration Statement" means a registration statement filed under the Securities Act that covers the sale of any equity securities.

(9) "Proportionate Share Percentage" with respect to UFRF, for purposes of Section 4.2, shall mean the percentage derived by dividing the aggregate Shares then owned by UFRF by the total number of issued and outstanding Shares on an as-converted basis at such time.

(10) "Securities Act" shall mean the Securities Act of 1933, as amended, or any similar U.S. federal statute, and the rules and regulations of the Securities and Exchange Commission issued under such act, as they each may, from time to time, be in effect.

(11) "Commission" shall mean the U.S. Securities and Exchange Commission or any other U.S. federal agency at the time administering the Securities Act.

(12) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

(13) "Proposed Financing" means that certain transaction by and between Licensee and *** pursuant to which (a) Licensee shall be merged into *** (b) be the surviving entity, with the shareholders of Licensee immediately preceding the completion of the transaction owning more than 50% of the outstanding shares of *** immediately following completion of the merger before taking into account the shares of *** to be issued in the Proposed Financing and (c) upon the consummation of the transaction *** shall have received at least *** in capital form the sale of its securities in one or more financings completed by no later than January 31, 2015.

(14) "Shares" shall mean the shares of Common Stock issuable to UFRF under this Agreement (i.e. the First Shares and the Second Shares).

(15) "Fully Diluted Basis" means assuming the conversion of all outstanding convertible securities and the exercise of all outstanding options, warrants and other similar securities, regardless of whether such securities, options or warrants are then convertible or exercisable.

Exhibit C - Stock Restrictions

(1) Restrictive Legend.

Each certificate representing (i) the Shares and (ii) any other securities issued in respect of the Shares upon any stock split, stock dividend, recapitalization, merger, consolidation or similar event, shall (unless otherwise permitted by the provisions of Section (2) below) be stamped or otherwise imprinted with a legend in substantially the following form (in addition to any legend required under applicable state securities laws).

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THESE SECURITIES HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO DISTRIBUTION OR RESALE, AND MAY NOT BE SOLD, MORTGAGED, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND ANY APPLICABLE STATE SECURITIES LAWS, OR THE AVAILABILITY OF AN EXEMPTION FROM THE REGISTRATION PROVISIONS OF THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS.

Each holder consents to Licensee's making a notation on its records and giving instructions to any transfer agent of the Shares in order to implement the restrictions on transfer established in this Section (1). Such legend shall be removed by Licensee from any certificate at such time as the holder of the Shares represented by the certificate satisfies the requirements of Rule 144(k) under the Securities Act, provided that Rule 144(k) as then in effect does not differ substantially from Rule 144(k) as in effect as of the date of this Agreement and other applicable regulations do not then require such legend to be included on the Shares, and provided further that Licensee has received from the holder a written representation that (i) such holder is not an Affiliate of Licensee and has not been an Affiliate during the preceding three months, (ii) such holder has beneficially owned the Shares represented by the certificate for a period of at least two years, (iii) such holder otherwise satisfies the requirements of Rule 144(k) as then in effect with respect to such Shares, and (iv) such holder will submit the certificate for any such Shares to Licensee for reapplication of the legend at such time as the holder becomes an Affiliate of Licensee or otherwise ceases to satisfy the requirements of Rule 144(k) as then in effect.

(2) Notice of Proposed Transfers.

The holder of each certificate representing Shares by acceptance thereof agrees to comply in all respects with the provisions of this Section (2). Prior to any proposed sale, assignment, transfer or pledge of Shares, unless there is in effect a registration statement under the Securities Act covering the proposed transfer, the holder thereof shall give written notice to the Licensee of such holder's intention to effect such transfer, sale, assignment or pledge in sufficient detail. Each certificate evidencing the Shares transferred as above provided shall bear, except if such transfer is made pursuant to Rule 144, the appropriate restrictive legend set forth in Section **(1)** above. Prior to any transfer of the Shares in accordance with this Section (2), such transferee shall execute and deliver a form of agreement reasonably acceptable to the Licensee wherein the transferee agrees to be bound by the provisions of this Exhibit C.

(3) Transfer to Competitor.

No holder shall transfer any Shares to a competitor of Licensee, as determined by the Board of Directors of Licensee in good faith. This provision shall terminate after the closing of the sale of Equity Securities of Licensee registered with the Commission pursuant to a Registration Statement filed under the Securities Act.

CERTAIN INFORMATION (INDICATED BY [***]) 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 REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

SPONSORED RESEARCH AGREEMENT

This **SPONSORED RESEARCH AGREEMENT** ("Agreement") is effective this 27 day of May, 2021 (the "Effective Date") and made by and between XORTX Therapeutics Inc. ("Sponsor"), having a principal place of business at Calgary, Alberta, Canada, and Regents of the University of Colorado, a body corporate, for and on behalf of the University of Colorado Denver, a public institution of higher education created under the Constitution and the law of the State of Colorado ("Institution"), having administrative offices at University of Colorado Denver, Office of Grants and Contracts, Mail Stop F428, Anschutz Medical Campus Bldg 500, W1124, 13001 E 17th Place, Aurora, CO 80045.

WITNESSETH:

WHEREAS, the Sponsor desires research services in accordance with the scope of work described in the attached Appendix A of this Agreement (the "Research"); and

WHEREAS, the performance of such Research is consistent and compatible with and beneficial to the academic role and mission of the Institution as an institution of higher education;

NOW THEREFORE, in consideration of the mutual premises and covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto expressly agree as follows:

Article 1 - Definitions

For purposes of this Agreement, the following terms shall have the following meanings:

1.1 "Institution Intellectual Property" means all patentable inventions conceived or reduced to practice in the conduct of the Research, during the term of this Agreement, solely by Institution's staff, employees, advisors, and agents, including Principal Investigator (collectively "Personnel"), including all United States and foreign patent applications claiming said patentable inventions, including any divisional, continuation, and foreign equivalents thereof, as well as any patents issued thereon or reissues or reexaminations thereof. Institution Intellectual Property also includes all significant copyrightable software created by Institution personnel in the conduct of the Research during the term of this Agreement.

1.2 "Sponsor Intellectual Property" means all patentable inventions conceived or reduced to practice in the conduct of the Research, during the term of this Agreement, solely by any Sponsor's personnel, including all United States and foreign patent applications claiming said patentable inventions, including any divisional, continuation, and foreign equivalents thereof, as well as any patents issued thereon or reissues or reexaminations thereof. Sponsor Intellectual Property also includes all significant copyrightable software created solely by Sponsor's personnel without the use of Institution administered funds or facilities in the conduct of the Research during the term of this Agreement.

1.3 "Joint Intellectual Property" means all patentable inventions conceived or reduced to practice in the conduct of the Research, during the term of the Agreement, by both Institution Personnel and Sponsor personnel, including all United States and foreign patent applications claiming said patentable inventions, including any divisional, continuation, and foreign equivalents thereof, as well as any patents issued thereon or reissues or reexaminations thereof. Joint Intellectual Property also includes the Research Results and all significant copyrightable software created jointly by Institution Personnel and Sponsor's personnel during the term of this Agreement.

1.4 "Research Results" means all data and information which are generated in the performance of the Research during the term of this Agreement, and expressly excludes Institution Intellectual Property, Sponsor Intellectual Property, and any Joint Intellectual Property that is not any of the data and information which are generated in the performance of the Research.

Article 2 - Research work

2.1 Institution shall use reasonable efforts to conduct the Research in accordance with the terms and conditions of this Agreement, and shall furnish the facilities necessary to carry out the Research. Notwithstanding the foregoing, Institution does not guarantee specific results and the Research shall be conducted on a reasonable efforts basis.

2.2 The Research shall be carried out under the direction and supervision of Institution's employee, **** ("Principal Investigator").

2.3 Institution shall keep accurate financial and scientific records relating to the Research and shall make such records available to Sponsor or its authorized representative throughout the duration of the Agreement during normal business hours at mutually agreeable times.

Article 3 - Compensation

This is a cost reimbursement Agreement. As consideration for the performance by Institution of its obligations under this Agreement, and subject to the terms contained herein, Sponsor agrees to pay Institution no more than *** in accordance with the budget described in the attached Appendix B of this Agreement. Institution shall invoice Sponsor for actual costs incurred while performing the Research. Sponsor shall reimburse Institution within thirty (30) days of receiving invoices from Institution. Invoices shall be sent to the Sponsor at the following address: c/o XORTX Therapeutics Inc., Suite 4000. 421 – 7th Avenue S.W., Calgary, Alberta T2P 4K9.

3.2 All payment checks shall be made payable to University of Colorado Denver. All payment checks shall be forwarded to the following address:

University of Colorado Denver
Grants and Contracts, # 213120 - CF
PO Box 910238
Denver, Colorado 80291-0238
Tax I.D. Number: 84-6000555

Version date: 09/05/2019

Article 4 - Reporting Requirements

4.1 Unless otherwise agreed by Sponsor and Institution, Institution shall provide reports on the progress of the Research to Sponsor annually, or as otherwise set forth in Appendix A. Such reports shall indicate the work completed, the work to be performed during the next reporting period, any problems encountered, and the proposed solution for each problem.

4.2 Institution shall provide a final written report summarizing all of the results of the Research within ninety (90) days following the early termination or expiration of this Agreement.

Article 5 - Confidential Information

5.1 When used in this Agreement, "Confidential Information" means confidential and proprietary information of any kind disclosed by Sponsor to Institution for purposes of the Research, whether disclosed in writing, orally or visually. For greater certainty, information which is orally or visually disclosed, or written information that is not marked with a legend indicating its confidential status shall be considered confidential if it would be apparent to a reasonable person that such information is of a confidential or proprietary nature. Notwithstanding the foregoing, Confidential Information shall not include information that: (a) was in Institution's possession before receipt from Sponsor; (b) is or becomes a matter of public knowledge through no fault of Institution; (c) is received by Institution from a third party having an apparent bona fide right to disclose the information without a duty of confidentiality to Sponsor; or (d) is independently developed by Institution without use of the Confidential Information.

5.2 Institution shall use the Confidential Information solely for the purposes of the Research, and shall maintain the Confidential Information in confidence. Institution may disclose or permit disclosure of any of the Confidential Information to its Personnel who need to know such Confidential Information in the performance of the Research and who are bound by obligations of confidentiality and non-use at least as restrictive as set forth herein. Institution's obligations of confidentiality with respect to use and non-disclosure of Confidential Infon¯nation provided under this Agreement shall survive for a period of three (3) years following termination or expiration of this Agreement.

5.3 Nothing in this Agreement shall be construed to prevent Institution from disclosing Confidential Information as required by law or legal process, as long as Institution, if permitted by applicable law, promptly notifies Sponsor of its obligation to disclose and provides reasonable cooperation to Sponsor in any efforts to contest or limit the scope of the disclosure.

5.4 When the Confidential Information is no longer required for the purposes of this Agreement, Institution shall, at the direction of Sponsor, either destroy or return to Sponsor all Confidential Information. Notwithstanding the foregoing, Institution: (i) may retain a single copy of Confidential Information for the sole purpose of ascertaining its ongoing rights and responsibilities in respect of such information; and (ii) shall not be required to destroy any computer files stored securely by Institution that are created during automatic system back up.

Article 6 - Publication and Publicity

6.1 Institution shall be free to publish the results of the Research and shall furnish Sponsor a copy of any proposed presentation or publication thirty (30) days prior to submission, for the sole purpose of review and comment by Sponsor and to ensure non-disclosure of any of Sponsor's Confidential Information. In the event any of Sponsor's Confidential Information is contained in the publication, Institution shall remove such Confidential Information in any event, and shall also do so at Sponsor's written request. Upon written notice by Sponsor that Sponsor believes a patent application relating to the research under the Agreement should be amended or filed prior to any publication or presentation, Institution agrees to delay publication or presentation for an additional reasonable period of time, not to exceed sixty (60) days, to allow such protection to be obtained.

6.2 Except as may be required by applicable laws or regulations, neither Institution nor Sponsor may use the name, trademark, logo, symbol, or other image or trade name of the other party or its employees and agents in any advertisement, promotion, or other form of publicity or news release or in any way that implies endorsement without the prior written consent of an authorized representative of the party whose name is being used. Such approval will not be unreasonably withheld. Institution may acknowledge the Sponsor's support, including but not limited to financial support, as may be required by academic journals, professional societies, funding agencies, and applicable regulations.

Article 7 - Research Results and Intellectual Property

7.1 Sponsor shall retain the right to use Research Results disclosed to Sponsor for its purposes including, without limitation, as supporting documentation in pending patent applications as well as for orphan drug filings, IND and NDA filings and any new patent filings. Institution shall retain a non-exclusive, perpetual, royalty-free license to use the Research Results generated by Institution in the performance of this Agreement for its own non-commercial: (i) internal research, and (ii) educational purposes.

7.2 It is recognized and understood that certain existing inventions and technologies, and those arising outside of the Research, are the separate property of Sponsor or Institution and are not affected by this Agreement, and neither party shall have any claims to or rights in such separate inventions and technologies. Nothing contained in this Agreement shall be deemed to grant either directly by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either party.

7.3 Institution shall retain all right, title and interest in and to the Institution Intellectual Property and any patents, copyrights and other intellectual property and intellectual property protections related thereto. Sponsor shall retain all right, title and interest in and to the Sponsor Intellectual Property and any patents, copyrights, software and tangible research materials and other intellectual property and intellectual property protections related thereto. Institution and Sponsor shall jointly retain all right, title and interest in and to the Joint Intellectual Property and any patents, copyrights, software and tangible research materials and other intellectual property and intellectual property protections related thereto.

7.4 Institution shall promptly disclose to Sponsor any Institution Intellectual Property. Sponsor shall advise Institution in writing, no later than thirty (30) days after receipt of such disclosure, whether it shall elect an option to the Institution Intellectual Property. In consideration of Sponsor's funding of the Research and payment for expenses related to filing of any patent protection related to Institution Intellectual Property, Institution hereby grants Sponsor an exclusive option to negotiate to acquire a royalty-bearing license to practice Institution Intellectual Property ("Option Rights"), which option shall extend for one hundred eighty (180) days after Sponsor's election ("Option Period"). In no event shall Sponsor file a patent application naming any Institution Personnel without the Institution's prior written consent.

7.5 During the Option Period, the parties shall proceed in good faith to negotiate a license agreement. If Sponsor does not exercise this option, or notifies Institution that it will not exercise this option, or the parties fail to sign a license agreement within the Option Period, then Sponsor's Option Rights shall terminate and Institution shall have the right to license its interest in the Institution Intellectual Property without any further accounting or notification to Sponsor.

7.6 Institution shall promptly disclose to Sponsor any Joint Intellectual Property. In consideration of Institution performing the Research, Institution shall have, and Sponsor hereby grants to Institution an exclusive, perpetual, royalty-free license to practice Joint Intellectual Property (including the Research Results) for academic purposes only. In consideration of Sponsor's funding of the Research and payment for expenses related to filing of any patent protection related to Joint Intellectual Property, the Sponsor shall have, and Institution hereby grants to Sponsor an exclusive, perpetual, royalty-free license to practice Joint Intellectual Property (including the Research Results) for any non-academic purposes.

7.7 Any license granted to Sponsor pursuant to Section 7 hereof shall be subject, if applicable. to the rights of the United States government reserved under to all of the terms and conditions of 35 U.S.C. 200-212, ("The Bayh-Dole Act") and 37 C.F.R. 401, and any regulations issued thereunder.

Article 8 - Insurance, and Disclaimer of Warranties

8.1 Institution shall be responsible for its own acts or omissions or those of its officers or employees while performing their professional duties required under this Agreement to the full extent allowed by law. Notwithstanding any other provision of this Agreement to the contrary, no term or condition of this Agreement shall be construed or interpreted as a waiver, either express or implied, of any of the immunities, rights, benefits or protection provided to the Institution under governmental immunity laws from time to time applicable to the Institution, including, without limitation, the Colorado Governmental Immunity Act (CRS Section 24-10-101 through 24-10-120) and the Eleventh Amendment to the United States Constitution.

8.2 Each party represents that it has liability insurance for the protection of itself and its officers and employees while acting within the scope of their employment by the party.

8.3 NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER INCLUDING, WITHOUT LIMITATION, WARRANTIES WITH RESPECT TO THE CONDUCT, COMPLETION, SUCCESS OR PARTICULAR RESULTS OF THE RESEARCH, OR THE CONDITION, OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY INSTITUTION INTELLECTUAL PROPERTY OR SPONSOR INTELLE1'UAL PROPERTY (AS THE CASE MAY BE) OR RESEARCH RESULTS, OR THAT USE THE INSTITUTION INTELLECTUAL PROPERTY OR SPONSOR INTELLECTUAL PROPERTY (AS THE CASE MAY BE) OR THAT RESEARCH RESULTS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHT OF A THIRD PARTY. NEITHER PARTY SHALL BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, PUNITIVE OR OTHER DAMAGES SUFFERED RESULTING FROM THE RESEARCH OR THE USE OF ANY INTELLECTUAL PROPERTY, ANY RESEARCH RESULTS OR ANY PRODUCTS RESULTING THEREFROM.

Article 9 - Term and Termination

9.1 The initial tern of this Agreement shall begin on the Effective Date of this Agreement and shall end on March 1, 2024, unless terminated early in accordance with this Article 9. This Agreement may be extended or renewed only by mutual written agreement executed by duly authorized representatives of the parties.

9.2 The Agreement may be terminated by either party upon written notice delivered to the other party at least forty-five (45) days prior to the intended date of termination. Either party may terminate this Agreement effective upon written notice to the other party, if the other party breaches any of the terms or conditions of this Agreement and fails to cure such breach within thirty (30) days after receiving written notice of the breach.

9.3 In the event of termination of this Agreement prior to its stated term, whether for breach or for any other reason whatsoever, Institution shall be entitled to retain from the payments made by Sponsor prior to termination Institution's reasonable costs of concluding the work in progress. Allowable costs include, without limitation, all costs or non-cancellable commitments incurred prior to the receipt, or issuance, by Institution of the notice of termination, and the full cost of each employee, student and faculty member supported hereunder through the end of such commitments.

9.4 Termination of this Agreement shall not affect the rights and obligations of the parties accrued prior to termination. The provisions of Articles 3, 4.2, 5, 6, 7, 8, 9, 11, and 12, and any other terms which by their nature are intended to continue, shall survive termination.

Version date: 09/05/2019

Article 10 - Equipment and Other Materials

10.1 Title to any equipment, laboratory animals, or any other materials made or acquired with funds provided under this Agreement shall vest in Institution, and such equipment, laboratory animals, or materials shall remain the property of Institution following termination of this Agreement.

Article 11 - Export Controls

Notwithstanding any other provision of this Agreement, the parties understand and agree that they are subject to, and agree to abide by, any and all applicable United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities. It is the expectation of the parties that the work done pursuant to this Agreement shall constitute fundamental research and be exempt from export control licensing requirements under the applicable export control laws and regulations. The parties do not wish to take receipt of Export-Controlled Information except as may be knowingly and expressly agreed to in writing signed by an authorized representative of the parties and for which the parties have made specific arrangements. "Export Controlled Information" includes, without limitation, information subject to U.S. export control laws and regulations the requirements of the Arms Export Control Act, 22 U.S.C. 2751-2794, the International Traffic in Arms Regulation, 22 C.F.R. 120 et seq., the Export Administration Act, 50 U.S.C. app. 2401-2420, the Export Administration Regulations, 15 C.F.R. 730-77, Nuclear Regulatory Commission, 10 C.F.R. 110 and Department of Energy, 10 C.F.R 810. The parties agree to work together to ensure that, with regard to this Agreement, both are in compliance with any and all applicable U.S. export control laws and regulations, as well any and all embargoes and/or other restrictions imposed by the Treasury Department's Office of Foreign Asset Controls.

Article 12 - Miscellaneous

12.1 In the performance of all services hereunder, neither party is authorized or empowered to act as agent for the other for any purpose and shall not on behalf of the other enter into any contract, warranty, or representation as to any matter. Neither party shall be bound by the acts or conduct of the other.

12.2 Each party agrees that it shall comply with all applicable federal, state and local laws, codes, regulations, rules and orders in the performance and direction of the work contemplated under this Agreement.

12.3 This Agreement shall be governed and construed in accordance with the laws of the State of Colorado.

12.4 Neither party shall assign or transfer any interest in this Agreement, nor assign any claims for money due or to become due during this Agreement, without the prior written approval of the other party, which approval shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, Sponsor shall not breach this agreement if it assigns this agreement to a successor in interest or assignee of all the business or assets of the Sponsor to which this agreement pertains. Prior to any assignment, the following conditions must be met: (i) Sponsor must give Institution ten (10) days prior written notice of the assignment, including the new assignee's contact information; and (ii) the new assignee must agree in writing to Institution to be bound by this Agreement.

Version date: 09/05/2019

12.5 This Agreement constitutes the complete agreement of the parties with respect to the subject matter hereof. It expressly supersedes any prior or contemporaneous oral or written representations or agreements. This Agreement including any of the Appendices may not be altered, amended or modified except by written document signed by all parties. The failure of either of the parties at any time or times to require performance by the other of any provisions hereof shall in no manner affect the right of the first-mentioned party thereafter to enforce the same. The waiver by either of the parties of any breach of any provision hereof shall never be construed to be a waiver of any succeeding breach of such provision or a waiver of the provisions itself.

12.6 If any provision of this Agreement is judicially determined to be void or unenforceable, such provision shall be deemed to be severable from the other provisions of this Agreement which shall remain in full force and effect. Either party may request that a provision otherwise void or unenforceable be reformed so as to be valid and enforceable to the maximum extent permitted by law.

12.7 All notices required by this Agreement shall be by written instrument executed by the parties hereto and shall be directed to the following individuals:

For the Institution:	Original to:	*** Division of Renal Diseases 12700 E. 19th Ave, Renal Box C281 Aurora, CO 80045 (Phone) 303-724-4810 (Fax) 303-724-4868 (Email) ***
	Copy to:	University of Colorado Denver: Office of Grants and Contracts, MS F428 Anschutz Medical Campus, Bldg 500, W1124 13001 E. 17th Place Aurora, CO 80045 Phone: (303) 724-0090 Fax: (303) 724-0814 OGC.C'ontracts@ucdenver.edu Attention: Thomas Keith, Contracts Director
For Sponsor:	Original to:	XORTX Therapeutics Inc. do Suite 4000, 421 — 7th Avenue S.W. Calgary, Alberta T2P 4K9 Attention: Dr. Allen Davidoff (Phone): (403) 260-3500 (Fax): (403) 260-3501
	Copy to:	McCarthy Tetrault LLP Suite 4000, 421 —7th Avenue S.W. Calgary, Alberta T2P 4K9 Attention: Rick Pawluk (Phone): (403) 260-3500 (Fax): (403) 260-3501

12.8 In the event of any inconsistency between this Agreement and any other attachments or documents, this Agreement shall control.

12.9 Noncompliance by either party with the obligations of this Agreement due to force majeure, (laws or regulations of any government, war, civil commotion, pandemics, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers), or any other causes beyond the reasonable control of the applicable party, shall not constitute breach of this Agreement and such party shall be excused from performance hereunder to the extent and for the duration of such prevention, provided it first notifies the other party in writing of such prevention.

INTENTIONALLY LEFT BLANK

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives.

XORTX THERAPEUTICS INC.

By: /s/ Allen Davidoff

Name: Allen Davidoff

Title: CEO

Date: June 9, 2021

REGENTS OF THE UNIVERSITY OF COLORADO

By: /s/ Mike Conner

Name: Mike Conner

Title: Sr. Contracts Associate

Date: June 9, 2021

READ AND ACKNOWLEDGEMENT BY

Principal Investigator

By: ***

Name: ***

Title: Professor

Date: June 9, 2021

Version date: 09/05/2019

Appendix A — Scope of Work

***

Appendix B – Budget

***

Exhibit 4.20

CERTAIN INFORMATION (INDICATED BY [***]) 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 REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Combined Master Services Agreement

This Agreement is made on 19th July 2021

Between

(1) **Quotient Sciences Limited** a company registered in England and Wales with registered number 05221615 whose registered office is at Trent House, Mere Way, Ruddington Fields Business Park, Ruddington, Nottingham, NG11 6JS, United Kingdom ("**Quotient**"); and

(2) **XORTX Therapeutics Inc.** a company registered in British Columbia whose registered office is at Suite 4000, 421 — 7th Avenue S.W, Calgary, Alberta, T2P 4K9 ("**Customer**");

Recitals

(A) Quotient and its Affiliates are engaged in developing formulations and conduct of clinical research in relation to pharmaceutical products.

(B) Customer is engaged in developing pharmaceutical products.

(C) Quotient and Customer wish to establish an ongoing relationship under which, from time to time, Customer may request that Quotient performs research and other services in relation to the Customer's pharmaceutical products. They have agreed to contract to set out the terms of such relationship.

It is agreed

1. **Definitions ABPI** means the Association of British Pharmaceutical Industry in the United Kingdom.

Affiliate(s): For this Agreement, an Affiliate of a Party is any person, corporation, joint venture, or other business entity that directly (or indirectly through one or more intermediaries) controls, is controlled by, or is under common control with such Party. For the preceding definition only, the terms "controls," "controlled," and "control" shall mean possessing the power to direct or cause the direction of the management and policies of an entity, whether through ownership or control of stock (or other ownership interest), by contract, or otherwise.

Agreement means this Master Services Agreement and its appendices.

Background Material means any and all data, materials, formulation methods, software, know-how, and other Intellectual Property, trade secrets, product samples, prototypes, processes, analyses, reports, manufacturing techniques, compilations, research notes, technology, equipment, providers, inventions and/or discoveries which is/are in existence at the date of this Agreement or which is/are developed or arise(s) independently of any Research.

Background Intellectual Property means any Intellectual Property in relation to any Background Material.

Clinical Protocol means a protocol for the conduct of Clinical Research agreed in writing between the Parties.

Commencement Date means the date of this Agreement set out above.

Confidential Information means the Background Material, Intellectual Property and all information disclosed by one Party to the other in relation to the Research including, but not limited to, Research Output, Materials, the Clinical Protocol, communications with the competent authorities and Ethics Committees, customers, suppliers or employees, sales and marketing information.

Customer Data means documents, data and information relating to any Materials and/or Research.

Force Majeure means any circumstance beyond the reasonable control of the Party affected by it and includes, strikes, lockouts, industrial disputes, telecommunications failure, power supply failure, computer breakdown, restrictive government or judicial orders or decrees, riots, insurrection, war, terrorism, Acts of God and failure of suppliers to meet delivery requirements and absence of personnel due to illness or injury.

Good Clinical Practice means good clinical practice as set out in the ICH guidance on Good Clinical Practice as defined in ICH Guideline topic E6 on "Good Clinical Practice", Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use.

Good Manufacturing Practice means current good manufacturing practice as appropriate to the location where the Services are performed consistent with (i) Directive 2003/94/EC and the requirements defined in: The Rules Governing Medicinal Products in the European Community Volume 4, including the Investigational Medicinal Products Annex 13, and as applied to APIs for Use in Clinical Trials, as covered within the EU Guidance to Good Manufacturing Practice Part II, Section 19 and ICH Q7 Section 19 or (ii) good manufacturing regulations as set out by the US FDA.

Intellectual Property means all patents, trade marks or trading names (whether or not registered), rights in know-how, design rights (whether or not registered), copyright, database rights, rights in inventions and know-how, all applications for the same and all rights having equivalent or similar effect, in each case subsisting at any time, anywhere in the world.

Materials means any materials and/or substances which are the subject of Research.

Non-Cancellable Costs means any costs and/or expenses to which Quotient is committed by this Agreement or any Work Order on behalf of Customer and which cannot be cancelled. Such Non-Cancellable Costs will be detailed within the Work Order and shall always include Quotient's or Service Providers' costs of labour and/or materials during such delay.

Payment Schedule means the document set out at Appendix 2 of a Work Order.

Personal Data means personal data as defined under the UK Data Protection Act 2018 and any successor legislation and, where applicable, the General Data Protection Regulation *((EU) 2016/679)*.

Proposal means the proposal and costing document set out at Appendix 1 of a Work Order.

Regulations means the Medicines for Human Use (Clinical Trials) Regulations 2004.

Research means any clinical trial, study and/or services to be carried out by Quotient set out in the Proposal.

Research Output means any data, and/or materials produced by Quotient, in the course of and relating to Research (whether individually, collectively or jointly with the Customer and on whatever media), which it must deliver to the Customer under the Proposal, including, without limitation, any reports and case report forms, but excluding any Background Materials.

Service Providers means Affiliates, subcontractors (of whatever level) and agents of Quotient and their employees.

Sponsor has the meaning given to it in the Regulations.

Term means the period of five (5) years from the Commencement Date.

Trial Subject means a person who is administered and/or who consumes any Materials in connection with the Research.

Work Order means a document (in substantially the same form as that set out in Schedule 1) which has been issued by Quotient and agreed by both Parties as envisaged under Clause 2.1.

2. The Research

2.1 In consideration of the first Work Order the Parties agree that if, during the Term, Quotient will perform any particular trial, study and/or services for the Customer, a document in substantially the form set out in Schedule 1 to this Agreement will be completed and issued by Quotient in relation to such trial, study and/or services, and will be signed by both Parties. Each such Work Order will constitute a separate contract between the Parties for the performance by Quotient and its Service Providers of the Research, and the payment by the Customer of the amounts set out in the Proposal (and the performance by the Customer of it's other obligations), under this Agreement and the Work Order (to the exclusion of any other terms and/or conditions which the Customer may attempt or purport to impose).

2.2 Quotient and its Service Providers shall carry out all Research in accordance with the Agreement, the Work Order, relevant Clinical Protocol and with reasonable skill and care and in accordance with the Regulations appropriate to the jurisdiction where the Research is to be performed including, Good Clinical Practice, Good Manufacturing Practice, and according to all relevant ICH guidelines

2.3 Quotient must inform Customer within 2 days of any serious adverse events and significant deviations from, or breaches of the standards applied to the Services including Regulations, the Clinical Protocol and a Work Order of this Agreement, to enable Customer to meet its requirements for reporting such events to the applicable Regulatory Authority.

2.4 Quotient shall use its reasonable endeavours to carry out all Research and to deliver the Research Output in accordance with the Proposal.

2.5 All services to be provided by Quotient under this Agreement and any Work Order will be deemed provided at the Customer's request and the Customer accepts that it is responsible for verifying that those services are suitable for its own needs.

2.6 The Customer may prior to and/or during the performance of any Work Order under this Agreement and for the requisite period thereafter, audit Quotient's performance of any Research upon giving Quotient reasonable prior written notice. The Customer shall use its reasonable endeavours not to cause any disruption to Quotient's business in carrying out such audit.

2.7 The Customer shall ensure that its employees co-operate fully with Quotient and any Service Providers in relation to the provision of any Research (including without limitation complying with Quotient's normal and reasonable codes of staff and security practice whilst at Quotient's sites). The Customer shall comply with its obligations as set out in any Proposal promptly.

2.8 The Customer shall provide to Quotient:

(a) all information and support necessary to enable Quotient to fulfil its obligations under the Regulations in relation to the Research including completing any necessary applications or notifications to the regulatory authority under the Regulations, any Ethics Committee, any other investigator, any medical practitioner and/or any person subject to or connected with the Research; and

(b) during the Research and during preparing any report relating to the same, with all information and data relating to the safety and safe usage of the Materials, including and in particular all relevant preclinical and clinical pharmacovigilance information and data which it has in its possession and that relates to or may affect the Research, Materials, and/or the health and safety of any individual whether before after or during any clinical trial.

The Customer warrants that all such data and information is and will at all times be accurate, complete and not false or misleading.

2.9 Subject to this Clause 2.9, if a Work Order provides that Quotient will act as the Legal Representative of the Customer for the Research, Schedule 2 shall apply to that Work Order. To avoid doubt, the Customer agrees that it shall be the Sponsor in relation to all Research and that Quotient is not taking on any Sponsor obligations under this Agreement or any Work Order. The Customer shall ensure that it complies with its obligations under the Regulations and with all other applicable laws and regulations. The Customer acknowledges that it shall be solely responsible for ensuring that it has all licences, permissions and authorisations necessary to carry out and to allow Quotient to carry out all Research and that any Clinical Protocol reflects all the requirements of the Regulations.

2.10 Use of Affiliates.

The Parties Agree that:

(a) Quotient may use the services of Quotient's Affiliate(s) to fulfil Quotient obligations under this Agreement. In such event:

(i) the Quotient Affiliate is to be identified on the Work Order they will be performing under;

(ii) any Quotient Affiliate completing Research shall be bound by the terms applicable to Quotient under this Agreement and entitled to the rights and protections afforded Quotient under this Agreement; and

(iii) Quotient shall be responsible for the performance of its Affiliate.

(b) Customer's Affiliate may use the services of Quotient (and its Affiliate) and such Customer Affiliate may enter into Work Orders with Quotient under this Agreement. In such event:

(i) the Customer Affiliate is to be identified on the Work Order the Research will be performed under;

(ii) Customer's Affiliate(s) shall be bound by the terms applicable to Customer under this Agreement and entitled to all rights and protections afforded Customer under this Agreement; and

(iii) Customer shall be responsible for the performance of its Affiliate.

(c) Customer may directly retain a Quotient Affiliate for the performance of Research under this Agreement, by such Quotient Affiliate entering into a Work Order to perform Research. Each Quotient Affiliate that enters into a Work Order shall be bound by this Agreement and shall have the rights and obligations of Quotient under this Agreement regarding such Work Order. The execution of a Work Order between Customer and Quotient Affiliate shall be evidence of their consent to be so bound.

(d) Notwithstanding anything to the contrary herein, Quotient shall have no liability regarding any Work Order entered into directly between Customer and a Quotient Affiliate except as otherwise agreed in writing.

2.11 The Customer shall promptly notify Quotient of these events in relation to the Research to enable Company to comply with its regulatory obligations under FDA Final Rule on 21 CFR 320, published in the Federal Register of 28 April 1993 for retention of bioavailability and bioequivalence reserve samples:

(a) discontinuance of the development of the Research Output;

(b) submission of an application for approval of the Research Output;

(c) date of approval of an application for the Research Output;

(d) withdrawal of an application for the Research Output; and

(e) date of communication from the regulatory authority documenting that the application is not approved for the Research Output.

2.12 Quality Unit

All GMP and GCP Research will be conducted under the oversight of the Quotient Quality Unit. A quality agreement will be completed between Quotient and Customer, prior to any GMP or GCP activities.

3. Payment

3.1 The Customer shall pay all Quotient's invoices within 30 days from the date of such invoice.

3.2 Quotient shall send all invoices to the Customer in accordance with the Payment Schedule. All charges set out in this Agreement and/or any Work Order are exclusive of Value Added Tax or any similar taxes, levies or duties, for which the Customer will be additionally liable.

3.3 If any undisputed payment due to be made under this Agreement and/or a Work Order is unpaid for 30 days after receipt of the invoice:

(a) Quotient reserves the right to charge interest thereon, after and before any judgement, on a day to day basis at an annual rate of 4% above the National Westminster Bank plc's base rate until the sum is paid; and

(b) Quotient may suspend all work under this Agreement and any Work Order until payment has been made or arrangements as to payment or credit have been established which are satisfactory to Quotient, provided that the safety and well-being of Trial Subjects is not put at risk.

3.4 Quotient's base currency is GBP. Where the project budget is specified in another currency (e.g. USD or Euros), the exchange rate used to calculate the budget will be specified in the Work Order or Proposal (the "Reference Exchange Rate"). If a movement in exchange rates occurs (as shown at www.xe.com) of greater than 5% from the Reference Exchange Rate during the term of the project, Quotient reserves the right to re-calculate any project milestones yet to be invoiced based upon the prevailing exchange rates.

4. Supply of Materials and Customer Data

4.1 The Customer shall promptly supply to Quotient, free, all Materials and a copy of Customer Data reasonably required by Quotient to enable it to perform the Research and authorises Quotient and its Service Providers to use, modify and copy the same to the extent necessary to enable Quotient to carry out such Research.

4.2 Quotient shall ensure that it uses Materials and Customer Data solely to carry out the Research. Title and risk of loss to Materials supplied by Customer shall remain with Customer while such items are in the possession of Quotient and during the services, and Quotient shall have no obligation to insure such Materials against any loss or damage.

4.3 Quotient shall maintain accurate records of its use, storage; handling and administration of Materials and shall supply the Customer with copies thereof upon reasonable written request.

4.4 As soon as is reasonably practicable following completion of the the Customer shall provide instructions to Quotient in writing to return to the Customer or dispose of at the Customer's expense, any Materials which remain unused and any copies of Customer Data provided to it by the Customer under this Agreement in Quotient's possession or control, save that Quotient may retain one copy for internal audit or regulatory processes.. If after sixty days Customer has not taken possession or provided instructions regarding such Materials, they will be considered abandoned and may be discarded according to Quotient's established procedures. If needed, Customer will be billed for any fees associate with disposition of these materials, components or equipment at cost + 10%.

4.5 The Customer warrants it has the right to give to Quotient all Materials and Customer Data which it provides to Quotient and that the use by Quotient and its Service Providers of such Materials and/or Customer Data will not the infringe the Intellectual Property or other rights of any person.

5. Confidentiality

5.1 Subject to Clauses 5.2 and 7.1, each Party warrants, represents and undertakes to keep confidential and not to disclose any Confidential Information of the other Party, except to its Affiliates and to those of its employees (and in the case of Quotient any Service Providers) who must have access to such confidential information to perform the obligations under this Agreement and/or any Work Order and who have been informed of the confidential nature of such information. The obligations set out *in* Clause 5.1 shall not apply to any Confidential Information which:

(a) at the date of its disclosure is in the public domain or which enters the public domain through no act or omission by the receiving Party;

(b) at the date of its disclosure is already known to the receiving Party;

(c) is independently developed by the receiving Party or is lawfully disclosed to the receiving Party by a third party; or

(d) must be disclosed by the receiving Party to comply with a legal obligation.

In relation to any information created by (rather than disclosed to) one Party but which is, under this Agreement and/or any Work Order, deemed to be the Confidential Information of the other Party on creation, any reference in Clauses 5.2 (a) to (b) above to "disclosure" shall mean "creation" and to "receiving Party" shall mean "creating Party".

5.2 All confidential information containing Personal Data will be handled in accordance with applicable law and the Data Privacy Addendum at the Appendix 3 of the Work Order.

6. Intellectual Property

6.1 Subject to Clauses 6.3, 6.5 and 6.6 and subject to the payment in full by the Customer to Quotient of all sums due under this Agreement and/or any Work Order, Quotient shall assign to Customer all their right, title and interest in and to any Research Output and the Intellectual Property rights.

6.2 At the request and expense of the Customer, Quotient shall do all such things and sign all documents or instruments reasonably necessary to vest in the Customer the rights in Research Output assigned under Clause 6.1.

6.3 Save as set out in Clauses 6.4 and 6.5, nothing in this Agreement and/or any Work Order shall transfer or grant any right, title or interest to any Background Material and/or Background Intellectual Property of either Party to the other Party.

6.4 The Customer grants to Quotient a royalty-free, non-exclusive licence to use the Customer's Background Intellectual Property solely to the extent necessary for Quotient to perform its obligations set out in this Agreement and/or any Work Order.

6.5 Quotient grants to the Customer a royalty-free, non-exclusive licence to use Quotient's Background Intellectual Property solely to the extent necessary for the Customer to use and/or develop any Research Output without restriction. Quotient shall own any improvements to its Background Intellectual Property arising and/or developed by it in the performance of this Agreement and/or any Work Order and shall be entitled to use and exploit as it deems fit any skills, techniques, concepts or know-how acquired, developed or used while performing any Research.

7. Publication

7.1 Quotient may publish the results of any Research, subject to the Customer's prior written consent, which shall not be unreasonably withheld or delayed. Following the receipt of such consent, Quotient shall submit a copy of the proposed publication to the Customer who shall have 30 days in which to request amendments which, if such proposed amendments are reasonable, Quotient shall have to incorporate before such publication. Customer may require Quotient to remove information or data which may impair Customer's ability to obtain patent protection or may be reasonably assumed to be a trade secret. In such circumstances, Quotient Sciences agrees to delay the proposed publication for an additional sixty (60) days to enable Customer to seek patent protection.

7.2 The Customer undertakes that, before publication of any information, article, paper, report or other material about any Research, it will submit a copy of such publication to Quotient who shall have 30 days in which to request amendments thereto which, if such proposed amendment are reasonable, the Customer shall have to incorporate before such publication.

8. Delays

8.1 If any part of any Research is delayed at the request of the Customer or due to the act or omission of the Customer or due to any delay in approving the Research by any regulator, ethics committee or similar body, then the Customer shall pay to Quotient any losses and increased costs and expenses including any Non-Cancellable Costs.

8.2 Quotient shall use its reasonable endeavours to mitigate the losses, costs and expenses referred to in Clause 8.1.

9. Duration and Termination

9.1 This Agreement shall come into force on the Commencement Date and shall, unless terminated earlier under the provisions of this Clause 9 (and subject to Clause 9.9) below, remain in force for the Term or until the Customer has received the final Research Output to be delivered by Quotient, and Quotient has received all sums payable to it, under this Agreement and all Work Orders. To avoid doubt, each Work Order shall come into force on the date it has been signed by both Parties and shall (subject to earlier termination under this Section 9 and to the provisions of Clause 9.9) remain in force until the Customer has received the Research Output to be delivered by Quotient, and Quotient has received all sums payable to it, under that Work Order.

9.2 Either Party may terminate this Agreement, and/or any Work Order (and the relevant Research), forthwith by giving thirty (30) days' notice in writing to the other Party if the other Party, (being a company) enters into liquidation or a provisional liquidator is appointed regarding it, shall pass a resolution or suffer an order of a court to be made for its winding up, or if a receiver, administrator, administrative receiver or manager or similar officer is appointed regarding the whole or any part of its assets, or if a notice of intention to appoint an administrator or an application to appoint an administrator shall be presented or filed regarding it, or (being an individual or partnership) the other shall suspend payment or propose to enter into any composition with creditors or become unable to pay its debts (or have no reasonable prospect of doing so) or suffer a bankruptcy order or if anything analogous or similar to the above occurs to the other in any jurisdiction.

9.3 Either Party may terminate a specific Work Order (and the Research), forthwith by giving notice in writing to the other party, if such party is in material breach of that Work Order and (where the breach is capable of remedy) fails to remedy the same within thirty (30) days of a request specifying the breach and requiring it to be remedied.

9.4 Subject to Clause 9.5, the Customer may terminate this Agreement or any Work Order (and the Research) on giving Quotient not less than thirty (30) days' notice in writing.

9.5 On termination of any Work Order (whether by termination of the Agreement or by termination of that Work Order) the Customer shall pay to Quotient (in full without set off or deduction of any kind) any:

(a) amounts which Quotient has invoiced to the Customer but which remain unpaid at the date of termination and/or which Quotient may invoice under the Payment Schedule; and

(b) reimburse and/or pay (as appropriate) to Quotient all losses, liabilities, Non-Cancellable Costs, third-party costs and expenses (always including the cost of labour and/or materials as set out in the Proposal):

(i) incurred by Quotient because of such termination;

(ii) which have been incurred regarding the Research at the date of termination but not yet invoiced; and/or

(iii) which Quotient has not yet incurred but will incur in the future regarding the Research; and

provided that any payment made under this Clause 9.6 shall not exceed the total amount set out in the Proposal

9.6 Quotient shall use its reasonable endeavours to mitigate the losses, costs *and* expenses referred to in Clause 9.5(b).

9.7 Termination of this Agreement and/or any Work Order shall be without prejudice to all rights and remedies which have accrued before such termination. Any provision of this Agreement and/or any Work Order which expressly or by implication should survive (including, without limitation, Clauses 1, 2.3, 2.7, 2.9, 2.11, 3.1, 3.35.1, 6.5, 8.1, 9.5, 9.8, 10.1, 10.2 and Sections 11, 12, 14 and 15) shall survive the expiry or sooner termination of this Agreement or that Work Order (as applicable). To avoid doubt, if this Agreement terminates, each Work Order shall terminate, it being understood and agreed that termination or expiry of one Work Order shall not of itself affect the continuation of another Work Order or (subject to Clause 8.1 above) this Agreement.

10. Indemnity

10.1 The Customer as Sponsor confirms that it accepts its obligations to compensate Trial Subjects in line with the Regulations and the ABPI Guidelines for Phase 1 Clinical Trials published in 2018 and any guidelines referenced, including but not limited to the Guidance for Insurance and Compensation in the event of injury in Phase I clinical trials and the Clinical Trial Compensation Guidelines issued in November 2014, and any further amendments to these Guidelines as appropriate.

10.2 The Customer shall indemnify and keep indemnified Quotient and shall pay such sums to Quotient as would keep Quotient's employees and Service Providers indemnified, from and against any and all losses, costs, expenses (including legal expenses), claims, damages and liabilities (collectively "Losses") arising out of or in connection with any claim made by a third party which arises out of the performance of the Research and/or administration to, and/or consumption by, any person of any Materials during any Research provided that the Customer shall not be liable under this Clause 10.2 for any Losses to the extent that these are directly caused by the failure of Quotient or of any Service Provider to comply with the Clinical Protocol for the Research or to observe Good Clinical Practice.

10.3 The Customer shall indemnify and keep indemnified Quotient against all Losses arising out of a breach by the Customer of any laws or Regulations in relation to any Research and/or the Materials including its obligations as Sponsor of any Research under the Regulations.

10.4 The Customer shall indemnify and keep indemnified Quotient in respect of any Losses incurred by Quotient and/or any Service Provider due to any third party allegation or claim that any such use referred to at Section 4 infringes the Intellectual Property of any third party.

10.5 Subject to Clause 12, Quotient shall indemnify and keep indemnified the Customer against all Losses arising out of any claim made by a third party which arises out of the administration to a Trial Subject of any Materials during the course of Research to the extent that this is directly due to Quotient's failure to comply with the Clinical Protocol for the Research or to observe Good Clinical Practice in administering the Materials as part of that Research.

10.6 If either Party receives written notice of any third party claim which may cause a right to indemnification from the other Party, the Party seeking indemnification (the "Indemnified Party") shall give written notice thereof to the other Party (the "Indemnifying Party") setting forth the nature and amount of the claim and the basis of the claim for indemnification. The Indemnifying Party, and/or its insurers, may, upon written notice to the Indemnified Party within thirty (30) days of its receipt of the claim for indemnification, subject to the Indemnified Party providing such security as to costs and damages as may reasonably be required, elect to assume defence of the claim; provided, however, that the Indemnifying Party may not, in defence of such claim, consent to the entry of any judgment or enter into any settlement without the consent of the Indemnified Party which does not include, as an unconditional term thereof, a full release of the Indemnified Party in respect thereof. If the Indemnifying Party elects to assume the defence of the third party claim, the Indemnified Party may retain legal counsel at its own expense to participate in the defence; provided, however, that the Indemnifying Party shall be liable to the Indemnified Party for any legal or other expenses incurred by the Indemnified Party in connection with its subsequent assumption of the defence at the request of the Indemnifying Party. If the Indemnifying Party does not elect to assume control of the defence, the Indemnified Party will allow the Indemnifying Party to participate in such defence, at the Indemnifying Party's own cost and expense, and will not settle or otherwise dispose of the claim without the consent of the Indemnifying Party, which such consent shall not be withheld unreasonably.

11. Insurance

11.1 Each party shall secure and maintain in full force and effect throughout the term of this Agreement appropriate insurance coverage for its responsibilities in connection with this Agreement.

11.2 Where applicable the Customer shall maintain in force a no fault clinical trials insurance coverage policy with a reputable insurer to provide coverage to Trial Subjects sustaining bodily injury as a result of their participation in the Research and the use of the Materials. Such cover shall provide for a minimum cover of GBP five million (£5,000,000). Customer will provide indemnity to Quotient in this regard and in accordance with Section 10, Indemnity and upon Quotient's request shall provide for Quotient's and/or Ethics Committee review, policy documents, certificates and any other relevant documents, as required, evidencing such insurance.

12. Limitation of Liability

12.1 Nothing in this Agreement or any Work Order shall exclude or restrict either Party's liability for death or personal injury caused by that Party's negligence, for fraudulent misrepresentation, or to the extent that any restriction or exclusion of liability is prohibited by law.

12.2 Subject to Clause 12.1, in no event shall Quotient be liable in contract (including under any indemnity), tort (including negligence), breach of statutory duty or otherwise howsoever for;

(a) any loss of profit, loss of business, loss of goodwill, loss of contracts, loss of revenues or loss of anticipated savings;

(b) any increased costs or expenses; or

(c) any special, indirect, or consequential loss or damage of any nature, whatever the cause thereof

in each case arising out of or in connection with this Agreement or any Work Order.

12.3 Subject to Clause 12.1, the entire liability of Quotient to the Customer arising out of or in connection with a relevant Work Order, whether arising from contract (including under any indemnity), tort (including negligence), or otherwise, shall not exceed the amount stipulated in the Proposal for that Work Order as to be paid by the Customer to Quotient.

12.4 The Customer accepts that Quotient cannot act other than in accordance with the terms of any authorisation issued by a regulatory authority for any Research *and* in accordance with the Regulations and all other relevant legal duties and obligations. Accordingly Quotient is not responsible for, and shall have no liability to the Customer for, any delay, damage, liability or loss of or to the Customer (whether arising in contract, tort (including negligence) or otherwise) arising from the actions or failure to act of any regulatory authority or Ethics Committee or because of Quotient complying with its obligations under the Regulations or other legal duty or obligation including any obligation to provide notice or information to others regarding any Research and/or any obligation to safeguard the health and safety of any of its employees, Trial Subject or any other person who may be affected by any such trial.

13. Debarment

13.1 Quotient certifies that it nor any of its employees have not been debarred, and have not been convicted of a crime which could lead to debarment of its provision of services under this Agreement in any relevant jurisdiction in accordance with the Regulations.

13.2 If Quotient or any Quotient employee becomes debarred or receives notice of action or threat of action regarding its debarment, Quotient shall notify Customer immediately.

13.3 Quotient certifies that it has not utilised, and shall not use the services of any individual in the performance of services under this Agreement or any Work Order that has been debarred or that has been convicted of a crime which could lead to debarment in any relevant jurisdiction in accordance with the Regulations.

14. Interpretation

14.1 Any references in this Agreement to Clauses or Schedules are to Clauses of, or Schedules to, this Agreement, and references in a Schedule or part of a Schedule to a paragraph are to paragraphs of that Schedule or part of that Schedule. The Schedules shall have effect as part of this Agreement.

14.2 Headings shall be ignored in construing this Agreement and/or any Work Order.

14.3 References to a statute or statutory provision includes that provision as from time to time modified or re-enacted or consolidated whether before or after this Agreement and any statutory instrument, order, by-law or other provision that may have been or may be made under it from time to time.

14.4 In the case of conflict or ambiguity, the order of precedence for this Agreement and the documents attached to or referred to in this Agreement shall be:

(a) the Clinical Protocol

(b) the Clauses of these terms; and

(c) the Schedules to this Agreement;

provided that, if any conflict occurs or inconsistency between a term of this Agreement and a term of a Work Order, the term of the Work Order shall (to interpret that Work Order) prevail.

14.5 All references to time in this Agreement and/or any Work Order are to UK time. A reference to "Business Days" are to any day other than a Saturday, Sunday or public holiday in England.

14.6 Unless the context otherwise requires, any reference in this Agreement or a Work Order to a "Party" shall be to one party thereto (and reference to "Parties" shall be construed accordingly).

15. General

15.1 Each Party warrants it shall not directly or indirectly pay or promise to pay, or authorise the payment of any money, or give, promise to give or authorise giving anything of value on behalf of the other Party to any person or entity, including any government official, political party, healthcare professional or person affiliated with a healthcare organisation, for (a) obtaining or retaining business or securing an improper advantage, or (b) influencing their acts or decisions, or (c) influencing such person or political party to use its influence with a government or any of its instrumentality, or iv) for any other purpose prohibited by public policies and any applicable anti-bribery laws, including the UK Bribery Act 2010 and industry and all other applicable professionals codes governing anti-bribery and anti-kickback practices.

15.2 Quotient will upon written notice to the Customer, and with Customer agreement, be entitled to sub-contract all or any of its obligations and to assign and/or novate all or any of its rights and/or obligations under this Agreement and/or any Work Order to any person.

15.3 The Customer shall not, without the prior written agreement of Quotient, assign, novate, transfer sub-contract or otherwise dispose of the Customer's rights or obligations arising under this Agreement and/or any Work Order.

15.4 Neither Party shall be liable for any failure to perform, or delay in performing, any of its obligations (other than payment and indemnity obligations) if and to the extent that the failure or delay is caused by Force Majeure and the time for performance of the obligation, the performance of which is affected by Force Majeure, shall be extended accordingly.

15.5 This Agreement (with all other documents to be entered into under it) sets out the entire agreement and understanding between the Parties in connection with the subject thereof, and supersedes all proposals and prior agreements, arrangements and understandings between the Parties.

15.6 Each Party acknowledges that in entering into this Agreement and/or any Work Order (and any other document to be entered into under it) it does not rely on any representation, warranty, collateral contract or other assurance of any person (whether Party to this Agreement or otherwise) that is not set out in this Agreement or that Work Order (as applicable) or any document referred to in it. Each Party waives all rights and remedies which, but for this Clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance. The only remedy available to any Party in respect of any representation, warranty, collateral contract or other assurance set out in this Agreement or a Work Order (or any document referred to in it) is for breach of contract under this Agreement or that Work Order (or the relevant document) as applicable.

15.7 Except as expressly stated in this Agreement (or a Work Order, in which case such exception will only apply for that Work Order) all conditions, warranties, stipulations and other statements whatsoever (except as to title to goods) that would otherwise be implied or imposed by statute, at common law, by a course of dealing or otherwise howsoever are excluded to the fullest extent permitted by law.

15.8 No variation of this Agreement or any Work Order shall be effective unless it is in writing and is signed by or on behalf of each of the Parties.

15.9 The rights and remedies of the Parties in connection with this Agreement and any Work Order are cumulative and, except as expressly stated in this Agreement or that Work Order as applicable, are without prejudice to and are not exclusive of any other rights or remedies provided by law or equity or otherwise. Except as expressly stated in this Agreement or any Work Order any right or remedy may be exercised (wholly or partially) from time to time.

15.10 Unless expressly stated elsewhere in this Agreement (or a Work Order), all notices to be given to a Party under this Agreement (or that Work Order, as applicable) shall be in writing in English and shall be marked for the attention of the person, and delivered by hand or sent by first class prepaid post to the address detailed at the first page. A notice shall be treated as having been received:

(a) if delivered by hand between 9.00 am and 5.00 pm on a Business Day (which time period is referred to in this Clause 13 as “Business Hours”), when so delivered; and if delivered by hand outside Business Hours, at the next start of Business Hours;

(b) if sent by first class post, at 9.00 am on the fifth Business Day after posting if posted on a Business Day and at 9.00 am on the seventh Business Day after posting in any other case; and

in proving that a notice has been given it shall be sufficient to prove that delivery was made, or that the envelope containing the notice was properly addressed and posted.

E-mailed notices are not valid for this Agreement and/or any Work Order but this does not invalidate any other lawful mode of service.

15.11 The Parties intend each provision of this Agreement and each Work Order to be severable and distinct from the others. If a provision of this Agreement or a Work Order is held to be illegal, invalid or unenforceable, in whole or in part, the Parties intend that the legality, validity and enforceability of the remainder of this Agreement or Work Order (as relevant) shall not be affected.

15.12 Any person who is not a Party to this Agreement (or a Work Order) cannot enforce any term of this Agreement (or that Work Order, as applicable) under the Contracts (Rights of Third Parties) Act 1999, but this does not affect any right or remedy of a third party which exists or is available apart from that Act.

15.13 This Agreement may be entered into in several counterparts and by the Parties on separate counterparts, which taken together shall constitute the same instrument. However, this Agreement shall not come into force until each of the Customer and Quotient have signed at least one counterpart.

15.14 The validity, construction and performance of this Agreement and any Work Order shall be governed by and construed in accordance with the laws of the state of Delaware. Each Party irrevocably agrees to submit to the exclusive jurisdiction of the courts of the state of Delaware over any claim, dispute or matter arising under or in connection with this Agreement or a Work Order.

15.15 In relation to all matters arising out of or in connection with this Agreement or a Work Order, each of the Parties waives any objections on the grounds of venue or forum *non conveniens* or any similar ground and consents to service of process by mail or in any other manner permitted by the relevant law.

Signed by the Parties or their duly authorized representative on the date of this Agreement.

Signed by duly authorised for and on behalf of **Quotient Sciences Limited**	)))	/s/ Michael Astle
Signed by duly authorized for an on behalf of **XORTX Therapeutics Inc.**	)))	/s/ Allen Davidoff

Schedule 1

WORK ORDER
(NUMBER [•])

Quotient Reference: QSC[XXXXXX]
Sponsor reference: [e.g. protocol number, study number, molecule name & v. brief description of service (e.g. Ibuprofen CMC, AZD4635 ADME, etc.)

This Agreement is made on [date]

This Work Order is entered into between ***[Insert same details for Customer as used at the start of the main Agreement]*** ("**Customer**") and Quotient Sciences Limited whose registered office is at Trent House, Mere Way, Ruddington, Nottingham, NG11 6JS, United Kingdom ("**Quotient**") and is supplemental, and entered pursuant, to the Master Services Agreement dated [•] between the Customer and Quotient ("**Agreement**").

The Parties agree;

1. Work Order

This document and its appendices constitute a "Work Order" under the Agreement. The terms set out in the Agreement (including, without limitation, Clause 10 of the Agreement) shall apply to this Work Order.

2. Services and Payment of Fees and Expenses

2.1 The specific services to be provided by Quotient, and the amount(s) to be paid by the Customer to Quotient in return, under this Work Order (with the related timescales, invoicing dates, and invoicing and payment details) are in the following appendices which shall for all purposes form part of this Work Order:

Appendix 1 Proposal

Appendix 2 Payment Schedule

Appendix 3 Data Privacy Addendum

The Research will be conducted at the Quotient facility at [•]

2.2 [Quotient will act as the Legal Representative of the Customer for the trial, study, and/or other services described in Appendix 1 to this Work Order]

3. Term

This Work Order shall come into force on the date it has been signed by or on behalf of both Parties and shall remain in force in accordance with Clause 8 of the Agreement.

4. **Amendments**

No modification, amendment, or waiver of this Work Order shall be effective unless in writing and duly executed and delivered by each Party to the other.

5. Signatures

Signed by)
duly authorised for and on behalf of)
Quotient Sciences Limited)
Date

Signed by)
duly authorised for an on behalf of)
XORTX Therapeutics Inc.)
Date

Appendix 1 (Work Order Number [◆])

Proposal

[◆][Insert agreed proposal and costing document]

Amount to be paid by the Customer: [◆]

Appendix 2 (Work Order Number [◆])

Payment Schedule

	Payment Milestone — Invoicing Dates	**Amount**
1	Signature of Work Order	40%
2	First dosing day	30%
3	Last Dosing Day	10%
4	Database lock	10%
5	Dispatch of draft report	5%
6	Dispatch of final report*	5%

*or 4 weeks after dispatch of draft report, whichever is sooner.

The non-cancellable recruitment and screening, clinic and manufacturing labour costs for the Research are:

Study Period	**Dates**	**Amount**
1	**[◆]**	£**[◆]**
2	**[◆]**	£**[◆]**
3	**[◆]**	£**[◆]**
4	**[◆]**	£**[◆]**

Invoices will be addressed to:

Name **[◆]**
Address **[◆]**
Phone **[◆]**
Fax **[◆]**
Email **[◆]**

Payments will be made by wire transfer to our ****** accounts:

******

Or such other account and/or payment method as Quotient may notify to the Customer for that purpose from time to time.

Appendix 3 (Work Order Number [•])

Data Privacy Addendum

This agreement is made on [date]

This Data Privacy Addendum is entered into between [Insert same details for Sponsor as used at the start of the main Agreement] ("Sponsor") and Quotient Sciences Limited whose registered office is at Trent House, Mere Way, Ruddington, Nottingham, NG11 6JS, United Kingdom ("Quotient") and is supplemental, and entered pursuant, to the [Services Agreement OR Work Order] dated [•] between the Sponsor and Quotient ("Agreement").

DEFINITIONS

Data Controller: XORTX Pharma Corp.

Data Processor: Quotient Sciences Limited

Data Protection Legislation: (i) unless the GDPR is no longer directly applicable in the UK, the General Data Protection Regulation *((EU) 2016/679)* and any national implementing laws, regulations and secondary legislation, as amended or updated from time to time, in the UK and then (ii) any successor legislation to the GDPR or the Data Protection Act 2018.

Protocol: [INSERT SPONSOR AND QUOTIENT STUDY NUMBER]

1. **DATA PROTECTION**

1.1 Both parties will comply with all applicable requirements of the Data Protection Legislation. This clause 1.1 is **in** addition to, and does not relieve, remove **or** replace, a party's obligations under the Data Protection Legislation.

1.2 The parties acknowledge that for the Data Protection Legislation, the Sponsor is the data controller and Quotient is the data processor (where **Data Controller** and **Data Processor** have the meanings as defined in the Data Protection Legislation). Schedule One (1) sets out the scope, nature and purpose of processing by Quotient, the duration of the processing and the types of personal data (as defined in the Data Protection Legislation, **Personal Data)** and categories of Data Subject. Schedule Two (2) sets out the name, contact details and, where applicable, the Data Privacy Representative and/or Data Protection Officer of each party.

1.3 Without prejudice to the generality of clause 1.1, the Sponsor will ensure that it has all necessary appropriate consents and notices in place to enable lawful transfer of the Personal Data to Quotient for the duration and purposes of this agreement.

1.4 Without prejudice to the generality of clause 1.1, Quotient shall, in relation to any Personal Data processed in connection with the performance by Quotient of its obligations under this agreement:

(a) process that Personal Data only on the written instructions of the Sponsor unless Quotient is required by the laws of any member of the European Union or by the laws of the European Union applicable to Quotient to process Personal Data (**Applicable Laws**). Where Quotient is relying on laws of a member of the European Union or European Union law as the basis for processing Personal Data, Quotient shall promptly notify the Sponsor of this before performing the processing required by the Applicable Laws unless those Applicable Laws prohibit Quotient from so notifying the Sponsor;

(b) ensure that it has in place appropriate technical and organisational measures, reviewed and approved by the Sponsor, to protect against unauthorised or unlawful processing of Personal Data and against accidental loss or destruction of, or damage to, Personal Data, appropriate to the harm that might result from the unauthorised or unlawful processing or accidental loss, destruction or damage and the nature of the data to be protected, having regard to the state of technological development and the cost of implementing any measures (those measures may include, where appropriate, pseudonymising Personal Data, ensuring confidentiality, integrity, availability and resilience of its systems and services and regularly assessing and evaluating the effectiveness of the technical and organisational measures adopted by it);

(c) ensure that all personnel who have access to and/or process Personal Data must keep the Personal Data confidential; and

(d) not transfer any Personal Data outside of the European Economic Area unless the prior written consent of the Sponsor has been obtained and these conditions are fulfilled:

(i) the Sponsor or Quotient has provided appropriate safeguards in relation to the transfer;

(ii) the data subject has enforceable rights and effective legal remedies;

(iii) Quotient complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data transferred; and

(iv) Quotient complies with reasonable instructions notified to it in advance by the Sponsor regarding the processing of the Personal Data;

(e) assist the Sponsor, at the Sponsor's cost, in responding to any request from a Data Subject and in ensuring compliance with its obligations under the Data Protection Legislation regarding security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;

(f) notify the Sponsor without undue delay on learning of a Personal Data breach;

(g) at the written direction of the Sponsor, delete or return Personal Data and copies thereof to the Sponsor on termination of the agreement unless required by Applicable Law to store the Personal Data; and

(h) maintain complete and accurate records and information to demonstrate its compliance with this clause one (1) and allow for audits by the Sponsor or the Sponsor's designated auditor.

1.5 The Sponsor consents to Quotient appointing third-party processors of Personal Data under this agreement. Quotient confirms that it has entered or (as the case may be) will enter with the third-party processor into a written agreement substantially on that third party's standard terms of business. As between the Sponsor and Quotient, Quotient shall remain fully liable for all acts or omissions of any third-party processor appointed by it under this clause 1.5.

1.6 Either party may, at any time on not less than 30 days' notice, revise this Addendum by replacing it with any applicable controller to processor standard clauses or similar terms forming party of an applicable certification scheme (which shall apply when replaced by attachment to this agreement).

1.7 If the Sponsor has nominated Quotient as a Data Privacy Representative in Schedule Two (2):

1.7.1 Quotient will promptly relay to Sponsor any communications received in its capacity as Data Privacy Representative but accepts no further obligations as part of its role; and

1.7.2 Sponsor shall indemnify, defend and hold harmless Quotient, and its respective employees, officers, directors, and agents, (each, an "Indemnified Party") from and against all liabilities, damages, penalties, costs, expenses and fines resulting or arising from any claims, actions, demand or suits from a third party, a judicial, government, regulatory or law enforcement authority or any other authority (collectively "Losses") that are incurred by or suffered by, made or instituted against an Indemnified Party, to the extent such Losses result from its capacity as, or performance of tasks related to, Data Privacy Representative of Sponsor, unless Quotient is in breach of its obligations at clause 1.7.1.

Signed by)
duly authorised for and on behalf of)
Quotient Sciences Limited)
Date

Signed by)
duly authorised for an on behalf of)
XORTX Pharma Corp.)
Date

SCHEDULE ONE

PROCESSING, PERSONAL DATA AND DATA SUBJECTS

1. PROCESSING BY QUOTIENT

1.1 **SCOPE**

Quotient will process the Personal Data of Trial Subjects in accordance with, and to meet the aims of, the Protocol and the Agreement.

1.2 **NATURE**

The processing will involve analysis and presentation of the Trial Subjects' Personal Data, including:

- [DELETE AS NECESSARY]
- statistical processes and reporting;
- review of PK data and associated calculations;
- comparisons with other Trial Subjects' Personal Data;
- presentation of raw data relating to clinical procedures;
- transmission of samples and tracking information to selected subcontractors, who return data for analysis and reporting; and
- collation with other Trial Subjects' Personal Data to produce summary findings.

Trial Subjects' Personal Data is pseudonymised at the earliest practical opportunity, resulting in the majority of the processing being undertaken on pseudonymised Personal Data only.

The processing will also involve use of employee's Personal Data, including:

- as part of internal correspondence and correspondence between the parties;
- recording of employee's actions and roles as part of the Protocol; and
- in the normal course of business to give effect to the agreement.

1.3 **PURPOSE OF PROCESSING**

The processing provides data to enable the Sponsor to assess the efficacy of the Sponsor's drug product.

1.4 **DURATION OF THE PROCESSING**

The processing of Personal Data by Quotient is estimated to be a period of no longer than one year after the last visit of the Trial Subject, which is [INSERT DATE OF LSLV PLUS 12 MONTHS], after which time no further processing is expected to be conducted.

Quotient must retain copies of Personal Data in accordance with applicable industry law for monitoring, regulatory and audit purposes, which could be for a period of up to 30 years or longer if prescribed by law.

2. TYPES OF PERSONAL DATA

Types of Personal Data processed may include:

- [DELETE AS NECESSARY]
- Name
- Address
- Email address
- Age
- Trial subject number
- Volunteer number
- Passport number
- National insurance number

Types of sensitive Personal Data processed may include:

- [DELETE AS NECESSARY]
- Health data, including medical records
- Racial or ethnic origin
- Genetic data
- Biometric data (e.g. photographs of the Data Subject)
- Data about a natural person's sex life or sexual orientation

3. **CATEGORIES OF DATA SUBJECT**

Categories of Data Subject include:

- Clinical trial volunteers
- Employees of the Sponsor, Quotient or any sub-contractors.

4. **TRANSFERS OF PERSONAL DATA OUTSIDE OF THE EUROPEAN ECONOMIC AREA (EEA)CONSENTED TO BY THE SPONSOR**

These transfers of Personal Data outside of the EEA have been consented to by the Sponsor:

[LIST ANY TRANSFERS OF PERSONAL DATA OUTSIDE OF THE EEA OR SPECIFY 'NONE]

SCHEDULE TWO

Data Controller

Company Name	XORTX Therapeutics Inc.
Contact Address	[*]
Contact Telephone Number	[*]
Contact Email Address	[*]
Data Privacy Representative	[if applicable]
Data Protection Officer	[if applicable]

[Note: It is for the Data Controller to decide whether it needs a Data Protection Officer. If they don't have one then please insert 'none specified'.]

[

Data Privacy Representative of Data Controller

Company Name	
Contact Address	
Contact Telephone Number	
Contact Email Address	
Data Protection Officer	[if applicable]

]

[Note: If the Data Controller is based outside of the EU it must nominate a Data Privacy Representative who can receive enquiries from individuals and the regulator. Note: this can be Quotient if the Data Controller so desires.]

[Note: It is for the Data Privacy Representative to decide whether it needs a Data Protection Officer, If they don't have one then please insert 'none specified'.]

	Data Processor
Company Name	Quotient Sciences Limited
Contact Address	Trent House Mere Way, Ruddington Fields Business Park, Ruddington, Nottingham, NG11 6JS
Contact Telephone Number	00 44 115 974 9000
Contact Email Address	dpo@quootientsciences.com
Data Protection Officer	Michael Astle

[To apply only where Quotient acts as the Legal Representative for the Customer— see Clause 2.9]

Schedule 2

The Medicines for Human use (Clinical Trials) Regulations 2004

1 For the purposes of the Regulations, Quotient agrees that it shall act as Legal Representative for the Research throughout the duration of the Research besides the other services described in this Agreement and/or the Work Order provided that the Customer fulfils and continues to fulfil all its obligations to Quotient under this Agreement and the Work Order, including to avoid doubt the obligation to pay all monies due to Quotient under this Agreement and the Work Order.

2 Quotient shall not provide any undertaking to any regulatory authority on behalf of Customer without the prior written consent of the Customer.

3 For this Schedule 2 any word or phrase with a defined meaning in the Regulations shall be construed in this Schedule in accordance with the meanings ascribed in the Regulations.

4 Quotient shall provide the Customer with a copy of all correspondence from the regulatory authority relating to the Research upon request from the Customer and will provide a copy of any authorisation and any notice received from the regulatory authority related to the Research within 2 Business Days of its receipt by Quotient.

Development and Clinical Manufacturing Services Agreement

(the "Agreement")

by and between

Lonza Ltd
Munchensteinerstrasse 38
CH-4002 Basel
Switzerland

- hereinafter "Lonza" -

and

XORTX

4000 421 7th Avenue SW
Calgary, AB, T2P 4K9
Canada

- hereinafter "Customer" -

Effective as of August 17, 2021 (the "Effective Date")

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Recitals

WHEREAS, Customer is engaged in the development and research of certain products and requires assistance in the development and manufacture of product;

WHEREAS, Lonza and its Affiliates have expertise in the evaluation, development and manufacture of products;

WHEREAS, Customer wishes to engage Lonza for Services relating to the development and clinical manufacture of the Product as described in this Agreement; and

WHEREAS, Lonza, or its Affiliate, is prepared to perform such Services for Customer on the terms and subject to the conditions set out herein.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the parties intending to be legally bound, agree as follows:

1. Definitions and Interpretation

"Affiliate"	means any company, partnership or other entity which directly or indirectly Controls, is Controlled by or is under common Control with the relevant Party. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the relevant Party.
"Agreement"	means this Development and Manufacturing Services Agreement incorporating all Appendices, as amended from time to time by written agreement of the Parties.
"Applicable Laws"	means all relevant Canadian, U.S. and European Union federal, state and local laws, statutes, rules, and regulations which are applicable to the performance of the Services (as defined below) and/or the Parties' respective obligations hereunder, including, without limitation, the applicable regulations and guidelines of any Regulatory Authority, Corruption laws, International Trade Restrictions, and all applicable cGMP together with amendments thereto.
"Approval"	means the first marketing approval by the FDA, Health Canada, or EMA of Product from the Facility for commercial supply.
"Background Intellectual Property"	means any Intellectual Property either (i) owned or controlled by a Party prior to the Effective Date or (ii) developed or acquired by a Party independently from the performance of the Services hereunder during the Term of this Agreement.
"Batch"	means the Product derived from a single run of the Manufacturing Process.
"Batch Price"	means the Price of each Batch.
"Campaign"	means a series of no less than three (3) cGMP Batches manufactured consecutively.

"Cancellation Fee"	has the meaning given in Clause 6.3.
"Capital Equipment"	means those certain pieces of equipment described in the Project Plan used to produce the Product that are purchased by Customer or for which Customer reimburses Lonza, including, without limitation, the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment.
"Certificate of Analysis"	means a document prepared by Lonza listing tests performed by Lonza or approved External Laboratories, the Specifications and test results.
"cGMP"	means those laws and regulations applicable in the U.S., Canada, and Europe, relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients", US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC. For the avoidance of doubt, Lonza's operational quality standards are defined in internal cGMP policy documents.
"cGMP Batches"	means any Batches which are required under the Project Plan to be manufactured in accordance with cGMP.
"Change"	means any change to the Services, pricing or Scope of Work incorporated into a written amendment to the Agreement in accordance with clause 16.3 or effected in accordance with the Quality Agreement.
"Commencement Date"	means the date of commencement of manufacturing activities for a Batch hereunder.
"Confidential Information"	means all Customer Information and Lonza Information, both collectively and individually as applicable.
"Corruption Laws"	means all anti-bribery and anti-corruption laws and regulations applicable to Lonza's relationship with Customer, including but not limited to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010, and the Organization for Economic Co-operation and Development Convention on Combating Bribery and Foreign Public Officials in International Business Transactions.

"Customer Information"	means all technical and other information not known to Lonza or in the public domain relating to the Manufacturing Process and the Product, from time to time supplied by the Customer to Lonza, including the Customer Materials and any other materials supplied by Customer to Lonza in accordance with the Project Plan and includes all New Customer Intellectual Property and all information that is proprietary to Customer or any Affiliate of Customer and that is maintained in confidence by Customer or any Affiliate of Customer and that is disclosed by Customer or any Affiliate of Customer to Lonza under or in connection with this Agreement, including without limitation, any and all Customer know-how and trade secrets and Customer Background Intellectual Property.
"Customer Materials"	means any Raw Materials, components of Product, or other materials of any nature provided by Customer.
"EMA"	means the European Medicines Agency, or any successor agency thereto.
"Engineering Batches"	means a Batch that is intended to demonstrate the transfer of the Manufacturing Process to the Facility.
"External Laboratories"	means any Third Party instructed by Lonza, with Customer's prior consent, which is to conduct activities required to complete the Services.
"Facility"	means Lonza's manufacturing facilities in (i) Nansha, China, or (ii) such other Lonza facility as may be agreed upon by the Parties.
"FDA"	means the United States Food and Drug Administration, or any successor agency thereto.
"Governmental Authority"	means any Regulatory Authority and any national, multi-national, regional, state or local regulatory agency, department, bureau, or other governmental entity in the U.S., Canada, or European Union.
"Intellectual Property"	means: (i) inventions (whether or not patentable), patents, trade secrets, copyrights, trademarks, trade names and domain names, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how) and any other intellectual property rights, in each case whether registered or unregistered; (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing sub-clause (i); and (iii) all rights and applications that are similar or equivalent to the rights and application described in the foregoing sub-clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world.
"International Trade Restrictions"	means all applicable United States, United Nations, and European Union export control, trade, and financial sanctions laws, rules, and regulations.
"Lonza Information"	means all information that is proprietary to Lonza or any Affiliate of Lonza and that is maintained in confidence by Lonza or any Affiliate of Lonza and that is disclosed by Lonza or any Affiliate of Lonza to Customer under or in connection with this Agreement, including without limitation, any and all Lonza know-how and trade secrets, New General Application Intellectual Property, and Lonza Background Intellectual Property.

"Manufacturing Process"	means the production process developed by Lonza on behalf of Customer for the manufacture of Product, as such process may be improved or modified from time to time by agreement of the Parties in writing.
"Master Batch Record"	means the document, proposed by Lonza and approved by Customer, which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of Product.
"New Customer Intellectual Property"	has the meaning given in Clause 10.2.
"New General Application Intellectual Property"	has the meaning given in Clause 10.3.
"Party"	means each of Lonza and Customer and, together, the "Parties".
"Product"	means the price for the Services and Products as set out in the applicable Project Plan.
"Project Plan"	means the molecule identified by Customer as Oxypurinol, to be manufactured using the Manufacturing Process by Lonza for Customer as specified in the Project Plan.
"Quality Agreement"	means the plan(s) describing the Services to be performed by Lonza under this Agreement, including any update and amendment of the Project Plan to which the Parties may agree from time to time. The initial Project Plan is attached hereto as Appendix A.
"Raw Materials"	means the quality agreement, attached hereto as Appendix B, setting out the responsibilities of the Parties in relation to quality as required for compliance with cGMP.
"Regulatory Authority"	means all ingredients, solvents, consumables, and other components of the Product required to perform the Manufacturing Process or Services.
"Release"	means the FDA, EMA and any other similar regulatory authorities as may be agreed upon in writing by the Parties.
"Services"	has the meaning given in Clause 7.1.
"Specifications"	means all or any part of the services to be performed by Lonza under this Agreement (including, without limitation, process and analytical method transfer, process development, process optimization, validation, clinical and commercial manufacturing, as well as quality control and quality assurance activities), particulars of which are set out in a Project Plan.

"Term"	means the specifications of the Product as specified in the applicable Project Plan, which may be amended from time to time in accordance with this Agreement.
"Third Party"	means any party other than Customer, Lonza and their respective Affiliates.

In this Agreement references to the Parties are to the Parties to this Agreement, headings are used for convenience only and do not affect its interpretation, references to a statutory provision include references to the statutory provision as modified or re-enacted or both from time to time and to any subordinate legislation made under the statutory provision, references to the singular include the plural and vice versa, and references to the word "including" are to be construed without limitation.

2. Performance of Services

2.1 Performance of Services. Subject to Clause 2.5, Lonza shall itself and through its Affiliates, diligently carry out the Services as provided in the Project Plan and use commercially reasonable efforts to perform the Services without any material defect and according to the estimated timelines as set forth in the Project Plan. Lonza shall retain appropriately qualified and trained personnel with the requisite Knowledge and experience to perform the Services in accordance with this Agreement. Lonza may subcontract or delegate any of its rights or obligations under this Agreement to perform the Services to External Laboratories; provided, that any External Laboratories shall be subject to the same obligations and other provisions contained in this Agreement or any applicable Project Plan. Lonza shall not be responsible for analytical lab services performed by External Laboratories.

2.2 Subcontractors. Lonza shall not subcontract Services as described in the Project Plan without first obtaining Customer's prior written consent. Any agreement entered into by Lonza with a third party subcontractor shall, at a minimum, provide for ownership and allocation of Intellectual Property and for obligations of confidentiality of information, record-keeping, access, and rights to data that are consistent with the intent and terms of this Agreement. Lonza shall remain liable for the performance of any of its obligations hereunder that it delegates to a subcontractor. For the avoidance of doubt, any External Laboratories shall not be deemed to be a subcontractor of Lonza.

2.3 Affiliates. Lonza, in its sole discretion, may instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement and any particular Project Plan as set forth in a Project Plan, provided, however, that Lonza shall remain fully responsible in respect of those obligations. Any of said Affiliates so used by Lonza shall be subject to all of the applicable terms and conditions applicable to Lonza under this Agreement and shall be entitled to all rights and protections afforded Lonza under this Agreement. An Affiliate of Lonza may execute a Project Plan with the Customer pursuant to this Agreement and submit invoices to the Customer under the Project Plan. In such circumstances all references in this Agreement to Lonza shall be deemed to be to the applicable Affiliate of Lonza with respect to that particular Project Plan. The Affiliate shall be entitled to enforce this Agreement with respect to such Project Plan in its own name as an intended third party beneficiary and the Affiliate shall be solely liable to the Customer for any obligations and liabilities undertaken pursuant to such Project Plan and subject to the terms of this Agreement and the Quality Agreement.

2.4 Technology Transfer. If Customer is providing Customer Information to Lonza, the Parties agree that they shall work together to transfer (as described in the Project Plan) the Customer Information to the Facility, including implementing the technology transfer plan set out in the Project Plan. Customer shall fully support such technology transfer as reasonably requested by Lonza. Customer shall (by such date as agreed between the Parties) supply to Lonza all such Customer Information and Customer Materials, and other information or materials that may be reasonably required by Lonza to perform the Services. Lonza shall not be responsible for any delays arising out of Customer's failure to provide such Customer Information, Customer Materials and/or other information and/or materials reasonably required to perform the Services to Lonza, and Customer shall be responsible for all additional costs and expenses arising out of such delay, including, if applicable, any idle Facility capacity costs.

2.5 Engineering Batches. If applicable, Lonza shall manufacture Engineering Batches in accordance with the Project Plan. Customer shall have the right to make whatever further use of the non-cGMP Engineering Batches as it shall determine, provided that Customer pays for such Batches, such use is not for human use and does not violate any Applicable Laws. Lonza makes no warranty that Engineering Batches will meet cGMP or the Specifications. If Lonza determines that an Engineering Batch does meet cGMP and the Specifications, it will release such Engineering Batch as a cGMP Batch. Regardless of whether any Engineering Batch meets cGMP or the Specifications, Customer shall pay to Lonza the Price for such Engineering Batch plus the Raw Materials Fee associated with such Engineering Batches.

2.6 cGMP Batches. Lonza will, in accordance with the terms of this Agreement and Quality Agreement, manufacture at the Facility and Release to Customer, cGMP Batches that comply with the Manufacturing Process, cGMP and the Specifications, together with a Certificate of Analysis; provided, however, that cGMP manufacture shall not commence until at least one (1) successful and consecutive Engineering Batch (at any given scale) has been manufactured in compliance with cGMP and Specifications. Prior to commencement of cGMP manufacturing, Lonza shall review the process assumptions. In the event that there is a material difference in the process assumptions as compared with the process results demonstrated during the manufacture of Engineering Batches, the Parties shall meet to discuss in good faith a revision to the Batch Price to reflect such difference.

2.7 Stability Testing. Lonza will perform stability testing in accordance with the applicable Project Plan and the Quality Agreement, as applicable.

2.8 Location of Services. All manufacturing will be done at Lonza's Nansha Facility located at Huangge N. Ave., Guangzhou, Nansha 511455 China unless otherwise agreed with Customer.

2.9 Supply of Customer Information and Customer Materials. Customer shall supply to Lonza all Customer Information and Customer Materials and other information or materials that may be reasonably required by Lonza to perform the Services. Lonza shall not be responsible for any delays arising out of Customer's failure to provide such Customer Information, Customer Materials, or other information or materials reasonably required to perform the Services to Lonza, and Customer shall be responsible for all additional costs and expenses arising out of such delay, including, if applicable, any idle Facility capacity costs.

2.10 Raw Materials. Lonza shall procure all required Raw Materials other than those Raw Materials that are Customer Materials. Quantities of Raw Materials ordered by Lonza shall be in alignment with quantities reasonably needed for planned production. Upon cancellation of any Batch or termination of the Agreement, all unused Raw Materials shall be paid for by Customer within thirty (30) days of invoice and at Customer's option will either be (a) held by Lonza for future use for the production of Product, (b) delivered to Customer, or (c) returned to the supplier, to the extent permitted by the supplier, or (d) disposed of by Lonza. Lonza will credit Customer for any credits received by Lonza in connection with the return of Raw Materials to the supplier.

2.11 Once a Product has achieved Proof of Concept (e.g. successful Phase 2a clinical study or equivalent), the Parties may negotiate in good faith a separate agreement on commercially reasonable terms and conditions for supply of commercial products.

3. Project Management / Steering Committee

3.1 Project Plans. With respect to a new project to be governed by this Agreement, a new Project Plan shall be added by agreement in a writing signed by the Parties and appended to Appendix A. Each Project Plan shall include a description of the Services to be provided, the Product to be manufactured, Specifications, a schedule for completion of the Project Plan, pricing details, and such other information as is necessary for relevant Services. In the event of a conflict between the terms of a Project Plan and this Agreement, the terms of this Agreement will govern.

3.2 Project Management. With respect to each Project Plan, each party will appoint a project manager who will be the party responsible for overseeing the Project Plan.

3.3 Steering Committee. Each Party shall name a mutually agreed upon equal number of representatives for the Steering Committee, which shall meet twice per calendar year, or as otherwise mutually agreed by the Parties. In the event that a Steering Committee dispute cannot be resolved, such dispute shall be escalated to a senior executive of each of Customer and Lonza.

The primary function of the Steering Committee is to ensure the ongoing communication between the Parties and discuss and resolve any issues arising under this Agreement. In addition to the primary function described above, the Steering Committee shall also take on the following responsibilities:

3.3.1 discuss and seek resolution of issues around management of the Services;

3.3.2 agree and monitor deadlines and milestones for the Services; and

3.3.3 discuss and recommend any changes to the Services (although such changes will not take effect until they have been incorporated into a written amendment to the Project Plan which has been signed by the Parties).

3.4 Facility. Lonza shall ensure that the Facility meets all the requirements of a drug establishment promulgated by the FDA at all times during the GMP-manufacture of the Product. As applicable, Lonza shall comply with all aspects required by the Quality Agreement pertaining to qualification to manufacture and ship GMP-manufactured Product.

3.5 Audit. In accordance with and subject to the Parties Quality Agreement, Lonza shall notify Customer of a FDA or other regulatory audit or inspection if such audit or inspection directly relates to a GMP Product. In accordance with and subject to the Parties Quality Agreement, Lonza shall provide to Customer correspondence and reports that it receives from a governmental agency or regulatory authority in connection with a GMP Product.

3.6 Person in Plant. Customer shall be permitted to have, at no additional cost, two (2) employees at the Facility as reasonably requested by Customer, at a time mutually agreed to by the Parties and during Lonza's normal business hours, for the purpose of observing, reporting on, and consulting as to the performance of the Services as may be approved in writing in advance by Lonza. Such employee shall be subject to and agree to abide by confidentiality obligations to Third Parties and Lonza's customary practices, operating procedures and security procedures regarding persons in plant, and such employee agrees to comply with all instructions of Lonza's employees at the Facility. Customer's employee(s) working at the Facility shall be and remain employees of Customer, and Customer shall be solely responsible for the payment of compensation for such Customer employee (including applicable federal, state and local withholding, FICA and other payroll taxes, workers' compensation insurance, health insurance, and other similar statutory and fringe benefits). Customer covenants and agrees to maintain workers' compensation benefits and employers' liability insurance as required by applicable federal and state laws with respect to all Customer employees working at the Facility.

4. Quality

4.1 Responsibility for quality assurance and quality control of Product shall be allocated between Customer and Lonza as set forth in the Quality Agreement and in Lonza standard operating procedures. If there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of the Quality Agreement shall prevail concerning quality, safety and efficacy issues. If the Quality Agreement is not in place at the Effective Date, Lonza and Customer commit to enter into the Quality Agreement in a timely manner, but in no event later than the commencement of cGMP manufacturing.

4.2 Provisions regarding inspections by Regulatory Authorities and audits shall be set out in the Quality Agreement.

4.3 Records. Lonza will maintain accurate records for the production of the Product, as required by applicable laws and regulations or in accordance with the Quality Agreement. Lonza will retain possession of the Master Batch Record, all Batch records and Lonza Operating Documents, and will make copies of the Master Batch Record and Batch records available to Customer upon Customer's request; Lonza will provide such copies at no cost to Customer except that Customer shall compensate Lonza for any related translation costs (such translation costs are set forth Appendix C). Lonza Operating Documents shall remain Lonza Information. Master Batch Records and executed Batch records are the property of Customer; for clarity, any Lonza Background Intellectual Property or New General Application Intellectual Property contained in any Batch records shall still be considered Lonza Information and subject to the obligations of confidentiality and non-use set forth in Section 13 of this Agreement. All Batch records shall, at Customer's cost and request, be translated into English prior to batch release. Lonza will make Lonza Operating Documents available during site visits by Customer but Customer shall not be permitted to make copies of and/or remove Lonza Operating Documents from the Lonza site. In connection with a filing for Regulatory Approval of the Product, and securing and maintaining such approval, Lonza shall provide the Lonza Operating Documents directly to the Regulatory Authority when possible, and to the extent that Lonza cannot so provide such Lonza Operating Documents, then such documents shall be provided under strict confidentiality (subject to a separate confidentiality undertaking) to the appropriate persons (regulatory affairs) at Customer for submission to the Regulatory Authority.

4.3.1 As used in this Section 4.3, "Lonza Operating Documents" means the corporate standards, standard operating procedures, standard manufacturing procedures, Lonza-customized manufacturing procedures developed prior to the Effective Date or outside the scope of this Agreement, electronic programs and files, raw material specifications, protocols, validation documentation, and supporting documentation used by Lonza, such as, without limitation, environmental monitoring, for operation and maintenance of the Facility and Lonza equipment used in the process of producing the Product, excluding any of the foregoing that are solely related to the manufacture of Product.

5. Insurance

5.1 Each Party shall, during the Term and for two (2) years after delivery of the last Product manufactured or Services provided under this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance including, but not limited to product liability coverage in the amount of at least two (2) million Swiss Francs (or an equivalent amount in another currency) per claim. Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.

6. Ordering and Cancellation

6.1 Order Confirmation. Lonza shall confirm the delivery date(s) and quantity of Product to be delivered as set out in a purchase order within ten (10) business days of receipt from Customer of the relevant purchase order. Upon confirmation, a purchase order will be regarded by the Parties as a binding commitment by Lonza to manufacture and to deliver to Customer the relevant quantity of Product according to the requirements set out in such purchase order. Any delivery date set forth in Lonza's written confirmation of a purchase order shall be an estimated delivery date only. All ordered Batches shall be scheduled in a single Campaign in each calendar year unless otherwise agreed by Lonza. Any additional or inconsistent terms or conditions of any Customer purchase order, acknowledgement or similar standardized form given or received pursuant to this Agreement shall have no effect and such terms and conditions are hereby rejected.

6.2 Rescheduling. Lonza shall have the right to reschedule a Commencement Date of any Batch or Campaign upon reasonable prior written notice to Customer, provided that the rescheduled Commencement Date is no later than sixty (60) days from the Commencement Date originally estimated at the time of Lonza's acceptance of the binding purchase order. If the Customer requests to change the Commencement Date, Lonza will make all reasonable attempts to accommodate the request; provided, however, in the event that this change would impact other projects scheduled for occupancy in the designated suite or suites, manufacture of the Customer's Batch or Campaign may be delayed until an adequate time period is available in the Facility schedule. Any such change requested by Customer may result in a rescheduling fee. Any delay requested by Customer of more than ninety (90) days shall be considered a cancellation pursuant to Section 6.3.

6.3 Cancellation of Services. Customer may cancel Services, including production of a Batch to be manufactured under a Project Plan, upon written notice to Lonza, subject to Customer's obligation to pay for all Services rendered up to the date of cancelation, including in respect of any Product in-process, all of Lonza's costs incurred through the date of cancelation in connection with such Services and/or Batch pursuant to the Project Plan, including any costs and handling fees for all Raw Materials used or purchased for use in connection with the Services in accordance with Section 2.9, plus the payment of a cancellation fee as calculated below (the "Cancellation Fee"):

Development Services

6.3.1 In the event that Customer provides written notice of cancellation to Lonza of work agreed under a Project Plan, Customer shall be responsible to reimburse Lonza for all work undertaken to that point and cost of all raw materials ordered to complete the work.

Manufacturing Services for Clinical Material (for scales less than or equal to 500 L)

6.3.2 In the event that Customer provides written notice of cancellation to Lonza less than or equal to three (3) months prior to the Commencement Date of one or more Batches, then seventy-five percent (75%) of the Batch Price of each such Batch cancelled is payable;

6.3.3 In the event that Customer provides written notice of cancellation to Lonza more than three (3) months but less than or equal to nine (9) months prior to the Commencement Date of one or more Batches, then fifty percent (50%) of the Batch Price of each such Batch cancelled is payable; and

6.3.4 In the event Customer provides written notice of cancellation more than nine (9) months prior to the Commencement Date of a subject Batch, then no Cancellation Fee is payable.

Manufacturing Services for Clinical Material (for scales of more than 500L but less than or equal to 1,500 L)

6.3.5 In the event that Customer provides written notice of cancellation to Lonza less than or equal to three (3) months prior to the Commencement Date of one or more Batches, then eighty-five percent (85%) of the Batch Price of each such Batch cancelled is payable;

6.3.6 In the event that Customer provides written notice of cancellation to Lonza more than three (3) months but less than or equal to nine (9) months prior to the Commencement Date of one or more Batches, then sixty percent (60%) of the Batch Price of each such Batch cancelled is payable; and

6.3.7 In the event that Customer provides written notice of cancellation to Lonza more than nine (9) months but less than or equal to nine (12) months prior to the Commencement Date of one or more Batches, then thirty (30%) of the Batch Price of each such Batch cancelled is payable; and

6.3.8 In the event Customer provides written notice of cancellation more than twelve (12) months prior to the Commencement Date of a subject Batch, then no Cancellation Fee is payable.

Manufacturing Services for Clinical Material (for scales of 10,000 L)

6.3.9 In the event that Customer provides written notice of cancellation to Lonza less than or equal to six (6) months prior to the Commencement Date of one or more Batches, then one hundred percent (100%) of the Batch Price of each such Batch cancelled is payable;

6.3.10 In the event that Customer provides written notice of cancellation to Lonza more than six (6) months but less than or equal to twelve (12) months prior to the Commencement Date of one or more Batches, then eighty-five percent (85%) of the Batch Price of each such Batch cancelled is payable; and

6.3.11 In the event Customer provides written notice of cancellation more than twelve (12) months prior to the Commencement Date of a subject Batch, then no Cancellation Fee is payable.

6.4 Payment of Cancellation Fee. Any Cancellation Fee shall be payable within thirty (30) days following the written notice of cancellation associated with the cancelled Batch. Any Cancellation Fee shall include all costs associated with the cancelled Batch, including any Raw Materials in accordance with Section 2.9.

6.5 Replacement Project. Notwithstanding the foregoing, Lonza will use commercially reasonable efforts to secure a new project (but excluding any project then under contract with Lonza) for the cGMP manufacturing space, and for the same dates and duration that would have been occupied by Customer, and then, in such case, the Cancellation Fee for each Batch cancelled that is replaced by a Batch of the new project shall be reduced by an amount equal to one hundred percent (100%) of the production fees associated with such replacement Batch.

7. Delivery and Acceptance

7.1 Delivery. All Product shall be delivered FCA (as defined by Incoterms® 2020) the Facility. Lonza shall deliver to Customer the Certificate of Analysis and such other documentation as is reasonably required to meet all applicable regulatory requirements of the Governmental Authorities not later than the date of delivery of Batches (the "Release"). With respect to any Customer Materials, title and risk of loss shall remain with the Customer and shall not transfer to Lonza. With respect to Product, title and risk of loss shall transfer to Customer upon Release in accordance with this provision.

7.2 Storage. Customer shall arrange for shipment and take delivery of such Batch from the Facility, at Customer's expense, within (30) days after Release or pay applicable storage costs. Lonza shall provide storage on a bill and hold basis for such Batch(es) at no charge for up to thirty (30) days; provided that any additional storage beyond thirty (30) days will be subject to availability and, if available, will be charged to Customer and will be subject to a separate agreement. In addition to Section 8.2, Customer shall be responsible for all value added tax (VAT) and any other applicable taxes, levies, import, duties and fees of whatever nature imposed as a result of any storage. Notwithstanding anything to the contrary contained in this Agreement, in no event shall Lonza be required to store any Batch for more than ninety (90) calendar days after Release. Within five (5) business days following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored Batch.

7.3 Acceptance/Resection of Product.

7.3.1 Promptly following Release of Batches, Customer shall inspect such Batches and associated batch documentation, and shall have the right to test such Batches to determine compliance with the Specifications. Customer shall notify Lonza in writing of any rejection of a Batch based on any claim that it fails to meet Specifications within thirty (30) days of Release, after which time all unrejected Batches shall be deemed accepted. Customer shall inform Lonza in writing in case of concealed or latent defects (i.e. not discovered by routine quality control means), promptly upon discovery of such defects but no later than one (1) year after delivery of the Product.

7.3.2 In the event that Lonza believes that a Batch has been incorrectly rejected, Lonza may require that Customer provide to it Batch samples for testing. Lonza may retain and test the samples of such Batch. In the event of a discrepancy between Customer's and Lonza's test results such that Lonza's test results fall within relevant Specifications, or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party, the Parties shall cause an independent laboratory promptly to review records, test data and perform comparative tests and analyses on samples of the Product that allegedly fails to conform to Specifications. Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

7.3.3 Lonza shall reprocess any Batch or, if reprocessing is not possible, replace any Batch that failed to conform with the Specifications (a "Failed Batch"), in the event that it is determined (by the Parties or the independent laboratory) that such failure was solely due to Lonza's material breach of its obligations hereunder, negligence or intentional misconduct ("Lonza Responsibility"). Such reprocessing or replacement shall be made as promptly as practicable, in light of available manufacturing capacity, after the confirmation of Lonza Responsibility, and in any case as soon as reasonably possible after confirmation of Lonza Responsibility. Where possible, any replacement Batch shall be manufactured with the next scheduled cGMP Batch or Campaign. Customer acknowledges and agrees that its sole remedy with respect to a Failed Batch that is a Lonza Responsibility is as set forth in this Clause 7.3.3, and in furtherance thereof, Customer hereby waives all other remedies at law or in equity regarding the foregoing claims. Lonza shall not be responsible for the cost of Raw Materials or Customer Materials consumed in any Failed Batch, except to the extent set forth in this Clause 7.3.3.

8. Price and Payment

8.1 Pricing for the Services provided by Lonza are set out in, and based on the assumptions and information set out in, the applicable Project Plan. In the event of changes to the Services based on Customer's request, Customer shall bear all additional costs.

8.2 Unless otherwise indicated in writing by Lonza, all Prices and charges are exclusive of value added tax (VAT) and of any other applicable taxes, levies, import, duties and fees of whatever nature imposed by or under the authority of any government or public authority and all such charges applicable to the Services shall be paid by Customer.

8.3 Lonza shall issue invoices to Customer for fifty percent (50%) of the Price for Products or Services upon commencement thereof and fifty percent (50%) upon Release of applicable Batches or deliverables, or completion of applicable Services, unless otherwise stated in the Project Plan. Charges for Raw Materials and the Raw Materials Fee for each Batch shall be invoiced upon the Release of each Batch, provided, that any Raw Materials required to be ordered more than six (6) months in advance shall be invoiced fifty percent (50%) at the time of order by Lonza and fifty percent (50%) upon Release of the Batch. All invoices are strictly net and payment must be made within thirty (30) days of date of invoice. Payment shall be made without deduction, deferment, set-off, lien or counterclaim.

8.4 If in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of (i) rate of two percent (2%) per month above the London Interbank Offered Rate (LIBOR) or (ii) the maximum rate allowable by applicable law, interest to accrue on a day to day basis until full payment; and Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights, be entitled to suspend the provision of the Services and or delivery of Product until all overdue amounts have been paid in full including interest for late payments.

9. Capital Equipment

9.1 Any Capital Equipment required for the performance of the Services shall be acquired on terms to be agreed by the Parties prior to commencement of the relevant Services.

10. Intellectual Property

10.1 Neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party or any of its Affiliates.

10.2 Subject to Clause 10.3, Customer shall own all right, title, and interest in and to any and all Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza develops, conceives, invents, first reduces to practice or makes solely or jointly with Customer or others, to the extent that it constitutes any aspect of the Manufacturing Process (excluding any Lonza Background Intellectual Property of Lonza and any New General Application Intellectual Property incorporated therein) or is both:

10.2.1 a derivative of, alteration, enhancement, modification, or improvement to Customer Information, and/or Customer Background Intellectual Property; and

10.2.2 severable from and does not incorporate any Lonza Background Intellectual Property, Lonza Information and/or New General Application Intellectual Property and does not disclose or reveal any unregistered Lonza Background Intellectual Property or any previously undisclosed Lonza Information;

(the "New Customer Intellectual Property"). For the avoidance of doubt, "New Customer Intellectual Property" shall include any material, processes or other items that embody, or that are claimed or covered by, any of the foregoing new Intellectual Property, but excluding any New General Application Intellectual Property.

10.3 Notwithstanding Clause 10.2, and subject to the license granted in Clause 10.5, Lonza shall own all right, title and interest in Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza, solely or jointly with Customer or others, develops, conceives, invents, or first reduces to practice or makes in the course of performance of the Services that:

10.3.1 is solely of general application to the development or manufacture of chemical or biological products or products components and in no way is specific to the manufacturing of the Product; or

10.3.2 is an improvement of, or direct derivative of, any Lonza Background Intellectual Property or Lonza Information;

(the "New General Application Intellectual Property"). For the avoidance of doubt, "New General Application Intellectual Property" shall include any material, processes or other items that embody, or that are claimed or covered by, any of the foregoing Intellectual Property.

10.4 Lonza hereby assigns to Customer all of its right, title and interest in any New Customer Intellectual Property. Lonza shall execute, and shall require its personnel as well as its Affiliates, External Laboratories or other contractors or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Customer's ownership of the New Customer Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Customer Intellectual Property and waiver of moral rights therein. To the extent that Customer has or obtains any rights, title or interest in New General Application Intellectual Property, Customer hereby assigns to Lonza all of its right, title and interest in any New General Application Intellectual Property. Customer shall execute, and shall require its personnel as well as its Affiliates, or other contractors or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Lonza's ownership of the New General Application Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New General Application Intellectual Property.

10.5 Subject to the terms and conditions set forth herein (including the payment of the Price as required above), Lonza hereby grants to Customer a non-exclusive, royalty free, world-wide, fully paid-up, perpetual, irrevocable, transferable license, under the New General Application Intellectual Property, to use, sell and import the Product (but no other products) manufactured under this Agreement.

10.6 Customer hereby grants Lonza and its Affiliates, sub-contractors and the External Laboratories the non-exclusive right to use the Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property and any and all other intellectual property supplied by or on behalf of the Customer, during the Term solely for the purpose of fulfilling their obligations under this Agreement.

10.7 Provided that (i) Customer is not in breach of this Agreement; and/or (ii) Lonza has not terminated this Agreement pursuant to Clauses 14.2.1 and/or 14.2.2, Customer will have the right to transfer the Manufacturing Process to itself and/or any Third Party (such Third Party shall be Customer's sub-licensee), and on the basis that such transfer shall be for the manufacture of Product (but no other products); provided, however, to the extent such technology transfer includes any Lonza Information, Lonza Background Intellectual Property or New General Application Intellectual Property, such technology transfer shall be subject to a mutually agreed upon reasonable technology transfer fee based on Lonza costs for support of the transfer and on terms to be agreed by the Parties (which shall be in a separate technology transfer agreement) prior to any such transfer. Lonza shall provide reasonably necessary documents to complete such technology transfer and Customer shall reimburse Lonza for any costs (based on a full-time employee rate for such support) and expenses. For the avoidance of doubt, until such terms are agreed, Customer shall not have any right to use any Lonza Information, Lonza Background Intellectual Property or New General Application Intellectual Property nor transfer it to any Third Party.

10.8 Unless the Parties expressly, mutually agree to the contrary in writing, including Without limitation by express reference to a given Other Agreement (as defined below), nothing in this Agreement (or any Project Plan entered into pursuant to this Agreement) shall supersede, amend or otherwise modify any terms or conditions or other provisions of any other agreement between the Parties that is entered into prior to or contemporaneously with the execution of this Agreement, including, without limitation, any agreement related to any gene expression system, or any intermediates of or precursors to any Product, or any services performed by Lonza or any Affiliate of Lonza for Customer, or any consumables or other products supplied by Lonza or any Affiliate to Customer (collectively, an "Other Agreement").

10.9 Lonza and Customer agree to cooperate in the filing of any patent application relating to Customer Property and Lonza Property. If any invention relates to both Customer Property and Lonza Property, and Customer and Lonza both desire to file or have filed patent applications claiming the Customer Property and the Lonza Property respectively, Customer and Lonza agree to file such applications simultaneously.

11. Warranties

11.1 Lonza represents and warrants that:

11.1.1 it has the necessary skill and expertise to perform the Services.

11.1.2 it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind, that would breach the provisions of this Agreement;

11.1.3 the execution and delivery of this Agreement by Lonza has been authorized by all requisite corporate or company action and this Agreement is and shall remain a valid and binding obligation of Lonza, enforceable in accordance with its terms;

11.1.4 to its knowledge, the conduct and the provision of the Services shall not infringe, misappropriate or violate (as the case may be) any proprietary or Intellectual Property rights of any Third Party;

11.1.5 it shall promptly notify Customer in writing if it receives or is notified of a formal written claim from a Third Party that Lonza Information, Lonza Background Intellectual Property or New General Application Intellectual Property, as it relates to the Services under this Agreement, or that the use by Customer thereof, to the extent permitted under this Agreement, infringes, misappropriates or violates (as the case may be) any proprietary or Intellectual Property rights of any Third Party;

11.1.6 the Services shall be performed in accordance with all Applicable Laws;

11.1.7 except with respect to any development services and Engineering Batches, the manufacture of Product shall be performed in accordance with cGMP and will meet the Specifications at the date of delivery; and

11.1.8 it or its Affiliates hold all necessary permits, approvals, consents and licenses to enable it to perform the Services at the Facility , except to the extent that failure to maintain such licenses, permits and approvals do not have a material adverse impact on the ability to manufacture the Product in the Facility, or on the Services provided under this Agreement.

11.2 Customer warrants that:

11.2.1 it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind, that would breach the provisions of this Agreement;

11.2.2 the execution and delivery of this Agreement by Customer has been authorized by all requisite corporate or company action and this Agreement is and shall remain a valid and binding obligation of Lonza, enforceable in accordance with its terms;

11.2.3 all Raw Materials actually supplied by Customer shall be provided with a certificate of analysis or other relevant documentation demonstrating that such Raw Materials meet the following Lonza acceptance criteria: (i) are not contaminated, (ii) test negative for mycoplasma and bioburden (if applicable), (iii) have been manufactured in accordance with GMP (if applicable), (iv) are free from all liens, charges, or encumbrances, and (v) meet other testing requirements and/or specifications as may be agreed in writing by the Parties. In addition, Customer has provided any environmental, health and safety information related to the Raw Materials (including employee health and safety, of the handling, manufacture, distribution, use and disposal of the Raw Materials), and will update, clarify, correct, supplement and amend such information as necessary;

11.2.4 it has all the rights necessary to permit Lonza and its relevant Affiliates to perform the Services without infringing the Intellectual Property rights of any Third Party and the performance of the Services, including the use of the Manufacturing Process, shall not infringe, misappropriate or violate (as the case may be) any proprietary or Intellectual Property rights of any Third Party; and

11.2.5 it shall promptly notify Lonza in writing if it receives or is notified of a formal written claim from a Third Party that Customer Information and/or Customer Intellectual Property or that the use by Lonza thereof for the provision of the Services infringes , misappropriates or violates (as the case may be) any proprietary or Intellectual Property or other rights of any Third Party;

11.2.6 In connection with its receipt and usage of the Services and Products, Customer shall comply with, and shall cause its Affiliates, subsidiaries, subcontractors, directors, officers, employees, agents or any other person acting on behalf of Customer (its "Relevant Agents") to comply with, all applicable Corruption Laws and International Trade Restrictions. Customer's receipt and usage of the Services and Products shall be in accordance with Applicable Laws; and

11.3 In connection with its receipt and usage of the Services and Products, Customer shall take appropriate technical and organizational measures to ensure compliance with the GDPR. Customer shall in compliance with GDPR as well as on Lonza's request, destroy all personal data, unless Applicable Law prevents Customer from destroying. Customer confirms that any customer personal identifiable data shared with Lonza is done in accordance with the requirements of the GDPR.

11.4 DISCLAIMER: THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE EXPRESSLY DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

12. Indemnification and Liability

12.1 Indemnification by Lonza. Lonza shall indemnify the Customer, its Affiliates, and their respective officers, employees and agents ("Customer Indemnitees") for any loss, damage, costs and expenses (including reasonable attorney fees) that Customer Indemnitees may suffer as a result of any Third Party claim arising directly out of (i) any material breach of the warranties given by Lonza in Clause 11.1 above or (ii) any claims alleging that the Services (excluding use by Lonza of Customer Information and Customer Background Intellectual Property) infringe any Intellectual Property rights of a Third Party except, in each case, to the extent that such claims resulted from the negligence, intentional misconduct or breach of this Agreement by any Customer Indemnitees.

12.2 Indemnification by Customer. Customer shall indemnify Lonza, its Affiliates, and their respective officers, employees and agents ("Lonza Indemnitees") from and against any loss, damage, costs and expenses (including reasonable attorney fees) that Lonza Indemnitees may suffer as a result of any Third Party claim arising directly out of (i) any material breach of the warranties given by Customer in Clause 11.1.1 above; or (ii) any claims alleging that the performance of Services infringes any Intellectual Property rights of third parties; or (iii) the manufacture, use, sale, or distribution of any Product, including any claims of product liability; except, in each case, to the extent that such claims resulted from the negligence, intentional misconduct or breach of this Agreement by any Lonza Indemnitees.

12.3 Indemnification Procedure. If the Party to be indemnified intends to claim indemnification under this Clause 12, it shall promptly notify the indemnifying Party in writing of such claim. The indemnitor shall have the right to control the defense and settlement thereof; provided, however, that any indemnitee shall have the right to retain its own counsel at its own expense. The indemnitee, its employees and agents, shall reasonably cooperate with the indemnitor in the investigation of any liability covered by this Clause 12. The failure to deliver prompt written notice to the indemnitor of any claim, to the extent prejudicial to its ability to defend such claim, shall relieve the indemnitor of any obligation to the indemnitee under this Clause 12.

12.4 DISCLAIMER OF CONSEQUENTIAL DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR LOST REVENUES ARISING FROM OR RELATED TO THIS AGREEMENT, EXCEPT TO THE EXTENT RESULTING FROM FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT.

12.5 LIMITATION OF LIABILITY. LONZA'S LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED, IN THE AGGREGATE, THE TOTAL AMOUNTS PAID BY CUSTOMER TO LONZA UNDER THE PROJECT PLAN GIVING RISE TO SUCH CLAIM FOR DAMAGES, EXCEPT TO THE EXTENT RESULTING FROM LONZA'S FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT.

13. Confidentiality

13.1 A Party receiving Confidential Information (the "Receiving Party") agrees to strictly keep secret any and all Confidential Information received during the Term from or on behalf of the other Party (the "Disclosing Party") using at least the same level of measures as it uses to protect its own Confidential Information, but in any case at least commercially reasonable and customary efforts. Confidential Information shall include information disclosed in any form including but not limited to in writing, orally, graphically or in electronic or other form to the Receiving Party, observed by the Receiving Party or its employees, agents, consultants, or representatives, or otherwise learned by the Receiving Party under this Agreement, which the Receiving Party knows or reasonably should know is confidential or proprietary.

13.2 Notwithstanding the foregoing, Receiving Party may disclose to any courts and/or other authorities Confidential Information which is or will be required pursuant to applicable governmental or administrative or public law, rule, regulation or order. In such case the Party that received the Confidential Information will, to the extent legally permitted, inform the other Party promptly in writing and cooperate with the Disclosing Party in seeking to minimize the extent of Confidential Information which is required to be disclosed to the courts and/or authorities.

13.3 The obligation to maintain confidentiality under this Agreement does not apply to Confidential Information, which:

13.3.1 at the time of disclosure was publicly available; or

13.3.2 is or becomes publicly available other than as a result of a breach of this Agreement by the Receiving Party; or

13.3.3 as the Receiving Party can establish by competent proof, was rightfully in its possession at the time of disclosure by the Disclosing Party and had not been received from or on behalf of Disclosing Party; or

13.3.4 is supplied to a Party by a Third Party which was not in breach of an obligation of confidentiality to Disclosing Party or any other party; or

13.3.5 is developed by the Receiving Party independently from and without use of the Confidential Information, as evidenced by contemporaneous written records.

13.4 The Receiving Party will use Confidential Information only for the purposes of this Agreement and will not make any use of the Confidential Information for its own separate benefit or the benefit of any Third Party including, without limitation, with respect to research or product development or any reverse engineering or similar testing. The Receiving Party agrees to return or destroy promptly (and certify such destruction) on Disclosing Party's request all written or tangible Confidential Information of the Disclosing Party, except that one copy of such Confidential Information may be kept by the Receiving Party in its confidential files for record keeping purposes only.

13.5 Each Party will restrict the disclosure of Confidential Information to such officers, employees, consultants and representatives of itself and its Affiliates who have been informed of the confidential nature of the Confidential Information and who have a need to know such Confidential Information for the purpose of this Agreement. Prior to disclosure to such persons, the Receiving Party shall bind its and its Affiliates' officers, employees, consultants and representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The Receiving Party shall notify the Disclosing Party as promptly as practicable of any unauthorized use or disclosure of the Confidential Information.

13.6 The Receiving Party shall at any time be fully liable for any and all breaches of the confidentiality obligations in this Clause 13 by any of its Affiliates or the employees, consultants and representatives of itself or its Affiliates.

13.7 Each Party hereto expressly agrees that any breach or threatened breach of the undertakings of confidentiality provided under this Clause 13 by a Party may cause irreparable harm to the other Party and that money damages may not provide a sufficient remedy to the non-breaching Party for any breach or threatened breach. In the event of any breach and/or threatened breach, then, in addition to all other remedies available at law or in equity, the non-breaching Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the non-breaching Party.

13.8 All obligations of confidentiality under this Clause 13 will terminate seven (7) years after the expiration or termination of the Term; provided however that the obligations of confidentiality for Confidential Information identified as a trade secret will survive indefinitely until such trade secret information no longer qualifies as a trade secret.

14. Term and Termination

14.1 Term. This Agreement shall commence on the Effective Date and shall end on the third (3rd) anniversary of the Effective Date unless terminated earlier as provided herein or extended by mutual written consent of the Parties (the "Term"). Notwithstanding the foregoing, each Project Plan may have separate term and termination provisions so long as the term of any Project Plan does not extend beyond the Term.

14.2 Termination. This Agreement may be terminated as follows:

14.2.1 by either Party if the other Party breaches a material provision of this Agreement or a Project Plan and fails to cure such breach to the reasonable satisfaction of the non-breaching Party within ninety (90) days ten (10) days for non-payment) following written notification of such breach from the non-breaching party to the breaching party; provided, however, that such ninety (90) day period shall be extended as agreed by the Parties if the identified breach is incapable of cure within ninety (90) days and if the breaching Party provides a plan and timeline to cure the breach, promptly commences efforts to cure the breach and diligently prosecutes such cure (it being understood that this extended period shall be unavailable for any breach regarding non-payment);

14.2.2 by either Party, immediately, if the other Party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy or has a receiver appointed for a substantial part of its assets; or

14.2.3 by either Party pursuant to Clause 15.

14.3 Consequences of Termination. In the event of termination hereunder, Lonza shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process; (ii) subject to Section 2.9, all costs incurred through the date of termination, including Raw Materials costs and Raw Materials Fees for Raw Materials used or purchased for use in connection with the Project Plan; (iii) all unreimbursed Capital Equipment and related decommissioning charges incurred pursuant to Clause 9; and (iv) any applicable Cancellation Fees. In the case of termination by Lonza for Customer's material breach, Cancellation Fees shall be calculated as of the date of written notice of termination.

14.4 Survival. The rights and obligations of each Party which by their nature survive the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement, including, as applicable, Clauses 5 (insurance), 8.3, 8.4, 10 (intellectual property), 12 (indemnification and liability), 13 (confidentiality), 14.3, and 16 (to the extent relevant).

15. Force Majeure

15.1 If Lonza is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives written notice thereof to Customer specifying the matters constituting Force Majeure together with such evidence as Lonza reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, Lonza shall be excused from the performance or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue. Provided that, if such Force Majeure persists for a period of six (6) months or more, Customer may terminate this Agreement by delivering written notice to Lonza.

15.2 "Force Majeure" shall be deemed to include any reason or cause beyond Lonza's reasonable control affecting the performance by Lonza of its obligations under the Agreement, including, but not limited to, any cause arising from or attributable to acts of God, strike, lockouts, labor troubles, restrictive governmental orders or decrees, riots, insurrection, war, terrorists acts, or the inability of Lonza to obtain any required raw material, energy source, equipment, labor or transportation, at prices and on terms deemed by Lonza to be reasonably practicable, from Lonza's usual sources of supply.

15.3 With regard to Lonza, any such event of Force Majeure affecting services or production at its Affiliates or suppliers shall be regarded as an event of Force Majeure.

16. Miscellaneous

16.1 Non-Solicitation. During the term of this Agreement and for two (2) years thereafter, Customer agrees not to seek to induce or solicit any employee of Lonza to discontinue his or her employment with Lonza in order to become an employee or an independent contractor of Customer or its Affiliates; provided, however, that Customer shall be in violation of this Section 16.1 as a result of making a general solicitation for employees or independent contractors. For the avoidance of doubt, the publication of an advertisement shall not constitute solicitation or inducement.

16.2 Severability. If any provision hereof is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties hereto undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the Purpose.

16.3 Amendments/Assignment. Modifications and/or amendments of this Agreement must be in writing and signed by the Parties. Lonza shall be entitled to instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement, but Lonza shall remain fully responsible in respect of those obligations. Subject thereto, neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that (a) Lonza may assign this Agreement to (i) any Affiliate of Lonza or (ii) any third party in connection with the sale or transfer (by whatever method) of all or substantially all of the assets of the business related to the Facility or providing the Services, and (b) Lonza shall be entitled to sell, assign and/or transfer its trade receivables resulting from this Agreement without the consent of the Customer. For purposes of this Clause 16.3, the terms "assign" and "assignment" shall include, without limitation (i) the sale of fifty percent (50%) or more of the outstanding stock of such Party to an Affiliate of such Party or an unrelated entity or natural person, (ii) the sale or transfer or other assignment of all or substantially all of the assets of the Party or the line of business or Product to which this Agreement relates, and (iii) a merger, consolidation, acquisition or other form of business combination. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

16.4 Notice. All notices must be written and sent to the address of the Party first set forth above. All notices must be given (a) by personal delivery, with receipt acknowledged, (b) by facsimile followed by hard copy delivered by the methods under (c) or (d), (c) by prepaid certified or registered mail, return receipt requested, or (d) by prepaid recognized next business day delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

16.5 Governing Law/Jurisdiction. This Agreement is governed in all respects by the laws of the State of New York, USA. The Parties agree to submit to the jurisdiction of the state and federal courts of the State of New York, USA.

16.6 Entire Agreement. This Agreement contains the entire agreement between the Parties as to the subject matter hereof and supersedes all prior and contemporaneous agreements with respect to the subject matter hereof. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by .pdf shall constitute an original signature for purposes of this Agreement.

[Signature page follows.]

IN WITNESS WHEREOF, each of the Parties hereto has caused this Development and Manufacturing Services Agreement to be executed by its duly authorized representative as of the Effective Date.

LONZA LTD

By: /s/ Bart van Aarnhem
Name: Bart van Aarnhem
Title: Associate General Counsel

By: /s/ Marie Leblanc
Name: Marie Leblanc
Title: Head of Sales EMEA, Small Molecues

XORTX

By: /s/ Allen Davidoff
Allen Davidoff
CEO

APPENDIX A
Project Plan A -1

Project Plan titled "GMP Manufacture of 14kg Oxypurinol", dated March 31, 2021

(Lonza Reference: PN-036484)

APPENDIX B
Quality Agreement

[To be attached once finalized]

APPENDIX C

Translation Costs

As of the Effective Date, Lonza's cost of translation that is referenced in Section 4.3 of the Agreement is as follows:

- $1,500 (One Thousand Five Hundred USD) per executed Batch record.

GLOBAL MASTER SERVICES AGREEMENT

THIS GLOBAL MASTER SERVICES AGREEMENT is made on the date of the last signature (the "**Effective Date**") by and between **ALTASCIENCES COMPANY INC.** ("**CRO**") having its principal place of business at 575, boul. Armand-Frappier, Laval, Quebec, Canada, H7V 4B3, and its Affiliates, and XORTX Therapeutics Inc. ("**Sponsor**"), having its principal place of business at c/o Suite 4000, 421 – 7th Avenue, Calgary, T29 4K9 (each a "Party," and collectively, the "Parties").

WHEREAS Sponsor desires to retain CRO to provide the Services, upon the terms and conditions hereinafter set forth, and CRO is willing to perform such Services;

WHEREAS the Parties have agreed to enter into this Agreement setting out the general terms and conditions for the performance by CRO of the Services to Sponsor;

NOW, THEREFORE, in consideration of the promises and the mutual covenants herein contained and other good and valuable consideration, the Parties hereby agree as follows:

1. DEFINITIONS

1.1 "**Affiliate(s)**" of a Party shall mean any entity which directly or indirectly controls, is controlled by, or is under common control with that Party at any time during the period for which the determination of affiliation is being made.

1.2 "**Agreement**" shall mean this Global Master Services Agreement, including all exhibits and all Statements of Work entered into in accordance with the terms hereof, as it may be amended from time to time in accordance with its terms.

1.3 "**Closing Date**" shall mean, in relation to a Drug or a Test Article, the date of the first dose administration of such Drug or Test Article.

1.4 "**Drugs**" shall mean the Study medications supplied by Sponsor and may include in certain situations, the devices supplied by Sponsor in connection with a clinical portion of a Study.

1.5 "**Protocol**" shall mean the approved protocol in connection with a Study and all amendments thereto.

1.6 "**Representatives**" shall mean any Affiliates, employees, officers, directors, shareholders, agents, subcontractors or advisors, including attorneys and accountants of a Party.

1.7 "**Samples**" shall mean the biological samples collected in connection with a Study.

1.8 "**Services**" shall mean the early stage drug development services to be performed by CRO as described in more detail in each SOW.

1.9 "**SOW**" shall mean a Statement of Work entered into by the Parties substantially in the form of **Schedule I** and incorporated by reference to this Agreement.

1.10 "**Stipend**" shall mean the payments received by Subjects to participate in a Study.

1.11 "**Site**" shall mean a third-party site or investigator that is contracted by CRO for a multi-site study.

1.12 "**Study**" shall mean a clinical, preclinical, bioanalytical, pharmacokinetic ("PK") analysis study program or any research services (such as toxicokinetic ("TK") and data management) and all related activities.

1.13 "**Subjects**" shall mean any individual enrolled by CRO to whom the Drugs will be given and who may provide biological substances for analysis of such Drugs.

1.14 "**Test Article**" shall mean any Study medications supplied by Sponsor and may include, in certain situations, materials, special equipment, or other substances supplied by Sponsor in connection with the preclinical portion of a Study.

2. SCOPE OF THE AGREEMENT

2.1 **Scope**. This Agreement governs the terms pursuant to which CRO shall perform the Services requested from time to time by Sponsor as set out in the SOW. The specific details and tasks for each Service shall be separately negotiated and specified in the SOW's signed by both Parties.

2.2 **Use of Affiliates**. The Parties agree that Affiliates of Sponsor and/or CRO may enter into SOW's, provided that they agree to abide by the terms and conditions of this Agreement to the extent applicable. Sponsor and CRO shall be responsible for any breach of this Agreement or any SOW by their respective Affiliates or for any failure to perform the obligations thereof.

3. RESPONSIBILITIES AND OBLIGATIONS OF CRO

3.1 **Responsibilities**. CRO shall:

a) perform the Services in compliance with the requirements of this Agreement, the SOW's and the Protocol;

b) comply with all federal, provincial and local laws and regulations applicable to the provision of Services and generally accepted industry standards, including the ICH guidelines E6 for Good Clinical Practices, applicable requirements as outlined in the FDA, OECD Principles of Good Laboratory Practices, and the Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (EMA/INS/GCP/532137/2010), all relevant professional standards and guidelines, and all local laws and regulations pertaining to animal care and use and animal welfare;

c) exercise reasonable care and a high standard of professional conduct in the performance of the Services and ensure that the Services are performed by qualified personnel;

d) notify Sponsor of any serious adverse event occurring during the performance of the Services and, if specified, in the manner that may be specified in the protocol;

e) in connection with the provision of preclinical services, perform the Services in a timely manner as detailed in the SOW;

f) in connection with the provision of clinical services, use its commercially reasonable efforts to complete recruitment and perform the Services in a timely manner as detailed in the SOW;

g) in connection with the provision of bioanalytical services, perform the analysis of the Samples in compliance with the bioanalytical method as described in the bioanalytical plan;

h) in connection with the provision of statistical and TK and/or PK analysis services, perform the analysis in compliance with the statistical analysis plan and/or the PK analysis plan;

i) following completion of the Study or analysis, as applicable, deliver to Sponsor the draft and final report, or the agreed upon final deliverables if there is to be no report;

j) notify Sponsor of any finding that could negatively affect the conduct of the Services or any finding that could affect the safety of the Subjects, including any safety issue or notice of defective product, or their willingness to continue their participation in a Study; and

k) in connection with a multi-site study, contract and manage Sites and perform other services as specified in the SOW.

3.2 **Changes to Services**. In the event that Sponsor initiates a change that affects the conduct of the Services including, without limitation, a change to the Drug, Test Article or to the Protocol, CRO will prepare a change order to the SOW which shall reflect the adjustments to the budget and the schedule to be agreed upon in writing. Sponsor shall have ten (10) days to review and accept this change order. If the change order is not signed, it shall be deemed to not be accepted and the Sponsor and CRO shall work together to achieve a mutually acceptable change order. CRO shall not be held responsible for any delay or non-observance of its deadlines resulting from the changes initiated by Sponsor or resulting from failure to obtain the necessary information or instructions from Sponsor.

3.3 **Repeat Sample Analysis**. If applicable, the parties agree that as of commencement of work, in some instances, repeat of sample analysis will be required. If this arises, the CRO will notify the Sponsor as soon as possible and determine, between the parties, if these repeats are required by the Sponsor. The price per sample analysis/occasion, as indicated in the applicable SOW, will apply to any additional repeats requested by the Sponsor, as well as any samples above the analytical range, which require dilution or samples that are pre-diluted (at the first analysis) at the Sponsor's request and using the Sponsor's dilution factor, if applicable. The CRO will endeavor, as much as possible, to proceed with current batches of sample analysis at the agreed price per sample; however, should additional batches be needed a mutually agreeable batch fee will apply.

4. RESPONSIBILITIES AND OBLIGATIONS OF SPONSOR

4.1 Responsibilities. Sponsor shall:

a) provide CRO in a timely fashion with all information and materials reasonably required to perform the Services described in the SOW;

b) comply with all laws and regulations applicable to the provision of Services;

c) notify CRO of any finding that could affect the conduct of the Services or any finding that could affect the safety of the Subjects, including any safety issue or notice of defective product, or their willingness to continue their participation in a Study; and

d) to the extent a Clinical study report is prepared by CRO, provide CRO with comments on the draft report within three (3) months after the receipt date of such report. In the event where CRO does not receive Sponsor's comment within three (3) months after the shipment date, CRO reserves the right to finalize and submit the final report to Sponsor. To the extent a Preclinical or other study report is prepared by CRO, provide comments on the draft report within thirty (30) days after receipt. If Sponsor's comments are not received within thirty (30) days, CRO reserves the right to finalize and submit the final report to Sponsor. Any amendment requested by Sponsor following the finalization and submission of the final report shall be subject to additional charges.

4.2 Preclinical Services. In connection with the provision of preclinical services, CRO shall make commercially reasonable efforts to, in material accordance with the schedule set forth in the Protocol, furnish the Sponsor with a draft report and a final report for the Study; provided, however, CRO shall have no liability to the Sponsor for any delay or failure to perform the Study in accordance with the Protocol if such delay or failure is a result of the Sponsor's failure to duly and timely perform any and all of its obligations hereunder. One additional revised draft report will be provided upon Sponsor's request; additional draft reports will be provided upon request at Sponsor's additional cost determined at CRO' s then prevailing rates. The final report shall summarize all the material procedures, data, observations and results obtained from the Study, and CRO shall make commercially reasonable efforts to issue the final report within thirty (30) days after the Sponsor's approval of the draft report (which approval may not be unreasonably withheld, conditioned or delayed).

4.3 Clinical services. In connection with the provision of clinical services, Sponsor shall:

a) ensure that the Drugs supplied to CRO are manufactured and packaged in accordance with the currently effective Good Manufacturing Practices regulations so that it is suitable for human intake;

b) ensure that the storage and transport of the Drugs have been done in compliance with applicable laws;

c) provide all necessary data on Drugs' formulation stability and storage requirements to CRO; and

d) supply CRO, at least seven (7) days prior to the agreed Dosing Date, with a sufficient quantity of the Drugs and provide a valid certificate of analysis for the Drugs, which would include the lot identification and the measured content of the Drugs and, if the certificate of analysis was issued more than six (6) months prior to the Dosing Date, the stability data related to such Drugs.

4.4 **Bioanalytical services**. In connection with the provision of bioanalytical services, Sponsor shall, if the clinical services have been performed by a party other than CRO, inform CRO prior to the starting date of the Services of any concomitant medication taken by Subjects during the clinical phase of a Study and compensate CRO for the costs, including but not limited to the cost of staff, supplies, facilities and instrument usage, incurred to perform the additional tests required as a result of the intake of such concomitant medication.

4.5 **Research Services**. Support Services (Toxicokinetic/ Pharmacokinetic/ Biostatistics/ Regulatory Affairs/ Data Management) If Research Services are required as per any SOW, the CRO agrees to perform the data management, TK/PK and statistical analyses of the data generated in compliance with the applicable guidelines for submission as asked by the Sponsor and detailed in the Protocol.

4.6 **Adverse event reporting**. Sponsor remains responsible for any adverse event reporting to Health Canada, Food & Drug Administration or any other regulatory authority in accordance with applicable laws and regulations.

5. FINANCIAL ARRANGEMENTS

5.1 **Service fees and payment milestones**. For the Services rendered, Sponsor agrees to pay to CRO the total fee indicated in the SOW and any other additional fees set forth herein.

5.2 **Payment terms**. Payments are due within thirty (30) days of the date of invoice. In the event of late payment and unless CRO has been notified in writing of any legitimate dispute, interest on unpaid invoices may be charged at the rate of 1.5% per month, calculated monthly on a compounded basis, on invoices which remain unpaid after thirty (30) days from the date of invoice. After ten (10) days from receipt by Sponsor of CRO's written notice regarding failure to pay the invoice in due time, CRO retains the right to delay or stop any Services provided under the SOW and/or retain any results or report. Additionally, CRO may be entitled to expenses incurred in its efforts to collect unpaid invoices from Sponsor, if necessary, including, without limitation, court costs and reasonable legal fees. All payments due shall be made unconditionally without defense, counterclaim, offset and shall not be conditioned or delayed pending Sponsor's receipt of payment from any third party.

5.3 **Pass-through Costs**. CRO will separately invoice Sponsor for the expenses incurred during the Services (the "Pass-through Costs") that have been agreed to by Sponsor. If applicable, the estimated Pass-through costs will be outlined in each SOW. The estimated Pass-through costs are included as an indication; the Sponsor agrees to pay the actual expenses incurred by the CRO during the services provided that CRO has notified Sponsor in advance of any material deviation from the estimated Pass-through Costs.

5.4 **If/when study is placed at Altasciences Clinical Kansas Inc.**, Altasciences Clinical Kansas, P.A. ("Kansas P.A.") will perform any part of the Services that constitutes the practice of medicine, as determined by Kansas law (the "Medical Services") as set forth in the applicable SOW.

5.5 **If the study is multi-site**, CRO will administer payments to Sites during the course of the Study as agreed upon in separate agreements between Sites and CRO that Sponsor has also approved. Sponsor will advance CRO the fees upon execution of the SOW to facilitate prompt and timely payments to. Concurrent with CRO's issuance of payments, CRO will invoice Sponsor for the same amount to ensure the initial advance is replenished and Sponsor will pay in accordance with Section 5.2. If the advance balance is not sufficient to make timely payments to Site, CRO will request additional advance monies. If the balance is greater than needed, CRO will reduce the advance by requesting a lower replenishment amount. Sponsor acknowledges and agrees CRO will only pay Site from advances or pre-payments received from Sponsor for Sites' services, and that CRO will not make payments to Sites prior to receipt of sufficient funds from Sponsor. Sponsor agrees and acknowledges that CRO requires a prepayment to maintain cash neutrality over the term of the Study. If the Study extends over more than one calendar year, the budget will include an annual cost adjustment.

6. GROSS-UP ON PAYMENTS

6.1 **Gross-up on payments**. Any and all payments made by Sponsor under this Agreement shall be made free and clear of, and without deduction or withholding for or on account of any present or future taxes, levies, duties, charges, fees, deductions or withholdings, now or hereafter imposed, levied, collected, withheld or assessed by any governmental authority, excluding net income taxes or any other taxes imposed on or measured by the net income, profit or capital of CRO, if applicable. If a deduction or withholding is required by any applicable law, Sponsor shall:

a) pay or cause to be paid to the appropriate authority the amount of the withholding or deduction by no later than the latest date permitted by that authority (including any extension of time granted by that authority);

b) produce to CRO no later than thirty (30) days after that payment a receipt of that authority evidencing that it has received the proper amount from Sponsor;

c) pay such sums to CRO, as may be necessary so that the net amount received by CRO after all required deductions or withholdings (including deductions and withholdings for or on account of taxes on any sums payable under this section) will not be less than the amount CRO would have received had no such deduction or withholding been required; and

d) Sponsor shall indemnify and hold CRO harmless from any liability, resulting from Sponsor's failure to make timely payments in accordance with this section. Any penalties, interest or other liabilities arising from such failure shall be the sole responsibility of and be paid for by Sponsor.

7. CONFIDENTIALITY

7.1 **Confidential Information**. For the purpose of this Agreement, "Confidential Information" shall mean all non-public, confidential and proprietary information disclosed before, on or after the Effective Date, by a Party or its Representatives (the "Disclosing Party") to the other Party or its Representatives (the "Receiving Party"), whether written or oral, including, without limitation (i) all information concerning the Disclosing Party's and its Affiliates' business affairs including, without limitation, customers, suppliers, investors, organizational structure, finances, sales, pricing and commercial strategies; (ii) all scientific or technical information (including know-how and information concerning manufacturing, production, sourcing of raw material, chemical compounds, patent applications, assays, test results, data or formula), clinical and laboratory information (including trial design, protocols, study data, study results and bioanalytical method) and internal processes and procedures; and (iii) the existence of this Agreement. The term "Confidential Information" will not include: (i) information which after disclosure becomes part of the public domain by publication or otherwise, without breach of this Agreement by the Receiving Party; (ii) information which the Receiving Party can establish by documentary evidence is known by or in possession of the Receiving Party before being disclosed by the Disclosing Party; (iii) information which the Receiving Party developed independently, as established by documentary evidence, provided that such development is not based in whole or in part on Confidential Information disclosed by the Disclosing Party; or (iv) information which the Receiving Party receives from a third party on a non-confidential basis, provided that such third party is not prohibited from disclosing such information by an obligation of confidentiality to the Disclosing Party.

7.2 **Confidentiality obligations**. The Receiving Party agrees that:

a) it will not use the Confidential Information except in connection with the Services and that it will not use the Confidential Information in any manner that is competitive with or detrimental to the business or operations of the Disclosing Party;

b) it will not disclose any of the Confidential Information to any person or entity without the prior written consent of the Disclosing Party; provided, however, that Confidential Information may be disclosed to its Representatives if such persons need to know such information in connection with the Services, including the Site, if applicable. The Receiving Party will ensure that its Representatives are bound by confidentiality obligations to the same extent as if they were parties hereto, and the Receiving Party shall be responsible for any breach of confidentiality by its Representatives; and

c) it will exercise commercially reasonable precautions to physically protect the integrity and confidentiality of the Confidential Information.

7.3 **No breach of IP**. The Disclosing Party represents that the disclosure of Confidential Information to the Receiving Party does not infringe, violate or misappropriate intellectual property of any third party and does not violate any contract or obligation to which the Disclosing Party is a party.

7.4 **Term of confidentiality**. This Section 7 (CONFIDENTIALITY) shall apply to any Confidential Information for a period of ten (10) years from the date of disclosure.

7.5 **Ownership**. The Disclosing Party remains the exclusive owner and retains all rights, title and interest, including intellectual property rights, of the Confidential Information disclosed to the Receiving Party. All Confidential Information will be promptly returned or destroyed upon request of the Disclosing Party, except that the Receiving Party may retain copies of Confidential Information: (i) for the purpose of determining the Receiving Party's obligations hereunder; (ii) as required by law; and (iii) that are maintained pursuant to automatic archiving and back-up procedures.

7.6 **Request from government**. In the event Confidential Information is required to be disclosed by a governmental agency, the Receiving Party will provide the Disclosing Party with prompt written notice of such request to enable the Disclosing Party to seek, at its sole cost and expense, an appropriate protective order or remedy. If the Receiving Party is required to disclose Confidential Information, it will use commercially reasonable efforts to disclose only that portion of the Confidential Information as is legally required to be disclosed.

7.7 **Medical records**. In the event Sponsor shall come into contact with a Subject's medical records, Sponsor shall hold in confidence the identity of the Subject and shall comply with all applicable laws regarding the confidentiality of such records, including without any limitation any privacy laws or regulations.

8. INTELLECTUAL PROPERTY

8.1 **Initial IP**. Neither Party transfers by operation of this Agreement to the other Party any patent right, copyright, nor other proprietary right that it owns as of the commencement of the Services, except as specifically set forth herein.

8.2 **Study Drug**. The Parties acknowledge that the Drug, Test Article and/or any material provided by Sponsor which Sponsor considers to be necessary to and/or useful for CRO for the performance of the Services are, and shall remain, the exclusive property of Sponsor.

8.3 **Study Data**. The Parties agree that Sponsor, upon complete payment of the service fees indicated in the SOW or upon reimbursement in accordance with Section 5.2, shall own all results, methods, data, case report forms and other reports completed by CRO pursuant to the Protocol, Agreement or other written instruction by Sponsor (the "Study Data") including all patent and other intellectual property rights therein, excluding the Subjects' medical records. Upon Sponsor's prior consent, CRO may use the Study Data for its own internal, marketing, non-commercial research and educational purposes.

8.4 **Other IP**. Other than as specified in Section 8.3. CRO agrees that any intellectual property arising out of Services performed hereunder that are dependent on Sponsor's patent claims or are expressly anticipated by the Protocol and/or the bioanalytical plan and/or statistical analysis plan and/or the PK analysis plan, as applicable, shall be owned by Sponsor and shall be promptly disclosed by CRO to Sponsor.

9. STORAGE

9.1 **Documentation**. CRO will maintain documentation for the Services in accordance with all applicable authorities' regulations or as outlined in the SOW. CRO will notify Sponsor in the event any additional charges will be incurred due to large volumes or extended durations, in which the parties will agree to any additional charges in writing.

9.2 **Test Article**. CRO will store, destroy or return Test Article after completion of study as indicated in the applicable SOW and/or Quotation.

9.3 **Drugs**. CRO will maintain complete and accurate inventory of the Drugs received from Sponsor

a) For a FDA submission, CRO will keep in adequate storage a reserve quantity of the Drugs in accordance with 21 CFR 320. Following the retention period, Sponsor will be contacted to complete the Drug Disposition Form. Any other remaining unused Drug will be destroyed or returned to Sponsor (at Sponsor's cost), as indicated on the provided Drug Disposition Form. Should a response not be received from Sponsor within thirty (30) days of request to complete the Drug Disposition Form, or should the Sponsor require extended storage of the remaining unused Drug, CRO will store the Drugs at the rate indicated in the applicable SOW.

b) For TPD or EMA submissions, CRO will contact Sponsor to confirm if the Drugs should be stored at a rate per the applicable SOW, destroyed on site, or returned to Sponsor (at Sponsor's cost). Should a response not be received from Sponsor within thirty (30) days, CRO will automatically store the Drugs at a rate indicated in the applicable SOW.

c) For ANVISA submissions, CRO will retain a quantity of the Drugs necessary to repeat the Study as per ANVISA requirements until the Drugs expire. After the Drugs expire CRO will contact Sponsor to confirm if the Drugs should be stored at a rate per the applicable SOW, destroyed on site, or returned to Sponsor (at Sponsor's cost). Should a response not be received from Sponsor within thirty (30) days, CRO will automatically store the Drugs at a rate indicated in the applicable SOW.

9.4 **Samples**. CRO will maintain complete and accurate inventory of the Samples collected in connection with the Services. Preclinical samples will be stored as indicated in the Protocol and/or the SOW, as applicable. For clinical studies, upon shipment of the draft Bioanalytical report, CRO will keep in adequate storage, at its own cost, all the Samples for a period of three (3) months. CRO will contact Sponsor to confirm if the Samples should be stored at the then current storage rate or the rate indicated in the applicable SOW and/or Quotation, destroyed or returned to Sponsor (at Sponsor's cost). Should a response not be received from Sponsor, before the end of the free storage period, CRO will automatically store the Samples at the applicable rate. At any time, Sponsor may terminate the storage of the Samples by sending a written notice to CRO, instructing CRO to destroy the Samples or to ship the Samples to Sponsor or to a third party. In such case, all shipping charges are the responsibility of Sponsor.

10. LIMITATIONS TO SERVICES

10.1 **CRO's obligation**. CRO's obligation under this Agreement and any related SOW is limited to performing the Services in accordance with this Agreement, the Statements of Work and Protocol, while ensuring the conduct of the Services in compliance with applicable laws and regulations and generally accepted industry standards.

10.2 **Physician Services**. The Sponsor acknowledges that CRO will not, in any event, be liable for the Physician Services rendered by Kansas P.A. in accordance with Section 5.4.

10.3 **No specific results**. CRO does not give any representation or warranty that specific results can be achieved or that the Drugs or Test Article covered by any SOW can, either during the term of the SOW or thereafter, be successfully manufactured or receive the required approval by drug administration authorities or any regulatory bodies.

10.4 **Number of Subjects**. In the event that CRO fails to meet the Protocol requirements on the number of Subjects to be recruited, Sponsor will be given the option to extend the recruitment period or to continue the Study with less Subjects.

10.5 OTHER THAN THE WARRANTIES EXPRESSLY STATED IN SECTIONS 3, 4, AND 10, THERE ARE NO EXPRESSED OR IMPLIED WARRANTIES RELATED TO ANY OF THE SERVICES COVERED BY THIS AGREEMENT OR ANY STATEMENT(S) OF WORK.

11. INDEMNIFICATION

11.1 **Sponsor's indemnification**. Sponsor shall defend, indemnify and hold harmless CRO and its Representatives from any loss, expense (including reasonable defense cost), cost, liability, damage, claim, action or suit, including but not limited to any personal injuries, death, or property damage, arising directly out of: 1) the negligence or wrongful acts or omissions of Sponsor or its Representatives, 2) any defect, deficiency, malfunction, hazard or adverse reactions in or resulting from the Drug or any equipment and supplies provided or manufactured by Sponsor in connection with the Services, and 3) any material breach by Sponsor or its Representatives of any of its obligations or duties under this Agreement.

11.2 **CRO's indemnification**. CRO shall defend, indemnify and hold harmless Sponsor and its Representatives from any loss, expense (including reasonable defense cost), cost, liability, damage, claim, action or suit arising directly out of: 1) the negligence or wrongful acts or omissions of CRO or, its Representatives, affiliates, assignees, subcontractors or successors and 2) any material breach by CRO or its Representatives, affiliates, assignees, subcontractors or successors of any of its obligations or duties under this Agreement.

11.3 **Limitations**. Section 11.1 and 11.2 are subject to the following limitations:

a) In no event shall any Party be liable for any incidental, consequential, special or punitive damages, including but not limited to loss of revenue or profit.

b) The parties agree that the CRO liability towards Sponsor pursuant to Section 11.2 shall not exceed the fees paid by the Sponsor to the CRO in respect of the relevant SOW under this Agreement, and not to exceed a total amount of three million dollars ($3,000,000 USD).

c) **Third Party Indemnification**. For Multi-Site studies, if Site requests an indemnification for loss or damage caused by Sponsor's Project, then Sponsor shall provide such indemnification directly to the Site. CRO shall not sign or assume such indemnifications on Sponsor's behalf.

11.4 **Notifications**. Any indemnified Party will promptly notify the indemnifying Party of any claim as to which indemnified Party intends to seek indemnification from indemnifying Party. Each Party shall fully cooperate with the other Party in defending any claim as to which a notice of intent to seek indemnification is provided and will make no compromise or settlement without the prior written approval of the other Party.

11.5 **Medical expenses**. Sponsor shall reimburse each Subject for any reasonable and necessary medical expenses incurred for any medical care, including hospitalization, required as a result of Drugs following their administration or use in accordance with the Protocol, to the extent such expenses are not covered by the Subject's medical or hospital insurance coverage and are in no way attributable to the gross negligence or intentional misconduct of CRO or its Representatives. The Parties agree that (a) medical care for the natural progression of an underlying pre-existing condition and (b) alleged lack of efficacy of Drug are not covered under this Section.

12. INSURANCE

12.1 **CRO insurance**. CRO represents that it carries professional liability insurance for a limit up to five million dollars ($5,000,000 USD). To the extent any work is performed in the United States, worker's compensation insurance shall be maintained in the applicable statutory limits.

12.2 **Sponsor insurance**. Sponsor represents that it carries and shall carry for the term of this Agreement general liability and product liability insurance coverage for a sufficient limit to cover Sponsor's total liability under this Agreement. Sponsor warrants that, in addition to its liability insurance, it has the financial capacity to compensate any claim for which it is responsible that may exceed the coverage of its insurance policy. The insurance policy shall be valid in Canada if Studies are performed in Canada and/or valid in the United States if studies are performed in the United States and have a limit of at least five million dollars ($5,000,000 USD). Upon signature of a SOW or upon request of the CRO, Sponsor shall furnish a certificate of insurance acceptable to CRO indicating the required coverage. Sponsor will promptly notify CRO of any notice of cancellation or non-renewal of, or material change in, or claim against, its insurance coverage.

12.3 **Sponsor insurance for multi-site studies**. In connection with a multi-site study, in the terms of Section 12.2 apply, however, Sponsor represents that it carries and shall carry for the term of this Agreement, general liability in amounts of at least three million dollars ($3,000,000 USD) and product liability insurance coverage in amounts of at least ten million dollars ($10,000,000 USD). Sponsor represents and warrants that it will (i) maintain product liability insurance that does not contain any conditions or exclusions in the policy that would not normally be included in insurance of this type, and (ii) include CRO as an additional insured on all applicable clinical trials and/or product liability policies. Insurance coverage and indemnification obligations will be outlined in a separate agreement between Sponsor and Site.

13. AUDIT

13.1 **Visits**. Upon reasonable notice, Sponsor and its Representative may visit and inspect the CRO facilities during CRO's normal business hours and in compliance with CRO's then current site requirements in order to maintain current and personal knowledge of the conduct of Services through review of the records, comparison with source documents, observation and discussions. CRO will fully cooperate in any monitoring, audit or inspection by a regulatory agency in connection with the provision of Services.

13.2 **Inquiries**. CRO agrees to answer in a timely manner any questions coming from regulatory authorities and/or Sponsor which are Services-related and within the original scope of work. Following completion of the Services specified in the SOW, CRO reserves the right to request compensation for any additional analysis or additional supporting documents required by regulatory authorities and/or Sponsor.

14. TERM, TERMINATION, SUSPENSION AND POSTPONEMENT

14.1 **Term**.

a) This Agreement shall enter into force on the Effective Date and shall continue following three years from the Effective Date, unless terminated by both Parties, in which case the rights and obligations under this Agreement shall remain in full force and effect until the termination of all outstanding SOWs.

b) Statements of Work shall enter into force upon signature and shall continue thereafter until the date of acceptance by Sponsor of final report, or final deliverable if no report, unless terminated earlier either jointly by both Parties or by any Party pursuant to Section 14.2 or 14.3.

14.2 **Termination by Sponsor**. Sponsor may terminate a SOW, effective upon written notice to CRO:

a) if the execution of the Services is no longer of technical or commercial interest.

b) if CRO breaches this Agreement, the SOW or the Protocol in a way that materially impacts the Services, and (i) such breach is incapable of cure, or (ii) with respect to a breach capable of cure, CRO does not cure the breach within thirty (30) days after receipt of written notice of such breach.

14.3 **Termination by any Party**. Any Party may, acting reasonably, terminate a SOW effective upon written notice to the other Party if any safety issue arises or in order to comply with any law, regulation or decision of any judicial authority.

a) Either Party may terminate this Agreement or any SOW at any time in its sole discretion, upon giving thirty (30) days prior written notice to the other party.

b) If CRO encounters any difficulties beyond its reasonable control (including without limitation any Force Majeure event) in performing any of the Studies in accordance with the Protocol, CRO shall notify the Sponsor in writing, and the parties shall make good faith efforts to resolve or overcome such difficulties by amending the Protocol or otherwise. If such difficulties cannot be resolved or otherwise eliminated to CRO's reasonable satisfaction, or if the Sponsor fails to duly and timely perform any and all of its obligations hereunder, CRO shall have the right to terminate the SOW upon giving thirty (30) days prior written notice to the Sponsor.

14.4 **Consequences**. In the event of termination:

a) Sponsor shall reimburse CRO all incurred fees for Services performed and expenses and costs incurred prior to the termination, including non-cancellable obligations incurred prior to such termination. Such fees, expenses and costs shall include, but not be limited to administrative expenses, items procured, Services undertaken, and all non-cancellable obligations incurred specifically for the Services (e.g., animal purchases and animal expenses, including animal disposition, as well as specialized supplies and/or equipment.)

b) For clinical and clinical related services, the following costs outlined above shall apply for termination/postponement by the Sponsor and the following termination/ postponement fees:

Days before dosing	Postponement/Termination Fees	
More than 42 days	0%	Of total Study Fee (less Subject Stipends and less bioanalytical fees)
29 to 42	5%	
15 to 28	10%	
8 to 14	20%	
1 to 7	30%	

c) For animal studies, study delay and cancellation charges will be assessed as follows:

Days Of Notice Given Prior To The Scheduled Start Of Study Acclimation	Delay Or Cancellation Charge, % Of Total Study Price
1-14	50% + animal costs
15-28	30% + animal costs
29-42	20% + animal costs
43-56	10% + animal costs
57-70	5% + animal costs
71+	0% + animal costs*

*Should any animal costs and/or additional applicable fees be charged by the animal supplier before animals are on site, these will be passed on to the Sponsor.

d) If the Study is terminated prematurely because the Study is no longer of technical or commercial interest by the Sponsor after the dosing date, then the Sponsor will pay to the CRO the costs related to pre-study activities and completed study activities plus 60% of total study cost (minus Bioanalytical Operations & Volunteer Indemnification).

14.5 **Suspension for safety**. CRO shall be entitled to suspend the Services without notice and without engaging its liability for such suspension if, to its reasonable opinion, there is a safety issue arising which can affect the safety of the Subjects. If it occurs that the suspected danger is averted, the suspension will end and the Services will be resumed. If it occurs that the suspected danger is confirmed, the suspension will end and either Party will be enabled to terminate the Services as per Section 14.3.

14.6 **Postponement by Sponsor**. Sponsor may postpone the Services, provided that Sponsor pays postponement fees in the same amount as terminations fees set forth in Section 14.4.

14.7 **Pass-through Costs**. Upon early termination of any SOW in accordance with Section 14.2 or 14.3, CRO will invoice to Sponsor all unavoidable Pass-through Costs that were incurred up to termination.

14.8 **Impact on Study**. If clinical services are provided, immediately upon receipt of a written notice of termination by Sponsor, CRO shall promptly stop entering Subjects into the Study and shall cease conducting procedures on Subjects already entered in the Study, provided that CRO shall complete Study procedures for any Subject as to whom it determines in his sole discretion that completion is medically necessary. Upon payment, CRO shall, upon request, furnish to Sponsor all case report forms, either completed or uncompleted, up to the date of the Study termination, as well as all other Study materials.

15. ASSIGNMENT, SUBCONTRACTING AND CHANGE OF CONTROL

15.1 **Affiliates**. This Agreement and all rights and obligations hereunder, shall not be assigned by either Party without prior written notice to the Parties hereto. Notwithstanding the foregoing, CRO may assign, transfer, delegate and subcontract all or any part of the portion of the Services to any of its Affiliates. In such case, such Affiliate shall (i) abide by the terms and conditions of this Agreement and (ii) be entitled to the rights and benefits of CRO under this Agreement, including the right to enforce any terms of this Agreement. Furthermore, CRO may assign its rights and obligations under this Agreement, without the prior written consent of the Sponsor, to a successor including, without limitation, by reason of merger, amalgamation, corporate reorganization, sale of all or substantially all of the its assets or portion of its business which relates to the Services provided herein.

15.2 **Subcontractors**. Provided Sponsor has consented in writing, CRO may subcontract or delegate the performance of all or part of the Services under this Agreement to a third-party subcontractor, and provided that such subcontractor perform such activities in a manner consistent with the terms and conditions in this Agreement and that CRO shall remain liable for any non-performance or breach of the terms of this Agreement by the subcontractor.

15.3 **Change of control and bankruptcy**. Either party may terminate this Agreement and any SOWs in the event of a change of control of the other party hereto, or if the other party becomes insolvent, or a enters into a proceeding in bankruptcy, receivership or similar proceeding is filed involving the other party during the term of this Agreement.

16. MISCELLANEOUS

16.1 **Entire Agreement**. This Agreement, together with all schedules and Statements of Work, constitutes the sole and entire agreement of the Parties with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter, except any confidentiality agreement still outstanding between the Parties, which shall complete the provisions of this Agreement. The terms of this Agreement shall control in the event of a conflict with the terms of a SOW.

16.2 **Relationship between the Parties**. CRO shall perform all the Services as an independent contractor. Neither CRO nor Representatives are employees, partners, representatives, or joint venturers of or with Sponsor, and nothing in this Agreement shall be construed to create such a relationship. CRO shall be solely responsible for the manner and working hours in which it will perform the Services. It is the intention of the Parties that no form of legal agency relationship be created between the Parties and nothing in this Agreement shall be deemed to create in either Party the right or authority to incur any obligation on behalf of the other Party or to bind such other Party in any way whatsoever except in accordance with the terms of this Agreement.

16.3 **Notices**. All written notices from one Party to the other under this Agreement are sufficient as sent by email, unless otherwise specified in the Protocol or otherwise requested by Sponsor.

16.4 **Force majeure**. Neither Party shall be held liable for non-fulfilment or delayed performance of the Agreement or part thereof due directly or indirectly to any cause outside the reasonable control of either Party, and which the affected Party was unable to foresee at the time of the signing of the SOW; provided that: (a) notice of its inability to perform and the causes thereof shall be provided immediately by the affected Party to the other; and (b) if such inability to perform shall continue for a period of three (3) months, the other Party shall have the right to terminate the SOW by written notice at any time thereafter.

16.5 **Severability and waiver**. The invalidity, illegality or unenforceability of any term or provision of this Agreement shall not affect the validity, legality or enforceability of any other term or provision hereof. No waiver by any Party of any provisions of this Agreement shall be effective unless explicitly set forth in writing and signed by the Party so waiting. Except as set forth in this Agreement, no failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement shall operate or be so construed as a waiver thereof, nor shall nay single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

16.6 **Amendment**. The Agreement may not be modified or amended except by a written agreement signed by both Parties.

16.7 **Successor and assigns**. This Agreement will be binding upon each Party and their permitted successors and assigns, and will inure to the benefit of each Party and their successors and assigns.

16.8 **Survival**. The rights and obligations of the Parties set forth in Sections 5.1, 7, 8, 9, 10, 11, 12, 13, 14 and 16.9 and any right or obligation of the Parties in this Agreement which, by its nature, should survive termination or expiration of this Agreement, will survive the termination or expiration of this Agreement.

16.9 **Governing Laws and forum**. This Agreement is governed by and construed in accordance with the laws of Alberta, without giving effect to any conflict of law principles. The Parties will use commercially reasonable efforts to settle all matters in dispute amicably and hereby agree that any dispute arising under this Agreement, or in connection with any breach thereof, shall be finally resolved through the courts of Alberta.

16.10 **Counterparts**. This Agreement may be executed in counterparts, each of which is deemed an original, but all of which together are deemed to be one and the same agreement. Signatures to this Agreement delivered by facsimile or similar electronic transmission (eg. Portable document format (PDF)) shall be deemed as binding as the original.

(Signatures to follow)

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by duly authorized representatives.

XORTX Therapeutics Inc.		**ALTASCIENCES COMPANY INC.**	
By:	/s/ Allen Davidoff	By:	/s/ Elizabeth Pivetta
Name:	Allen Davidoff	Name:	Elizabeth Pivetta
Title:	CEO	Title:	Associate Director, Contracts and Client Experience
Date:	Dec 22, 2021	Date:	12/22/2021

Exhibit 4.23

Proposal for XORTX Therapeutics Inc.

Development of Prototype Capsule and Tablet Formulations for Potential Phase III Clinical Studies

Document: QUO.XOR.002

Covar Pharmaceuticals Inc.
2/21/2022

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1. Introduction

XORTX Therapeutics Inc. (XORTX) is a biotechnology company with three drug development programs, two of which are clinically advanced products under development — XRx-008 for Autosomal Dominant Polycystic Kidney Disease (ADPKD), XRx-101 for Coronavirus / COVID-19 infection and XRx-225 for Type 2 Diabetic Nephropathy (T2DN). XORTX is working to advance its clinical development stage products — XRx-008 and XRx-101 - that target xanthine oxidase to inhibit production of uric acid.

The drug substance of interest in this proposal is Oxypurinol for the treatment of ADPKD and COVID-19. The molecule was previously formulated as a capsule and conditionally approved by the FDA. The innovator company never sought full approval. XORTX gained the rights to the drug and intends to file an NDA via the 505(b)(2) pathway for treatment of ADPKD in mid-2025.

The current drug formulations are based on powder filled capsules including an organic base (L-arginine) to increase the drug substance bioavailability which was a factor in the earlier application.

L-arginine is hygroscopic and exposure to moisture may adversely affect the manufacturability, stability and performance of the product. Therefore, exposure to excessive moisture and humidity will be avoided during development, manufacturing and storage of the product.

The intent of this proposal is to develop prototype, immediate release, capsule and tablet formulations with the following characteristics:

- Each formulation will contain Oxypurinol (200 mg), L-arginine (600 mg), and other appropriate excipients
- Use of appropriate excipients to facilitate product performance and manufacturability
- Comparative dissolution profiles for existing formulation and the formulations being developed will be evaluated, apply f2 comparison if acceptable
- Scalable to large-scale manufacturing.

The development work in this proposal will be conducted under non-GMP condition.

2. Environmental, Health and Safety

The Environmental, Health and Safety (EH&S) requirements for handling the active pharmaceutical ingredient (API) was provided by client.

3. Analytical Method Transfer and Development

3.1 Cleaning Assay by HPLC Transfer

A validated HPLC method for the API cleaning assay will be transferred to Covar to support cleaning qualification of equipment for the manufacture of oxypurinol products.

3.2 Analytical Method Development

The following test methods will be developed for the present study

- Content and related impurities assay for tablets and capsules by HPLC

It is assumed that the same dissolution method by HPLC for existing capsules will be suitable for use in the present study.

Phase appropriate method validation may be conduct upon request at additional cost.

The following compendial tests may be evaluated before testing

- Appearance
- ID by FTIR (ATR)
- Disintegration
- Loss on drying

4. API Characterisation

The following physical properties of oxypurinol drug substance will be studied:

- Appearance
- Flow properties by Flodex
- Optical microscopy
- Bulk and tap density (compressibility)
- Particle size distribution by sieve analysis
- Particle size distribution by laser diffraction if aggregates can be dispersed in water
- Powder x-ray diffraction
- Differential scanning calorimetry

5. Granulate Size Reduction

The API is expected to be supplied as an agglomerated material. Different granule size reduction approaches will be evaluated in the following order:

1. Granule size reduction by high shear mixing

Oxypurinol and L-arginine (mass ratio to be defined) will be mixed under different conditions in a conventional high shear granulator at different chopper speeds and time. The powder blend will be examined under an optical microscope after high shear mixing. Based on the results, a powder blend (after high shear mixing) will be dispersed in water to dissolve the L-arginine and the particle size distribution of the sheared drug substance will be determined by laser diffraction. The powder blend will also be filled into gelatin capsules and tested for dissolution (3 vessels)

2. Granule size reduction by sieving

Oxypurinol and L-arginine (mass ratio to be defined) will be blended (e.g. using a V-blender) and sieved (screen size to be defined). The sieved blend will be examined under the optical microscope and the particle size distribution of the API will be determined by laser diffraction. The dissolution profile of the powder blend after sieving will also be determined.

3. Milling in the presence of L-arginine or a suitable excipient

Milling trials will be conducted using a Quadro Comil U5, which is a milling equipment known to be scalable by design. The following strategies will be considered:

- Milling of a mixture of API and excipient such as L-arginine or microcrystalline cellulose (e.g. Avicel PH102).
- Milling of API and excipient such as L-arginine or microcrystalline cellulose using a screen with larger openings than that being used (screen with a openings of 150 micron). A multiple pass process may be considered and evaluated.
- Milling of API alone at sub-ambient temperature may be considered. A low milling temperature may be maintained by addition of dry ice to the input milling material.
- Milling of a mixture of API and excipient such as L-arginine or microcrystalline cellulose at sub-ambient temperature may be considered. A low mill temperature may be maintained by addition of dry ice to the input milling material.

In each milling trial, sufficient quantity of oxypurinol with or without L-arginine/excipient (mass ratio to be defined) will be blended (e.g. using a v-blender) and milled using the Quadro Comil (screen size 150 micron, except for multiple pass trials) for up to one hour. The temperature of the impeller will be monitored using an infrared thermometer during the milling process and the milling rate will be monitored online using a suitable balance.

A de-agglomeration method will be selected, and the de-agglomerated material will be examined by:

- Appearance
- Particle size distribution by laser diffraction

- Optical microscopy
- Powder X-ray diffraction (optional, non-GMP in-house or by third party)
- Differential scanning calorimetry (DSC)
- Assay and related impurities by HPLC

6. Excipient Compatibility (optional)

Preformulation data such as those collected from existing formulations and API characterisation will be studied. Excipient candidates will be proposed to client for the excipient compatibility study.

The following will be considered for potential excipients:

- Degradation pathway and potential degradation pathway of the API
- Moisture content and hygroscopicity
- Compression behavior
- Particle size distribution
- Regulatory acceptance
- Bioavailability impact
- Supplier sourcing

Effort will be made to avoid excessive use of excipients to preserve the impact of L-arginine on the bioavailability of the drug substance.

Up to 10 powder blends of formulations will be prepared and compressed into round biconvex tablets (compression weight around 1000 mg) using a tabletop single-station (manual) compression machine. The samples will be packaged in 40mL HDPE bottle and induction sealed with and without desiccant. The packaged tablets will be stored at 25, 40 and 50°C. The 50°C samples will be evaluated using the following tests:

- Appearance
- Assay and impurities
- Disintegration

Samples stored under other conditions will be tested if needed with additional cost.

Based on the excipient compatibility study results, a lead formulation and a backup formulation will be identified and tested for dissolution for further formulation development.

7. Development of Capsule Formulation

Based on the composition of the lead formulation from excipient compatibility study and/or existing formulation development data, up to five prototype capsules blends will be prepared and evaluated for the following properties:

- Appearance before and after storage with and without desiccant
- Flow properties by Flodex
- Tap and bulk density

Based on the blend testing results, a lead blend and a backup capsule blend will identified for processability and physical stability, The lead formulation will be filled into white opaque size 00 elongated or 000 hard gelatin capsules using a manual encapsulation machine and tested for:

- Appearance
- Fill weight
- Disintegration
- Dissolution

8. Development of Tablet Formulation

Based on the composition of the lead capsule blend and background stability information from oxypurinol formulations, up to 6 prototype blends (about 500 g each) will be prepared. The composition of the prototype blends may be taken directly from those of the capsule blends. The prototype blends may also be prepared to evaluate to the effect of lubricant, disintegrant, and binder levels on their flow and compression properties.

The compression blends will be evaluated before compression for:

- Appearance
- Flow properties by Flodex
- Bulk and tap densities

The compression blends will be compressed into tablets (of different tablet hardness) of plain biconvex capsule shaped tablets of 1 g or less. Plain, biconcave, capsule shape tooling will be used for tablet compression. It is assumed that the formulation blends will be directly compressible. Otherwise, a dry granulation method will be employed by slugging or by roller compaction using a tabletop roller compactor to be acquired by Covar a its own cost. At present, several used tabletop roller compactors is available for purchase in North America and for immediate delivery.

The formulations will be prepared using the following equipment

- PK V-blender
- Instrumented Piccola bilayer tablet press (partially tooled, B tooling)

The compressed tablets will be evaluated for:

- Appearance
- Crushing strength
- Friability
- Thickness

Based on the results, a suitable batch of tablets will be prepared at 1 kg scale. 500 g of the compressed tablets will be packaged in induction sealed (HDPE, 40 mL) bottles with and without desiccant and stored at 25°C ± 2°C / 60% ± 5% RH and 40°C ± 2°C / 75% ± 5% RH.

9. Tablet Film Coating (Optional)

About 250 g of the compressed tablets will be aqueous film coated using a moisture barrier coating composition, Opadry® amb II. An enhanced O'Hara pan coater (Labcoat M10, 8 inch perforated coating pan) will be used for the coating operation. The coated tablets will be evaluated for dissolution and packaged in induction sealed (HDPE, 40 mL) bottles with and without desiccant and stored at 25°C ± 2°C / 60% ± 5% RH and 40°C ± 2°C / 75% ± 5% RH, for further stability testing if required with additional cost.

10. Cleaning Qualification

Cleaning qualification campaign will be performed for the process training. The cleaning process is considered validated if three satisfactory cleaning verification is achieved using the same equipment.

11. Stability Assessment of Formulations

The package capsules and uncoated tablets packaged without desiccant will be tested in accordance with the following schedule:

- Initial
- 2 wk, 1 and 3 months at 40°C ± 2°C / 75% ± 5% RH (accelerated condition)
- 2 wk, 1 and 3 months at 25°C ± 2°C / 60% ± 5% RH (long term condition; optional testing)

The packaged capsules and uncoated tablets with desiccant will also be tested after storage at 40°C ± 2°C / 75% ± 5% RH (accelerated condition) for 2 wk, 1 and 3 months.

The following tests will be conducted:

- Appearance
- Content uniformity by HPLC (initial only)
- Assay and related impurities by HPLC
- Water content by LOD
- Disintegration
- Dissolution by HPLC
- Crushing strength (tablets only)
- Friability (tablets only)
- Weight (bottle and tablets) loss on storage

The coated tablets (if prepared) and the rest of the formulations packaged with or without desiccant will be tested upon requested with additional cost.

Because of the known satisfactory chemical stability of the drug substance, it may be possible to define the composition and the packaging components for the potential Phase III clinical formulation using the 2 week (accelerated and long term) stability data.

12. Report

A development report will be prepared by Covar.

13. API Requirement

API (GMP API and/or non-GMP) and reference standards for analytical testing will be supplied by the client. Contract service for reference standard preparation and qualification by a third party is available upon request.

Preformulation, API milling trial and excipient compatibility		= 1 kg
Capsule development		= 0.5 kg
Tablet development including film coating		= 1.5 kg
Contingency		= 1 kg
	Total	= 4 kg

14. Project Management

A project manager will be assigned to coordinate project activities with project team members. A kickoff meeting will be held after execution of agreement and deposit is received. A dedicated project team from Covar will teleconference with the Client on regular basis.

15. Timeline

See MS Project file.

16. Budget Summary

Activity	Estimated Cost (CAD)
Material Management	1,796.88
Material purchase and management	
Method Transfer and Development	11,767.38
Cleaning Assay by HPLC method transfer	
Method Development for content and related impurities assay for tablets and capsules by HPLC	
API Characterisation	3,346.50
Appearance	
Flow properties by Flodex	
Optical microscopy	
Bulk and tap density (compressibility)	
Particle size distribution by sieve analysis	
Particle size distribution by laser diffraction if aggregation can be dispersed in sample preparation	
Powder x-ray diffraction	
Differential scanning calorimetry	
Data analysis and reporting	
Granule Size Reduction of API	14,961.50
Granule size reduction by high shear mixing trials	
Granule size reduction by sieving	
Milling in the presence of L-arginine or a suitable excipient	
Setup and cleanup	
Appearance	
Particle size distribution by laser diffraction	
Optical microscopy	
Powder X-ray diffraction (optional, non-GMP by third party)	
Differential scanning calorimetry (DSC)	
Assay and related impurities by HPLC	
Data analysis and reporting	
Excipient Compatibility (optional)	13,943.75
Sample preparation	
Appearance	
Assay and impurities	
Disintegration	
Report results	
Development of Capsule Formulation	8,420.88
Sample preparation	
Appearance before and after storage with and without desiccant	
Setup and cleanup	
Flow properties by Flodex	
Tap and bulk density	
Encapsulation	

Activity	Estimated Cost (CAD)
Appearance	
Fill weight of capsules	
Disintegration	
Dissolution	
Development of Tablet Formulation	22,482.50
Set up	
Prototype preparation (6 batches)	
● Appearance	
● Flow properties by Flodex	
Bulk and tap densities	
Packaging	
Clean up	
Data analysis and reporting	
Tablet Film Coating (Optional)	6,307.75
Setup	
Coating	
Clean up	
Dissolution	
Packaging	
Dissolution	
Cleaning Qualification	10,511.00
Protocol	
Sampling	
Testing	
Reporting	
QA approval	
Stability Assessment of Capsule and Tablet Formulations	
Protocol	8,711.25
Set up	
Initial	10,084.06
Appearance	
Content uniformity by HPLC (initial only)	
Assay and related impurities by HPLC	
Water content by LOD	
Disintegration	
Dissolution by HPLC	
Crushing strength (tablets only)	
Friability (tablets only)	
Weight (bottle and tablets) loss on storage	
2 weeks	15,306.50
Appearance	
Assay and related impurities by HPLC	
Water content by LOD	
Disintegration	

Activity	Estimated Cost (CAD)
Dissolution by HPLC	
Crushing strength (tablets only)	
Friability (tablets only)	
Weight (bottle and capsules/tablets) loss on storage	
1 month	15,306.50
Appearance	
Assay and related impurities by HPLC	
Water content by LOD	
Disintegration	
Dissolution by HPLC	
Crushing strength (tablets only)	
Friability (tablets only)	
Weight (bottle and capsules/tablets) loss on storage	
3 months	15,306.50
Appearance	
Assay and related impurities by HPLC	
Water content by LOD	
Disintegration	
Dissolution by HPLC	
Crushing strength (tablets only)	
Friability (tablets only)	
Weight (bottle and capsules/tablets) loss on storage	
Development Report	13,800.00
Subtotal	172,052.94
Project management fee (5%)	25,807.94
Total	197,860.88

Third-party contractor fees will be cross charged plus 5% service fee. Other fees, including but not limited to input processing materials, shipping, customs duties, and consumables such as chromatography columns and solvents will be cross charged at cost plus 10% service fee.

Xortx Therapeutics Inc.	**Covar Pharmaceuticals Inc.**
By: /s/ Allen Davidoff	By: /s/ Kwok Chow
Name: Allen Davidoff	Name: **Kwok Chow, PhD**
Title: CEO	Title: **President**
Date: Feb 24, 2022	Date: Feb 25, 2022

17. Terms and Conditions

Services

Covar Pharmaceuticals Incorporated (Covar) agrees to perform the pharmaceutical development services described in the Project Scope ("**Services**") of this **Agreement.** Services will be performed in the Preferred Provider Laboratories (**Provider**) selected by **Covar.** Unless otherwise stated the **Services** will be non-GMP.

Parties must agree on Changes to the Services ("**Changes**").

Minor Changes will be confirmed by electronic mail, or other written document. Significant Changes (such as a request by the **Client** to change the Project Scope) will be confirmed by a Change of Scope **Agreement.**

Payment

Client will pay **Covar** for the **Services.**

Client will pay **Covar** a refundable deposit equal to 30% of the estimated cost provided in this proposal. The deposit will be used for the final payments of the project.

Services Covar may issue an invoice upon completion of each milestone set out in the Budget Summary or revised Budget Summary in Changes.

Covar invoice will be due and payable within 30 days of the date of the invoice.

Interest on past due accounts will accrue at a rate of 1.5% per month.

In the event that payment in full is not received by **Covar** within thirty (30) days of **Client's** receipt of the data and results, this **Agreement** may be terminated at **Covar's** sole discretion and all right and title to the data and results.

Ownership of Data

Client will own all data and information specifically and directly arising from the provision of the Services, and as such **Covar** will have no claim on any intellectual property that may be derived from any such data and information.

Intellectual Property

The term "Intellectual Property" includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, trade secrets, inventions, copyright, industrial designs and know-how.

For the term of this Agreement, Client hereby grants to Covar, a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property which Covar must use in order to perform the Services.

All Intellectual Property generated or derived by Covar in the course of performing the Services, to the extent it is specific to the development, manufacture, use and sale of the Client's Product that is the subject of the Services, will be the exclusive property of Client.

All Intellectual Property generated or derived by Covar while performing the Services which is not specific to, or dependent upon, Client's Product and which has application to manufacturing processes or formulation development of drug products or drug delivery systems will be the exclusive property of Covar. Covar hereby grants to Client, a non-exclusive, paid-up, royalty-free, transferable license of the Intellectual Property which Client may use for the manufacture of Client's Product.

Confidentiality

The confidentiality agreement entered into between the parties will apply to all confidential information about the parties and the Services to be conducted under this **Agreement** and the Confidentiality **Agreement** is deemed to be incorporated herein by reference. If the Confidentiality **Agreement** expires or terminates prior to the expiration or termination of this **Agreement,** then the terms of the Confidentiality **Agreement** will nonetheless continue to govern the parties' obligations of confidentiality for the term of this **Agreement** and for five years thereafter. **Covar** shall have the right to disclose confidential information hereunder to its Preferred Providers solely for the purpose of performing the Services. **Covar** represents that it has entered into confidentiality **Agreements** with each Preferred Provider consist with the terms hereof.

Providers shall hold in confidence and not disclose or use for any purpose other than for the provision of the Services any **"Confidential Information"** provided by **Client.** "Confidential Information" means any information provided by the **Client** to **Providers** in confidence and any **Client** samples and/or materials associated with the Services, and shall further include any information and all related data and information generated pursuant to the provision of the Services.

Confidential Information shall not include or otherwise encompass any information and materials which:

- are part of the public domain, or become part of the public domain through no fault of **Providers;**

- are obtained from a third party who is not under a duty of confidentiality respecting the Confidential Information and said third party has a legal right to disclose such information;
- are identified by the **Client** as no longer constituting Confidential Information of the **Client**;
- are already known at the time of disclosure by **Client** to **Providers,** as can be demonstrated by written or other records/information; or
- are developed independently by **Providers** without access to the Confidential Information of the **Client,** as can be demonstrated by written or other records/information.

In the event that **Covar** is required to disclose **Client** Confidential Information by law or an order of a court, tribunal or government agency, **Covar** shall promptly notify **Client** and give **Client** a reasonable opportunity to seek a confidentiality order or take other appropriate action in respect of the proposed disclosure.

This obligation of confidentiality in respect of any particular Confidential Information shall survive for a period of **three (3) years** from the earlier of (i) the full and final provision of the specific Services associated with the particular Confidential Information, or (ii) the expiration or earlier termination of this **Agreement.**

Term and/or Termination

Notwithstanding, a Party may earlier terminate this **Agreement** upon the provision of thirty (30) day notice to the other Party, and the Parties shall immediately cease all unnecessary activities and shall cooperate to minimize all costs associated with this cessation/termination of activities associated with the provision of said Services.

Either party may terminate this **Agreement** if a party is in material breach of any part of this **Agreement** and that party fails to remedy the breach within 30 days after receiving notice of the breach from the non-breaching party.

Client may terminate this **Agreement** upon 5 days prior written notice for any business reason.

Covar may terminate the **Agreement** if the **Client** requests to reschedule any part of the Services beyond 180 days.

Upon completion or expiry of the **Agreement** or if the **Client** terminates the **Agreement** for any business reason or if **Covar** terminates the **Agreement** because of: (i) **Client**'s failure to cure any default within the 30 day notice period; or (ii) **Client** rescheduling any part of the Services beyond the 180 days, then **Client** will pay to **Covar** any fees and expenses due to **Covar** and any additional costs incurred by **Covar** with the **Services.**

Client will arrange for the pickup from the **Covar** site of all materials owned by **Client** within ten days after the earlier of the completion, or termination of this **Agreement.**

Shipping of API and Materials

Client will, at its expense, supply **Covar** with sufficient quantities of API for **Covar** to perform the Services. For all shipments of API and materials from **Client** to **Covar, Client** will pay all costs including transportation, import duties and taxes. All shipments of API will be accompanied by appropriate Safety Data Sheet (e.g. MSDS).

For import of API, **Client** or **Client**'s broker will be the "Importer of Record." **Client**'s obligation will include obtaining the proper release of API from the local customs and health authorities.

For shipments (if applicable) of **Client**'s Product or **Client**'s API, the **Client** will pay all transportation costs and also bear the risks for bringing the goods to their final destination.

Indemnity

Client shall indemnify and save harmless **Covar** against all costs, actions, suits, claims, losses or damages and for all other matters arising out of its (i.e **Client**'s) use or any other exploitation of the data, results, conclusions, and products derived therefrom, arising out of, or resulting from, this **Agreement** (and any intellectual property associated therewith), except to the extent that such were caused by **Covar's** gross negligence, willful misconduct or material breach of this **Agreement.**

Covar will defend, indemnify and hold the **Client** harmless against **Covar** of any of its obligations or warranties under this **Agreement** except to the extent that these Losses are determined to have resulted from the negligence or willful misconduct of **Client.**

Limitation of Liability

Covar (and its directors, officers, employees, staff members, students, research trainees and agents) shall not be liable for any direct, indirect, consequential, or other damages suffered by **Client** or any others resulting from the use of the data, results or conclusions, and any products and intellectual property associated therewith, conceived, discovered, or otherwise premised on, or developed under or as a result of, or consequential to, this **Agreement.** The entire risk as to any use of said data, conclusions or results (and any products and intellectual property associated therewith), and the design, development, manufacture, offering for sale, sale, or other disposition and/or performance of the data, results, conclusions and products arising therefrom (and any intellectual property associated therewith) is assumed entirely by **Client,** without any legal or equitable recourse to **Covar**

If **Covar** fails to materially perform any part of the Services in accordance with the terms of this **Agreement**, **Covar** may repeat that part of the Service at **Covar's** costs if **Client** supplies the API. Under no circumstances whatsoever will **Covar** reimburse **Client** for the cost of the API. Under no circumstances whatsoever will either party be liable to the other in **Agreement**, tort, negligence, breach of statutory duty or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business or goodwill or (ii) any other liability, damage, cost or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of the damages.

No Warranty

Covar makes no warranty of any kind, either expressed or implied, by fact or law, other than those expressly set forth in this Agreement. Covar makes no warranty for any particular results from the performance of the services or with respect to any data or information generated therefrom, or of fitness for a particular purpose or warranty of merchantability for the Client's product.

Disputes

All negotiations under this provision shall be considered confidential and shall be treated as compromise and settlement negotiations and deemed to be "off the record" and without prejudice.

General Provisions

This **Agreement** shall be construed according to the laws of the Province of Ontario and the federal laws of Canada applicable therein.

Each provision of this **Agreement** shall be deemed separate, severable and distinct. If any part of any provision of this **Agreement** is found by a court to be invalid, illegal or unenforceable in any way, the finding shall not limit or affect the validity, legality or enforceability of the remaining provisions.

For the purposes of this **Agreement** and all services to be provided under it, each Party shall be deemed to be an independent **Agreement** or and not an agent or employee of the other Party. No Party shall have the authority to make any statements, representations or commitments of any kind, or take any action which shall be binding on the other Party, except as may be explicitly provided for herein or authorized by the other Party in writing.

Except as otherwise required by law, neither Party shall, without the consent of the other Party, (i) use the name(s), logo(s), trade-mark(s) or trade-name(s) of the other Party in connection with any products, publicity, promotion, news release, advertising or similar public statements in respect of the **Agreement** and the Services provided, **and** (ii) make any other public disclosure in respect of this **Agreement** and its subject matter. Notwithstanding, Covar may disclose the general subject matter and monies received further to this **Agreement** without any further consent of Client.

This **Agreement** constitutes the entire **Agreement** and understanding between the Parties and supersedes any prior **Agreements** between or among the Parties with respect to the **Services**.

This **Agreement** may be signed in separate counterparts and delivered by mail, facsimile or electronically, and, when so signed and delivered, all the counterparts will together constitute one and the same instrument which is deemed to be an original.

Neither this **Agreement**, nor any of either party's rights hereunder, may be assigned or otherwise transferred by either party without the prior written consent of the other party, which consent will not be unreasonably withheld.

Except for payment obligations, neither party will be responsible for delay or failure in performance resulting from acts beyond the reasonable control and without the fault or negligence of the party, including, but not limited to, strikes or other labour disturbances, wars, riot, crime, communicable disease outbreaks,, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, power or regulation compliance of any government or act of God.

Any termination or expiration of this **Agreement** will not affect any outstanding obligations or payments due hereunder prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this **Agreement**.

Exhibit 4.24

Proposal for XORTX Therapeutics Inc.

Oxypurinol Capsules for Phase 1 Bioavailability Study

Document: QUO.XOR.001

Covar Pharmaceuticals Inc.
12/6/2021

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1. Introduction

Xortx Therapeutics Inc. (**Client**) is developing Oxypurinol for the treatment of ADPKD and COVID-19. The molecule was previously formulated as a capsule and conditionally approved by the FDA. XORTX intends to file an NDA via the 505(b)(2) pathway for treatment of ADPKD in mid-2025. The drug formulation will be a powder filled capsule including an organic base to increase the drug substance bioavailability.

This proposal provides the scope and budget estimate for preparation and testing of the following formulations to support a Phase I bioavailability study in Canada. The CTA filing and bioavailability study are targeted for 1Q2022

Capsule A

- Hard gelatin capsules
- Target fill weight of 200 mg
- Hard gelatin capsules containing Oxypurinol and L-Arginine at a weight ratio of 1:1 and magnesium stearate of not more than 1% w/w

3. Method Transfer

3.1 Assay and Related Impurities by HPLC

A validated HPLC method for the API assay and related impurities testing will be transferred to **Covar** to support the development program.

To accelerate the program, dedicated equipment such as change parts for semi-automatic encapsulator, and milling equipment will be used for processing (estimated cost of not more than CAN $10,000). The contact parts for blending will be passivated before and after GMP manufacture. Alternatively, cleaning qualification using an HPLC method may be conducted. An estimated cost for cleaning qualification can be provided upon request.

3.2 Method development and validation (Phase 1)

The following test methods will be developed and validated for Phase 1 bioavailability study:

- Product assay and related impurities by HPLC
- Dissolution by UV
- Product Microbial Enumeration Test <USP 61> including E Coli by a GMP contract laboratory
- API Particle size distribution by laser diffraction

The following compendial tests may be evaluated before testing

- Appearance
- ID by FTIR (ATR)
- Disintegration
- Loss on drying

4. Milling

A milling trial will be conducted using one or more of the following milling equipment to establish milling parameters and to achieve target particle size distribution:

- Jet milling (for micronization)
- Microfine grinder (IKA) with appropriate screen size
- Comil (tabletop Quadro Comil, U5)

A target of 3 milling trials is planned. Representative samples of milled and unmilled API will be evaluated using the following methods:

- Appearance
- Particle size distribution by laser diffraction (sieve analysis by Sonic Sifter may be used for unmilled API)
- Optical microscopy
- Powder X-ray diffraction (optional, non-GMP by third party)
- Differential scanning calorimetry (DSC)

- Assay and related impurities by HPLC

The results will be used to confirm whether milling will cause solid state transition or chemical degradation of the API. The crystallinity of milled material will be evaluated using DSC and/or powder x-ray diffraction.

5. Manufacture of Development Batches

One non-GMP batch (100 to 200 capsules) of each capsule formulation will be manufactured and packaged in induction sealed HDPE bottles (40mL) using the following procedure:

- Dispensing
- Particle size reduction of API
- Blending
- Encapsulation
- Packaging

The following equipment will be used to manufacture and packaging the development batches:

- Balance & scale
- Jet mill (for micronization), microfine grinder (IKA) or Comil (tabletop Quadro Comil, U5)
- Patterson-Kelley Blend Master Lab Blender (or equivalent)
- Semi-automatic encapsulator
- Induction sealer

The milling procedure will be included as part of secondary manufacture. Alternately a separate batch of milled API will be prepared from unmilled API and tested on stability under ICH storage conditions at additional cost for CTA filing.

Based on the capsule drug loading, high shear mixing may not be required. However, mixing with high shear equipment can be performed, if needed to achieve acceptable content uniformity. An optional content uniformity assay by HPLC for the lowest drug loading formulation (Capsule B) may be performed for information only, at additional cost. The content uniformity assay by HPLC will not be validated.

One month stability data will be collected under ICH conditions (25°C/60%RH, 30°C/65%RH (optional at additional cost) and 40°C/75%RH) for Capsule B and Capsule C batches. The results may be included as supporting data in the Quality Overall Summary of the CTA.

The stability tests for the development batches include:

- Appearance
- Assay and related impurities by HPLC
- Dissolution by UV
- Content uniformity by weight (initial only)
- Disintegration (initial only)
- Water content by loss on drying

MET data will be collected from CTM batches and included in the CTA.

Development batch records will be used for the stability batches.

6. Manufacture of Stability/CTM Batches

6.1 Batch Manufacture

One GMP (CTM) batch (approximately 700 capsules per batch) of each capsule formulation (Capsule A, Capsule B, or Capsule C; total of three batches) will be manufactured and packaged in induction sealed in HDPE bottles (40 mL HDPE bottles and polypropylene caps with induction seal liner) using the following procedure:

- Dispensing
- Particle size reduction of API
- Blending
- Encapsulation
- Packaging

The following equipment will be used for the manufacture and packaging of the CTM batches:

- Balance & scale
- Jet mill (for micronization), microfine grinder (IKA) or Comil (tabletop Quadro Comil)
- Patterson-Kelley Blend Master Lab Blender
- Semi-automatic encapsulator
- Induction sealer

The milling procedure will be included as part of the secondary (product) manufacture.

USP-NF ingredients will be used and capsule shells will be certified BSE free. Packaging components with DMF (FDA) filing will be sourced for the development program.

Elemental impurities content of the input materials will be reviewed for justification of product specifications without the inclusion of elemental impurities. ICP MS testing of elemental impurities of input materials including the API, as well as capsule products may be conducted by a contractor if needed at additional cost.

6.2 ICH Stability Study for CTM Batches

The following stability program is proposed for the three CTM batches.

- Initial
- 1, 3 and 6 months at 40°C ± 2°C / 75% ± 5% RH (accelerated condition)
- 1, 3, 6, 9, and 12 months at 30°C ± 2°C / 65% ± 5% RH (intermediate condition)*
- 1, 3, 6, 9, 12, 18 and 24 months at 25°C ± 2°C / 60% ± 5% RH (long term condition)

*optional with additional cost

The stability program for Capsule C CTM will discontinue when dosing of the human subjects is completed.

The following tests will be conducted for the stability studies:

- Appearance
- Assay and related impurities by HPLC
- Disintegration (initial only)
- Dissolution by UV
- Water content by loss on drying
- Uniformity of content by weight (initial only)
- MET including E Coli
- Elemental impurities by ICP MS (optional)

A stability time point report will be generated for each pull-point.

7. Report

A development report will be prepared by **Covar**.

8. API Requirements

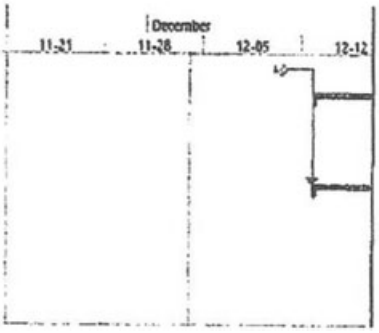
GMP API, non-GMP API and reference standards for analytical testing will be supplied by the client. Contract service for reference standard preparation and qualification by a third party is available upon request.

9. Project Management

A project manager will be assigned to coordinate project activities with project team members. A kickoff meeting will be held after execution of agreement and deposit is received. A dedicated project team from Covar will teleconference with the Client on regular basis.

10. High Level Timeline

Task Name	Duration	Start	Finish
Project initiation	1 day	Fri 21-12-10	Fri 21-12-10
API shipment	23 days	Mon 21-12-13	Fri 22-01-14
Analytical method development	38 days	Mon 21-12-20	Fri 22-02-11
Milling trial	8 days	Mon 21-12-20	Fri 21-12-31
Development batches preparation	13 days	Mon 21-12-13	Fri 21-12-31
Dev batches stability testing	31 days	Mon 22-01-03	Mon 22-02-14
CTM batch manufacture	25 days	Mon 22-01-03	Fri 22-02-04
CTM/stability testing	11 days	Mon 22-02-07	Mon 22-02-21
CTA filing	1 day	Tue 22-02-22	Tue 22-02-22



11. Budget Summary

Item	Estimated Cost (CAD)
Material Management	1,562.50
Material management, BSE statement, LOA for DMF, customs	
Method Development and Validation	76,500.00
API method transfer	
Product assay/impurity development	
Product assay/impurity validation	
Dissolution method development	
Dissolution method validation	
Particle size method validation	
MET validation	
Particle Size Reduction of API	7,745.00
Milling trials	
API assay before and after milling (one set)	
Appearance/Description	
Particle Size, Laser Diffraction (non-GMP)	
X-ray diffraction, powder	
DSC	
Optical microscopy	
Development Batches Preparation (3 batches)	9,605.00
Development batch record	
Jet milling	
Blending	
Encapsulation	
Packaging	
Stability Testing of Development Batches (2 batches)	27,920.00
Protocol	
On stability	
Initial	
Appearance	
Assay and related impurities	
Dissolution	
Disintegration	
Loss on drying	
Weight uniformity	
Timepoint report	
2 week	
Appearance	
Assay and related impurities	
Dissolution	
Loss on drying	
Timepoint report	
1 month	
Appearance	

Item	Estimated Cost (CAD)
Assay and related impurities	
Dissolution	
Loss on drying	
Timepoint report	
CTM Batches Preparation	42,625.00
Set up Specifications for API and product	
Set up Specifications for input materials and pack	
Master batch record batch record	
Issue batch record	
Release testing of API	
Release testing of packaging material	
Release testing of excipients	
Set up	
Jet milling	
Blending	
Encapsulation	
Packaging	
Labelling of CTM	
Clean up	
Batch record review and approval	
ICH Stability Assessment for 3 CTM batches for 6, 24 and 24 months	
Protocols (total of 3 protocols)	7,425.00
On stability, stability set up (3 batches), coordination up to 24 months	3,937.50
Initial	11,353.75
Appearance	
Assay and related impurities	
Dissolution	
MET with E coli	
Loss on drying	
Weight uniformity	
Disintegration	
Timepoint report	
1 month	11,935.00
Appearance	
Assay and related impurities	
Dissolution	
Loss on drying	
Timepoint report	

Item	Estimated Cost (CAD)
3 month	11,935.00
Appearance	
Assay and related impurities	
Dissolution	
Loss on drying	
Timepoint report	
6 month	12,222.50
Appearance	
Assay and related impurities	
Dissolution	
Loss on drying	
MET with E coli	
Timepoint report	
9 month	5,395.00
Appearance	
Assay and related impurities	
Dissolution	
Loss on drying	
Timepoint report	
12 month	5,682.50
Appearance	
Assay and related impurities	
Dissolution	
Loss on drying	
MET with E coil	
Timepoint report	
18 month	5,395.00
Appearance	
Assay and related impurities	
Dissolution	
Loss on drying	
Timepoint report	
24 month	5,682.50
Appearance	
Assay and related impurities	
Dissolution	
Loss on drying	
MET with E coli	
Timepoint report	

Item	Estimated Cost (CAD)
Report	12,000.00
Development report	
Subtotal	271276.25
Project management fee (5%)	13563.81
Total (CAD)	284840.06

Third-party contractor fees will be cross charged plus 5% service fee. Other fees, including but not limited to input processing materials, shipping, customs duties, and consumables such as chromatography columns and solvents will be cross charged at cost plus 10% service fee.

Xortx Therapeutics Inc.	**Covar Pharmaceuticals Inc.**
By: /s/ Allen Davidoff	By: /s/ Kwok Chow, PhD
Name: Allen Davidoff	Name: Kwok Chow, PhD
Title: CEO	Title: President
Date: Dec 8, 2021	Date: Dec 9, 2021

12. Terms and Conditions

Services

Covar Pharmaceuticals Incorporated (**Covar**) agrees to perform the pharmaceutical development **Services** described in the Project Scope ("**Services**") of this **Agreement**. Services will be performed in the Preferred Provider Laboratories (**Provider**) selected by **Covar**. Unless otherwise stated the **Services** will be non-GMP.

Parties must agree on Changes to the **Services** ("**Changes**").

Minor Changes will be confirmed by electronic mail, or other written document. Significant Changes (such as a request by the **Client** to change the Project Scope) will be confirmed by a Change of Scope **Agreement**.

Payment

Client will pay **Covar** for the **Services**.

Client will pay **Covar** a refundable deposit equal to 30% of the estimated cost provided in this proposal. The deposit will be used for the final payments of the project.

Services Covar may issue an invoice upon completion of each milestone set out in the Budget Summary or revised Budget Summary in Changes.

Covar invoice will be due and payable within 30 days of the date of the invoice.

Interest on past due accounts will accrue at a rate of 1.5% per month.

In the event that payment in full is not received by **Covar** within thirty (30) days of **Client's** receipt of the data and results, this **Agreement** may be terminated at **Covar's** sole discretion and all right and title to the data and results.

Ownership of Data

Client will own all data and information specifically and directly arising from the provision of the **Services**, and as such **Covar** will have no claim on any intellectual property that may be derived from any such data and information.

Intellectual Property

The term "Intellectual Property" includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, trade secrets, inventions, copyright, industrial designs and know-how.

For the term of this Agreement, Client hereby grants to Covar, a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property which Covar must use in order to perform the Services.

All Intellectual Property generated or derived by Covar in the course of performing the Services, to the extent it is specific to the development, manufacture, use and sale of the Client's Product that is the subject of the Services, will be the exclusive property of Client.

All Intellectual Property generated or derived by Covar while performing the Services which is not specific to, or dependent upon, Client's Product and which has application to manufacturing processes or formulation development of drug products or drug delivery systems will be the exclusive property of Covar. Covar hereby grants to Client, a non-exclusive, paid-up, royalty-free, transferable license of the Intellectual Property which Client may use for the manufacture of Client's Product.

Confidentiality

The confidentiality agreement entered into between the parties will apply to all confidential information about the parties and the Services to be conducted under this **Agreement** and the Confidentiality **Agreement** is deemed to be incorporated herein by reference. If the Confidentiality **Agreement** expires or terminates prior to the expiration or termination of this **Agreement**, then the terms of the Confidentiality **Agreement** will nonetheless continue to govern the parties' obligations of confidentiality for the term of this **Agreement** and for five years thereafter. **Covar** shall have the right to disclose confidential information hereunder to its Preferred Providers solely for the purpose of performing the **Services**. **Covar** represents that it has entered into confidentiality **Agreement**s with each Preferred Provider consist with the terms hereof.

Providers shall hold in confidence and not disclose or use for any purpose other than for the provision of the Services any "**Confidential Information**" provided by **Client**. "Confidential Information" means any information provided by the **Client** to **Providers** in confidence and any **Client** samples and/or materials associated with the **Services**, and shall further include any information and all related data and information generated pursuant to the provision of the Services.

Confidential Information shall not include or otherwise encompass any information and materials which:

- are part of the public domain, or become part of the public domain through no fault of **Providers**;
- are obtained from a third party who is not under a duty of confidentiality respecting the Confidential Information and said third party has a legal right to disclose such information;
- are identified by the **Client** as no longer constituting Confidential Information of the **Client**;
- are already known at the time of disclosure by **Client** to **Providers**, as can be demonstrated by written or other records/information; or
- are developed independently by **Providers** without access to the Confidential Information of the **Client**, as can be demonstrated by written or other records/information.

In the event that **Covar** is required to disclose **Client** Confidential Information by law or an order of a court, tribunal or government agency, **Covar** shall promptly notify **Client** and give **Client** a reasonable opportunity to seek a confidentiality order or take other appropriate action in respect of the proposed disclosure.

This obligation of confidentiality in respect of any particular Confidential Information shall survive for a period of **three (3) years** from the earlier of (i) the full and final provision of the specific Services associated with the particular Confidential Information, or (ii) the expiration or earlier termination of this **Agreement**.

Term and/or Termination

Notwithstanding, a Party may earlier terminate this **Agreement** upon the provision of thirty (30) day notice to the other Party, and the Parties shall immediately cease all unnecessary activities and shall cooperate to minimize all costs associated with this cessation/termination of activities associated with the provision of said **Services**.

Either party may terminate this **Agreement** if a party is in material breach of any part of this **Agreement** and that party fails to remedy the breach within 30 days after receiving notice of the breach from the non-breaching party.

Client may terminate this **Agreement** upon 5 days prior written notice for any business reason.

Covar may terminate the **Agreement** if the **Client** requests to reschedule any part of the Services beyond 180 days.

Upon completion or expiry of the **Agreement** or if the **Client** terminates the **Agreement** for any business reason or if **Covar** terminates the **Agreement** because of: (i) **Client's** failure to cure any default within the 30 day notice period; or (ii) **Client** rescheduling any part of the Services beyond the 180 days, then **Client** will pay to **Covar** any fees and expenses due to **Covar** and any additional costs incurred by **Covar** with the **Services**.

Client will arrange for the pickup from the **Covar** site of all materials owned by **Client** within ten days after the earlier of the completion, or termination of this **Agreement**.

Shipping of API and Materials

Client will, at its expense, supply **Covar** with sufficient quantities of API for **Covar** to perform the Services. For all shipments of API and materials from **Client** to **Covar**, **Client** will pay all costs including transportation, import duties and taxes. All shipments of API will be accompanied by appropriate Safety Data Sheet (e.g. MSDS).

For import of API, **Client** or **Client's** broker will be the "Importer of Record." **Client's** obligation will include obtaining the proper release of API from the local customs and health authorities.

For shipments (if applicable) of **Client's** Product or **Client's** API, the **Client** will pay all transportation costs and also bear the risks for bringing the goods to their final destination.

Indemnity

Client shall indemnify and save harmless **Covar** against all costs, actions, suits, claims, losses or damages and for all other matters arising out of its (i.e **Client's**) use or any other exploitation of the data, results, conclusions, and products derived therefrom, arising out of, or resulting from, this **Agreement** (and any intellectual property associated therewith), except to the extent that such were caused by Covar's gross negligence, willful misconduct or material breach of this **Agreement**.

Covar will defend, indemnify and hold the **Client** harmless against **Covar** of any of its obligations or warranties under this **Agreement** except to the extent that these Losses are determined to have resulted from the negligence or willful misconduct of **Client**.

Limitation Of Liability

Covar (and its directors, officers, employees, staff members, students, research trainees and agents) shall not be liable for any direct, indirect, consequential, or other damages suffered by **Client** or any others resulting from the use of the data, results or conclusions, and any products and intellectual property associated therewith, conceived, discovered, or otherwise premised on, or developed under or as a result of, or consequential to, this **Agreement**. The entire risk as to any use of said data, conclusions or results (and any products and intellectual property associated therewith), and the design, development, manufacture, offering for sale, sale, or other disposition and/or performance of the data, results, conclusions and products arising therefrom (and any intellectual property associated therewith) is assumed entirely by **Client**, without any legal or equitable recourse to **Covar**.

If **Covar** fails to materially perform any part of the Services in accordance with the terms of this **Agreement**, **Covar** may repeat that part of the Service at **Covar's** costs if **Client** supplies the API. Under no circumstances whatsoever will **Covar** reimburse **Client** for the cost of the API. Under no circumstances whatsoever will either party be liable to the other in **Agreement**, tort, negligence, breach of statutory duty or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business or goodwill or (ii) any other liability, damage, cost or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of the damages.

No Warranty

Covar makes no warranty of any kind, either expressed or implied, by fact or law, other than those expressly set forth in this **Agreement**. **Covar** makes no warranty for any particular results from the performance of the **Services** or with respect to any data or information generated therefrom, or of fitness for a particular purpose or warranty of merchantability for the **Client's** product.

Disputes

All negotiations under this provision shall be considered confidential and shall be treated as compromise and settlement negotiations and deemed to be "off the record" and without prejudice.

General Provisions

This **Agreement** shall be construed according to the laws of the Province of Ontario and the federal laws of Canada applicable therein.

Each provision of this **Agreement** shall be deemed separate, severable and distinct. If any part of any provision of this **Agreement** is found by a court to be invalid, illegal or unenforceable in any way, the finding shall not limit or affect the validity, legality or enforceability of the remaining provisions.

For the purposes of this **Agreement** and all **Services** to be provided under it, each Party shall be deemed to be an independent **Agreement** or and not an agent or employee of the other Party. No Party shall have the authority to make any statements, representations or commitments of any kind, or take any action which shall be binding on the other Party, except as may be explicitly provided for herein or authorized by the other Party in writing.

Except as otherwise required by law, neither Party shall, without the consent of the other Party, (i) use the name(s), logo(s), trademark(s) or trade-name(s) of the other Party in connection with any products, publicity, promotion, news release, advertising or similar public statements in respect of the **Agreement** and the Services provided, **and** (ii) make any other public disclosure in respect of this **Agreement** and its subject matter. Notwithstanding, **Covar** may disclose the general subject matter and monies received further to this **Agreement** without any further consent of **Client**.

This **Agreement** constitutes the entire **Agreement** and understanding between the Parties and supersedes any prior **Agreement**s between or among the Parties with respect to the **Services**.

This **Agreement** may be signed in separate counterparts and delivered by mail, facsimile or electronically, and, when so signed and delivered, all the counterparts will together constitute one and the same instrument which is deemed to be an original.

Neither this **Agreement**, nor any of either party's rights hereunder, may be assigned or otherwise transferred by either party without the prior written consent of the other party, which consent will not be unreasonably withheld.

Except for payment obligations, neither party will be responsible for delay or failure in performance resulting from acts beyond the reasonable control and without the fault or negligence of the party, including, but not limited to, strikes or other labour disturbances, wars, riot, crime, communicable disease outbreaks,, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, power or regulation compliance of any government or act of God.

Any termination or expiration of this **Agreement** will not affect any outstanding obligations or payments due hereunder prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this **Agreement**.

Exhibit 4.25

CERTAIN INFORMATION (INDICATED BY [***]) 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 REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

STRATEGIC CHEMICAL DEVELOPMENT CAPABILITIES ACROSS THE CURIA NETWORK

Program for cGMP Manufacture of Oxypurinol API

PREPARED FOR

XORTX Therapeutics Inc Inc.

REF NUMBER	0-90687 Version 07	DATE OF ISSUE	29Mar2022

TO: **Grace Jung, PhD**
Chemistry and Manufacturing
XORTX Therapeutics Inc.
4000 421 7th Avenue SW
Calgary, Alberta T2P 4K9
CANADA

FROM: **Richard Decina**
Senior Director, CMO-CS Sales & Business Development
Curia
richard.decina@curiaglobal.com

THIS PROPOSAL IS VALID until March 21

Proposal Reference: O-90687
Version: 07
curiaglobal.com

Curia and XORTX hereby agree that this proposal amends, supersedes and replaces proposal O-90687 dated March 17, 2022 between the parties (the "legacy proposal") and upon execution of this proposal by both parties, the legacy proposal shall be of no further force and effect.

Program Overview

Pursuant to your recent request, Curia Spain, S.A.U. ("Curia") is pleased to provide XORTX Therapeutics Inc. ("XORTX") with this proposal for process familiarization/feasibility study and analytical method transfer of the API as well as preliminary costing for the activities required to conduct the cGMP manufacture of API as a registration and validation campaigns for XORTX's budgetary purposes.

Curia will manage this program in conjunction with XORTX, to an agreed project plan and budget. Table 1 outlines the initial process familiarization work to start the program. Table 2 outlines the additional activities based on the outcome of the process transfer/familiarization work. Table 3 outlines the invoicing schedule.

Table 1. Process Familiarization Activities

Part	Description of Services	Price ($)	Anticipated *Timeframe
I.	Process Familiarization/Transfer	$65,000	2.5 Months
II.	Analytical Method Transfer including Reference Standard Qualification	$156,000	3 Months
III.	Raw Material vendor qualification	$12,000	4month
	TOTAL	**$233,000**	

- Parts I, II, and PartI-III tasks will be carried out in parallel to compress timeline to facilitate engineering and registration batches execution in a timely manner.

Curia has provided XORTX with costing for the activities required to conduct the Registration, Validation, and Commercial campaigns of the API.

*Pricing will be updated if the costs vary by more than 5% following process familiarization and analytical methods transfers. Prices for validation and commercial quantities are the best estimates at this time and will be finalized after registration batches

^ Curia will use its best effort to manufacture the Engineering Batch as a GMP batch.

Table 2. Activities to Support Registration, Validation and Commercial Campaigns

Part	Description of Services	Price ($)	Anticipated Timeframe
IV.	PGI assessment & Risk Assessment Nitrosamines	$13,000	2 Months
V	Non —GMP batch (minimum 10Kg)	61,700	3 weeks

Part	Description of Services	Price ($)	Anticipated Timeframe
VI.	^Production Engineering Batch (20 Kg)	$69,700	3 weeks
VII.	Production Clinical batch (40 kg)	$139,400	3 weeks
VIII.	Production Registration Batches (3 x 40 Kg)	$418,400	4 Months
IX.	Critical Process Parameters Study (CPP)	$156,000	6 Months
X.	*Validation Batches (3x 50 Kg)	$337,300	4 Months
XI.	*Commercial Manufacturing (Assuming 300 kg manufacture with 50 Kg batch size)	2250/Kg (Total: $675,000)	TBD
XII.	Stability Program ● Engineering Batch ● Clinical Batch ● Registration Batches ● Validation Batches	 $24,700 $24,700 $73,900 $73,900	36 Months
XIII.	Regulatory Support *(Documentation to support registration Batches)*	$29,800	3 Months
	TOTAL:	**$2,097,500**	

The actual timeframe for completion of each Part of this proposal is dependent upon resource and equipment availability and the timely receipt of materials. Upon signature of this proposal, Curia shall provide a Gantt chart detailing the activities as appropriate. Company policy dictates that we can commit resources and equipment only after receipt of written approval. Curia will use it's best effort to follow the outline below:

Date	**Services**
February 22	Selection of vendor
March 22	Due diligence and receipt of PO, order raw mats for lab and campaign
April 22-June 22	Familiarization, AMTE, process fit, HAZOP, qualification sample prep
July 22	MBR review and agreement, testing and release of raw material for campaign
July 22	Minimum 10 Kg non-GMP batch
August 22	Summer shutdown
September 22	Engineering batch 20 kg and testing
September 22	Clinical batch 40 kg
October 22-November 22	3x40 kg registration batches
December 22	Registration batches release and Registration campaign report
Q1 2023	Process validation preparation
Q2 2023	Process validation

Table 3. Invoice Schedule

Description of Services	Payment
Process Familiarization/Transfer	● To be billed monthly
Analytical Method Transfer including Reference standard qualification	● Due upon issuance of AMTE sign-off
Raw Material vendor qualification	● Due upon completion and issue of report
PGI assessment & Risk Assessment Nitrosamines	● Due upon completion and issue of report
Non-GMP batch (10 Kg)	● Due in 30 days upon issuance of COA
Production Engineering Batch (20 Kg)	● Due in 30 days upon issuance of COA or release
Production Clinical batch (40 Kg)	● Due in 30 days upon issuance of COA or release
Production Registration Batches (3 x 40 Kg)	● Due in 30 days upon issuance of COA or release
Validation Batches (3x 50 Kg)	● Due in 30 day upon issuance of COA or release

In order to best accommodate XORTX's project timeline, Curia will utilize its global network to complete each piece of work, where applicable. Curia shall invoice the work as it is being completed from the site where the work is performed.

The fastest path to approval and commercialization is using our in-house regulatory team. Our team has decades of combined experience and real time knowledge of current global regulatory trends. Working closely with our technical team to define what parameters are Established Conditions (EC's); we can devise appropriate regulatory strategies, clear hurdles, and produce submission ready documentation.

Let us know if you would like to speak with our regulatory experts about how we can fast track your commercial strategy.

This section specifies the services and deliverables to be provided by Curia as outlined in Table 1.

“cGMP” or “GMP” as specified in the International Conference on Harmonization (“ICH”) guide Q7 “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients” (“API”), as applied to the manufacture, testing, and quality control of APIs.

I. Process Familiarization/transfer

Prior to initiating the scale-up activities, Curia shall evaluate and familiarize with the current process provided by XORTX to ensure reproducibility, quality, and safety on scale.

We recommend utilizing our Full-Time Equivalent (“FTE”) program since this approach allows XORTX the flexibility of changing scope and direction during the course of the work. Curia estimates that this process transfer/familiarization effort will require an overall effort of 2.5 FTE months. Under the FTE program, the scientists are dedicated to your project and will provide XORTX with regular updates on its progress. The FTE rate for this project is $26,000 per month per scientist to be billed on a monthly basis.

The total labor fee, reimbursable expenses for all chemicals and materials, and anticipated timeframe for this work are outlined in the table below.

Description of Services	Estimated Fee ($)	Anticipated Timeframe
Process Familiarization/transfer	$65,000	2.5 Months

Please appreciate that depending on the ongoing observations made and results obtained for this work, it is possible that this work may be completed in more time than is estimated herein. Should this be the case, Curia will not proceed with, nor bill XORTX for any further work unless XORTX provides written approval to do so.

II. Analytical Method Transfer and Raw Material vendor Qualification

Curia shall transfer and qualify the analytical methods which are required to support this program. This work shall include the following activities.

Verification of analytical methods for:

- Raw material carbonitrile
- Intermediate carboxamide hemisulfate
- Oxypurinol API
- Reanalysis of the impurities and WS after reception

The fixed fee and anticipated timeframe for this work are outlined in the table below.

Description of Services	Fixed Fee ($)	Anticipated Timeframe
Analytical Method Transfer including Reference standard qualification	$156,000	3 Months
Raw Material vendor qualification	$12,000	1month

Assumptions

- Should any additional analytical work other than what is estimated herein be required, XORTX would be contacted and updated on this information. At that point, XORTX, at its sole discretion, will have the option to extend this portion of the program.
- Analytical methods for the raw material carbonitrile 2, intermediate carboxamide hemisulfate (3), and Oxypurinol API are available. The methods for the API have been validated.

Deliverables

- Written Test methods which includes a summary of the results.
- Raw materials and vendors qualification summary report

Terms and Conditions

All work specified herein is governed by Curia's Manufacturing and Supply of Active Pharmaceutical Ingredients, Intermediates and/or Fine Chemicals ("API") Terms and Conditions which can be found at https://www.curiaglobal.com/terms-and-conditions/Terms - Ex works, Curia Spain
Payment — net 3o days
Cancellation - In the unlikely event Xortx needs to terminate the project during its implementation for any valid reason (e.g. unfavorable clinical results) or the product development should cease, the following cancellation costs will apply:

- Curia will charge for the work completed, work in-progress, unreturnable raw materials, unused site capacity which could not be filled, raw materials contract obligations, any cancellation on equipment installation for production ramp up, and disposal costs pertaining to raw materials or intermediates.
- Raw material credits: To the extent Curia can cancel/return orders for raw materials or to the extent Curia can allocate RMs to other customers/projects, Curia will credit such amounts to the cancellation fees owed by Xortx above.

Any terms and conditions contained in a purchase order or other document which are additional to or inconsistent with the above Terms and Conditions shall be void, unless specifically agreed to by Curia in writing, signed by Curia's duly authorized representative.

Fee for Additional Services

Should XORTX request Curia to perform any of the following services in connection with this project then the following fees will apply:

FEE FOR SERVICE	
DESCRIPTION	**PRICE ($)**
Handling costs per shipment (processing paperwork related to shipping) of project related materials	$250 per shipment Does not include XORTX Specific Packaging
Shipping of Any Materials (FIO Samples, intermediates, API, etc.) is the Responsibility of XORTX	In addition to the above handling fees; shipping costs will be dependent on size, conditions, and destination
Issue of Certificate of Destruction or Disposal of Material (per request - *includes accountability, the preparation of materials for destruction, and the charges related directly to the actual transportation and destruction of materials*	$500 for up to 50 g $1,000 for 51 g - 1 kg $1,300 for >1 kg
Storage of XORTX Materials, Intermediates and APIs	From $1,500 per project per month and a Storage Agreement will be provided
Storage of Stability/Retention Samples After Completion of Protocol/Project	From $1,500 per project per month
XORTX Specific Packaging	TBD
cGMP Repackaging	From $2,500 per batch
High Potency or Controlled Substance cGMP Repackaging	From $3,500 per batch

Project Pricing Notes

- If additional services are required that exceed the standard Curia practices (i.e. per a client specific Quality Agreement) additional costs may be incurred. This also includes changes to the scope of work due to new objectives or incomplete information.
- In the event that the compound is determined to require the use of Curia's high-potency laboratories, special handling requirements (controlled substance or under nitrogen) or other containment, a revision to this proposal will be necessary.
- The pricing in this proposal applies only to the specific services and deliverables listed herein. Any increase or change to the scope of services and/or deliverables including, but not limited to, analytical testing beyond regulatory requirements, supply of reference standards, technology transfer to third parties, regulatory consulting and support, out-of-specifications investigations and process safety evaluations will require a price change and a revised or additional proposal.

- Any meetings, shipping or travel charges incurred outside of Curia facilities in connection with the performance of this project will be agreed in advance with XORTX and separately invoiced.

Contractual Agreement & Sign-Off

Your acceptance and execution of this proposal is expressly limited to you either countersigning this proposal or issuing a purchase order against it; provided that issuing a purchase order is only permitted for administrative purposes and its underlying terms shall not apply to this project.

Once signed, a copy of the entire document may be emailed to BusDevHelp@curiaglobal.com and the appropriate Business Development Representative.

Hard copies, if needed, should be mailed to:
Curia Spain, S.A.U
Attention: Customer Service
Parque Tecnológico de Boecillo, Parcela 105
47151 Boecillo, Valladolid, Spain
Tel: +34 983 54 8o 72, Fax: + 34 983 54 81 13
Email: raquel.poveda@curiaglobal.com

Please feel free to contact me if there is any further information that Curia can provide about any aspect of this proposal. I look forward to hearing from you.

Sincerely,

/s/ Richard Decina

Richard Decina
Senior Director, Business Development

Agreed and Understood:

/s/ Allen Davidoff
Signature
Allen Davidoff
Name (Print)

March 31, 2022
Date

XORTX Financial Details

If a Purchase Order is required for administrative purposes:		Yes		No
If Yes is selected, please record the P.O. number here:				
	Initial:		Date:	
If XORTX requires a purchase order for administrative purposes; we request that XORTX provide the applicable purchase order # within five to ten days of XORTX's signature of this proposal. The purchase order must reference the Curia proposal reference number in order for Curia to schedule project and the purchase order underlying terms shall not apply to this project.				

Payments are requested to be remitted by wire/ACH. Curia's electronic funds transfer information is as follows:

***

Exhibit 4.26

CONSULTING AMENDING AGREEMENT

THIS AGREEMENT made as of Jan 27, 2022

BETWEEN:

Stephen Haworth, of the State of Pennsylvania (hereinafter referred to as the **"Consultant")**

OF THE FIRST PART,

- and -

XORTX Therapeutics Inc., a corporation incorporated under the laws of British Columbia, Canada (hereinafter referred to as the **"Corporation")**

OF THE SECOND PART.

THIS AGREEMENT WITNESSES that in consideration of the covenants and agreements contained herein, the parties hereto agree as follows:

WHEREAS the Corporation and the Consultant (collectively, the **"Parties")** entered into an Independent Contractor Agreement dated July 1, 2021 (the **"Original Agreement");**

AND WHEREAS the Parties wish to amend the Original Agreement and to continue the engagement of the Contractor with the Company on the terms and conditions set out in the Original Agreement, as amended by this Consulting Amending Agreement;

NOW THEREFORE in consideration of the premises and the mutual covenants herein contained, and other good and valuable consideration, the Parties hereby covenant and agree as follows:

1. Term of Agreement

Section 1.02 is replaced entirely with the following language:

The provision of services by the Consultant to the Corporation hereunder shall commence on November 1, 2021 and shall continue for a period of 12 months and supersedes any prior agreements and will terminate on October 31, 2022, subject to earlier termination of this Agreement as set forth in Article Five herein.

2. Change in Fee

Section 2.01 is replaced entirely with the following language:

The Corporation shall pay to the Consultant for the services provided under this Agreement a rate of:

- $18,750 USD per month to devote 100% of their efforts on behalf of XORTX Therapeutics Inc.

- and will be eligible for an additional payment of up to 30% of the total of the contract at the time of the grant of the payment, subject to the discretion of the compensation committee.

3. Law and Jurisdiction

All references to "Ontario" in Sections 6.09 and 6.10 are hereby changed to "Alberta".

4. Section 2.04 and 5.03

Section 2.04 and Section 5.03 are removed entirely.

5. Other Terms

All other terms of the Original Agreement remain unchanged.

6. Legal Advice and Entire Agreement

This Amending Agreement, together with the Original Agreement, constitutes the entire agreement between the Parties and supersedes and replaces any prior agreements between the Parties, whether oral or in writing. The Contractor and Principal acknowledge that they have had the time and opportunity to obtain independent legal advice with respect to the execution of this Amending Agreement or have waived that opportunity, and that the Contractor and Principal have read, understand, and agree with all of the terms and conditions contained herein.

IN WITNESS WHEREOF the Parties have executed and delivered this Amending Agreement as of the day and year first written above.

XORTX Therapeutics Inc.	On behalf of Stephen Haworth and in his personal capacity as Principal
per:	
/s/ Allen Davidoff	/s/ Stephen Haworth
Allen Davidoff, President and CEO	Stephen Haworth

Exhibit 4.27

THIS AGREEMENT is made as of the 1st Day of November, 2021.

BETWEEN:

XORTX Therapeutics Inc. a body corporate, incorporated under the laws of the Canada in the Province of Alberta and having an office in the city of Calgary, in the Province of Alberta, (hereinafter called the "**CORPORATION**")

-and-

Amar Keshri, of the city of Calgary, in the Province of Alberta,
(hereinafter called the "**EMPLOYEE**")

EMPLOYMENT AGREEMENT

WHEREAS the CORPORATION is principally engaged in the business of biotechnology research and development, and in particular developing drugs and therapeutics and accumulating and protecting intellectual property in respect of the foregoing;

AND WHEREAS the CORPORATION is desirous of employing the EMPLOYEE on the terms, conditions and for the considerations as hereinafter set forth and the EMPLOYEE wishes to accept such employment with the CORPORATION;

AND WHEREAS the parties desire to enter into this Agreement to set forth their respective rights and obligations;

NOW THEREFORE THIS AGREEMENT WITNESSETH that in consideration of the premises, the mutual covenants and agreements herein contained and other good and valuable consideration, the parties hereto mutually covenant and agree as follows:

ARTICLE 1- CONTRACT FOR SERVICES

1.1 Subject to the earlier termination of this Agreement as hereinafter provided, the CORPORATION hereby agrees employ the EMPLOYEE as Chief Financial Officer in accordance with the terms and provisions hereof.

1.2 The EMPLOYEE shall be responsible for and shall have such authority as is consistent with the position of Chief Financial Officer (CFO) of the CORPORATION all subject to the power, direction and control of the Chief Executive Officer and President and Board of Directors of the CORPORATION.

1.3 Notwithstanding Section 1.2 hereof, the EMPLOYEE'S services hereunder shall be provided on the basis of the following terms and conditions:

(a) The EMPLOYEE'S title shall be Chief Financial Officer of the CORPORATION;

(b) the EMPLOYEE shall faithfully, honestly and diligently serve the CORPORATION and cooperate with the CORPORATION and utilize maximum professional skill and care to ensure that all services rendered hereunder are to the satisfaction of the CORPORATION, acting reasonably, and to provide any other services not specifically mentioned herein, but which by reason of his capability he knows or ought to know to be necessary to ensure that the best interests of the CORPORATION are maintained;

(c) the EMPLOYEE shall assume, obey, implement and execute such duties, directions, responsibilities, procedures, policies and lawful orders as may be determined or given by the Chief Executive Officer (CEO) and Board of Directors of the CORPORATION from time to time and report results of same as may from time to time be determined by the Board of Directors of the CORPORATION,

(d) the EMPLOYEE will, when it is deemed by the CORPORATION to be beneficial, join in or participate with organizations, clubs, associations or groups that may provide good business contacts and learning facilities for the benefit of the CORPORATION; and

(e) the EMPLOYEE shall have the authority to make the usual contracts necessary to carry on the business of the CORPORATION in the ordinary course, upon approval by the Chief Executive Officer (CEO).

1.4 The EMPLOYEE agrees to devote the whole of his time, attention and best efforts to further the business and interests of the CORPORATION during the period of this Agreement to the exclusion of all other employment.

1.5 It is acknowledged and agreed between the parties hereto that the services to be provided by the EMPLOYEE hereunder are of such nature that regular business may be impossible and that the EMPLOYEE may be required to perform services in excess of eight (8) hours per day or five (5) days per week. It is also anticipated that there will be certain evenings, weekends and holidays during which the EMPLOYEE may be required to provide services. The EMPLOYEE therefore agrees that the consideration herein set forth shall be in full and complete consideration herein set forth shall be in full and complete satisfaction for his work and services to be provided hereunder, no matter when and how performed and the EMPLOYEE releases the CORPORATION from any additional pay or compensation, whatsoever which he might have by reason of any existing or future legislation or otherwise.

1.6 The services to be carried out and performed by the EMPLOYEE shall be carried out and performed in the City of Calgary in the Province of Alberta, or such other places as may be mutually agreed between the EMPLOYEE and the CORPORATION. It is understood that a reasonable amount of business travel outside of Calgary may be required.

ARTICLE 2 -TERM OF CONTRACT

2.1 Subject to earlier termination pursuant to the terms hereof, this contract for services shall be for an indefinite term from and including the date hereof,

ARTICLE 3 -COMPENSATION

3.1 In consideration of the services to be provided by the EMPLOYEE to the CORPORATION pursuant to Article 1 hereof, the CORPORATION shall pay to the EMPLOYEE an annual salary of One Hundred Ninty Two Thousand ($192,000) Dollars, payable once per month in equal instalments on the the last day of each month during the term hereof

3.2 The EMPLOYEE shall be reimbursed for all reasonable expenses incurred by him in or about the execution of his services hereunder, including living expenses while absent from his city of residence, travel and meeting/entertainment expenses. All such expenses shall be verified by statements, receipts or other reasonable evidence satisfactory to the CORPORATION.

3.3 In accordance with the terms and conditions of the applicable benefit plan texts, as amended by the Board of Directors from time the EMPLOYEE shall be entitled to participate in all executive, medical, dental, and other health care, life insurance, group accident, long term disability, savings, profit sharing, share option, share purchase and any other benefit plans of whatsoever nature which the CORPORATION may provide from time to time. The EMPLOYEE understands and agrees that the CORPORATION monitors such plans and benefits and may, from time to time, modify or terminate the plans and benefits.

3.4 The CORPORATION will provide the EMPLOYEE with a parking stall convenient to his location of work when in Calgary.

3.5 The Board may cause the Corporation to, in its abosolute and sole discretion, pay to the Executive a bonus. The payment of any bonus does not constitute an obligation to pay another bonus at a future date nor does the non-payment of a bonus constitue a constructive dismissial at common law or Just Cause under subsection 9.1.

ARTICLE 4-REVIEW OF COMPENSATION

4.1 The remuneration payable pursuant to Section 3.1 hereof shall be reviewed by the Compensation Committee and Board of Directors of the CORPORATION on or before the anniversary date hereof, and annually thereafter, at which time the Board of Directors shall consider such matters, as it may consider relevant and shall determine, in its absolute discretion, whether to increase the annual remuneration payable by the CORPORATION to the EMPLOYEE hereunder, provided always however, that the remuneration payable to the EMPLOYEE pursuant to Article 3 hereof shall not, as a result of such review, be reduced.

ARTICLE 5 -INCAPACITY

5.1 The EMPLOYEE shall be entitled to reasonable time from his services, without loss of compensation, due to sickness or illness or other incapacity.

5.2 In the event the EMPLOYEE is insured either personally or through the CORPORATION or through a group plan provided by the CORPORATION for loss of income as a result of disability and the EMPLOYEE receives compensation or disability income pursuant thereto, then the amount of remuneration which the EMPLOYEE is otherwise entitled to receive hereunder during the period of illness or incapacity shall be reduced by the amount of compensation or disability income paid by such insurer to the EMPLOYEE and the EMPLOYEE covenants and agrees that he shall immediately advise the CORPORATION from time to time of the receipt of any such disability income paid by such insurer to the EMPLOYEE.

ARTICLE 6 - CONFIDENTIAL INFORMATION

6.1 The EMPLOYEE covenants and agrees that during the term hereof and for a period of five (5) years thereafter, he will keep in strict confidence and shall not use, directly or indirectly, for any other purpose other than for the purpose of providing services hereunder, all knowledge, information (whether oral or written) and materials obtained or acquired during the course of his providing services hereunder relating to the CORPORATION or its business and affairs. Other than information disclosed or divulged to the Board of Directors and duly authorized officers and employees of the CORPORATION, the EMPLOYEE will not disclose, divulge, publish or transfer, or authorize or permit anyone else to disclose, divulge, publish or transfer or use to his own advantage any suchknowledge, materials, business data or other information obtained pursuant to this Agreement or which relate in any manner to the business affairs of the CORPORATION, without the prior written consent of the CORPORATION, which consent may be arbitrarily or unreasonably withheld.

6.2 The obligation of the EMPLOYEE, as identified in Section 6.1, hereof shall not apply to such knowledge, information, material or business data obtained pursuant to this Agreement or relating in any manner to the business affairs of the CORPORATION which:

(a) was demonstrably unknown to the EMPLOYEE prior to receipt thereof pursuant to this Agreement;

(b) is available to the public in the form of written publication;

(c) shall have become available to the EMPLOYEE in good faith from a third party who has a bona fide right to disclose same; and

(d) that information which is required to be disclosed to any federal, provincial, state or local government or governmental branch, board, agency car instrumentality necessary to comply with relevant timely disclosure laws or regulatory authorities, including stock exchanges having jurisdiction in respect of securities of the CORPORATION.

ARTICLE 7 -VACATION

7.1 During the term hereof, the EMPLOYEE shall be entitled to six (6) weeks paid vacation in each calendar year hereof. The EMPLOYEE understands and agrees that vacation is to be taken at a time mutually agreed upon between the EMPLOYEE and the CORPORATION.

ARTICLE 8 –NON-ASSIGNABILITY

8.1 This contract for services and all other rights, benefits, and privileges herein conferred are personal to the EMPLOYEE and accordingly may not be assigned by the EMPLOYEE.

ARTICLE 9 -TERMINATION

9.1 Notwithstanding the term of this Agreement as set forth in Section 2.1 hereof, this Agreement shall be terminated upon the occurrence of any one of the following events:

(a) the death of the EMPLOYEE;

(b) the EMPLOYEE becoming bankrupt or making an assignment for the benefit of creditors in general;

(c) thirty (30) days written notice by the EMPLOYEE of his intention to terminate this Agreement;

(d) thirty (30) days written notice by the CORPORATION of its intention to terminate this Agreement and in conjunction with Section 9.3 below;

(e) incapacity due to illness or injury to the EMPLOYEE, such that in the opinion of an independent medical expert acceptable to the EMPLOYEE (or his legal personal representative) and the CORPORATION, which will keep the EMPLOYEE from his duties for a period longer than six (6) consecutive months;

(f) at any time by the CORPORATION, without notice, for "**Just Cause**"("**Just Cause**" will include just cause for dismissal at common law in addition to the conviction of the EMPLOYEE for a indictable criminal offense or the breach by the EMPLOYEE of any of the material covenants or terms of this Agreement).

9.2 In the event this Agreement is terminated in accordance with the provisions of subsections 9.1(a), (b), (c), (e) and (f) hereto the EMPLOYEE shall not be entitled to additional remuneration hereunder from and after the "**Termination Date**" ("**Termination Date**" means the last day the EMPLOYEE is actively performing his duties at work, regardless of the reason for termination.)

9.3 If the CORPORATION terminates this Agreement in accordance with 9.1(d)hereof, the parties agree that the CORPORATION shall pay to the EMPLOYEE an amount of severance calculated in accordance with the following, and that such amount shall constitute full and final settlement of any amounts owing to the EMPLOYEE as a result of such termination:

(a) the equivalent of six times his then current monthly salary, if terminated prior to the first anniversary of the date hereof; or

(b) the equivalent of twelve times his then current monthly salary, if terminated on or after the first anniversary of the date hereof but prior to the second anniversary of the date hereof.

(c) It is understood and agreed that the payments referred to in this Section 9.3 include the minimum statutory pay in lieu of notice prescribed by the Alberta *Employment Standards Code*, as amended.

It is further understood that the EMPLOYEE will sign a Release and Confidentiality Agreement similar to that attached as Schedule "A" prior to receiving any amounts owing which exceed the minimum entitlements in accordance with the *Employment Standards Code* (Alberta), as amended, and the EMPLOYEE will provide all required resignations of any positions he holds in the CORPORATION.

ARTICLE 10 -NON COMPETITION & NON-SOLICITATION

10.1 The EMPLOYEE covenants and agrees with the CORPORATION that during the term hereof and for a period of two (2) years thereafter, he will not, either individually or in partnership or jointly or in conjunction with any person, association or syndicate, as principal, agent, shareholder, director, officer, employee or in any other manner whatsoever carry on or be engaged in or be concerned with or interested in or advise, lend money to, guarantee the debts or obligations of or permit his name or any part thereof to be used or employed by any person or persons, including, without limitation, any individual, firm, association, syndication, company, corporation, or other business enterprise, engaged in or concerned with or interested in any business or any part thereof presently carried on by the CORPORATION with respect to its business of any other business at any time during the term hereof carried on by the CORPORATION, except with written consent of the CORPORATION, which consent will not be reasonably withheld.

10.2 During the period identified in Section 10.1, the EMPLOYEE shall not solicit, engage in, assist or have an interest in or be connected with any person, firm or corporation soliciting any customer known or ought to be known to the EMPLOYEE to be a customer or business associate of the CORPORATION.

10.3 During the period identified in Section 10.1, the EMPLOYEE shall not induce, entice or attempt to obtain the withdrawal from the CORPORATION of any employee, consultant, contract researcher or management personnel either before or after the termination of this Agreement.

10.4 If the CORPORATION ceases to carry on business for a continuous period of six (6) months or more, then the provisions of Article 6 and Article 10 hereof shall be null and void and shall cease to have any force and effect after the expiration of the aforesaid period of time.

10.5

The EMPLOYEE confirms that the obligations in Sections 10.1, 10.2 and 10.3 of this Agreement are reasonably necessary for the protection of the CORPORATION and its shareholders and, given the EMPLOYEE's knowledge and experience, will not prevent the EMPLOYEE from being gainfully employed if the EMPLOYEE's employment with the CORPORATION ends.

ARTICLE 11- CHANGE OF CONTROL

11.1 In the event that any third party (which third party has a market capitalization of greater than Cdn.$200,000,000 or has an average daily trading volume of greater than $250,000 (based on the 30 days preceding the date of merger or acquisition and excluding any unusual block trades)) acquires greater than fifty (50%) of the outstanding common shares of the CORPORATION and, within thirty (30) days of such acquisition, the EMPLOYEE'S employment with the CORPORATION is terminated by the CORPORATION or the EMPLOYEE, then the EMPLOYEE shall be entitled to a cash payment equal to 12 times his then current monthly salary (less any payments received by or owing to the EMPLOYEE pursuant to Section 9.3 hereof).

ARTICLE 12 – INDEMNITY

The CORPORATION shall indemnify and save harmless the EMPLOYEE from and against any personal liability which he incurs in the performance of his employment duties on behalf of the CORPORATION, with the exception of the following:

(a) any liability arising from the EMPLOYEE's gross negligence or fraud or other acts of willful misfeasance; and

(b) any liability which the CORPORATION is prohibited from assuming by law.

ARTICLE 13- NOTICES

12.1 All notices required or allowed to be given under this Agreement shall be made either personally or by mailing same by prepaid registered post, addressed as hereinafter set forth or to such other address as may be designated from time to time by such party in writing, and any notice mailed as aforesaid shall be deemed to have been received by the addresses thereof on the fifth business day following the day of mailing:

The CORPORATION
XORTX Therapeutics Inc.
29 Aspen Park Meadows S.W.
Calgary, Alberta T3H 5Z7

The EMPLOYEE
Amar Keshri
11 Stoneypointe Place
Calgary, Alberta T3L 0C9

Any party may, from time to time, change its address for service hereunder on written notice to the other party. Any notice may be served by hand delivery or by mailing same by prepaid, registered post, in a properly addressed envelope, addressed to the party to whom the notice is to be given at its address for service hereunder.

ARTICLE 14 -SEVERABILITY

13.1 Each provision of this Agreement is declared to constitute a separate and distinct covenant and to be severable from all such other separate and distinct covenants. Without limiting and foregoing, each provision contained in Article 6 and Article 10 hereof, are declared to-constitute separate and distinct covenants in respect of each capacity and each activity specified in Articles 6 and 10, and to be severable from all other such separate and distinct covenants. If any of the capacities, activities or periods specified in Articles 6 and 10, are considered by a court of as being unreasonable, the parties hereto agree that the said court will have authority to limit such capacities, activities, periods or areas to such capacities, activities, periods of areas as the court deems proper in the circumstances.

13.2 If any covenant or provision herein is determined to be void or unenforceable in whole or in part, it will not be deemed to affect or impair the enforceability or validity of any other covenant or provision of the Agreement or any part thereof.

ARTICLE 15 -RELIEF

l4.l The parties to this Agreement recognise that a breach by the EMPLOYEE of any of the covenants herein contained would result in damages to the CORPORATION and the CORPORATION could not adequately be compensated for such damages by monetary award. Accordingly, the EMPLOYEE agrees that in the event of any such breach, in addition to all other remedies available to the CORPORATION at law or in equity, the CORPORATION will be entitled as a matter of right to apply to a court of competent equitable jurisdiction of such relief by way of restraining order, injunction, decree or otherwise, as may be appropriate to ensure compliance with the provisions of this Agreement.

ARTICLE 16 -WAIVER

15.1 The parties agree that all restrictions in this Agreement are necessary and fundamental to the protection of the CORPORATION and are reasonable and valid, and all defences to the strict enforcement thereof by the CORPORATION are hereby waived by the EMPLOYEE.

ARTICLE 17 -GENERAL

16.1 The parties hereto agree that they have expressed herein their entire understanding and agreement concerning the subject matter of this Agreement and it is expressly agreed that no implied covenant, condition, term or reservation or prior representation or warranty shall be read into this Agreement relating to or the subject matter hereof or any matter or operation provided for herein.

16.2 The provisions of this Agreement will enure to the benefit of and be binding upon the heirs, executors, administrators and legal personal representatives of the EMPLOYEE and the successors and assigns of the CORPORATION, respectively.

16.3 Wherever the singular or masculine or neuter is used in this Agreement, the same shall be construed as meaning the plural or feminine or a body politic or corporate and vice versa where the context of the parties hereto so require.

16.4 Time is of the essence hereof.

16.5 This Agreement shall be construed and interpreted in accordance with the laws of the province of Alberta and Canada and each of the parties hereto hereby irrevocably attorns to the jurisdiction of the Courts of such province.

IN WITNESS WHEREOF the parties acknowledge and agree that they have read and understand the terms of this Agreement, and that they have had an opportunity to seek independent legal advice prior to entering into this Agreement, and that they have executed this Agreement with full force and effect from the date first written above.

XORTX Therapeutics Inc.

Per: /s/ Allen Davidoff

Allen Davidoff, CEO Director

Per: /s/ Amar Keshri

Amar Keshri

SIGNED, SEALED AND DELIVERED in the presence of:

/s/ Charlotte May
Witness as to the signature of
Amar Keshri

/s/ Amar Keshri
Amar Keshri

Appendix A:

Position Summary:

The Chief Financial Officer (CFO) of a company has primary responsibility for the planning, implementation, managing and running of all the finance activities of a company, including business planning, budgeting, forecasting and negotiations. The CFO job description should also extend to obtaining and maintaining investor relations and partnership compliance.

CFO duties and responsibilities of the job

As part of an executive management team, the CFO will have interaction with various members of a company, both senior and junior. A CFO job description should include:

- Providing leadership, direction and management of the finance and accounting team
- Providing strategic recommendations to the CEO/president and members of the executive management team
- Managing the processes for financial forecasting and budgets, and overseeing the preparation of all financial reporting
- Advising on long-term business and financial planning
- Establishing and developing relations with senior management and external partners and stakeholders
- Reviewing all formal finance, HR and IT related procedures
- Must be willing to travel on behalf of the company at least 20% of the time when required, per quarter.

Compensation:
Salary: $192,000 per annum (payment to be made at the end of each month)
Participation in the XORTX Option plan with participation in future grants.
Participation the XORTX Healthcare benefit - $20,000 per year.

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

XORTX THERAPEUTICS INC.

CODE OF CONDUCT

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 nonpublic 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 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 ●

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 ●;

(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 issuer'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)) for the issuer 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;

(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: May 3, 2022

/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 issuer'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)) for the issuer 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;

(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: May 3, 2022

/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, 2021, 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: May 3, 2022

/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, 2021, 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: May 3, 2022

/s/ Amar Keshri

Amar Keshri

Chief Financial Officer

(principal financial officer)

XORTX THERAPEUTICS INC.

Management Discussion and Analysis
For the year ended December 31, 2021

This management discussion and analysis of financial position and results of operations ("**MD&A**") is prepared as at April 12, 2022 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, 2021, 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 principal executive offices are located at Suite 4000, 421 – 7th Avenue SW, Calgary, Alberta, Canada T2P 4K9. The Company's shares trade on the TSX Venture Exchange ("**TSXV**"), on the Nasdaq Stock Exchange ("**Nasdaq**") under the symbol "XRTX", and on the Börse Frankfurt under the symbol "ANU".

FORWARD LOOKING STATEMENTS

This MD&A contains certain statements, other than statements of historical fact that are forward-looking statements, which reflect the current view of the Company with respect to future events including corporate developments, financial performance and general economic conditions which may affect the Company.

All statements other than statements of historical fact contained in this MD&A, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our ability to obtain additional financing;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- the success and timing of our preclinical studies and clinical trials;
- our ability to obtain and maintain regulatory approval of XORLO and any other product candidates we may develop, and the labeling under any approval we may obtain;
- regulatory approvals and other regulatory developments in the United States and other countries;
- the performance of third-party manufacturers and contract research organizations;

- our plans to develop and commercialize our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the successful development of our sales and marketing capabilities;
- the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available; and
- the loss of key scientific or management personnel.

XORTX relies on certain key expectations and assumptions in making the forecasts, projections, predictions or estimations set out in forward-looking information. These factors and assumptions are based on information available at the time that the forward-looking information is provided. These include, but are not limited to, expectations and assumptions concerning:

- the availability of capital 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 clinical-stage biotechnology company, focused on identifying, developing and commercializing therapies to treat progressive kidney disease modulated by aberrant purine and uric acid metabolism in orphan (rare) disease indications such as autosomal dominant polycystic kidney disease ("**ADPKD**") and larger, more prevalent type 2 diabetic nephropathy ("**T2DN**") as well as acute kidney injury ("**AKI**") due to coronavirus infection.

Our focus is on developing three therapeutic products to:

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

We believe that our 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 develop therapeutic products that include new or existing drugs that can be adapted to address different disease indications where aberrant purine metabolism and/or elevated uric acid is a common denominator, including polycystic kidney disease, pre-diabetes, insulin resistance, metabolic syndrome, diabetes, diabetic nephropathy, and infection. We are focused on building a pipeline of assets to address the unmet medical needs for patients with a variety of serious or life-threatening diseases using our innovative formulation of Oxypurinol, and our proprietary pipeline-in-a-product strategy supported by our intellectual property, established exclusive manufacturing agreements, and proposed clinical trials with experienced clinicians,

Our three lead product candidates are XRx-008, for the treatment of ADPKD; XRx-101, to treat AKI associated with Coronavirus / COVID-19 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 designed to provide unique solutions for acute and chronic disease. Our therapeutic platforms can be used alone, or in combination, with synergistic activity to develop a multifunctional tailored approach to a variety of indications that can address disease in multiple body systems through management of chronic or acute hyperuricemia, immune modulation, and metabolic disease. We continue to leverage these therapeutic platforms to expand our pipeline of novel and next generation drug-based therapies that we believe could represent significant improvements to the standard of care in multiple acute and chronic cardiovascular diseases and specifically kidney disease.

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

Highly Modular and Customizable

Our platforms can be combined in multiple ways and this synergy can be applied to address acute, intermittent or chronic disease progression. For example, our 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. The capabilities of our formulation technology allow us to manage the unique challenges of cardiovascular and renal disease by modulating purine metabolism, inflammatory and oxidative state.

Fit-for-purpose

Our platforms can also be utilized to engineer new chemical entities and formulations of those agents that have enhanced properties. For example, our XRx-225 product candidate program, some of the intellectual property for which we license from third parties, represents a potential new class of xanthine oxidase inhibitor(s) with a targeted design to enhance anti-inflammatory activity. The capability of tailoring the therapeutic benefit of this class of new agents permits us to identify targets and disease that we wish to exploit and then, through formulation design, optimize those small molecules and proprietary formulations to maximize clinically meaningful therapeutic effect.

Readily scalable and transferable

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

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

Product Candidate Pipeline

Our lead product candidates are XRx-008, XRx-101, and XRx-225. The XRx-008 program is currently screening subjects for bridging pharmacokinetic characterization before initiating a Phase 3 registration clinical trial, the last stage of clinical development before United States Food and Drug Administration ("**FDA**") approval. Similarly, a second "pharmacokinetic" study is planned to support both the XRx-008 and XRx-101 program and future late-stage clinical studies targeting attenuation or reversal of acute kidney disease in hospitalized individuals with COVID-19. XRx-225 is at the non-clinical stage and advancing toward the clinical development stage.

Products

The Company's most advanced development program, XRx-008, is a late clinical stage program focused on demonstrating the potential of our novel therapy for ADPKD. XRx-008 is the development name given to XORTX's proprietary oral formulation of oxypurinol. This proprietary formulation of oxypurinol has shown increased oral bioavailability and the potential for an enhanced therapeutic range. XORTX is also developing a second oral formulation of oxypurinol, XRx-101, for use in treating patients with AKI due to respiratory virus infection and/or associated co-morbidities including sepsis.

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

Patents

XORTX is the exclusive licensee of two U.S. granted patents with claims to the use of all uric acid lowering agents to treat insulin resistance or diabetic nephropathy. Counterparts for some of these patent applications have also been submitted in Europe. In both the US and Europe, XORTX has been granted patents for unique proprietary formulations of xanthine oxidase inhibitors. In addition, XORTX has also submitted two patent applications to cover the use of uric acid lowering agents for the treatment of the health consequences of coronavirus infection, as well as a new provisional patent for novel therapeutics to treat polycystic kidney disease.

OUR STRATEGY

The Company's goal is to apply our interdisciplinary expertise and pipeline-in-a-product strategy to further identify, develop and commercialize novel treatments in orphan indications, with an initial focus on renal and significant unmet medical needs.

Our ability to implement our business strategy is subject to numerous risks.

These risks include, among others (see "Risks Related to the Business"):

- we have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future;
- we will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to alter, delay, scale back, or cease our product development programs or operations;
- we have not generated any revenue to date and may never be profitable;
- we have a limited number of product candidates, all of which are still in preclinical or clinical development, and we may fail to obtain regulatory approval or experience significant delays in doing so;
- our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales;
- we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements, and the denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations;
- security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation;
- the COVID-19 pandemic may materially and adversely affect our business and financial results;
- our existing strategic partnerships are important to our business, and future strategic partnerships may also be important to us; if we are unable to maintain any of these strategic partnerships, or if these strategic partnerships are not successful, we may not realize the anticipated benefits of our strategic partnerships and our business could be adversely affected;
- we rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates;
- our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties;
- our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged;
- if we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed; and
- if we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

Funding Requirements

The Company has not generated any revenue from product sales to date and does not expect to do so until such time as XORTX obtains regulatory approval for and commercializes one or more of our product candidates. As the Company is currently in clinical and preclinical stages of development, it will be some time before we expect to achieve this and it is uncertain that we ever will. We expect that we will continue to increase our operating expenses in connection with ongoing clinical trials and preclinical activities and the development of product candidates in our pipeline. We also expect to continue our strategic partnerships and we continue to seek additional collaboration opportunities. Further, we expect to continue our efforts to pursue additional grants and refundable tax credits from the Canadian government in order to further our research and development. Although it is difficult to predict our funding requirements, based upon our current operating plan, the Company anticipates that our existing cash and cash equivalents as of December 31, 2021, combined with the net proceeds of future financings, will enable us to advance the clinical development of XRx-008 and XRx-101 product candidates. XORTX may also be eligible to receive certain research, development and commercial milestone payments in the future. However, because successful development of our product candidates and the achievement of milestones by our strategic partners is uncertain, we are unable to estimate the actual funds we will require to complete the research, development and commercialization of product candidates.

RECENT DEVELOPMENTS

Consolidation and Exchange Uplistings

On September 20, 2021, the Company announced that further to receipt of shareholder approval at the special meeting of shareholders held September 2, 2021 (announced on August 13, 2021), the Company would complete a share consolidation of the issued and outstanding common shares of the Company on the basis of 11.74 pre-consolidation common shares for each one (1) post-consolidation common share. On September 24, 2021, the share consolidation was affected resulting in consolidated shares outstanding on that date of 9,528,687.

On October 13, 2021, the Company announced that it had received approval to list its common shares on the Nasdaq under the symbol "XRTX".

On November 2, 2021, the Company announced that it had received final approval to list its common shares on the TSXV under the symbol "XRTX". The Company's shares were de-listed from trading on the Canadian Securities Exchange effective November 4, 2021 and trading on the TSXV commenced on November 5, 2021.

Public Offering and Private Placement

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

In January and February 2021, 350,204 warrants that were issued in connection with the February 2020 private placement were exercised. Of the warrants exercised, 339,801 were exercised at $2.94 per common share and 10,703 were exercised at $1.64 per common share in respect to certain finder's warrants that were issued in relation to that private placement.

On February 9, 2021, the Company 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 (the "**Private Placement**"). 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 (adjusted to reflect the share consolidation of 11.74:1 effected on September 24, 2021) 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 also subject to a ratchet provision that provided for an adjustment in the exercise price in the event the Company issued or sold 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. With the US IPO Offering being undertaken at a higher price than the Private Placement, the ratchet provision terminated on October 15, 2021.

In connection with the Private Placement, the Company paid $116,216 in cash commissions and issued 58,288 finders' warrants. 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.

Patent Advancements

On December 29, 2020, the Company announced the receipt of notification that the patent "Formulations of Xanthine Oxidase Inhibitors" will be granted for XRx-225 by the European Patent Office. The patent covers compositions and methods of using XORTX's proprietary formulations of xanthine oxidase for, renal and other diseases where aberrant purine metabolism has been implicated in disease progression. On September 1, 2021, the Company announced the grant of the patent titled "EPO National Stage of PCT International Application for Compositions and Methods for Treatment and Prevention of Hyperuricemia Related Health Consequences".

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

On December 20, 2021, the Company filed a provisional patent for polycystic kidney disease entitled "Compositions and Methods for Diagnosis, Treatment of and Prevention of Kidney Disease". This provisional patent filing was based upon findings of two independent investigator led studies that: (1) studied the role of aberrant purine metabolism in ADPKD kidney tissue, the results showing that xanthine oxidase enzyme expression and activity in kidney tissue in ADPKD is increased substantially and significantly, potentially revealing a new mechanism of injury in ADPKD; and (2) explored the health consequences of high uric acid in a mouse model of autosomal dominant polycystic kidney disease that successfully demonstrated that increased levels of serum uric acid can accelerate structural and functional changes in kidneys of patients with ADPKD.

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 "Compositions and Methods for Enhancing Anti-Viral Therapies". This patent is based on retrospective clinical data from XORTX scientific partners suggesting that an important therapeutic opportunity lies with addressing aberrant purine metabolism combined with hyperuricemia in patients most at risk to severe COVID-19 outcome. Since the advent of COVID-19 and during 2020, accumulating evidence suggests that individuals most at risk for more severe health consequences fall within a group that includes individuals with obesity, hypertension, metabolic syndrome, insulin resistance, pre-diabetes, diabetes or chronic kidney disease have a higher incidence of hyperuricemia and endothelial dysfunction. Low grade systemic inflammation associated with these disease states and pre-existing vascular injury may suppress an individual's ability to respond with a sufficiently robust response to fight infection and leaves the individual more prone to excessive pro-inflammatory and pro-coagulative state. This new patent filing proposes compositions and methods for enhancing anti-viral therapies for the treatment of individuals most at risk.

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. 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.

Regulatory Advancements

On March 14, 2022, the Company announced the submission of its clinical trial application ("**CTA**") with Health Canada for a XRX-OXY-101 bridging pharmacokinetics study. The study is an important first clinical step in the Company's 505(b)2 clinical and regulatory plan for 2022 and will support the XRx-008 program for ADPKD as well as the planned phase 3 registration trial.

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

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

Partnership with Icahn School of Medicine

On November 16, 2020, the Company announced the topline results from the Company's partnership with the Icahn School of Medicine at Mount Sinai, New York. 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 suggest 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 are warranted, and may improve AKI, dialysis, recovery and mortality outcomes.

On October 14, 2021, the Company announced that the results of the study provide support for the Company's provisional patent applications for XRx-101 with the conclusion of the study indicating, *"In patients admitted to the hospital for COVID-19, higher uric acid levels were independently associated with major adverse kidney events and mortality in a dose-dependent manner. In addition, hyperuricemia was associated with higher procalcitonin and troponin levels."*

Appointment of LONZA Group as Manufacturer

On April 30, 2020, the Company announced the appointment of LONZA Group as the manufacturer of GMP oxypurinol for the XRx-008 and XRx-101 clinical trial programs. The launch of oxypurinol manufacturing for both XRx-008 and XRx-101 is the first step to advance these programs toward clinical testing. Lonza is a leading global supplier to the pharmaceutical, biotech and specialty ingredients markets.

Appointment of Altasciences as Contract Research Organization

On December 2, 2021, the Company announced the appointment of Altasciences Company Ltd., a contract research organization ("**CRO**") for its planned Bridging pharmacokinetic study in support of the XRx-008 program for ADPKD and XRx-101 for AKI associated with Coronavirus / COVID-19 infection. The goal of the planned bridging pharmacokinetics study – XRX-OXY-101, is to characterize the increased bioavailability of oxypurinol in humans and follows successful results in two animal models where increased bioavailability was demonstrated for this formulation.

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 advisory board.

On December 20, 2021, Raymond Pratt was elected to the Board of Directors to replace Bruce Rowlands who resigned effective that date.

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

FUTURE PLANS AND OUTLOOK

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

For the balance of 2022, the Company anticipates a number of advancements and changes in its business.

In 2022, XORTX is focused on advancing XRx-008 into a clinical trial, the submission of an Orphan Drug Designation application, initiation of special protocol assessment discussions with the FDA and continuing formulation development for other kidney disease applications. To achieve these objectives, XORTX's action plan includes:

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

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

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

4. **Commence XRX-OXY-301 Registration trial in ADPKD.** XRX-OXY-301 is a multi-site, multi-national, placebo controlled, study in ADPKD patients with progressing stage 2 or 3 kidney disease. The objective of this study is to evaluate the safety and effectiveness of XRx-008 over a 24-month period and study the ability of xanthine oxidase inhibition to decrease the rate of decline of glomerular filtration rate. An estimated 350 patients will be enrolled. This study is planned to start in the second half of 2022, subject to SPA negotiations with the FDA.

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

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

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

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

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 our investor base.

SUMMARY OF QUARTERLY RESULTS

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

(unaudited)	2021 Q4	2021 Q3	2021 Q2	2021 Q1
Amortization of Intangible Assets	4,739	4,526	4,373	4,244
Foreign Exchange (gain) loss	(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 [2]	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 Income (loss)	9,094,231	(8,354,613)	(218,446)	(2,173,454)
Earnings (loss) per Share	0.74	(0.89)	(0.02)	(0.26)

(unaudited)	2020 Q4	2020 Q3	2020 Q2	2020 Q1
Accretion	-	-	425	421
Amortization of Intangible Assets	5,140	5,154	5,095	5,050
Foreign Exchange loss (gain)	7,006	42,230	90,907	(143,104)
Consulting	39,172	15,000	33,708	15,000
General and administrative	1,933	1,742	3,445	2,396
Interest	815	839	2,525	8,487
Investor Relations	109,973	52,848	40,081	38,275
Listing fees	15,510	10,802	14,063	11,763
Professional Fees	75,000	37,819	22,785	26,976
Research and Development	142,548	120,033	12,452	2,422
Share Based Payments [2]	6,748	90,443	189,524	6,728
Travel	-	-	-	8,460
Wages and Benefits	79,808	48,000	49,740	50,357
Impairment of intangible assets	64,562	-	-	-
Recovery of provision for patent acquisition[1]	(95,490)	-	-	-
Forgiveness of debt	-	-	(91,014)	-
Total Comprehensive Loss	(452,725)	(424,910)	(373,736)	(33,231)
Loss per Share	(0.07)	(0.06)	(0.05)	(0.01)

Notes:

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

(2) Share based payments relate to the vesting of options over the period.

Three months ended December 31, 2021

The Company earned comprehensive income of $9,094,231 ($0.22 per share) for the three months ended December 31, 2021, compared to a loss of $452,725 ($0.07 per share) in the three months ended December 31, 2020.

Variances within the loss items are as follows:

Foreign Exchange (Gain) Loss - $(346,716) (2020 - $7,006) – Our foreign exchange gain was $346,716 for the three months ended December 31, 2021 as compared to loss of $7,006 primarily due to an unrealized translation gain on the U.S. dollar denominated cash balance.

Consulting - $368,662 (2020 - $39,172) – Consulting expenses increased during the three months ended December 31, 2021, as more consultants were engaged during 2021 due to an increase in Company activity with respect to corporate development.

Directors' fees - $22,700 (2020 - $nil) – Directors' fees expenses increased during the three months ended December 31, 2021, as the Company began paying annual and meeting fees to its independent directors on July 1, 2021.

General and administrative **-** $146,012 (2020 – $1,933) General and administrative costs increased significantly mostly due to an increase in the director and officer insurance premium.

Listing fees - $148,487 (2020 - $15,510) – Listing fees increased during the three months ended December 31, 2021 due to costs related to the Company's listings on the TSXV and Nasdaq stock exchanges.

Research and development - $430,948 (2020 - $142,548) – Research and development expenses increased in the three months ended December 31, 2021, as the result of commencement of various feasibility studies.

Share-based payments - $143,496 (2020 - $6,748) – The share-based payment expense increased in the three months ended December 31, 2021, as more options were granted that vested over the period.

Gain on derivative warrant liability - $11,895,882 (2020 – nil). This gain relates to the warrants included in the units issued under the Private Placement and IPO. The Private Placement warrants were classified as a derivative financial liability as they contained a ratchet provision that provided for an adjustment in the exercise price of the warrants if shares or securities convertible to shares were sold at a price lower than the exercise price. The IPO warrants have an exercise price in US dollars and have a derivative financial liability as the exercise price is in a different currency than the functional currency of the entity. The warrants are initially recognized at fair value and subsequently measured at fair value with changes recognized through profit or loss. Of this amount, a gain of $9,068,213 relates to the Private Placement warrants and was recognized as the ratchet provision on the warrants described above ended, thereby resulting in the derecognition of the derivative warrant liability during the quarter. A gain of $2,827,669 relates to the IPO warrants and the derivative liability recognized. Gains and losses resulting from the revaluation of the derivative warrants are non-cash and do not impact our cash flows.

Selected Annual Financial Information

The financial information reported here in 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 2021, 2020, and 2019.

Selected Statement of Operations Data

	2021	2020	2019
Revenue	$Nil	$Nil	$Nil
Comprehensive loss for the year	$1,652,282	$1,284,602	$629,576
Weighted average shares	9,847,641	6,664,025	5,359,429
Loss per share, basic and diluted	$0.17	$0.19	$0.12

Selected Statement of Financial Position Data

	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
Cash and cash equivalents	$18,851,244	$171,271	$58,614
Net working capital (deficiency)	$19,472,340	$1,021,928	$(484,450)
Total assets	$22,035,902	$2,290,457	$1,087,977
Long-term liabilities	$Nil	$Nil	$Nil

Comparison of Operations for the 2021 and 2020 Financial Years

Results of Operations

	2021	2020	Change $	Change %
Amortization	17,882	20,439	(2,557)	(13%)
Consulting	724,272	102,880	621,392	604%
Directors' fees	62,200	-	62,200	-
General and administrative	176,099	9,516	166,583	1751%
Investor relations	518,615	241,177	277,438	115%
Listing fees	236,801	52,138	184,663	354%
Professional fees	272,943	162,580	110,363	68%
Research and development	853,124	277,455	575,669	207%
Share-based payments	499,158	293,443	205,715	70%
Travel	2,339	8,460	(6,121)	(72%)
Wages and benefits	286,090	227,905	58,185	26%
Accretion	-	846	(846)	(100%)
Foreign exchange (gain)	(326,751)	(2,961)	(323,790)	10935%
Gain on derivative warrant liability	(3,299,768)	-	(3,299,768)	-
Interest and other expenses	5,598	12,666	(7,068)	(56%)
Impairment of intangible assets	-	64,562	(64,562)	(100%)
Recovery of provision	-	(95,490)	95,490	(100%)
Transaction costs on derivative warrant liability	1,623,680	-	1,623,680	-
Forgiveness of debt	-	(91,014)	91,014	(100%)
Comprehensive Loss for the Year	1,652,282	1,284,602	367,680	29%
Loss per Share	0.17	0.19	0.53	289%

Comparison of cash flows for the year ended December 31, 2021

The Company realized a net cash inflow of $18,679,973 for the year ended December 31, 2021, compared to $112,657 for the year ended December 31, 2020. The variances in the cash flow for the year ended December 31, 2021, compared to December 31, 2020. were as follows:

Operating activities – Cash used in operating activities for the year ended December 31, 2021, was $6,062,510 (2020 - $728,401). The cash used in operating activities was primarily due to the net loss during the period offset by the non-cash items.

Investing activities – Cash used in investing activities for the year ended December 31, 2021, was $39,809 (2020 - $14,350). The cash used related to the acquisition of intangible assets during the period.

Financing activities – Cash provided by financing activities in the year ended December 31, 2021, was $24,456,551 (2020 - $855,408). 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, 2021, the Company had a cash balance of $18,851,244 and working capital of $19,472,340 as compared to a cash balance of $171,271 and working capital of $1,021,928 as at December 31, 2020. During the year ended December 31, 2020, the Company closed a $2,556,320 private placement and during the year ended December 31, 2021, the Company closed a 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. 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.

COMMITMENTS

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

	December 31 2021	December 31 2020
	$	$
Management services – officers	380,000	192,000

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, 2021, equated to US$300,000.

OFF BALANCE SHEET ARRANGEMENTS

The Company has no off-balance sheet arrangements.

TRANSACTIONS WITH RELATED PARTIES

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

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

a) Wages and benefits were paid or accrued to officers of the Company in the amount of $278,840 (2020 - $196,097).

b) Professional fees were paid or accrued to a former officer of the Company in the amount of $58,500 (2020 - $30,000).

c) Professional fees were paid or accrued to an officer of the Company in the amount of $53,000 (2020 -$nil).

d) Research and development fees were paid or accrued to an officer of the Company in the amount of $106,366 (2020 - $nil).

e) 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).

f) 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.

g) Management compensation transactions for the year ended December 31, 2021 and 2020 are summarized as follows:

	Short-term employee benefits	Share-based payments	Total
	$	$	$
Year ended December 31, 2020			
Directors and officers	262,097	217,816	479,913
Year ended December 31, 2021			
Directors and officers	**593,856**	**331,809**	**925,665**

FINANCIAL AND CAPITAL RISK MANAGEMENT

The Company's financial instruments consist of cash, accounts payable and accrued liabilities, and warrant liability. These financial instruments are classified as financial assets at FVTPL and financial liabilities at amortized cost. The fair values of these financial instruments approximate their carrying values at December 31, 2021, 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, 2021 and 2020 and categorized into levels of the fair value hierarchy:

		December 31, 2021		December 31, 2020	
	Level	Carrying Value	Estimated Fair Value *	Carrying Value	Estimated Fair Value *
		$	$	$	$
FVTPL					
Cash	1	18,851,244	18,851,244	171,271	171,271
Other financial liabilities					
Accounts payable and accrued liabilities	2	700,999	700,999	1,034,213	1,034,213
FVTPL					
Derivative liability	3	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. The fair value of the derivative warrant liability is revalued at the end of each period.

There were no transfers for levels of change in the fair value measurements of financial instruments for the years ended December 31, 2021 and 2020.

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, 2021	December 31, 2020
	$	$
Cash	18,851,244	171,271

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, 2021 and 2020 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 funds held in trust, and the financial liabilities are comprised of its accounts payable and accrued liabilities and the liability component on convertible loans.

The contractual maturities of these financial liabilities as at December 31, 2021 and 2020 are summarized below:

	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	-	-

	Payments due by period as of December 31, 2020			
	Total	Less than 3 months	Between 3 months and 1 year	1-3 years
	$	$	$	$
Accounts payable and accrued liabilities	1,034,213	1,034,213	-	-
	1,034,213	1,034,213	-	-

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, 2021, the Company is exposed to currency risk on the following financial assets and liabilities denominated in US Dollars ("**USD**") and British Pounds ("**GBP**"). The sensitivity of the Company's net earnings due to changes in the exchange rate between the USD and GBP against the Canadian dollar is included in the table below in Canadian dollar equivalents:

	USD amount	GBP amount	Total
	$	$	$
Cash	13,813,058	-	13,813,058
Accounts payable and accrued	(76,178)	(143,900)	(220,078)
Net exposure	13,736,880	(143,900)	13,592,980
Effect of +/- 10% change in currency	1,373,688	(14,390)	

Capital Management

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

The Company includes the following items in its managed capital as at the following periods:

Equity is comprised of:	**December 31 2021**	**December 31 2020**
	$	$
Share capital	20,009,154	8,258,395
Share-based payments, warrant reserve and other	6,386,459	1,003,609
Obligation to issue shares	32,238	32,238
Deficit	(9,690,280)	(8,037,998)

Since inception, the Company's objective in managing capital is to ensure sufficient liquidity to finance its research and development activities, general and administrative expenses, expenses associated with intellectual property protection and its overall capital expenditures. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

OUTSTANDING SHARE DATA

As at April 12, 2022, the Company had the following shares outstanding:

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

Options Outstanding:

The following table summarizes information on the 606,067 stock options outstanding as at April 12, 2022:

Exercise Price	Number Outstanding	Expiry Date
$5.87	127,760	March 19, 2023
$5.87	21,294	November 5, 2023
$1.64	170,354	June 23, 2025
$2.82	12,776	August 27, 2025
$3.29	59,624	January 11, 2026
$1.88	42,588	May 12, 2026
$1.76	21,294	June 16, 2026
$2.41	63,882	July 14, 2026
$2.54	86,495	December 21, 2026
$2.54	127,500	January 12, 2027
$2.54	5,000	February 18, 2027

Warrants Outstanding:

The following table summarizes information on the 5,329,796 outstanding warrants as at April 12, 2022:

Exercise Price	Number Outstanding	Expiry date
$4.70	1,842,596	February 9, 2026
US$4.77	3,487,200	October 15, 2026

RISKS RELATED TO THE BUSINESS

An investment in the Company is speculative and involves a high degree of risk. Accordingly, prospective investors should carefully consider the specific risk factors set out below, in addition to the other information contained in this MD&A, before making any decision to invest in the Company. The Directors consider the following risks and other factors to be the most significant for potential investors in the Company, but the risks listed do not necessarily comprise all those associated with an investment in the Company and are not set out in any particular order of priority. Additional risks and uncertainties not currently known to the Directors may also have an adverse effect on the Company's business. If any of the following risks actually occur, the Company's business, financial condition, capital resources, results or future operations could be materially adversely affected. In such a case, the price of the common shares could decline, and investors may lose all or part of their investment.

Speculative Nature of Investment Risk

An investment in the common shares of the Company carries a high degree of risk and should be considered as a speculative investment by purchasers. The Company has limited cash reserves, a limited operating history, has not paid dividends, and is unlikely to pay dividends in the immediate or near future. The Company is in the development stage. Operations are not yet sufficiently established such that the Company can mitigate the risks associated with planned activities.

Limited Operating History

The Company has no present prospect of generating revenue from the sale of products. The Company is therefore subject to many of the risks common to early-stage enterprises, including under-capitalization, cash shortages, limitations with respect to personnel, financial, and other resources and lack of revenues. There is no assurance that the Company will be successful in achieving a return on shareholders' investment and the likelihood of success must be considered in light of the early stage of operations.

Negative Cash Flow for the Foreseeable Future

The Company has a no history of earnings or cash flow from operations. The Company does not expect to generate material revenue or achieve self-sustaining operations for several years, if at all. To the extent that the Company has negative cash flow in future periods, the Company may need to allocate a portion of its cash reserves to fund such negative cash flow.

Reliance on Management

The success of the Company is dependent upon the ability, expertise, judgment, discretion and good faith of its management. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on the Company's business, operating results or financial condition.

Clinical trials for potential drug candidates will be expensive and time consuming, and their outcomes uncertain.

Before the Company can obtain regulatory approval for the commercial sale of any drug candidate or attract major pharmaceutical companies with which to collaborate, it will be required to complete extensive clinical trials to demonstrate safety and efficacy. Clinical trials are expensive and are difficult to design and implement. The clinical trial process is also time-consuming and can often be subject to unexpected delays.

The timing and completion of clinical trials may be subject to significant delays relating to various causes, including but not limited to: inability to manufacture or obtain sufficient quantities of materials for use in clinical trials; delays arising from collaborative partnerships; delays in obtaining regulatory approvals to commence a study, or government intervention to suspend or terminate a study; delays, suspensions or termination of clinical trials by the applicable institutional review board or independent ethics board responsible for overseeing the study to protect research subjects; delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites; slow rates of patient recruitment and enrollment; uncertain dosing issues; inability or unwillingness of medical investigators to follow clinical protocols; variability in the number and types of subjects available for each study and resulting difficulties in identifying and enrolling subjects who meet trial eligibility criteria; scheduling conflicts; difficulty in maintaining contact with subjects after treatment, resulting in incomplete data; unforeseen safety issues or side effects; lack of efficacy during clinical trials; reliance on clinical research organizations to efficiently and properly conduct clinical trials in accord with contracted arrangements and regulations, or other regulatory delays.

Risks Related to Food and Drug Administration (FDA) Approval

In the United States, the FDA regulates the approval of therapeutics and the FDA notification and approval process requires substantial time, effort and financial resources, and the Company cannot be certain that any approvals for its products will be granted on a timely basis, if at all.

Foreign jurisdictions have similar government regulatory bodies and requirements that the Company must meet prior to selling products in those jurisdictions.

The Company must be considered in light of the risks, expenses, shifts, changes and difficulties frequently encountered with companies whose businesses are regulated by various federal, state and local governments. The health care, wellness, workers' compensation and similar companies are subject to a variety of regulatory requirements and the regulatory environment is ever changing particularly with recent legislation, the full impact of which is not yet understood as regulations have not been issued. Failure to follow applicable regulatory requirements will have a materially negative impact on the business of the Company. Furthermore, future changes in legislation cannot be predicted and could irreparably harm the business of the Company.

Intellectual Property Rights

The Company could be adversely affected if it does not adequately protect its intellectual property rights. The Company regards its marks, rights, and trade secrets and other intellectual property rights as critical to its success. To protect its investments and the Company's rights in these various intellectual properties, it may rely on a combination of patents, trademark and copyright law, trade secret protection and confidentiality agreements and other contractual arrangements with its employees, clients, strategic partners, acquisition targets and others to protect proprietary rights. There can be no assurance that the steps taken by the Company to protect proprietary rights will be adequate or that third parties will not infringe or misappropriate the Company's copyrights, trademarks and similar proprietary rights, or that the Company will be able to detect unauthorized use and take appropriate steps to enforce rights. In addition, although the Company believes that its proprietary rights do not infringe on the intellectual property rights of others, there can be no assurance that other parties will not assert infringement claims against the Company. Such claims, even if not meritorious, could result in the expenditure of significant financial and managerial resources.

The Company will rely on trade secrets to protect technology where it does not believe patent protection is appropriate or obtainable. Trade secrets are difficult to protect. While commercially reasonable efforts to protect trade secrets will be used, strategic partners, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose information to competitors.

If the Company is not able to defend patents or trade secrets, then it will not be able to exclude competitors from developing or marketing competing products, and the Company may not generate enough revenue from product sales to justify the cost of development of products and to achieve or maintain profitability.

The results of preclinical studies or initial clinical trials are not necessarily predictive of future favorable results.

Preclinical tests and initial clinical trials are primarily designed to test safety and to understand the side effects of drug candidates and to explore efficacy at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Favorable results in early trials may not be repeated in later ones.

Difficulty to Forecast

The Company must rely largely on its own market research to forecast sales as detailed forecasts are not generally obtainable from other sources at this early stage of the industry. A failure in the demand for its products to materialize as a result of competition, technological change or other factors could have a material adverse effect on the business, results of operations and financial condition of the Company.

Litigation

The Company may become party to litigation from time to time in the ordinary course of business which could adversely affect its business. Should any litigation in which the Company becomes involved be determined against the Company such a decision could adversely affect the Company's ability to continue operating and the market price for the Company's common shares. Even if the Company is involved in litigation and wins, litigation can redirect significant Company resources.

Commercial success of the Company will depend in part on not infringing upon the patents and proprietary rights of other parties and enforcing its own patents and proprietary rights against others. The research and development programs will be in highly competitive fields in which numerous third parties have issued patents and pending patent applications with claims closely related to the subject matter of the Company's programs. The Company is not currently aware of any litigation or other proceedings or claims by third parties that its technologies or methods infringe on their intellectual property.

While it is the practice of the Company to undertake pre-filing searches and analyses of developing technologies, it cannot guarantee that it has identified every patent or patent application that may be relevant to the research, development, or commercialization of its products. Moreover, it cannot assure that third parties will not assert valid, erroneous, or frivolous patent infringement claims.

Uninsurable Risks

The business of the Company may not be insurable or the insurance may not be purchased due to high cost. Should such liabilities arise, they could reduce or eliminate any future profitability and result in increasing costs and a decline in the value of the Company.

The market price of the Company's common shares may be subject to wide price fluctuations.

The market price of the Company's common shares may be subject to wide fluctuations in response to many factors, including variations in the operating results of the Company and its subsidiaries, divergence in financial results from analysts' expectations, changes in earnings estimates by stock market analysts, changes in the business prospects for the Company and its subsidiaries, general economic conditions, legislative changes, and other events and factors outside of the Company's control. In addition, stock markets have from time-to-time experienced extreme price and volume fluctuations, which, as well as general economic and political conditions, could adversely affect the market price for the Company's common shares.

Dividends

The Company has no earnings or dividend record and does not anticipate paying any dividends on the common shares in the foreseeable future.

Dilution

The financial risk of the Company's future activities will be borne to a significant degree by purchasers of the common shares. If the Company issues common shares from its treasury for financing purposes, control of the Company may change and purchasers may suffer additional dilution.

Rapid Technological Change

The business of the Company is subject to rapid technological changes. Failure to keep up with such changes may adversely affect the business of the Company. The Company is subject to the risks of companies operating in the medical and healthcare business. The market in which the Company competes is characterized by rapidly changing technology, evolving industry standards, frequent new service and product announcements, introductions and enhancements and changing customer demands. As a result, an investment in the stocks of the Company is highly speculative and is only suitable for investors who recognize the high risks involved and can afford a total loss of investment.

Risks Associated with Acquisitions

If appropriate opportunities present themselves, the Company may acquire businesses, technologies, services or products that the Company believes are strategic. The Company currently has no understandings, commitments or agreements with respect to any other material acquisition and no other material acquisition is currently being pursued. There can be no assurance that the Company will be able to identify, negotiate or finance future acquisitions successfully, or to integrate such acquisitions with its current business. The process of integrating an acquired business, technology, service or product into the Company may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of the Company's business. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to goodwill and other intangible assets, which could materially adversely affect the Company's business, results of operations and financial condition. Any such future acquisitions of other businesses, technologies, services or products might require the Company to obtain additional equity or debt financing, which might not be available on terms favorable to the Company, or at all, and such financing, if available, might be dilutive.

Economic Environment

The Company's operations could be affected by the economic context should the unemployment level, interest rates or inflation reach levels that influence consumer trends and consequently, impact the Company's future sales and profitability.

Global Economy Risk

The ongoing economic problems and downturn of global capital markets has generally made the raising of capital by equity or debt financing more difficult. Access to financing has been negatively impacted by the ongoing global economic risks. As such, the Company is subject to liquidity risks in meeting its development and future operating cost requirements in instances where cash positions are unable to be maintained or appropriate financing is unavailable. These factors may impact the Company's ability to raise equity or obtain loans and other credit facilities in the future and on terms favorable to the Company. If uncertain market conditions persist, the Company's ability to raise capital could be jeopardized, which could have an adverse impact on the Company's operations and the trading price of the Company's Shares on the stock exchange.

Going-Concern Risk

The Company's future operations are dependent upon the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that the Company will be successful in completing an equity or debt financing or in achieving profitability.

Financial Risk Exposures

The Company may have financial risk exposure to varying degrees relating to the currency of each of the countries where it operates and has financial risk exposure towards digital currencies. The level of the financial risk exposure related to a currency and exchange rate fluctuations will depend on the Company's ability to hedge such risk or use another protection mechanism.

Attracting and keeping senior management and key scientific personnel

The success of the Company depends on the continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel and to develop and maintain important relationships with leading academic institutions, companies, and thought leaders. Allen Davidoff, the Company's Chief Executive Officer and Director, exercises significant control over the day-to-day affairs of the Company. The Company depends on Dr. Davidoff to engage with third parties and contractors to operate the business.

SEGMENT REPORTING

We view our operations and manage our business in one segment, which is the development and commercialization of bio-pharmaceuticals, initially focused on the treatment of progressive kidney disease.

TREND INFORMATION

Other than as disclosed elsewhere we are not aware of any trends, uncertainties, demands, commitments, or events that are reasonably likely to have a material effect on our net revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause reported financial information not necessarily to be indicative of future operating results or financial condition.

MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL STATEMENTS

The Company's management is responsible for presentation and preparation of the financial statements and the MD&A. The MD&A have been prepared in accordance with the requirements of securities regulators, including National Instrument 51-102 of the Canadian Securities Administrators.

The financial statements and information in the MD&A necessarily include amounts based on informed judgments and estimates of the expected effects of current events and transactions with appropriate consideration to materiality. In addition, in preparing the financial information, we must interpret the requirements described above, make determinations as to the relevancy of information included, and make estimates and assumptions that affect reported information. The MD&A also includes information regarding the impact of current transactions and events, sources of liquidity and capital resources, operating trends, risks and uncertainties. Actual results in the future may differ materially from our present assessment of this information because future events and circumstances may not occur as anticipated.

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

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

3.3 Number of Members

The Committee shall consist of three or more Directors.

3.4 Independence of Members

Each 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 Compensation

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

7. **Remuneration of Committee Members**

7.1 Remuneration of Committee Members

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

7.2 Directors' Fees

No member of the Committee may earn fees from the 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 Auditors 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.

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 August 9, 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 (No. 333-258741) of XORTX Therapeutics Inc. (the "Company") of our report dated April 7, 2022, relating to the consolidated financial statements of the Company, appearing in the Company's Annual Report on Form 20-F for the year ended December 31, 2021, filed with the Securities and Exchange Commission.

/s/ Smythe LLP

Chartered Professional Accountants
Vancouver, Canada
May 3, 2022