As filed with the Securities and Exchange Commission on September 21, 2022.
Registration Statement No. 333-267328

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2

FORM F-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

XORTX THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

British Columbia	**2834**	**N/A**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

3710 – 33rd Street NW
Calgary, Alberta, Canada T2L 2M1
(403) 455-7727

(Address, including zip code and telephone number, including area code, of registrant's principal executive offices)

C T Corporation
1015 15th Street N.W., Suite 1000
Washington, D.C., 20005
(202) 572-3133

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act.

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 7(a)(2)(B) of the Securities Act.† ☒

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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

SUBJECT TO COMPLETION, DATED SEPTEMBER 21, 2022

PRELIMINARY PROSPECTUS

4,878,048 Common Share Units and Pre-Funded Warrant Units consisting of 4,878,048 Common Shares Pre-Funded Warrants to Purchase Common Shares and Warrants to Purchase up to 4,878,048 Common Shares

XORTX Therapeutics Inc.

We are offering 4,878,048 common shares, no par value (the " **Shares**"), and warrants to purchase 4,878,048 common shares (the " **Warrants**") pursuant to this prospectus. Each whole Warrant is exercisable to purchase one common share (each, a "**Warrant Share**") at an assumed exercise price of US$1.23, will be exercisable upon issuance and will expire five years from the date of issuance. The Shares and Warrants will be issued and sold to purchasers in the ratio of one-to-one. Warrants will be issued in book-entry form pursuant to a warrant agency agreement between us and Continental Stock Transfer & Trust Company as warrant agent. This prospectus also relates to the offering of the Warrant Shares issuable upon exercise of the Warrants.

We are also offering to certain purchasers whose purchase of Shares in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common shares immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, pre-funded warrants ("**Pre-Funded Warrants**"), in lieu of Shares that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common shares. Each Pre-Funded Warrant will be exercisable for one common share (each, a "**Pre-Funded Warrant Share**"). The exercise price of each Pre-Funded Warrant will be US$0.0001 per Pre-Funded Warrant Share. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. This offering also relates to the Pre-Funded Warrant Shares issuable upon exercise of any Pre-Funded Warrants sold in this offering.

The Shares and the accompanying Warrants will be sold in units (each, a " **Common Share Unit**") and the Pre-Funded Warrants and the accompanying Warrants will be sold in units (each, a "**Pre-Funded Warrant Uni** t" and, together with the Common Share Units, the " **Units**"), with each Common Share Unit consisting of one Share and one Warrant and each Pre-Funded Warrant Unit consisting of one Pre-Funded Warrant and one Warrant. For each Pre-Funded Warrant Unit we sell, the number of Common Share Units we are offering will be decreased on a one-for-one basis. The Shares, Pre-Funded Warrants, and Warrants will be immediately separable on issuance. Each Common Share Unit will be sold at a price of US$1.23 per Common Share Unit (assuming a public offering price of US$1.23 per common share representing the closing price of our common shares on the Nasdaq Stock Market ("Nasdaq") of US$1.23 per common share on September 20, 2022). The purchase price of each Pre-Funded Warrant Unit will be equal to the price at which each Common Share Unit is sold to the public in this offering, minus US$0.0001, and the exercise price of each Pre-Funded Warrant will be US$0.0001 per Pre-Funded Warrant Share.

The public offering price per Common Share Units and any Pre-Funded Warrant Units will be determined by negotiation between us and the underwriter in this offering at the time of pricing, and may be at a discount to the current market price so long as they are in accordance with applicable national securities exchange rules and/or policies. Therefore, the recent market price used throughout this prospectus may not be indicative of the actual public offering price for our Common Share Units and Pre-Funded Warrant Units. There is no established public trading market for the Warrants or Pre-Funded Warrants, and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Warrants or Pre-Funded Warrants on any national securities exchange. Without an active trading market, the liquidity of the Warrants or Pre-Funded Warrants will be limited.

Our common shares are currently traded under the symbol "XRTX" on the TSX Venture Exchange (the " **TSXV**") and on Nasdaq.

We are an "emerging growth company" as defined by the Jumpstart Our Business Startups Act of 2012 (the " **JOBS Act**") and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. However, 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 of 1933, as amended, (the "**Securities Act**").

Investing in our securities involves a high degree of risk. See " *Risk Factors*" beginning on page 13.

	Per Common Share Unit	Per Pre-Funded Warrant Unit(2)	Total
Public offering price			
Underwriting discounts and commissions(1)			
Proceeds, before expenses, to us(3)			

(1) The underwriter will receive compensation in the form of reimbursement of expenses, in addition to the underwriting discount and commissions. See "*Underwriting*" for additional information regarding total compensation paid to the underwriter.

(2) The public offering price and underwriting discounts and commissions correspond to an assumed public offering price per Common Share Unit of US$1.23, an assumed public offering price per Pre-Funded Warrant Unit of US$1.2299.

(3) The amount of the offering proceeds to us presented in this table does not give effect to any exercise of the Warrants or Pre-Funded Warrants being issued in this offering.

We have granted the underwriter the right to purchase up to an additional 731,707 Shares and/or Warrants to cover over-allotments, if any, assuming a public offering price of US$1.23 per Common Share Unit. The underwriter can exercise this option at any time within 45 days after the date of this prospectus. In addition, we will issue to the underwriter Warrants to purchase a number of Shares equal to an aggregate of 5.0% of the Shares and/or Pre-Funded Warrants sold in the offering. The exercise price of the Underwriter's Warrants is equal to 100% of the offering price of the Shares and/or Pre-Funded Warrants offered hereby. The Underwriter's Warrants are exercisable beginning six months from the effective date of the offering, from time to time, in whole or in part, within five years commencing from the effective date of the offering.

The underwriter expects to deliver the securities against payment on or about , 2022.

Neither the Securities and Exchange Commission, Canadian securities commission nor any domestic or international securities body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

A.G.P.

Prospectus dated , 2022

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registrat statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities a we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form F-1 that we filed with the Securities and Exchange Commission ("**SEC**").

You should read this prospectus and the related registration statement carefully. This prospectus and registration statement contain important information you should consider when making your investment decision. See "*Where You Can Find More Information*" in this prospectus.

Neither we nor the underwriter has authorized anyone to provide you with information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give to you. The information contained in this prospectus or any free writing prospectus is accurate only as of the date of this prospectus or such free writing prospectus, regardless of the time of delivery of this prospectus or any free writing prospectus.

We are offering to sell, and seeking offers to buy, securities only in jurisdictions where offers and sales are permitted. Neither we nor the underwriter has taken any action to permit a public offering of our securities or the possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourself about and to observe any restrictions relating to this offering and the distribution of this prospectus.

We express all amounts in this prospectus in Canadian dollars, except where otherwise indicated. References to "$" are to Canadian dollars and references to "US$" are to U.S. dollars.

Except as otherwise indicated, references in this prospectus to "XORTX," "the Company," "we," "us" and "our" refer to XORTX Therapeutics Inc. and its consolidated subsidiaries.

PROSPECTUS SUMMARY

*This summary highlights certain information contained elsewhere in this prospectus. This summary does not contain all of the information that may be important to you. You should read and carefully consider the following summary together with the entire prospectus, especially the "*Risk Factors*" section of this prospectus and our consolidated financial statements and the notes thereto appearing elsewhere in this prospectus before deciding to invest in our securities. For more information on our business refer to the "*Business*" section of this prospectus. Some of the statements in this prospectus constitute forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in such forward-looking statements as a result of certain factors, including those discussed in the "*Risk Factors*" beginning on page 13 and other sections of this prospectus. See "*Cautionary Note Regarding Forward-Looking Statements.*"

Overview

We are 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 disease indications such as autosomal dominant polycystic kidney disease ("**ADPKD**"), acute kidney injury ("**AKI**") associated with coronavirus COVID-19 infection, and type 2 diabetic nephropathy ("**T2DN**").

Our focus is on developing three therapeutic products 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 induced AKI, and to treat patients with type 2 diabetic nephropathy. We are also looking to identify other opportunities where our existing and new intellectual property can be leveraged to address health issues. We believe that our technology is underpinned by research and insights into the underlying biology of aberrant purine metabolism, its health consequences and of oxypurinol, a uric acid lowering agent that is designed to effectively inhibit xanthine oxidase.

While oxypurinol has not received final U.S. Food and Drug Administration (the "**FDA**") marketing approval, we plan to leverage existing published studies and the prior FDA review and approval of Zyloprim (allopurinol) under the 505(b)(2) development pathway. Oxypurinol is an active metabolite of allopurinol. We believe 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 proprietary 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 novel formulations are supported by our intellectual property. Exclusive manufacturing agreements, and our plan to conduct clinical trials with experienced clinicians provides the Company with the ability to build, are focused on building a robust pipeline of assets. These programs are designed to address 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, 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.

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.

Product Candidates

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 product candidates for the treatment of kidney disease or the health consequences of diabetes.

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 a New Drug Application ("**NDA**") to the FDA following the successful completion of a Phase 3 clinical registration trial of the XRx-008 product candidate program in order to potentially 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 to develop additional proprietary formulations leveraging our experience selecting renal indications and complement our developments through acquisitions or in-licensing opportunities in nephrology and diabetes when opportunities arise.

Recent Developments

On October 15, 2021, the Company announced the closing of 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. 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 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 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 public offering, the Company received conditional approval to list its common shares on the Nasdaq under the symbol "XRTX" on October 13, 2021. The common shares began to trade on the Nasdaq on October 15, 2021. In order to qualify for listing on Nasdaq, the Company completed the consolidation of our shares on a one (1) post-consolidated share for 11.74 pre-consolidated shares basis which took effect on September 23, 2021.

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 COVID-19 infection.

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

For the balance of 2022, the Company anticipates a number of advancements and changes in its business. In 2022, XORTX is focused on continuing to advance clinical trial development of XRx-008, the re-submission

of the Orphan Drug Designation application, discussions with the FDA and EMA regarding next steps in the clinical development plan, and continuing formulation development for other kidney disease applications. To achieve these objectives, XORTX's action plan includes:

1. Complete 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 a Marketing Authorization Application ("**MAA**") to the EMA. This study was initiated in May 2022. The XRX-OXY-101 study is currently enrolling subjects in four parts. Part 1 of the study has completed enrollment, dosing and pharmacokinetic testing and topline results have been positive. Part 2 of the study has completed enrollment of subjects and reported topline results in August, 2022. Part 3 is anticipated to enroll patients in October, 2022. We intend to leverage the results of this bridging study to support our XRx-101 development program as well.

2. Re-Submission of Orphan Drug Designation request. In November 2018, the FDA denied the Company's request for orphan drug designation of XRx-008, citing a need for additional data and clarification around the intended patient population. We plan to re-submit our request and attempt to address the issues raised by FDA in its earlier denial. Current research being conducted will be used to support the re-submission in the near future. We cannot guarantee that FDA will grant our request.

3. 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 350 patients will be enrolled. This study is planned to start in the second half of 2022, or early 2023, subject to SPA negotiations with the FDA.

4. Ongoing CMC Work. In parallel to the XRX-OXY-101 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.

5. Preparation of 505(b)(2) IND. In parallel with initiation of XRX-OXY-101 a 505(b)(2) based IND was submitted and accepted in the second quarter of 2022 for the XRx-008 program.

6. Activities Related to Potential Commercial Launch. In preparation for a possible NDA filing in 20252026 in the U.S. for XRx-008 program, 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 2026.

7. Activities Related to XRx-008 for European Registration. XORTX intends to seek 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 2026.

On July 19, 2022, XORTX announced that it had submitted a request for scientific advice to the European Medicines Agency (EMA) to initiate discussions regarding the development pathway for XRx-008 in the EU. On August 4, 2022, XORTX announced that the pre-Phase 3 meeting request made to the FDA resulted in the grant of a virtual meeting which was held on September 16, 2022. On August 22, 2022, XORTX announced positive topline results from its Pharmacokinetics Bridging Study — XRX-OXY-101 — Part 2 showing a substantial increase in oral bioavailability of XORTX's proprietary oxypurinol formulation provided with food compared to the fasted state. In addition, accompanying the improved

bioavailability findings in Part 2 was a clean safety and pharmacologic profile with no drug related adverse or serious adverse events related to oral administration of oxypurinol.

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.

Risk Factors Summary

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled "*Risk Factors*" in this prospectus. These risks include, among others:

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. Such additional funding 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. The need for additional capital may cause dilution to our shareholders.
- Unstable market and economic conditions and negative macroeconomic and geopolitical trends may have adverse consequences on our business and financial condition and could affect our ability to access capital.
- We have not generated any revenue to date and may never be profitable and 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.

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 clinical development, and we may fail to obtain regulatory approval or experience significant delays in doing so.
- Clinical trials are very expensive, time consuming and difficult to design and implement and involve uncertain outcomes. Various factors could prohibit us from launching trials or delay, prolong, stop, or negatively impact such trials, which could cause us to incur additional costs, threaten product development and our ability to ultimately obtain regulatory approvals.
- 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.
- Changes in drug supply manufacturers or methods of product candidate manufacturing or formulation may result in additional costs or delay.
- We may be unable to take full advantage of regulatory programs designed to expedite drug development and may face challenges in gaining and or maintaining necessary regulatory approvals and obtaining or maintaining regulatory approval o in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

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. If we are not able to obtain, or are delayed in obtaining, required approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.
- We face significant competition and if our competitors develop and market products that are perceived as advantageous, our commercial opportunities will be negatively impacted.

- If any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance and we may not be able to maintain such approvals.
- We may seek orphan drug status for one or more of our product candidates.
- Even if we obtain FDA approval of our product candidates, we may never obtain approval or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.
- Market opportunities for our product candidates may not develop, prove different than expected, or we may fail to capitalize on opportunities to commercialize product candidates.
- Our business entails a significant risk of product liability claims and we may need to have in place increased product liability coverage when we begin the commercialization of our product candidates.
- Security breaches, loss of data and other disruptions could compromise sensitive information or protected health information or prevent us from accessing critical information and expose us to liability.
- 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.
- We operate in many jurisdictions and are subject to risks attendant to international operations, including differing regulatory regimes and legal standards, import and export controls, anti-corruption and money laundering laws, and foreign currency fluctuation risks.
- We have no marketing organization and have no experience in marketing prescription drug products.
- The COVID-19 pandemic and the efforts to mitigate it may adversely affect our business and results.

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 rely on, and expect to continue to rely, on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and to supply and manufacture our product candidates. We face competition in establishing such relationships and the loss of or failure of such relationships could harm our prospects.

Risks Related to Our Intellectual Property

- Our success depends on our ability to operate without infringing the intellectual property rights of others.
- We may be unable to secure or preserve intellectual property or the confidentiality of our proprietary information for our products or product candidates, such protections may prove inadequate, and we may face challenges and expenses in protecting our intellectual property and proprietary information.

Risks Related to Additional Legal and Compliance Matters

- Our employees and independent contractors may engage in misconduct or other improper activities.
- Our relationships with others are subject to laws and regulations that could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and earnings.
- If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Risks Related to Employee Matters and Managing Growth

- Our future success depends on our ability to attract, retain and motivate qualified personnel.
- We will need to grow our organization, and we may experience difficulty in managing this growth. Additionally, business disruptions could seriously harm our future revenue and financial condition.

Risks Related to Our Securities and this Offering

- Our share price is likely to be volatile and our shares may be inactively traded.
- We incur significant costs as a result of operating as a public company. 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.
- Our disclosure requirements could differ from other U.S. domestic reporting companies owing to our status as a "foreign private issuer" and "emerging growth company" and such statuses are subject to change.
- There is no public market for the Warrants, Pre-Funded Warrants or Units being offered by us in this offering and the holders of such securities will have no rights as common shareholders until such securities are converted into Shares.
- Our management team will have broad discretion to use the net proceeds from this offering.
- We are governed by the corporate laws of British Columbia, Canada which in some cases have a different effect on shareholders than the corporate laws of the United States. Additionally, this may make bringing an action or enforcing any potential judgment against us, our directors, or our executive officers difficult.
- U.S. shareholders may suffer adverse tax impacts if we are deemed a passive foreign investment company.
- 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.

Our Corporate Information

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 a reverse take-over transaction on January 10, 2018, with APAC Resources Inc., a company incorporated under the laws of British Columbia, we changed our name to "XORTX Therapeutics Inc." and XORTX Pharma Corp. became a wholly-owned subsidiary.

Our registered office is located at 3710 – 33rd Street NW, Calgary, Alberta, Canada T2L 2M1 and our telephone number is (403) 455-7727. Our website address is www.xortx.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company

As a company with less than US$1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- reduced executive compensation disclosure;
- exemptions from the requirement to hold a non-binding advisory vote on executive compensation, including golden parachute compensation; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We may take advantage of these provisions until we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: (1) the last day of our fiscal year following the fifth anniversary of the completion of this offering; (2) the last day of the fiscal year in which we have total annual gross revenue of US$1.07 billion or more; (3) the date on which we have issued more than US$1.0 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. 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.

We report under the Exchange Act, as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we continue to qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations with respect to a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial statements and other specified information, and current reports on Form 8-K upon the occurrence of specified significant events, although we report our results of operations on a quarterly basis under the Canadian securities laws.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

We would cease to be a foreign private issuer at such time as more than 50% of our outstanding voting securities are held by U.S. residents, and any one of the following three circumstances applies: (i) the majority of our executive officers or directors are U.S. citizens or residents, (ii) more than 50% of our assets are located in the United States or (iii) our business is administered principally in the United States.

In this prospectus, we have taken advantage of certain of the reduced reporting requirements as a result of being an emerging growth company and a foreign private issuer. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold equity securities.

	The Offering
Shares offered by us	4,878,048 Shares.
Pre-Funded Warrants offered by us	We are also offering to certain purchasers whose purchase of Shares in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Shares immediately following the consummation of this offering, the opportunity to purchase, if such purchasers so choose, Pre-Funded Warrants, in lieu of Shares that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common shares. Each Pre-Funded Warrant will be exercisable for one Pre-Funded Warrant Share. The purchase price of each Pre-Funded Warrant will equal the price at which the Shares are being sold to the public in this offering, minus US$0.0001 and the exercise price of each Pre-Funded Warrant will be US$0.0001 per share. The Pre-Funded Warrants will be exercisable immediately and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. This offering also relates to the Pre-Funded Warrant Shares issuable upon exercise of any Pre-Funded Warrants sold in this offering. For each Pre-Funded Warrant we sell, the number of Shares we are offering will be decreased on a one-for-one basis. For additional information, see "*Description of Share Capital — Pre-Funded Warrants to be Issued as Part of this Offering*" on page of 131 this prospectus.
Warrants offered by us	Warrants to purchase an aggregate of 4,878,048 Warrant Shares. Each Warrant will have an assumed exercise price of US$1.23 per share, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The Shares, Warrants and Pre-Funded Warrants will be issued separately and will be immediately separable upon issuance. This prospectus also relates to the offering of the Warrant Shares issuable upon exercise of the Warrants. For additional information, see "*Description of Share Capital — Warrants to be Issued as Part of this Offering*" on page 133 of this prospectus
Over-allotment option	We have granted the underwriter a 45-day option to purchase up to 731,707 additional Shares and/or Warrants at the public offering price, less underwriting discounts and commissions on the same terms as set forth in this prospectus.
Common Share Units	The Shares and accompanying Warrants will be sold in Units, with each Unit consisting of one Share and one Warrant. Each Unit will be sold at a price of US$1.23 per Unit (assuming a public offering price of US$1.23 per Share, representing the closing price of our common shares on the Nasdaq of US$ 1.23 per common share on September 20, 2022). The Units will be separable immediately upon issuance.
Pre-Funded Warrant Units	The Pre-Funded Warrants and accompanying Warrants will be sold in Units, with each Unit consisting of one Pre-Funded Warrant and one Warrant to purchase one Share. The

	assumed purchase price of each Pre-Funded Warrant Unit will equal the price at which a Common Share Unit is being sold to the public in this offering, minus US$0.0001. The Pre-Funded Warrant Units will be separable immediately upon issuance. For each Pre-Funded Warrant Unit we sell, the number of Common Share Units we are offering will be decreased on a one-for-one basis.
Common shares to be outstanding after this offering	17,867,735 shares (18,599,442 shares if the over-allotment option is exercised in full and assuming none of the Warrants issued in this offering are exercised and no sale of any Pre-Funded Warrants).
Use of Proceeds	We estimate that the net proceeds to us from the sale of securities in this offering will be approximately US$4.73 million, or US$5.55 million if the underwriter exercises its over-allotment option in full, assuming a public offering price of US$1.23 per share and related Warrants as set forth on the cover page of this prospectus, and assuming no exercise of the Warrants, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds of this offering to fund our ongoing research and development activities, and for working capital and general corporate purposes. See "*Use of Proceeds*".
TSXV and Nasdaq trading symbol	"XRTX"
No Listing of Warrants or Common Share Units	We do not intend to apply for listing of the Warrants, Pre-Funded Warrants or Units on any national securities exchange or trading system.
Risk factors	See "*Risk Factors*" beginning on page 13 and the other information included in this prospectus for a discussion of factors you should consider carefully before investing in our common shares.

The number of common shares to be outstanding after this offering is based on 12,989,687 common shares outstanding as of September 20, 2022 and excludes:

- 1,128,389 common shares issuable upon the exercise of outstanding options to issue common shares, as of June 30, 2022, at a weighted-average exercise price of $2.51 per share;
- 5,127,076 common shares issuable upon the exercise of outstanding common share purchase warrants, as of June 30, 2022, at a weighted-average exercise price of $5.64 per share; and
- 202,720 common shares issuable upon the exercise of outstanding common share purchase finders' warrants, as of June 30, 2022, at a weighted-average exercise price of $5.74 per share.

Unless otherwise indicated, all information in this prospectus reflects or assumes: (i) no exercise of the Warrants or warrants issued to the underwriter; and (ii) no exercise by the underwriter of its option to purchase up to an additional 731,707 Shares and/or Pre-Funded Warrants in this offering.

Summary Historical Consolidated Financial Data

The following tables summarize our historical consolidated financial data for the periods presented and should be read together with "*Management's Discussion and Analysis of Financial Condition and Results of Operations*", and our consolidated financial statements and related notes appearing elsewhere in this prospectus. The summary historical consolidated statements of operations data for the years ended December 31, 2021 and 2020 have been derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("**IFRS**") and are presented in Canadian dollars except where otherwise indicated. Our historical results are not necessarily indicative of the results we expect in the future.

	Year Ended	
	December 31, 2021	December 31, 2020
	$	$
Expenses		
Amortization	17,882	20,439
Consulting	724,272	102,880
Directors' fees	62,200	—
General and administrative	176,099	9,516
Investor relations	518,615	241,177
Listing fees	236,801	52,138
Professional fees	272,943	162,580
Research and development	853,124	277,455
Share-based payments	499,158	293,443
Travel	2,339	8,460
Wages and benefits	286,090	227,905
Loss before other items	(3,649,523)	(1,395,993)
Accretion	—	(846)
Transaction costs on derivative warrant liability	(1,623,680)	—
Fair value adjustment on derivative warrant liability	3,299,768	—
Foreign exchange gain (loss)	326,751	2,961
Impairment of intangible assets	—	(64,562)
Interest and other expenses	(5,598)	(12,666)
Forgiveness of debt	—	91,014
Recovery of provision for patent acquisition	—	95,490
Net loss and comprehensive loss for the year	(1,652,282)	(1,284,602)
Basic and diluted loss per common share	(0.17)	(0.19)
Weighted average number of common shares outstanding		
Basic and diluted	9,847,641	6,664,025

RISK FACTORS

*Investing in our securities is speculative and involves a high degree of risk. You should consider carefully the following risk factors, as well as the other information in this prospectus, including our consolidated financial statements and notes thereto, before you decide to purchase our securities. If any of the following risks actually occur, our business, financial conditions, results of operations and prospects could be materially adversely affected, the value of our securities could decline and you may lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "*Cautionary Note Regarding Forward-Looking Statements*"*

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 2021 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 beyond this contemplated offering 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 this 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, including purchasers of securities in this offering, 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, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. 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.

The conflict between Russia and Ukraine could destabilize global markets and threaten global peace.

On February 24, 2022, Russian military forces launched a full-scale military invasion of Ukraine. In response, Ukrainian military personal and civilians are actively resisting the invasion. Many countries throughout the world have provided aid to Ukraine in the form of financial aid and in some cases military equipment and weapons to assist in their resistance to the Russian invasion. The North Atlantic Treaty Organization ("**NATO**") has also mobilized forces to NATO member countries that are close to the conflict as deterrence to further Russian aggression in the region. The outcome of the conflict is uncertain and is likely to have wide ranging consequences on the peace and stability of the region and the world economy. Certain countries including Canada and the United States, have imposed strict financial and trade sanctions against Russia and such sanctions may have far reaching effects on the global economy. The long-term impacts of the conflict and the sanctions imposed on Russia remain uncertain.

Negative macroeconomic and geopolitical trends could affect the Company's ability to access sources of capital.

The COVID-19 pandemic and the Russian invasion of Ukraine could negatively impact the Company's ability to obtain financing and access sources of capital. Both events have led to significant market volatility as governments undertake measures to prevent the spread of COVID-19 and discourage political conflict. These events have contributed to significant uncertainty in global markets, record inflation, and could lead to a tightening of credit markets and a decline in economic activity. These impacts could have a material adverse effect on the Company's liquidity and ability to obtain financing in the future. As the Company has a history of losses and present revenues do not allow it to sustain its operations, an inability to access credit or capital markets could undermine the Company's ability to continue as a going concern.

Inflation may increase our costs and alter our capital requirements.

Recently, inflation has increased to historic levels across the U.S. and global economy, driving up the costs of goods and services. Inflation can adversely affect us by increasing the costs of our materials, clinical trials and research, the development of our product candidates, administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

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 current good manufacturing practice ("**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 contract research organizations ("**CROs**"), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delay or failure to obtain institutional review board ("**IRB**") approval to conduct a clinical trial at each prospective clinical trial site;
- slower than expected trial subject rates of patient recruitment and enrollment, or other failures to recruit and enroll subjects, which could be particularly challenging for our trials relating to AKI associated with COVID-19;
- 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. Enrollment could be particularly challenging for clinical trials relating to AKI associated with COVID-19. 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 product candidates 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 Risk Evaluation and Mitigation Strategy ("**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, including the United States, 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 expediated 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 (a "**CRL**"). Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Additionally, regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

The Hatch-Waxman Amendments added section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act (the "**FDCA**"), as well as several other provisions. Section 505(b)(2) of the FDCA permits the filing of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for the purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA may also require the applicant to perform additional clinical trials or measurements to support any deviation from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The FDA may require an applicant's product label to have all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require the label to have additional limitations, contraindications, warnings or precautions. We plan to use the Section 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 Section 505(b)(2) application will not be approved until any non-patent exclusivity listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. An inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially

adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and other actors have objected to the FDA's interpretation of Section 505(b)(2) of the FDCA to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit in the future. Moreover, the FDA has adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if it does not rely on the previously-approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's interpretation, the approval of one or more of our product candidates may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with our product candidates, even if our Section 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 good clinical practice ("**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 associated 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 Section 505(b)(2) NDA pathway, the Hatch-Waxman Amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to abbreviated new drug applications ("**ANDAs**"). An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug and must demonstrate to the FDA that the generic drug product is identical to the reference listed drug 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 reference listed drug. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the reference listed drug. 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 Section 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 plan to 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 ("**Orphan Drug Designation**"). We plan to 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 plan to seek Orphan Drug Designation for one or more of our product candidates, but the FDA may not approve any such request. Even if the FDA grants Orphan Drug Designation 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 Drug Designation indication. Even if we were to obtain Orphan Drug Designation 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 Designation 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 Designation 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 Affordable Care Act 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 the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") or state securities laws, and regulatory penalties. We are in the process of implementing security measures to prevent unauthorized access to our valuable trade secrets, patient data, and other confidential information, there is no guarantee that we can continue to protect our systems from breach. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or providers, process claims and appeals, conduct research and development activities, collect, process and prepare company financial information, provide information about any future products, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

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

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

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

We may also be subject to litigation for data security breaches under various state laws. The California Consumer Privacy Act ("**CCPA**"), which has been effective only since January 1, 2020, has already resulted in numerous class action lawsuits for companies suffering data breaches in which they are accused of failing to

use reasonable security measures to protect the personal information of California residents. In addition, if we violate the CCPA and we are not able to cure the violation within thirty (30) days of notice, we may be subject to penalties ranging from US$2,500 for a non-intentional violation to US$7,500 for an intentional violation. Many other states are in the process of adopting similar laws, so we may potentially face litigation and penalties under the laws of other states as well.

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

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

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

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

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

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

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

We are subject to laws and regulations affecting international trade and transactions administered by the U.S. Government and other governments in the jurisdictions in which we conduct business, including

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

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

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

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

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

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

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

The 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 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, 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 prospectus 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 partes, we and our strategic partners will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or product candidates infringe or misappropriate their patent or other intellectual

property rights and/or that we breached our obligations under the license agreement, and we and our strategic partners would need to defend against such proceedings.

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

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

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

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

able to obtain or maintain protection for certain inventions. Therefore, the issuance, validity, enforceability, scope and commercial value of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product candidate and practicing our own patented technology.

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

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

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

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

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

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

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we or our strategic partners own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we obtain marketing approval for product candidates containing such compounds, and because patents have a limited life, which may

begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or vice versa, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications. We have systems in place to remind us to pay these fees, and we rely on our

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

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

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

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

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

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

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

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

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also

known as the America Invents Act, was signed into law. The America Invents Act 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 America Invents Act 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 America Invents Act 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 America Invents Act 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 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 active pharmaceutical ingredient used. We currently have granted U.S. patents with claims to the use of uric acid lowering agents to treat insulin resistance or diabetic nephropathy, and patent applications filed in the U.S., EU and under the Patent Cooperation Treaty with similar claims for the treatment of metabolic syndrome, diabetes, fatty liver disease as well as a composition of matter patent for formulations of xanthine oxidase inhibitors.

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

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

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

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

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

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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- 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.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize product candidates could suffer.

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

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

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

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

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

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

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

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

Risks Related to Additional Legal and Compliance Matters

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

We are exposed to the risk of fraud or other misconduct by our employees or independent contractors. Misconduct by these parties could include intentional 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 Business Conduct and Ethics ("**Code of Conduct**"), but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, monetary damages, fines, disgorgement, imprisonment, loss of eligibility to obtain marketing approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, reputational harm, diminished profits and future earnings, additional reporting requirements if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and the curtailment or restructuring of our operations.

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 Centers for Medicare & Medicaid Services, 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;
- 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 Centers for Medicare & Medicaid Services 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 U.S. Foreign Corrupt Practices Act of 1977, as amended, 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 blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. We do not maintain workers' compensation insurance. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the research and development, clinical and business expertise of Dr. Allen Davidoff, our President and Chief Executive Officer, Mr. 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 Mr. 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 prospectus, 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, contract manufacturing organizations and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, such as the ongoing COVID-19 epidemic, 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.

Risks Related to Our Securities and this Offering

Our share price is likely to be volatile and the market price of our common shares after this offering may drop below the price you pay.

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 public offering price 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 in this offering 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 continue to incur significant costs as a result of operating as a public company in the United States, and our management will continue to 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, in connection with becoming a public company in the United States, we adopted additional internal controls, disclosure controls and procedures and policies specific to complying with the requirements of a public company in the United States. We will bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the applicable securities laws.

In addition, while we are currently listed on the TSXV and Nasdaq 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, 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 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 and the Audit Committee, and our Board 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 also have four months after the end of each fiscal year to file our annual reports with the SEC and are not 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 SEC. We may in the future lose foreign private issuer status if a majority of our common shares are held in the United States and we fail to meet the additional requirements necessary to avoid loss of foreign private issuer status, such as if: (i) a majority of our directors or executive officers are U.S. citizens or residents; (ii) a majority of our assets are located in the United States; or (iii) our business is administered principally in the United States. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer will be significantly more than the costs incurred as a Canadian foreign private issuer. If we are not a foreign private issuer, we would be required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are generally more detailed and extensive than the forms available to a foreign private issuer. In addition, we may lose the ability to rely upon exemptions from corporate governance requirements that are available to foreign private issuers.

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may choose to take advantage of exemptions from various reporting

requirements applicable to other public companies that are not "emerging growth companies," including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002, 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 can remain an "emerging growth company" for up to five fiscal years from the completion of our initial public offering in October 2021, 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 of the Sarbanes-Oxley Act of 2002 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 are required to disclose changes made in our internal controls and procedures on a periodic basis and our management is 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 of the Sarbanes-Oxley Act of 2002. We could be an "emerging growth company" for up to five fiscal years following our initial public offering in October 2021. 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 the Pre-Funded Warrants, Warrants or Units being offered by us in this offering.

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

Holders of Pre-Funded Warrants, Warrants and Units purchased in this offering will have no rights as common shareholders until such holders exercise their Warrants and acquire Warrant Shares.

Until holders of Pre-Funded Warrants and Warrants acquire Shares upon exercise thereof, such holders will have no rights with respect to the Pre-Funded Warrant and Warrant Shares. Upon exercise of

the Pre-Funded Warrants or Warrants, the holders will be entitled to exercise the rights of a common shareholder only as to matters for which the record date occurs after the exercise date.

Our management team will have broad discretion to use the net proceeds from this offering and its investment of these proceeds may not yield a favorable return. They may invest the proceeds of this offering in ways with which investors disagree.

Our management team will have broad discretion in the application of the net proceeds from this offering and could spend or invest the proceeds in ways with which our shareholders disagree. Accordingly, investors will need to rely on our management team's judgment with respect to the use of these proceeds. We intend to use the proceeds from this offering in the manner described under "*Use of Proceeds.*" The failure by management to apply these funds effectively could negatively affect our ability to operate and grow our business.

We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. In addition, the amount, allocation and timing of our actual expenditures will depend upon numerous factors, including milestone payments received from our strategic partnerships and royalties received on sale of our approved product and any future approved product.

Accordingly, we will have broad discretion in using these proceeds. Until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value.

Investors in this offering will pay a much higher price than the book value of our common shares and therefore you will incur immediate and substantial dilution of your investment.

The public offering price will be substantially higher than the net tangible book value per common share based on the total value of our tangible assets less our total liabilities immediately following this offering. Therefore, if you purchase securities in this offering, you will experience immediate and substantial dilution of approximately $0.48 per share, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to this offering at an assumed public offering price of US$1.23 per security. As at September 20, 2022, we have issued 1,128,389 outstanding stock options and 5,329,796 outstanding warrants to purchase common shares. To the extent these outstanding options and warrants are ultimately exercised, you will experience further dilution. See "*Dilution*."

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

Our common shares are listed on the TSXV and Nasdaq. We cannot assure you that an active trading market for our common shares will develop on the TSXV, Nasdaq, 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 your Shares when desired, or the trading prices that you may obtain for your Shares.

Nasdaq or the TSXV 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 or the TSXV. If Nasdaq or the TSXV delists our common shares from trading on their exchanges, 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 British Columbia, Canada which in some cases have a different effect on shareholders than the corporate laws of the United States.

We are governed by the *Business Corporation Act* (British Columbia) (the "**BCBCA**") and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a U.S. jurisdiction, and may, together with our charter documents, have the effect of delaying, deferring or discouraging another party from acquiring control of our company by means of a tender offer, a proxy contest or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the BCBCA and Delaware General Corporation Law (the "**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 66⅔% of shareholders, or as set out in the articles, as applicable, whereas DGCL generally only requires a majority vote; and (ii) under the BCBCA a holder of 5% or more of our common shares can requisition a special meeting of shareholders, whereas such right does not exist under the DGCL. We cannot predict whether investors will find our company and our common shares less attractive because we are governed by foreign laws.

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

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

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.

Furthermore, provisions in our articles will become effective upon receipt of shareholder approval and subsequent filing with corporate registry, and prior to the consummation of this offering provided 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*") for

U.S. federal income tax purposes. Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets (generally, using a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income (including cash), we would be characterized as a PFIC for U.S. federal income tax purposes. The determination of whether we are a PFIC, which must be made annually after the close of each taxable year, depends on the particular facts and circumstances and may also be affected by the application of the PFIC rules, which are subject to differing interpretations. Our status as a PFIC will depend on the composition of our income and the composition and value of our assets (including goodwill and other intangible assets), which will be affected by how, and how quickly, we spend any cash that is raised in this offering or in any other subsequent financing transaction. Moreover, our ability to earn specific types of income that will be treated as non-passive for purposes of the PFIC rules is uncertain with respect to future years. We believe we 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. For more information, see the discussion below under "*Material U.S. Federal Income Tax Considerations to U.S. Holders — Passive Foreign Investment Company Rules*". You 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 Canada Business Corporation Act (the "**CBCA**"), having jurisdiction, and the appellate courts therefrom), will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action or proceeding asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us, (3) any action or proceeding asserting a claim arising pursuant to any provision of the CBCA or our articles or bylaws; or (4) any action or proceeding asserting a claim otherwise related to our "affairs" (as defined in the CBCA). Our forum selection provision also provides that our shareholders are deemed to have consented to personal jurisdiction in the Province of Alberta and to service of process on their counsel in any foreign action initiated in violation of our provision. Therefore, it may not be possible for shareholders to litigate any action relating to the foregoing matters outside of the Province of Alberta. To the fullest extent permitted by law, our forum selection provision will also apply to claims arising under U.S. federal securities laws. In addition, investors cannot waive compliance with U.S. federal securities laws and the rules and regulations thereunder.

Our forum selection provision seeks to reduce litigation costs and increase outcome predictability by requiring derivative actions and other matters relating to our affairs to be litigated in a single forum. While forum selection clauses in corporate charters and bylaws/articles are becoming more commonplace for public companies in the United States and have been upheld by courts in certain states, a recent decision of the Supreme Court of Canada has cast some uncertainty as to whether forum selection clauses would be upheld in Canada. Accordingly, it is possible that the validity of our forum selection provision could be challenged and that a court could rule that such provision is inapplicable or unenforceable. If a court were to find our forum selection provision inapplicable to, or unenforceable in respect of, one or more of the specified types

of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions and we may not obtain the benefits of limiting jurisdiction to the courts selected.

Future sales and issuances of our common shares or rights to purchase common shares, including pursuant to our Stock Option 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, including securities sold in this offering.

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 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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*" in this prospectus. Furthermore, unless otherwise stated, the forward-looking statements contained in this prospectus 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.

PRESENTATION OF FINANCIAL INFORMATION

We prepare and report our consolidated financial statements in accordance with IFRS. We maintain our books and records in Canadian dollars.

We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that precede them.

EXCHANGE RATE DATA

We express all amounts in this prospectus in Canadian dollars, except where otherwise indicated. References to "$" are to Canadian dollars and references to "US$" are to U.S. dollars. The following table sets forth, for the periods indicated, average rate of exchange for one U.S. dollar, expressed in Canadian dollars, for the years ended December 31, 2021, 2020 and 2019, as supplied by the Bank of Canada:

Year Ended	Average
December 31, 2021	0.7978
December 31, 2020	0.7454
December 31, 2019	0.7536

On September 20, 2022, the Bank of Canada average daily rate of exchange was $1.00 = US$0.7493.

MARKET, INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the market in which we operate, including our market position, market opportunity and market size, is based on information from various third-party sources not prepared at the direction of the Company, such as industry publications, and assumptions that we have made based on such data and other similar sources and on our knowledge of the markets for our products. These data involve a number of assumptions and limitations. We believe that this data is accurate and that its estimates and assumptions are reasonable, but there can be no assurance as to the accuracy or completeness of this data. We have not independently verified any of the data from third-party sources referred to in this prospectus or analyzed or verified the underlying studies or surveys relied upon or referred to by such sources, or ascertained the underlying economic assumptions relied upon or referred to by such sources.

In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled "*Risk Factors*" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately US$4.73 million, based upon a public offering price of US$1.23 per Unit, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and assuming none of the Warrants issued in this offering are exercised. If the underwriter exercises its over-allotment option to purchase additional Shares and/or Pre-Funded Warrants from us in full, we estimate that the net proceeds will be approximately US$5.55 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We are undertaking this offering in order to increase our liquidity and raise capital to further develop and advance our pipeline of product candidates, including the conduct of clinical studies and initiation of a registration trial (Phase 3) for our lead program XRx-008. We intend to use proceeds from the offering in approximately the following proportions: XRx-008: 90%; XRx-101: 5%; XRx-225: 5%. We anticipate 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. With respect to XRx-008, we intend to use proceeds to support regulatory filings necessary to initiate and advance a registration trial in ADPKD patients. With respect to XRx-101, we intend to use proceeds to develop further supporting evidence. With respect to XRx-225, we intend to use the proceeds to conduct animal testing and a proof-of-concept study.

We will give the highest priority to fund the advancement of the XRx-008 program. The rationale for this approach is that we perceive that the probability of a large pharmaceutical company partnership is higher for this XRx-008 program. We expect that additional public capital market raises will be needed to advance the above-mentioned programs.

We currently intend to use the net proceeds from the sale of the securities offered hereby for general corporate purposes, which may include the further research and development, clinical trials, manufacture and commercialization of our product candidates and of our technologies (as set forth above), working capital, capital expenditures and other general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, as well as for capital expenditures.

DIVIDEND POLICY

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

CAPITALIZATION

The following table sets forth our cash as well as capitalization as of June 30, 2022:

- on an actual basis;
- on an as adjusted basis to give effect to the sale of securities offered hereby at the assumed offering price of US$1.23 per security, ($1.58 per security), without deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us; and
- U.S. Dollar amounts have been translated into Canadian Dollars based on the June 30, 2022 daily rate of exchange, which was US$1.00 = $1.2886 or $1.00 = US$0.7760 as reported by the Bank of Canada and have been provided solely for the convenience of the reader.

You should read this table together with "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" included elsewhere in this prospectus, and our financial statements and related notes thereto.

	As of June 30, 2022	
	Actual	Pro forma as adjusted[1]
	(In thousands, except share data)	
Cash	$ 13,420	$ 21,152
Equity		
Share capital	$ 20,009	$ 27,741
Common shares, unlimited authorized shares, without par value; 12,989,687 shares issued and outstanding, actual; 17,867,735 shares issued and outstanding, pro forma as adjusted		
Share-based payments, warrant reserve and other	$ 6,898	$ 6,898
Obligation to Issue Shares	$ 32	$ 32
Deficit	$ (14,695)	$ (14,695)
Total Equity	$ 12,244	$ 19,976
Total Capitalization	$ 12,244	$ 19,976

(1) Pro-forma as adjusted does not give effect to the impact of Warrants or the underwriter's over-allotment option.

Each US$1.00 ($1.2886) increase (decrease) in the assumed combined public offering price of US$1.23 per Unit ($1.58 per security), would increase (decrease) the pro forma amount of cash and cash equivalents, total shareholders' equity and total capitalization by approximately US$4,878,048 ($6,285,852), assuming the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same and without deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of securities we are offering. Each increase (decrease) of 100,000 securities in the number of securities offered by us would increase (decrease) the pro forma amount of cash and cash equivalents, total shareholders' equity and total capitalization by approximately US$123,000 ($158,497), assuming that the assumed public offering price remains the same, and without deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

The number of common shares to be outstanding after this offering is based on an aggregate of 12,989,687 shares outstanding as of June 30, 2022. The table above excludes:

- 1,128,389 common shares issuable upon the exercise of outstanding options to issue common shares, as of June 30, 2022, at a weighted-average exercise price of $2.51 per share; and
- 5,127,076 common shares issuable upon the exercise of outstanding common share purchase warrants, as of June 30, 2022, at a weighted-average exercise price of $5.64 per share.

- 202,720 common shares issuable upon the exercise of outstanding common share purchase finders' warrants, as of June 30, 2022, at a weighted-average exercise price of $5.74 per share.

For additional information regarding our capital structure, see "*Description of Share Capital.*"

DILUTION

Investors purchasing Units in this offering will experience immediate and substantial dilution in the as adjusted net tangible book value of their Shares. Dilution in as adjusted net tangible book value represents the difference between the assumed public offering price per Unit and the as adjusted net tangible book value per Share immediately after the offering.

The historical net tangible book value of our common shares as of June 30, 2022 was $11,985,438 or $0.92 per share. Historical net tangible book value per common share represents our total tangible assets (total assets less intangible assets) less total liabilities divided by the number of common shares outstanding as of that date.

After giving effect to the sale of 4,878,048 Units in this offering (excluding the Warrant Shares issuable upon the exercise of the Warrants being offered in this offering) at the offering price of US$1.23 per Unit ($1.58 per Unit) (without deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of June 30, 2022 would have been $19,717,038, or $1.10 per share. The assumed offering price may not be the final price of the Offering and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing. This amount represents an immediate increase in net tangible book value of $0.18 per share to our existing shareholders and an immediate dilution in net tangible book value of approximately $0.48 per share to new investors purchasing our Shares in this offering. We determine dilution by subtracting the net tangible book value per share after the offering from the amount of cash that a new investor paid for a Unit. U.S. dollar amounts have been translated into Canadian dollars at a rate of US$1.00 to $1.2886, and have been provided solely for the convenience of the reader.

The following table illustrates this dilution on a per share basis:

Assumed offering price per Unit[(1)]	$1.58
Historical net tangible book value per share as of June 30, 2022	$0.92
Increase in net tangible book value per share attributable to Investors	$0.18
Net tangible book value per share after the offering	$1.10
Dilution per share to new investors	$0.48

(1) The assumed offering price may not be the final price of the offering and will be adjusted based on the actual public offering price and other terms of our initial public offering determined at pricing.

If the underwriters exercise their option to purchase 731,707 additional Shares and/or Warrants, the as adjusted net tangible book value of our common shares after this offering would be $20,876,777 or $1.12 per share representing an immediate increase in net tangible book value of approximately $0.20 per share to existing shareholders and an immediate dilution of $0.46 per share to the investors in this offering, without deducting the underwriting discount and estimated offering expenses payable by us.

The number of common shares to be outstanding after this offering is based on an aggregate of 12,989,687 common shares outstanding as of June 30, 2022 and excludes:

- 1,128,389 common shares issuable upon the exercise of outstanding options to issue common shares, as of June 30, 2022, at a weighted-average exercise price of $2.51 per share;
- 5,127,076 common shares issuable upon the exercise of outstanding common share purchase warrants, as of June 30, 2022, at a weighted-average exercise price of $5.64 per share; and
- 202,720 common shares issuable upon the exercise of outstanding common share purchase finders' warrants, as of June 30, 2022, at a weighted-average exercise price of $5.74 per share.

To the extent that outstanding options or warrants are exercised, you may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our shareholders.

FINANCIAL STATEMENTS AND MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussions of our financial condition and results of operations, incorporated by reference to our Annual Report on Form 20-F filed with the SEC on May 3, 2022 and Exhibit 99.2 to our Form 6-K filed August 11, 2022, contain important information about XORTX's business and its performance for the years ended December 31, 2021 and 2020 and the three and six months ended June 30, 2022, respectively, and should be read together with our consolidated financial statements for the years ended December 31, 2021 and 2020 and the three and six months ended June 30, 2022, prepared in accordance with IFRS, and the related notes, incorporated by reference to our Annual Report on Form 20-F filed with the SEC on May 3, 2022 and Exhibit 99.1 to our Form 6-K filed August 11, 2022 and the other financial information included or incorporated by reference in this prospectus. Our actual results, performance and achievements could differ materially from those anticipated in these forward looking statements as a result of various factors, including those discussed below and elsewhere in this prospectus, particularly under "*Risk Factors*" and "*Cautionary Note Regarding Forward-Looking Statements*."

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 renal indications such as ADPKD, AKI associated with 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 AKI associated with COVID-19 infection, and to treat patients with type 2 diabetic nephropathy. We are also looking to identify other opportunities where our existing and new intellectual property can be leveraged to address health issues. We believe that our innovative technology is underpinned by well-established research and insights into the underlying biology of oxypurinol, a powerful uric acid lowering agent that is designed to effectively inhibit xanthine oxidase.

While oxypurinol has not received final FDA marketing approval, we plan to leverage existing published studies and the prior FDA review and approval of Zyloprim (allopurinol) under the Section 505(b)(2) development pathway. Oxypurinol is an active metabolite of allopurinol. We believe 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 lead product candidate is XRx-008, a novel product candidate program for the treatment of ADPKD. We are also developing 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, 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.

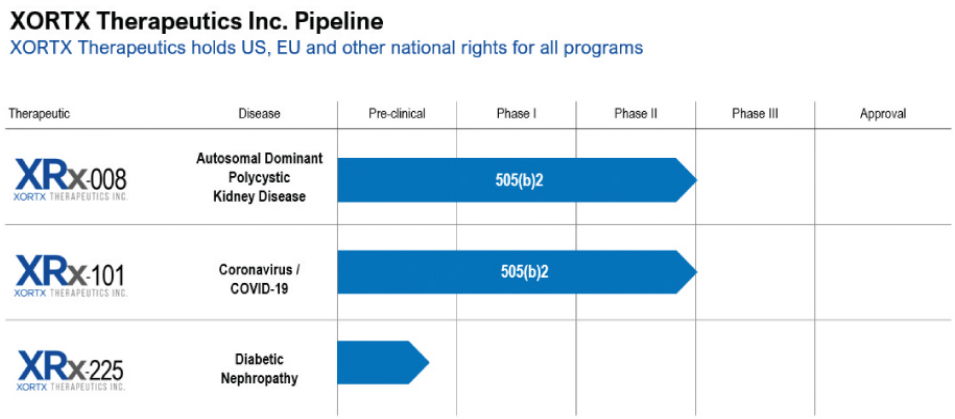
Our team's expertise in uric acid lowering agents, specifically in the development and use of xanthine oxidase inhibitors, has enabled the development of our therapeutic pipeline to treat the symptoms of, and potentially delay the progression of, ADPKD, AKI associated with COVID-19 infection, and T2DN. 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 candidate is XRx-008. We are also developing XRx-101 and XRx-225. We intend to pursue FDA approval for each based upon existing published studies and the prior FDA review and approval of Zyloprim (allopurinol) utilizing the development pathway established in Section 505(b)(2) of the FDCA. XORTX intends to use allopurinol as a reference drug under the Section 505(b)2 development path. However, there is no guarantee that the FDA will ultimately allow the use of the Section 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. In April 2022, XORTX submitted an IND to the FDA to advance the XRx-008 program in preparation for discussions with FDA regarding the design of the Phase 3 study and to conduct a clinical bridging pharmacokinetics study. In May 2022, XORTX received a Study May Proceed letter from FDA allowing us to begin the bridging study. We plan to leverage the results of the bridging study being conducted under the XRx-008 IND to support the XRx-101 development program. In response to our pre-IND submission for our XRx-101 program, FDA provided written guidance regarding next steps in the development program. Subject to further discussions with FDA and results of the bridging study, we plan to conduct a Phase 3 clinical trial for the treatment of AKI in hospitalized individuals infected with COVID-19 to support approval under the 505(b)(2) pathway. On August 4, 2022, XORTX announced that the pre-Phase 3 meeting request made to the FDA resulted in the grant of a virtual meeting

which was held on September 16, 2022. On August 22, 2022, XORTX announced positive topline results from its Pharmacokinetics Bridging Study — XRX-OXY-101 — Part 2 showing a substantial increase in oral bioavailability of XORTX's proprietary oxypurinol formulation provided with food compared to the fasted state. In addition, accompanying the improved bioavailability findings in Part 2 was a clean safety and pharmacologic profile with no drug related adverse or serious adverse events related to oral administration of oxypurinol. The XRx-225 product candidate program is at the non-clinical stage.

XORTX Pipeline:



The interpretation by XORTX based upon FDA discussions is that the Section 505(b)(2) pathway may 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 be required to do so to gain marketing approval in the aforementioned programs.

Our Strategy

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

1. Subject to discussions with FDA, submit an NDA to the FDA following the successful completion of the Phase 3 clinical registration trial of the XRx-008 product candidate program in order to establish a new standard of care for ADPKD.
2. Maximize the potential of the XRx-008 product candidate program, if approved, through independent commercialization and through opportunistic collaborations with third parties.
3. Leverage our pipeline-in-a-product strategy, developing additional proprietary formulations leveraging our experience selecting renal indications and complementing our developments through acquisitions or in-licensing opportunities in nephrology and diabetes when opportunities arise.

Background

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

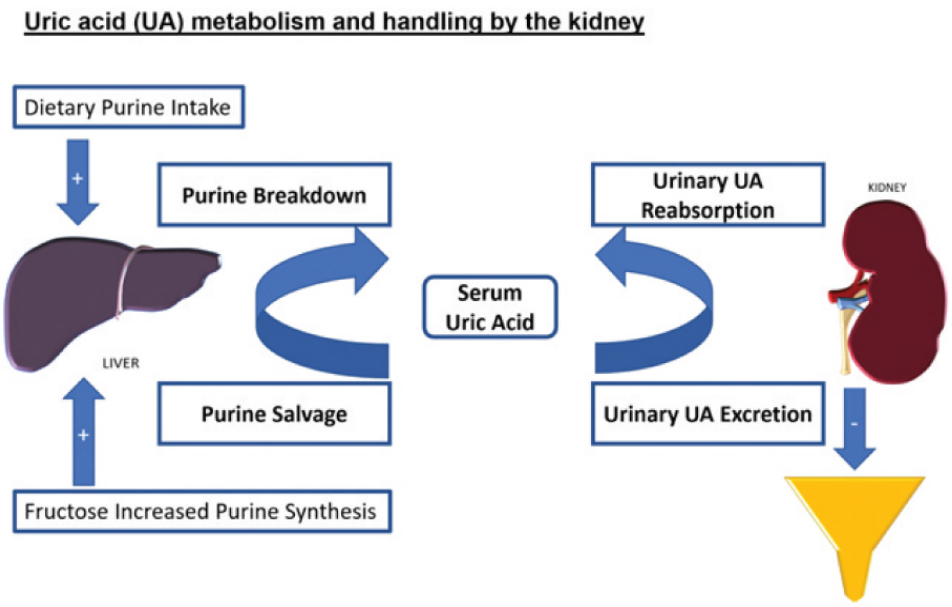


Figure 1: Dietary sources of purines such as yeast, shellfish, organ meats can lead to chronically increased nucleic acids and purines in the circulation. Both are broken down by the liver into uric acid for excretion. Fructose stimulates the liver to produce endogenous purines and can lead to increased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

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

ADPKD is caused by mutations from the PKD1 or PKD2 genes, which encode for proteins called polycystin-1 and polycystin-2, respectively. In ADPKD, fluid-filled cysts develop and enlarge in both kidneys, eventually leading to kidney failure. The average size of a typical kidney is a human fist, but polycystic kidneys can get much larger, some growing as large as a football, and can weigh up to 30 pounds each. The onset of ADPKD is often diagnosed at ages between 30 to 50 years. Common symptoms of ADPKD include increased SUA, hypertension, endothelial dysfunction, increased protein in the urine and decreased filtering capacity. ADPKD is a painful disease that impacts quality of life, and more than 50 percent of people with ADPKD will develop kidney failure by age 50. Once a person has end stage renal disease, 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 end stage renal disease.

ADPKD represents approximately 90% of polycystic kidney disease cases and is amongst the most rapidly progressing form of polycystic kidney disease, and is the most significant genetic cause of kidney failure. In 2014, close to 32,000 patients on long-term renal therapy were attributable to ADPKD, making it the fourth leading cause of new kidney disease cases behind diabetes, hypertension, and glomerulonephritis in the U.S. There are an estimated 150,000 diagnosed cases of ADPKD in the U.S., 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 end stage renal disease, 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, lixivaptan, and GLPG2737.

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

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 being developed for the treatment of 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 end stage renal disease.

Current treatment of diseases

Currently, the only FDA approved ADPKD-targeted therapy is tolyaptan, which is marketed as Jynarque by Otsuka Pharmaceuticals. One of the current established treatments for gout is allopurinol, which is a xanthine oxidase inhibitor used for decreasing production of SUA. Oxypurinol was 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 patients 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, the current cardiovascular and renal portfolio of Otsuka Pharmaceuticals Co., Ltd. includes Entresto, Jynarque, and Samsca. While XRx-008 has not been clinically evaluated in combination with other product candidates, we believe 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. We plan to rely on the prior research conducted and published in peer-reviewed journals and the prior FDA review and approval of Zyloprim (allopurinol), as well as study results sponsored by XORTX. 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 clinical bridging pharmacokinetics study, and planned registration phase 3 clinical trial. 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 initiated 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 planned 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 XRX-OXY-101 study is currently enrolling subjects in four parts. Part 1 of the study has completed enrollment, dosing and pharmacokinetic testing and topline results have been positive. Part 2 of the study has completed enrollment of subjects and reported topline results in August, 2022. Part 3 is anticipated to enroll patients in October, 2022. Subject to further discussions with FDA and the results of the bridging study, 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. 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 worsened clinical outcome. Studies have shown a strong association between elevated interleukin-6 and creatinine reactive protein 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 the Journal of the American Medical Association, titled *Assessment of Acute Kidney Injury and Longitudinal Kidney Function After Hospital Discharge Among Patients With and Without COVID-19* (the Journal of the American Medical Association Network 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

Only one drug, Remdesvir, has been approved by the FDA for the treatment of COVID-19. Additional drugs, 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, 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 AKI associated with COVID-19 infection.

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 intensive care units. 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-19 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 FDA marketing approval, as the XRx-101 product candidate includes oxypurinol, we plan to rely on the prior research conducted and published in peer-reviewed journals and the prior FDA review and approval of Zyloprim (allopurinol), as well as 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 plan to leverage the results of the ongoing pharmacokinetics bridging study being conducted under the XRx-008 IND to support the XRx-101 development program as XRx-101, like XRx-008, includes oxypurinol. Subject to discussions with FDA and the results of the bridging study, we plan to conduct a Phase 3 trial of XRx-101. FDA input will be required to determine the design of the Phase 3 trial and whether additional clinical trials will be required prior to initiation of the Phase 3 trial.

We submitted a request for a pre-IND meeting in August 2020. Our submission to the FDA summarized currently available data supporting the XRx-101 program. On October 8, 2020, we announced that we received a written response (in lieu of a meeting) from the FDA. The response provided guidance regarding next steps in the development path forward for XRx-101. Subject to further discussions with FDA and the results of the ongoing bridging study, we plan to conduct a Phase 3 clinical trial designed to show that XRx-101 can 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 (Diabetes Care; Vol. 27, No. 5, May 2004), studied and estimated the number of individuals with diabetes in the year 2000 and 2030. The total number of adults 20 years of age or older with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030. The number of individuals with diabetes who develop diabetic kidney disease is established to be between 30 and 40%. More recently, studies have predicted that “the global diabetes prevalence in 2019 is estimated to be 9.3% (463 million people) rising to 10.2% (578 million) by 2030 and 10.9% (700 million) by 2045”. Interpreted together these reports suggest an oncoming crisis of chronic kidney disease associated with rising numbers of individuals with diabetes.

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

Over many years, diabetes in some individuals slowly damages the kidneys’ filtering system, and can progress to kidney failure. End stage renal disease, 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

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

Anticipated clinical development of XRx-225

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

Strategic Partnerships and Collaborations

On April 30, 2020, we announced the appointment of LONZA Group ("**LONZA**") as manufacturer of cGMP oxypurinol for the XRx-008 and XRx-101 programs. LONZA is a leading global provider of integrated healthcare solutions. As of the date of this prospectus, LONZA's manufacturing work on behalf of XORTX has been completed.

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 prospectus, 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, application. XORTX-owned Patent Family Member No. 3 includes a pending Patent Cooperation Treaty 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 prospectus, 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 associated with 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 nor 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:

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

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.

Pursuant to an amended and restated license agreement (the '**UFRF License Agreement**") dated June 23, 2014, between the Company and the University of Florida Research Foundation, Inc. ("**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:

- an annual license fee of US$1,000 (2021 fees — paid);
- reimburse UFRF for United States and/or foreign costs associated with the maintenance of the licensed patents;
- the issuance or agreement to issue to UFRF of 51,423 shares of common stock of the Company;
- 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;

- 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
- 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 30, 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 chemistry manufacturing and control 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, European Medicines Agency ("**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 associated with COVID-19 infection. Remdesvir has been approved by the FDA for treatment of COVID-19. The FDA recently approved baricitinib for the treatment of certain hospitalized patients with COVID-19.

Additional drugs 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, 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. Therapeutic interventions used to treat individual with T2DN include medications intended to achieve 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 safe and effective. No regulatory agency has made any such determination that any of our product candidates are safe and effective to support regulatory approval.

Government Regulation

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

U.S. Small Molecule Drug Product Development Process

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

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

- completion of nonclinical laboratory tests, animal studies and formulation studies conducted according to good laboratory practices 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 good laboratory practices.

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 IRB, at or servicing each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical study subject or his or her legal representative. The IRB must monitor the clinical study until completed.

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

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

- Phase 2. The product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labelling.

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

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

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of certain FDA-regulated products are required to register and disclose certain clinical trial information on a public registry maintained by the U.S. National Institutes of Health, 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 U.S. National Institutes of Health's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both U.S. National Institutes of Health and FDA have signaled the government's willingness to begin enforcing those requirements against non-compliant clinical trial sponsors.

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP 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 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 CRL. The approval process is lengthy and often difficult, and notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA does not satisfy its regulatory criteria for approval and deny approval or may require additional clinical or other data and information. If the agency decides not to approve an NDA, the FDA will issue a CRL, that describes all of the specific deficiencies in the NDA identified by the FDA. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the CRL may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. If, or when, those deficiencies have

been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter to the applicant. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug product with the accompanying approved prescribing information for specific indications. Even if a product receives regulatory approval, the approval may be limited to specific indications and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA also may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS plan in addition to the approved labeling, to help ensure that the benefits of the drug outweigh its risks. A REMS could include communication plans for healthcare professionals, medication guides for patients, and/or elements to assure safe use. Elements to assure safe use 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 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 (the "**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 Section 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 Section 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 Section 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 Section 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 Section 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 Section 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 Section 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 an 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 Section 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, Section 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 USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Pediatric Clinical Trials and Exclusivity

Under the Pediatric Research Equity Act, NDAs or certain types of supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The sponsor must submit an initial Pediatric Study Plan within 60 days of an end-of-phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial Pediatric Study Plan 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 Pediatric Study Plan. A sponsor can submit amendments to an agreed-upon initial Pediatric Study Plan at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may grant full or partial waivers, or deferrals, for submission of pediatric assessment data.

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

Orphan Drug Designation and Orphan Product Exclusivity

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

In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means the FDA may not approve any other application to market the same product for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer with orphan exclusivity is unable to assure

sufficient quantities of the approved orphan designated product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor's approved product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what was previously designated, it may not be entitled to orphan product exclusivity.

Expedited Development and Review Programs

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

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

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

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

Fast track designation, priority review, and breakthrough therapy designation do not change the standards for approval and may not ultimately expedite the development or approval process. Even if a

product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Accelerated Approval

A product candidate may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. Accelerated approval allows the FDA to approve the product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. The FDA may also grant accelerated approval for such a drug when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, and that is reasonably likely to predict an effect on irreversible morbidity or mortality 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 irreversible morbidity or mortality 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 Prescription Drug Marketing Act, 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 Prescription Drug Marketing Act and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Most recently, the Drug Supply Chain Security Act was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The Drug Supply Chain Security Act mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. From time to time, new

legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of prescription drug products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Additional Regulation

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

Anti-Corruption Laws

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the Canadian Corruption of Foreign Public Officials Act and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities, such as the United Kingdom Bribery Act 2010 and the United Kingdom 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 U.S. Foreign Corrupt Practices Act of 1977, as amended, the Canadian Corruption of Foreign Public Officials Act, the United Kingdom Bribery Act 2010 and possibly other Anti-Corruption Laws. In the healthcare sector, anti-corruption risk can also arise in the context of improper interactions with doctors, key opinion leaders, and other healthcare professionals who work for state-affiliated hospitals, research institutions, or other organizations.

Data Privacy and the Protection of Personal Information

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

State laws protecting health and personal information are becoming increasingly stringent. For example, California has implemented the California Confidentiality of Medical Information Act that imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information, and California has recently adopted the CCPA. The CCPA mirrors a number of the key provisions of the GDPR. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating

a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Additionally, a new privacy law, the California Privacy Rights Act was approved by California voters in the election on November 3, 2020. The California Privacy Rights Act will modify the CCPA significantly, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Other states in the U.S. are considering privacy laws similar to CCPA, with Virginia enacting its own such law in early 2021.

Government Regulation Outside of the United States

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

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application 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 clinical trial application 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 EU member states resulting from the national implementation of underlying EU 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 EU, the sponsor must obtain approval of a marketing authorization application. The way in which a medicinal product can be approved in the EU 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 EU, 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 EU, 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 Committee for Medicinal Products for Human Use ("**CHMP**"), with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: the seriousness of the disease to be treated; the absence of an appropriate alternative therapeutic approach, and anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

The mutual recognition procedure for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the EU. Basically, the mutual recognition procedure may be applied for all human drugs for which the centralized procedure is not obligatory. The mutual recognition procedure 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 mutual recognition procedure, 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 EU 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 EU, 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 EU-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 EU Commission approved Standard Contractual Clauses). On July 16, 2020, the Court of Justice of the European Union, 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 Court of Justice of the European Union 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 EU 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 an EU presence or "establishment" (e.g., EU based subsidiary or operations), when conducting clinical trials with EU based data subjects, whether the trials are conducted directly by us or through a vendor or partner, or offering approved products or services to EU-based data subjects, regardless of whether involving an EU based subsidiary or operations.

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

Some third-party payors also require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these

requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

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

Healthcare Reform and Potential Changes to Healthcare Laws

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our future products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Moreover, among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

By way of example, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, was enacted in March 2010 and has had a significant impact on the healthcare industry in the U.S. The Affordable Care Act expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to biopharmaceutical products, the Affordable Care Act, 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 Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or 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 average sales price to the Department of Health and Human Services ("**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 Affordable Care Act and we expect there will be additional challenges and amendments to the Affordable Care Act 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 Affordable Care Act. For example, the TCJA was enacted in 2017 and, among other things, removed penalties, starting January 1, 2019, for not complying with the Affordable Care Act'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 Affordable Care Act, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the Affordable Care Act 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 Affordable Care Act but not specifically related to the individual mandate or health insurance could be severed from the rest of the Affordable Care Act 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 Affordable Care Act or any of its provisions. Complying with any new legislation or reversing changes implemented under the Affordable Care Act 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 Affordable Care Act 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, 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 Coronavirus Aid, Relief, and Economic Security 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 Affordable Care Act, 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 pharmaceutical benefit managers 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 21st Century Cures Act was signed into law. The 21st Century 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 21st Century 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 Affordable Care Act, 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 Affordable Care Act, among other things, imposes reporting requirements on manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report, on an annual basis, to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors and, beginning in 2022 for payments and other transfers of value provided in the previous year, certain advanced non-physician healthcare practitioners), teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("**HITECH**"), and their respective implementing regulations impose specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, which include certain healthcare providers, health plans, and healthcare clearinghouses, that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions;
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers;
- State laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act, as well as state and local laws that require the registration of pharmaceutical sales representatives; and
- State laws and foreign laws and regulations (particularly EU 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.

Facilities

We do not lease or own any real property.

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.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any material legal proceedings.

Corporate Structure

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 a reverse take-over transaction on January 10, 2018 with APAC Resources Inc., a company incorporated under the laws of British Columbia, we changed our name to "XORTX Therapeutics Inc." and XORTX Pharma Corp. became a wholly-owned subsidiary.

Our registered office is located at 3710 – 33rd Street NW, Calgary, Alberta, Canada T2L 2M1 and our telephone number is (403) 455-7727. Our website address is www.xortx.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

MANAGEMENT

Executive Officers and Directors

The following table provides information with respect to our directors and executive officers as of the date of this prospectus. The address for our directors and executive officers is c/o XORTX Therapeutics Inc., 3710 — 33rd Street NW, Calgary, Alberta, Canada T2L 2M1.

Name	Residence	Age	Position(s)
Executive Officers			
Allen Warren Davidoff	Alberta, Canada	61	President, Chief Executive Officer and Director
Amar Keshri	Alberta, Canada	43	Chief Financial Officer
Stephen Haworth	Pennsylvania, United States	71	Chief Medical Officer
Directors			
William Farley	New York, United States	67	Director
Anthony Giovinazzo	Ontario, Canada	66	Director
Ian Klassen(1)	British Columbia, Canada	56	Director
Jacqueline Le Saux(1)	Ontario, Canada	69	Director
Raymond Pratt	Maryland, United States	71	Director
Paul Van Damme(1)	Ontario, Canada	72	Director

(1) Member of the Audit Committee

Executive Officers

Allen Warren 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.

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.

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.

Board of Directors

Allen Warren Davidoff, PhD

See Dr. Davidoff's details in the Executive Officers section above.

William Farley, BSc

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

Anthony Giovinazzo, MBA, C.Dir. and A.C.C.

Anthony Giovinazzo was appointed as a director of the Company on June 6, 2022. Mr. Giovinazzo has 43 years' experience, is an internationally recognized expert in intellectual property, drug development and commercialization, including numerous licensing agreements, with more than 25 years' experience in Central Nervous System diseases. He was most recently, the co-inventor, Chief Executive Officer and Director of Cynapsus Therapeutics, a NASDAQ listed specialty pharmaceutical company that developed the first successful sublingual apomorphine thin film strip for Parkinson's disease. Mr. Giovinazzo was a co-inventor of the drug, built the leadership team, set the strategy, raised US $136 million including an over-subscribed IPO and NASDAQ listing and led the negotiations with several pharmaceutical companies that resulted in the CAD $841 million all cash acquisition by Sunovion Pharmaceuticals (Dainippon Sumitomo Pharmaceuticals), a 120% premium to market close on the day of announcement. He is the current Executive Chair of Kalgene Inc., a Canadian/American private specialty pharmaceutical company focused on Alzheimer's disease. He is also a director of Titan Medical Inc., a developer of the Enos System, a robotics assisted single port surgery system. Mr. Giovinazzo is the co-author of several peer reviewed papers and author of several papers on strategic and financing issues in the biopharmaceutical industry. In 2014, he was a Canadian finalist in Life Sciences for the E&Y Entrepreneur of the Year and in 2017, he was the recipient of the Finance Monthly Game Changers award as well as having been chosen as the inaugural recipient of the Bloom Burton Award, which honors a single winner from several candidates, as the best of the best in Canadian Life Sciences as judged by a panel of US experts. He is a Chartered Director and Audit Committee Certified, both from The Directors College, a degree granting affiliate of McMaster University, Hamilton, Ontario. He also completed the Leadership and Strategy in Pharmaceuticals and Biotech from Harvard Business School, Boston, Massachusetts in 2006, a Master of Business Administration from IMD, Geneva, Switzerland in 1986, a Graduate Certificate Studies in Canadian Law from Osgoode Hall Law School, York University, Toronto, Ontario in 1984, and a Bachelor of Arts in Economics and Accounting from McMaster University in 1978.

Ian Klassen, B.A.

Ian Klassen has served as a director of the Company since August 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 has served as a director of the company since June 2021. Ms. Le Saux is a seasoned Canadian health care legal executive who has held senior positions at large and small public and private life science companies. Jacqueline's legal experience is focused on securities, pharmaceutical regulatory and intellectual property law. As a Vice President, Legal in both public and private companies Ms. Le Saux has led multiple financings, mergers and acquisitions and product licensing transactions, mitigating risk and executing strategies in the Canadian healthcare industry. Her broad industry experience spans big pharma to early and late-stage research and development, as well as consumer products and pharmaceutical manufacturing. Prior to entering the health care industry, she was a partner at a top tier Canadian law firm, specializing in securities and corporate law. From 2009 to 2018, Ms. Le Saux served as Vice-President, Legal and Compliance for Purdue Pharma (Canada). In 2019, she worked as counsel to Purdue Pharma (Canada) on certain select issues. Ms. Le Saux holds a BScL from Laurentian University, an MBA from the University of Ottawa, and an LLB from the University of Toronto.

Dr. Raymond Pratt, MD FACP

Dr. Raymond Pratt has been a director of the Company since December 2021. Dr. Pratt is an accomplished Physician Executive with 40 years' experience in both clinical medicine and Nephrology. In his 25 years in the pharmaceutical industry, he has led global clinical trials, clinical pharmacology, drug safety and regulatory affairs in both large and small companies. His leadership has led to the approval of drugs for renal, hematology and central nervous system patients in the US and other global markets. Dr. Pratt is the current Principal, RDP Pharma Consulting since April 2022, the former 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, Research and Development and Scientific Leader and various other senior management positions with Shire Pharmaceutical Development.

Paul Van Damme, B Comm, CPA, MBA

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

Corporate Governance

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 33⅓% of the outstanding shares of the company's common shares. Pursuant to Nasdaq's 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 comply with the rules generally applicable to U.S. domestic companies listed on 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 Nasdaq, may provide less protection than is accorded to investors under listing requirements applicable to U.S. domestic issuers.

The Canadian Securities Administrators has issued corporate governance guidelines pursuant to National Policy 58-201 — Corporate Governance Guidelines (the "**Corporate Governance Guidelines**"), together with certain related disclosure requirements pursuant to National Instrument 58-101 — Disclosure of Corporate Governance Practices ("**NI 58-101**"). The Corporate Governance Guidelines are recommended as "best practices" for issuers to follow. We recognize that good corporate governance plays an important role in our overall success and in enhancing shareholder value and, accordingly, we have adopted certain corporate governance policies and practices which reflect our consideration of the recommended Corporate Governance Guidelines.

The disclosure set out below includes disclosure required by NI 58-101 describing our approach to corporate governance in relation to the Corporate Governance Guidelines.

Board Composition and Election of Directors

Composition and Removal of Directors

Our Board currently consists of seven members. Under our articles and the BCBCA, a director may be removed with or without cause by a resolution passed by a special majority of the votes cast by shareholders present in person or by proxy at a meeting and who are entitled to vote.

Replacement or Removal of Directors

To the extent directors are elected or appointed to fill casual vacancies or vacancies arising from the removal of directors, in both instances whether by shareholders or directors, the directors shall hold office until the remainder of the unexpired portion of the term of the departed director that was replaced.

Under the articles, the number of directors of XORTX will be set at a minimum of three and the directors are authorized to determine the actual number of directors to be elected from time to time.

We have no formal policy regarding Board diversity. Our priority in the selection of our Board members is identifying members who will further the interests of our shareholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among Board members, knowledge of our business and understanding of the competitive landscape.

Director Terms, Term Limits and Other Mechanisms of Board Renewal

Directors are elected on an annual basis. Our Board has not adopted director term limits or other automatic mechanisms of Board renewal.

Independence of the Members of the Board of Directors

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. The policies of the TSXV require that we comply with applicable corporate law in connection with outside directors or unrelated directors and the TSXV encourages its listed issuers to consider the appropriateness of outside directors and unrelated directors on their boards. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in addition to Nasdaq's definition of independence, in the opinion of the listed company's board of directors, that person does not have a material relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Under NI 58-101, a director is considered to be independent if he or she is independent within the meaning of National Instrument 52-110-Audit Committees ("**NI 52-110**"). Pursuant to NI 52-110, an independent director is a director who is free from any direct or indirect relationship which could, in the view of our Board, be reasonably expected to interfere with a director's independent judgment.

Consistent with these considerations, and based on information provided by each director concerning his or her background, employment and affiliations, our Board has affirmatively determined that William Farley, Anthony Giovinazzo, Ian Klassen, Jacqueline Le Saux, Raymond Pratt and Paul Joseph Van Damme, representing six of the seven members of our Board, are "independent" as that term is defined under the listing standards of Nasdaq and NI 58-101. In making this determination, our Board considered the current and prior relationships that each non-employee director has with our Company and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director. Dr. Davidoff is not independent by reason of the fact that he is our Chief Executive Officer.

Mandate of the Board

Our Board holds regularly scheduled quarterly meetings as well as ad hoc meetings from time to time. The independent members of our Board also meet, as required, without the non-independent directors and members of management before or after each regularly scheduled board meeting.

A director who has a material interest in a matter before our Board or any committee on which he or she serves is required to disclose such interest as soon as the director becomes aware of it. In situations where a director has a material interest in a matter to be considered by our Board or any committee on which he or she serves, such director may be required to absent himself or herself from the meeting while discussions and voting with respect to the matter are taking place. Directors are also required to comply with the relevant provisions of our articles and the BCBCA regarding conflicts of interest.

Meetings of Directors

Our Board is responsible for the stewardship of the Company and providing oversight as to the management of our business and affairs, including providing guidance and strategic oversight to management. Our Board has adopted a formal mandate that includes the following:

- appointing our Chief Executive Officer;
- developing the corporate goals and objectives that our Chief Executive Officer is responsible for meeting and reviewing the performance of our Chief Executive Officer against such corporate goals and objectives;
- taking steps to satisfy itself as to the integrity of our Chief Executive Officer and other executive officers and that our Chief Executive Officer and other executive officers create a culture of integrity throughout the organization;
- reviewing and approving our Code of Conduct and reviewing and monitoring compliance with the Code of Conduct and our enterprise risk management processes;
- adopting a strategic planning process to establish objectives and goals for our business and reviewing, approving, and modifying, as appropriate, the strategies proposed by management to achieve such objectives and goals; and
- reviewing and approving material transactions not in the ordinary course of business.

Position Descriptions

Our Board has adopted a written position description for the Chairman of the Board, which sets out the Chairman's key responsibilities, including, among others, duties relating to setting Board meeting agendas, chairing Board and shareholder meetings, director development and ensuring the Board is provided with timely and relevant information to effectively discharge its duties and responsibilities.

Our Board has adopted a written position description for each of our committee chairs which sets out each of the committee chair's key responsibilities, including, among others, duties relating to setting committee meeting agendas, chairing committee meetings and working with the respective committee and management to ensure, to the greatest extent possible, the effective functioning of the committee.

Our Board has adopted a written position description for our Chief Executive Officer which sets out the key responsibilities of our Chief Executive Officer, including, among other duties in relation to providing overall leadership, working with the Board to develop our strategic direction and the annual corporate plan and budget, and managing the day-to-day business and affairs of the Company and carrying out such duties and responsibilities as is customary for a Chief Executive Officer of a company in a similar industry and stage of development.

Director Attendance

Each director has attended all Board meetings that we have held since January 1, 2021.

Orientation and Continuing Education

Historically, members of the Board who have been nominated and elected as directors are familiar with the Company and the nature of its business. The Company has established a thorough directors handbook for the purposes of onboarding new directors, providing for their initial education on the Company's policies and their responsibilities as directors, as well as providing for their ongoing director educational requirements. Additionally, the Company's legal counsel provides correspondence so that directors are up to date with developments in relevant corporate and securities law matters.

Board Committees

Our Board has an Audit Committee, a Compensation Committee and a Corporate Governance and Nominating Committee.

Audit Committee

Our Audit Committee consists of Ian Klassen, Jacqueline Le Saux, and Paul Van Damme. Mr. Van Damme serves as the chair of our Audit Committee and has been identified as an "audit committee financial expert" as that term is defined in the rules and regulations established by the SEC. The members of our Audit Committee are "financially literate" and "independent" within the meaning of Nasdaq and NI 52-110. For additional details regarding the relevant education and experience of each member of our Audit Committee see "*Management — Executive Officers and Directors*." The principal purpose of our Audit Committee is to assist our Board in its oversight of:

- the quality and integrity of our financial statements and related information;
- the independence, qualifications, appointment and performance of our external auditor;
- our disclosure controls and procedures, internal control over financial reporting and management's responsibility for assessing and reporting on the effectiveness of such controls;
- our compliance with applicable legal and regulatory requirements; and
- our enterprise risk management processes.

Our Board has established a written charter that sets forth the purpose, composition, authority and responsibility of our Audit Committee, consistent with the rules of Nasdaq, the SEC and NI 52-110. The Audit Committee Charter is attached as Exhibit 15.2 to our Annual Report on Form 20-F for the year ended December 31, 2021, which is incorporated herein by reference.

Our Audit Committee has access to all of our books, records, facilities and personnel and may request any information about us as it may deem appropriate. It also has the authority in its sole discretion and at our expense, to retain and set the compensation of outside legal, accounting or other advisors as necessary to assist in the performance of its duties and responsibilities.

Both our independent auditors and internal financial personnel regularly meet privately with the Audit Committee and have unrestricted access to this Committee. Smythe LLP was retained as auditor of the Company's predecessor, XORTX Pharma Corp., and continued as auditor of the Company effective January 9, 2018, the date of the reverse take-over between APAC Resources Inc. and XORTX Pharma Corp. to form XORTX Therapeutics Inc. Prior to Smythe LLP being retained, Manning Elliott LLP acted as auditor of the

Company from May 31, 2011 to January 9, 2018. Aggregate fees billed by our independent auditors, Smythe LLP for the year ended December 31, 2021 were approximately $49,000.

	December, 31 2021 ($)	December, 31 2020 ($)	December, 31 2019 ($)	December 31, 2018 ($)
Audit Fees[1]	$ 49,000	$ 18,750	$ 13,500	$ 13,500
Audit-Related Fees[2]	397	—	—	—
Tax Fees[3]	2,500	—	3,000	3,000
All Other Fees[4]	16,000	—	—	950
Total Fees Paid	$ 67,897	$ 18,750	$ 25,500	$ 17,450

(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.

Compensation Committee

The Compensation Committee has the responsibility of assisting our 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 Chief Executive Officer compensation, evaluating the Chief Executive Officer's performance in light of these goals and objectives and, either as a committee or together with other independent directors, determining and approving the Chief Executive Officer's compensation level based on this evaluation;

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

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

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

The Compensation Committee is composed of independent directors, being William Farley, Ian Klassen and Paul Van Damme. The Chair of the Compensation Committee is Ian Klassen. The time and place of the meetings of the Committee and the calling of meetings and the procedure in all things at such meetings shall be determined by the Compensation Committee; provided, however, the Compensation Committee shall meet at least on an annual basis.

*Corporate Governance and Nominating Committee (the "**CGN Committee**")*

The CGN Committee has the responsibility of assisting the Board 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 CGN 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 CGN 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 Chair 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 CGN Committee;

(d) whenever considered appropriate, directing the Chair 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 Board, the allocation of the 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 CGN 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 CGN Committee is composed of independent directors, being William Farley, Jacqueline Le Saux and Paul Van Damme. The Chair of the CGN Committee is Jacqueline Le Saux. The CGN Committee shall meet at least semi-annually at the discretion of the Chair of the CGN Committee or a majority of its members, as circumstances dictate or as may be required by applicable legal or listing requirements.

Code of Business Conduct and Ethics

The Code of Conduct is applicable to all of our directors, officers and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other persons performing similar functions, which is a "code of ethics" as defined in Item 16B of Form 20-F promulgated by the SEC and Section 406(c) of the Sarbanes-Oxley Act of 2002, and which is a "code" under NI 58-101. The Code of Conduct sets out our fundamental values and standards of behavior that are expected from our directors, officers, employees, consultants and contractors with respect to all aspects of our business. The objective of the Code of Conduct is to provide guidelines to promote integrity and deter wrongdoing.

The full text of the Code of Conduct is attached as Exhibit 11.1 to our Annual Report on Form 20-F for the year ended December 31, 2021, which is incorporated herein by reference. and is posted on our website at www.xortx.com. The written Code of Conduct has also been filed with the Canadian securities regulatory authorities on the System for Electronic Document Analysis and Retrieval for Canadian public companies ("**SEDAR**") at www.sedar.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. If we make any amendment to the Code of Conduct or grant any waivers, including any implicit waiver, from a provision of the code of ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC and the Canadian Securities Administrators. Under Item 16B of the SEC's Form 20-F, if a waiver or amendment of the Code of Conduct applies to our principal executive officer, principal financial officer, principal accounting officer or controller and relates to standards promoting any of the values described in Item 16B(b) of Form 20-F, we will disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B.

Monitoring Compliance with the Code of Conduct

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.

EXECUTIVE AND DIRECTOR 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 and our Compensation Committee are responsible for setting our executive compensation and establishing corporate performance objectives. In considering executive compensation, the Board 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 "*Management — Executive Officers and Directors*." 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 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, we formed a Compensation Committee.

Our Board and Compensation Committee 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 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 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.

Risk-Management Implications

Our Board and Compensation Committee exercise discretion in relation to compensation and the allocation of "at-risk" compensation (being cash bonuses and securities-based compensation), to encourage and reward performance that advances the Company's strategic objectives while mitigating the Company's exposure to business and financial risks including those identified in the Company's Annual Information Form and Management's Discussion and Analysis. The nature of the business and the competitive environment in which the Company operates requires some level of risk-taking to achieve growth. The following aspects of the Company's executive compensation program are designed to encourage practices

and activities that should enhance long-term value and sustainable growth and limit incentives that could encourage inappropriate or excessive risk-taking:

- an annual cash bonus target, determined as a percentage of an executive's annual salary, that may be earned in a calendar year;
- staged vesting over a three-year period of Options granted to executives with a maximum of one-third vesting per annum; and

The Compensation Committee regularly considers risks associated with the Company's compensation policies and practices. The Compensation Committee has not identified compensation policies or practices that are reasonably likely to have a material adverse effect on the Company.

Other Compensation

Amounts shown in the "All Other Compensation" column in the Summary Compensation Table relate to contributions to our life insurance premiums through our group extended benefit plan, and extended medical benefits.

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 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 consolidation of our shares on a one (1) post-consolidated share for 11.74 pre-consolidated shares basis which took effect on September 23, 2021. 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 Chief Executive Officer	2021	221,840	25,000	Nil	Nil	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)] Chief Financial Officer	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 Chief Financial Officer	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

	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 ($)	Total Compensation ($)
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 consolidation of our shares on a one (1) post-consolidated share for 11.74 pre-consolidated shares basis which took effect on September 23, 2021.

	Compensation Securities						
Name and Position	Type of Compensation 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] *Chief Executive Officer*	Stock Option	42,859	Mar 19, 2018	$5.87	$5.87	$2.50	Mar 19, 2023
		42,859	Jun 23, 2020	$1.64	$1.64		Jun 23, 2025
		0.7%					
Amar Keshri[3] *Chief Financial Officer*	Stock Option	21,294	Jul 14, 2021	$2.41	$2.41		Jul 14, 2026
		0.2%					
James Fairbairn *Former Chief Financial Officer*	N/A	Nil	N/A	N/A	N/A	N/A	N/A
William Farley[4] *Director*	Stock Option	21,294	May 12, 2021	$1.88	$1.88	$2.50	May 12, 2026
		13,706	Dec 21, 2021	$2.54	$2.54		Dec 21, 2026
		0.3%					

	Compensation Securities						
Name and Position	**Type of Compensation 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**
Ian Klassen[5]	Stock Option	12,776	Aug 27, 2020	$2.82	$2.82	$2.50	Aug 27, 2025
Director		29,812	Jan 11, 2021	$3.29	$3.29		Jan 11, 2026
		7,412	Dec 21, 2021	$2.54	$2.54		Dec 21, 2026
		0.4%					
Jacqueline Le Saux[6]	Stock Option	21,294	Jun 16, 2021	$1.76	$1.76	$2.50	Jun 16, 2026
Director		13,706	Dec 21, 2021	$2.54	$2.54		Dec 21, 2026
		0.3%					
Raymond Pratt[7]	Stock Option	30,000	Dec 21, 2021	$2.54	$2.54	$2.50	Dec 21, 2026
Director		0.2%					
Bruce Rowlands	N/A	Nil	N/A	N/A	N/A	N/A	N/A
Former Director							
Paul Van Damme[8]	Stock Option	12,776	Mar 19, 2018	$2.82	$2.82	$2.50	Mar 19, 2023
Director		25,553	Jun 23, 2020	$1.64	$1.64		Jun 23, 2025
		21,671	Dec 21, 2021	$2.54	$2.54		Dec 21, 2026
		0.5%					
Allan Williams	N/A	Nil	N/A	N/A	N/A	N/A	N/A
Former Director							

Notes:

(1) Adjusted to reflect consolidation of 1:11.74 that occurred September 24, 2021.

(2) In addition to the options outlined in the table as at December 31, 2021, Allen Davidoff holds an aggregate of 200,000 options, including 94,822 options exercisable at $1.60 issued on June 6, 2022 and expiring June 6, 2027.

(3) In addition to the options outlined in the table as at December 31, 2021, Amar Keshri holds an aggregate of 31,294 options, including 10,000 options exercisable at $2.54 issued January 12, 2022 and expiring January 12, 2027.

(4) In addition to the options outlined in the table as at December 31, 2021, William Farley holds an aggregate of 65,000 options, including 30,000 exercisable at $1.60 issued on June 6, 2022 and expiring June 6, 2027.

(5) In addition to the options outlined in the table as at December 31, 2021, Ian Klassen holds an aggregate of 80,000 options, including 30,000 options exercisable at $1.60 issued on June 6, 2022 and expiring June 6, 2027.

(6) In addition to the options outlined in the table as at December 31, 2021, Jacqueline Le Saux holds an aggregate of 65,000 options, including 30,000 options exercisable at $1.60 issued on June 6, 2022 and expiring June 6, 2027.

(7) In addition to the options outlined in the table as at December 31, 2021, Raymond Pratt holds an aggregate of 60,000 options, including 30,000 options exercisable at $1.60 issued on June 6, 2022 and expiring June 6, 2027.

(8) In addition to the options outlined in the table as at December 31, 2021, Paul Van Damme holds an aggregate of 90,000 options, including 30,000 options exercisable at $1.60 issued on June 6, 2022 and expiring June 6, 2027.

Executive Employment Arrangements and Termination and Change in Control Benefits

The Company employs Dr. Allen Davidoff as the Company's President and Chief Executive Officer at an annual salary of US$300,000, pursuant to an Employment Agreement dated January 1, 2018, between the Company and Dr. Allen Davidoff (the "**Davidoff Agreement**"). The Davidoff Agreement contains standard confidentiality and non-compete clauses and has an indefinite term. The Davidoff Agreement can be terminated by Dr. Davidoff or the Company by providing 30 days' notice. In the case of the Company providing termination notice, Dr. Davidoff would receive the equivalent of six times his then current monthly salary in a lump sum payment if terminated prior to the first anniversary and if after the first anniversary, Dr. Davidoff is entitled to a lump sum payment of 12 times his then current monthly salary. In the case of a change of control, the Davidoff Agreement provides for a lump sum payment equal to 12 times his monthly base salary amount in effect at the time. As well, all unvested options then held by Dr. Davidoff shall be deemed to have vested upon any such termination.

The Company employs Amar Keshri as the Company's Chief Financial Officer at an annual salary of $192,000, pursuant to an employment agreement (the "**Keshri Agreement**"). The Keshri Agreement provides for a discretionary bonus up to 30% of the annual salary and contains standard confidentiality and non-compete clauses and has an indefinite term. The Keshri Agreement can be terminated by Mr. Keshri or the Company by providing 30 days' notice. In the case of the Company providing termination notice, Mr. Keshri would receive the equivalent of six times his then current monthly salary in a lump sum payment if terminated prior to the first anniversary and if after the first anniversary, Mr. Keshri is entitled to a lump sum payment of 12 times his then current monthly salary. In the case of a change of control, the Keshri Agreement provides for a lump sum payment equal to 12 times his monthly base salary amount in effect at the time.

The Company entered into a contract with Haworth Biopharmaceutical Consulting Services Inc., dated July 1, 2021 and effective July 1, 2021, as amended by the Consulting Amending Agreement, dated as of January 27, 2022, by and between the Company and Stephen Haworth, for consulting services to the Company to appoint Stephen Haworth as the appointed consultant to act in the capacity as chief medical officer, pursuant to which Haworth Biopharmaceutical Consulting Services Inc. is entitled to compensation for the provision of such services of base fees of US$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 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 agreement with W.B. Rowlands & Co. Ltd. and Rowlands for consulting services to the Company, dated December 20, 2021 (the "**WBR Consulting Agreement**"), pursuant to which, in lieu of any additional cash compensation, Rowland's 51,106 stock options issued under the Company's stock option plan will remain outstanding in accordance with the stock option plan for the term of the WBR Consulting Agreement. Of those stock options, 12,776 are exercisable at $5.87 and 38,330 are exercisable at $1.64. The WBR Consulting Agreement will be in effect for an 18 month period and may only be terminated for cause.

In addition to the arrangements set forth above, the Company entered into a contract with W.B. Rowlands & Co. Ltd. for consulting services to the Company, dated March 1, 2018 (the "**Rowlands Consulting Agreement**"), pursuant to which W.B. Rowlands & Co. Ltd. was 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 shares, 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 was 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.

The table below shows the estimated amounts of the termination payments and benefits that will be made to our named executive officers upon the termination of their employment, if such termination were to occur immediately following the completion of this offering. These amounts represent the payments and benefits under the terms of the employment or consulting agreements.

Name and Principal Position	Event	Severance ($)[1]	Options ($)[2]	Other Payments ($)	Total ($)
Allen Davidoff, Chief Executive Officer	Termination by the Company	389,595		—	—
	Change of Control	389,595		—	—
Amar Keshri, Chief Financial Officer	Termination by the Company	96,000	—	—	—
	Change of Control	192,000	—	—	—

(1) Severance payments are calculated based on the executive's base salary.

(2) All options would immediately vest. The value of accelerated vesting of options above is calculated based on the assumed public offering price of US$ per share.

Share Compensation Plan

The following table sets forth aggregated information as at December 31, 2021 with respect to compensation plans of the Company under which equity securities of the Company are authorized for issuance.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (#)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights ($)	Number of Securities remaining available for Future Issuance under Equity Compensation Plans (#)
Equity compensation plans approved by security holders[1]	606,067	3.29	692,902
Equity compensation plans not approved by security holders	—	—	—
Total	606,067	3.29	692,902

(1) The Plan is a "rolling" stock option plan whereby the maximum number of common shares that may be reserved for issuance pursuant to the Plan will not exceed 10% of the issued shares of the Company at the time of the stock option grant.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation arrangements discussed under "*Management*," the following is a description of the material terms of those transactions with related parties to which we are party and which we are required to disclose pursuant to the disclosure rules of the SEC and the Canadian Securities Administrators.

Employment and Consulting Agreements

We have entered into employment agreements with certain of our executive officers and key employees. For more information regarding these agreements and arrangements, see "*Management*."

Beneficial Ownership

Since January 1, 2019, no director or executive officer of the Company beneficially owns, or controls or directs, directly or indirectly more than 10% of the outstanding common shares and no 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. As of September 20, 2022, Prevail Partners LLC ("**Prevail**"), owns 977,318 common shares, currently representing 7.5% of the 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 future clinical plans and is anticipated to participate in clinical trials to support XRx-008, XRx-101 and XRx-225 programs in the future.

Policy on Future Related Party Transactions

All future transactions between us and our officers, directors, principal shareholders and their affiliates will be approved by the Audit Committee, or a similar committee consisting of entirely independent directors, according to the terms of our Code of Business Conduct and Ethics.

Requirements under the Business Corporations Act (British Columbia)

Pursuant to the BCBCA, directors and officers are required to act honestly and in good faith with a view to the best interests of the company. Under the BCBCA, subject to certain limited exceptions, a director who holds a disclosable interest in a material contract or transaction into which we have entered or propose to enter shall not vote on any directors' resolution to approve the contract or transaction. A director or officer has a disclosable interest in a material contract or transaction if the director or officer:

- is a party to the contract or transaction;
- is a director or officer, or an individual acting in a similar capacity, of a party to the contract or transaction; or
- has a material interest in a party to the contract or transaction.

Generally, as a matter of practice, directors or officers who have disclosed a material interest in any contract or transaction that our Board is considering will not take part in any Board discussion respecting that contract or transaction. If such directors were to participate in the discussions, they would abstain from voting on any matters relating to matters in which they have disclosed a disclosable interest.

Interests of Management and Others in Material Transactions

Other than as described elsewhere in this prospectus, 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. See "*Management's Discussion and Analysis of Financial Condition and Results of Operations*", "*Business*" and "*Certain Relationships and Related Party Transactions*."

PRINCIPAL SHAREHOLDERS

The following table indicates information as of September 20, 2022, regarding the beneficial ownership of our common shares, after giving effect to the sale of Shares offered in this offering 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 September 20, 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 September 20, 2022, we had 16 registered holders of our Shares, with nine record holders in Canada, representing 61.6% of our outstanding Shares, and six record holders in the United States, representing 38% of our outstanding Shares, and one record holder in Japan, representing 0.4% of our outstanding.

Except for Prevail, the address of each of the persons in this table is c/o 3710 — 33rd Street NW, Calgary, Alberta, Canada T2L 2M1.

Name and Address of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% and Greater Shareholders:		
Prevail Partnerships LLC(1)	977,318	7.5%
Directors and Named Executive Officers:		
Davidoff, Allen(2)	533,871	4.1%
Farley, William(3)	65,000	*%
Giovinazzo, Anthony(4)	150,000	1.1%
Haworth, Stephen(5)	12,241	*%
Keshri, Amar(6)	20,741	*%
Klassen, Ian(7)	122,759	*%
Le Saux, Jacqueline(8)	65,000	*%
May, Charlotte(9)	26,467	*%
Pratt, Raymond(10)	60,000	*%
Van Damme, Paul(11)	153,993	1.2%
All executive officers and directors as a group (10 persons)	1,210,072	9.2%

* Indicates beneficial ownership of less than 1%.

(1) Consists of 977,318 Common Shares held by Prevail Partners LLC. The address of Prevail Partnerships LLC is 211 N. 13th Street, 6th Floor, Philadelphia, PA 19107.

(2) Consists of 430,917 Common Shares, warrants exercisable for 8,517 Common Shares, and options exercisable for 94,437 Common Shares within 60 days of September 20, 2022, held personally by Mr. Davidoff.

(3) Consists of options exercisable for 65,000 Common Shares within 60 days of September 20, 2022, held personally by Mr. Farley.

(4) Consists of options exercisable for 12,241 Common Shares within 60 days of September 20, 2022, held personally by Mr. Haworth.

(5) Consists of options exercisable for 150,000 Common Shares within 60 days of September 20, 2022, held personally by Mr. Giovinazzo.

(6) Consists of 8,500 Common Shares and options exercisable for 12,241 Common Shares within 60 days of September 20, 2022, held personally by Mr. Keshri.

(7) Consists of 42,759 Common Shares, and options exercisable for 80,000 Common Shares within 60 days of September 20, 2022, held personally by Mr. Klassen.

(8) Consists of options exercisable for 65,000 Common Shares within 60 days of September 20, 2022, held personally by Ms. Le Saux.

(9) Consists of options exercisable for 26,467 Common Shares within 60 days of September 20, 2022, held personally by Ms. May.

(10) Consists of options exercisable for 60,000 Common Shares within 60 days of September 20, 2022, held personally by Mr. Pratt.

(11) Consists of 63,993 Common Shares and options exercisable for 90,000 Common Shares within 60 days of September 20, 2022, held personally by Mr. Van Damme.

DESCRIPTION OF SHARE CAPITAL

General

The following is a summary of the material rights of our share capital as contained in our notice of articles and articles and any amendments thereto. This summary is not a complete description of the share rights associated with our capital stock. For more detailed information, please see our notice of articles and articles, which are filed as exhibits to the registration statement of which this prospectus forms a part.

Our authorized share capital consists of an unlimited number of common shares, each without par value. We have no preferred shares authorized under our notice of articles or articles. Immediately following the closing of this offering, we expect to have 17,867,735 issued and outstanding common shares (18,599,442 common shares if the underwriter's over-allotment option is exercised in full). Immediately following the closing of this offering, we also expect to have 1,128,389 outstanding vested and unvested options granted pursuant to our equity incentive plans to acquire common shares, 658,384 options available for grant under our equity incentive plans to acquire common shares and 10,207,844 outstanding warrants to acquire common shares.

Common Shares

Outstanding Shares

Our authorized share capital consists of an unlimited number of common shares, each without par value.

As of September 20, 2022, we had 1,128,389 common shares issuable pursuant to exercisable outstanding stock options, 583,095 common shares issuable pursuant to outstanding options that are not currently exercisable, 5,329,796 common shares issuable upon the exercise of outstanding common share warrants, and we had approximately 16 holders of record of our common shares.

Voting Rights

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.

Dividends

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

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common shares are 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.

Rights and Preferences

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

by the rights of the holders of any series of new preferred shares that may be created, authorized, designated, and issued in the future.

Fully Paid and Non-assessable

All of our outstanding common shares are, and the common shares to be issued pursuant to this offering, when paid for, will be fully paid and non-assessable.

Corporate Governance

Under the BCBCA, we are required to hold a general meeting of our shareholders at least once every year at a time and place determined by our Board, provided that the meeting must not be held later than 15 months after the preceding annual general meeting. A notice to convene a meeting, specifying the date, time and location of the meeting must be sent to shareholders, to each director and the auditor not less than 21 days prior to the meeting or such other minimum period as required by the applicable securities laws. Under the BCBCA, shareholders entitled to notice of a meeting may waive or reduce the period of notice for that meeting, provided applicable securities laws requirements are met.

Pursuant to our articles, all business transacted at a special meeting of shareholders, except business relating to the conduct of or voting at the meeting, and all business transacted at an annual meeting of shareholders, (except business relating to the conduct of or voting at the meeting) consideration of the financial statements, consideration of any director or auditor's report, election of directors, setting or changing of the number of directors, appointment of the auditor, remuneration of the auditor, business arising out of a report of the directors not requiring the passage of a special resolution, and any other business which, under the articles or BCBCA, may be transacted at a meeting of shareholders without prior notice of the business being given to the shareholders, is deemed to be special business. Notice of a meeting of shareholders at which special business is to be transacted shall (a) state the general nature of that business; and (b) if the special business includes considering, ratifying, adopting or authorizing any document, or the signing of any document, have attached to it the document or state that such document is available for inspection.

Under our articles, our Board has the power at any time to call a meeting of our shareholders where special business is to be considered.

Those entitled to vote at a meeting are entitled to attend meetings of our shareholders. Every shareholder entitled to vote may appoint one or more (but not to exceed five) proxyholders to attend the meeting in the manner and to the extent authorized and with the authority conferred by the proxy. Directors, auditors, legal counsels, secretaries (if any), and any other persons invited by the directors are entitled to attend any meeting of our shareholders but will not be counted in quorum or be entitled to vote at the meeting unless he or she or it is a shareholder or proxyholder entitled to vote at the meeting.

Material Differences Between the BCBCA and the DGCL

The material differences between the BCBCA and the DGCL that may have the greatest such effect include, but are not limited to, the following: (i) for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions or amendments to our articles) the BCBCA generally requires a two-thirds majority vote by shareholders (including, in some circumstances, shareholders that otherwise do not have the right to vote), whereas the DGCL generally requires only a majority vote; (ii) under the BCBCA, holders of 5% or more of our shares that carry the right to vote at a meeting of shareholders can requisition a general meeting of shareholders at which special matters may be conducted, whereas such right does not exist under the DGCL; and (iii) unlike the DGCL which does not provide for any oppression remedy for shareholders of Delaware entities, the BCBCA provides an oppression remedy that enables a court to make an order, whether interim or final, if an application is made to the court by a shareholder in a timely manner and it appears to the court that there are reasonable grounds for believing (A) that the affairs of the corporation are being or have been conducted, or the powers of the directors are being or have been exercised, in a manner that is oppressive to one or more shareholders, or (B) that some act of the corporation has been done or is threatened, or that some resolution of the shareholders or of the shareholders holding shares of a class or series of shares has been passed or is proposed, that is unfairly prejudicial to one or more of the shareholders.

Certain Takeover Bid Requirements

Unless such offer constitutes an exempt transaction, an offer made by a person, an "offeror", to acquire outstanding shares of a Canadian entity that, when aggregated with the offeror's holdings (and those of persons or companies acting jointly with the offeror), would constitute 20% or more of the outstanding shares in a class, would be subject to the take-over provisions of Canadian securities laws. The foregoing is a limited and general summary of certain aspects of applicable securities law in the provinces and territories of Canada, all in effect as of the date hereof.

In addition to those takeover bid requirements noted above, the acquisition of our shares may trigger the application of statutory regimes including among others, the Investment Canada Act (Canada) and the Competition Act (Canada).

Limitations on the ability to acquire and hold our shares may be imposed by the Competition Act (Canada). This legislation permits the Commissioner of Competition (the "**Commissioner**"), to review any acquisition of control over or of a significant interest in us. This legislation grants the Commissioner jurisdiction, for up to one year after closing, to challenge this type of acquisition before the Canadian Competition Tribunal on the basis that it would, or would be likely to, substantially prevent or lessen competition in any market in Canada.

Since we are a publicly-traded corporation, this legislation also requires any person who intends to acquire our voting shares to file a notification with the Canadian Competition Bureau if certain financial thresholds are exceeded and if that person (and their affiliates) would hold more than 20% of our voting shares as a result of such acquisition. If a person already owns more than 20% of our voting shares, a notification must be filed before the acquisition of additional voting shares that would bring that person's holdings to over 50%. Where a notification is required, the legislation prohibits completion of the acquisition until the expiration of a statutory waiting period or, if applicable, a second statutory waiting period, unless the Commissioner provides written notice that he does not intend to challenge the acquisition. A common closing condition of acquisitions subject to notification under the Competition Act (Canada) is clearance from the Commissioner, even if the applicable statutory waiting period has expired and the parties are in a legal position to close.

The Investment Canada Act (Canada) requires any person that is a "non-Canadian" (as defined in the Investment Canada Act (Canada)) who acquires control of an existing Canadian business, where the acquisition of control is not a reviewable transaction, to file a notification with Innovation, Science and Economic Development. The Investment Canada Act (Canada) generally prohibits the implementation of a reviewable transaction unless, after review, the relevant minister is satisfied that the investment is likely to be of net benefit to Canada. Under the Investment Canada Act (Canada), the acquisition of control of us (either through the acquisition of our shares or all or substantially all our assets) by a non-Canadian would be reviewable under the "net benefit" standard only if the applicable specified financial threshold is met or exceeded and no exemption applied.

The acquisition of a majority of the voting interests of an entity is deemed to be acquisition of control of that entity. The acquisition of less than a majority but one-third or more of the voting shares of a corporation or an equivalent undivided ownership interest in the voting shares of a corporation is presumed to be an acquisition of control of that corporation unless it can be established that, on the acquisition, the corporation is not controlled in fact by the acquirer through the ownership of voting shares. The acquisition of less than one-third of the voting shares of a corporation is deemed not to be an acquisition of control of that corporation

Under the national security regime in the Investment Canada Act (Canada), a national security review on a discretionary basis may also be undertaken by the federal government in respect of a much broader range of investments by a non-Canadian to "acquire, in whole or in part, or to establish an entity carrying on all or any part of its operations in Canada", provided that the entity has a specified nexus to Canada. The relevant test is whether such an investment by a non-Canadian could be "injurious to national security." The relevant minister has broad discretion to determine whether an investor is a non-Canadian and may be subject to national security review. Review on national security grounds is at the discretion of the federal government and, depending on the facts, may occur on a pre- or post-closing basis and includes the ability to block a transaction or, for a completed transaction, order divestiture.

There is no law, governmental decree or regulation in Canada that restricts the export or import of capital or which would affect the remittance of dividends or other payments by us to non-Canadian holders of our common shares or preferred shares, other than withholding tax requirements.

Neither our notice of articles to be in effect upon the completion of this offering nor articles to be in effect upon the completion of this offering contain any change of control limitations with respect to a merger, acquisition or corporate restructuring that involves us.

This summary above is not a comprehensive description of relevant or applicable considerations regarding such requirements and, accordingly, is not intended to be, and should not be interpreted as, legal advice to any prospective purchaser and no representation with respect to such requirements to any prospective purchaser is made. Prospective investors should consult their own Canadian legal advisors with respect to any questions regarding the foregoing and securities law in the provinces and territories of Canada.

Actions Requiring a Special Majority

Under our articles, the number of votes required for the corporation to pass a special resolution at a meeting of shareholders is two-third of the votes cast on the resolution. Special resolutions include resolutions to: (i) create special rights or restrictions for, and attach such special rights or restrictions to, any class or series of shares; (ii) vary or delete any special rights or restrictions attached to any class or series of shares; and (iii) remove a director before the expiration of his or her term of office.

Advance Notice Procedures and Shareholder Proposals

Under the BCBCA, shareholders may make proposals for matters to be considered at the annual general meeting of shareholders. Such proposals must be sent to us in advance of any proposed meeting by delivering a timely written notice in proper form to our registered office in accordance with the requirements of the BCBCA. The notice must include information on the business the shareholder intends to bring before the meeting. In addition, our articles that will be in place after our upcoming annual general meeting of shareholders and prior to the consummation of this offering, require that shareholders must give advance notice to nominate directors or to submit proposals for consideration at shareholders' meetings.

These provisions could have the effect of delaying until the next shareholder meeting the nomination of certain persons for director that are favored by the holders of a majority of our outstanding voting securities.

Ownership and Exchange Controls

There is currently no law, governmental decree or regulation in Canada that restricts the export or import of capital, or which would affect the remittance of dividends, interest or other payments by us to non-resident holders of our common shares, other than withholding tax requirements, as discussed below under "*United States and Canadian Income Tax Considerations — Certain Canadian Federal Income Tax Information*."

There is currently no limitation imposed by Canadian law or our articles that will be in effect prior to closing on the right of non-residents to acquire, hold or vote our common shares, other than those imposed by applicable securities laws and the Investment Canada Act (Canada). The Investment Canada Act (Canada) will generally not apply except in respect of national security and where control of a Canadian business, which has an enterprise value or assets at or over a certain threshold, is acquired and will not frequently apply to trading generally of securities listed on a stock exchange.

Listing

Our common shares are listed on Nasdaq and the TSXV under the symbol "XRTX".

Transfer Agent, Registrar and Auditor

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

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

February 2021 Private Placement Warrants

The following summary of certain terms and provisions of the warrants issued by the Company in February 2021 (the "**Private Placement Warrants**") is not complete and is subject to, and qualified in its entirety by, the provisions of the Private Placement Warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Private Placement Warrants for a complete description of the terms and conditions of the Private Placement Warrants.

On February 9, 2021, the Company closed a private placement with the issuance of 2,085,714 units at a subscription price of $2.94 per unit for gross proceeds of $6,121,572. Each unit comprised one common share and one Private Placement Warrant. Each Private Placement Warrant entitles the holder, on exercise, to purchase one additional common share in the capital of the Company, at a price of $4.70 for a period of 5 years from the issuance of the units; provided, however, that, if, at any time following the expiry of the statutory four month hold period, the closing price of the common shares on the TSXV is greater than $14.09 for 10 or more consecutive trading days, the warrants will be accelerated upon notice and the Private Placement Warrant will expire on the 30th calendar day following the date of such notice. In addition, the Private Placement Warrant 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.

Common Share Purchase Warrants Issued as Part of the 2021 Public Offering

The following is a summary of certain terms and provisions of the common share purchase warrants (the "**IPO Common Share Purchase Warrants**") that were offered in connection with the 2021 Public Offering is not complete and is subject to, and qualified in its entirety by, the provisions of the IPO Common Share Purchase Warrants, the form of which is filed as exhibit 4.6 to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of IPO Common Share Purchase Warrants for a complete description of the terms and conditions of the IPO Common Share Purchase Warrants.

Duration and Exercise Price

Each IPO Common Share Purchase Warrant included has an initial exercise price equal to US$4.77 per common share. The IPO Common Share Purchase Warrants are immediately exercisable and expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The IPO Common Share Purchase Warrants were sold as units consisting of one IPO Common Share Purchase Warrant and one Share. The IPO Common Share Purchase Warrants were issued separately from the Shares included in such units. An IPO Common Share Purchase Warrant to purchase one Share was included in each common share unit purchased in the 2021 public offering.

Cashless Exercise

If, at the time a holder exercises its IPO Common Share Purchase Warrants, a registration statement registering the issuance of the shares of common shares underlying the IPO Common Share Purchase Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of common shares determined according to a formula set forth in the IPO Common Share Purchase Warrants.

Exercisability

The IPO Common Share Purchase Warrants are exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of common shares purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the IPO Common Share Purchase Warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's IPO Common Share Purchase Warrants up to 9.99% of the number of common shares outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the IPO Common Share Purchase Warrants. Purchasers of IPO Common Share Purchase Warrants in the 2021 public offering could also elect, prior to the issuance of the IPO Common Share Purchase Warrants, to have the initial exercise limitation set at 9.99% of our outstanding common shares.

Fractional Shares

No fractional common shares will be issued upon the exercise of the IPO Common Share Purchase Warrants. Rather, the number of common shares to be issued will be rounded up to the nearest whole number, or the Company shall pay a cash adjustment in respect of the fractional share.

Transferability

Subject to applicable laws, the IPO Common Share Purchase Warrants may be offered for sale, sold, transferred or assigned without our consent. There is currently no trading market for the IPO Common Share Purchase Warrants.

Exchange Listing

There is no trading market available for the IPO Common Share Purchase Warrants on any securities exchange or nationally recognized trading system. We do not intend to list IPO Common Share Purchase Warrants on any securities exchange or nationally recognized trading system.

Right as a Shareholders

Except as otherwise provided in the IPO Common Share Purchase Warrants or by virtue of such holder's ownership of common shares, the holders of the IPO Common Share Purchase Warrants do not have the rights or privileges of holders of our common shares, including any voting rights, until they exercise their IPO Common Share Purchase Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the IPO Common Share Purchase Warrants and generally including any reorganization, recapitalization or reclassification of our common shares, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common shares, the holders of the IPO Common Share Purchase Warrants will be entitled to receive upon exercise of the IPO Common Share Purchase Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the IPO Common Share Purchase Warrants immediately prior to such fundamental transaction.

Pre-Funded Warrants to be Issued as Part of this Offering

Duration and Exercise Price

Each Pre-Funded Warrant offered hereby will have an initial exercise price per share equal to US$0.0001. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until the Pre-Funded Warrants are exercised in full. The exercise price and number of Shares issuable upon exercise is

subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common shares and the exercise price. The Pre-Funded Warrants will be issued separately from the accompanying common warrants, and may be transferred separately immediately thereafter.

Exercisability

The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of common shares purchased upon such exercise (except in the case of a cashless exercise as discussed below). Purchasers of the Pre-Funded Warrants in this offering may elect to deliver their exercise notice following the pricing of the offering and prior to the issuance of the Pre-Funded Warrants at closing to have their Pre-Funded Warrants exercised immediately upon issuance and receive Shares underlying the Pre-Funded Warrants upon closing of this offering. A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would own more than 4.99% of the outstanding common shares immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Pre-Funded Warrants up to 9.99% of the number common shares outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. Purchasers of Pre-Funded Warrants in this offering may also elect prior to the issuance of the Pre-Funded Warrants to have the initial exercise limitation set at 9.99% of our outstanding common shares. No fractional common shares will be issued in connection with the exercise of a Pre-Funded Warrant. In lieu of fractional shares, we will pay a cash adjustment in respect of such fraction or round up to the next whole share.

Cashless Exercise

If, at the time a holder exercises its Pre-Funded Warrants, a registration statement registering the issuance of the common shares underlying the Pre-Funded Warrants under the Securities Act is not then effective or available, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of Shares determined according to a formula set forth in the Pre-Funded Warrants.

Transferability

Subject to applicable laws, a Pre-Funded Warrant may be transferred at the option of the holder upon surrender of the Pre-Funded Warrant to us together with the appropriate instruments of transfer.

Exchange Listing

There is no trading market available for the Pre-Funded Warrants on any securities exchange or nationally recognized trading system. We do not intend to list the Pre-Funded Warrants on any securities exchange or nationally recognized trading system.

Right as a Stockholder

Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of our common shares, the holders of the Pre-Funded Warrants do not have the rights or privileges of holders of our common shares, including any voting rights, until they exercise their Pre-Funded Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our common shares, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common shares, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common shares, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded

Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction.

Book Entry Form

Pursuant to a warrant agency agreement between us and Continental Stock Transfer & Trust Company, as warrant agent, the Pre-Funded Warrants and the Warrants will be issued in book-entry form and the Common Share Purchase Warrants and Pre-Funded Warrants shall each initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Warrants to be Issued as Part of this Offering

The following summary of certain terms and provisions of the warrants to be issued as part of this offering (the "**Warrants**") that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrants, the form of which is filed as exhibit 4.2 to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Warrants for a complete description of the terms and conditions of the Warrants.

Duration and Exercise Price

Each Warrant included in the Units will have an initial exercise price equal to US$ per Warrant Share. The Warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of Warrant Shares issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common shares and the exercise price. The Warrants will be issued separately from the Shares included in the Units. A Warrant to purchase one Warrant Share will be included in each Unit purchased in this offering.

Cashless Exercise

If, at the time a holder exercises its Warrants, a registration statement registering the issuance of the Warrant Shares underlying the Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of Warrant Shares determined according to a formula set forth in the Warrants.

Exercisability

The Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of Warrant Shares purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Warrant to the extent that the holder would own more than 4.99% of the outstanding common shares immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Warrants up to 9.99% of the number of shares of our common shares outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. Purchasers of Warrants in this offering may also elect prior to the issuance of the Warrants to have the initial exercise limitation set at 9.99% of our outstanding common shares.

Fractional Shares

No fractional Warrant Shares will be issued upon the exercise of the Warrants. Rather, the number of Warrant Shares to be issued will be rounded up, to the nearest whole number, or the Company shall pay a cash adjustment in respect of the fractional share.

Transferability

Subject to applicable laws, the Warrants may be offered for sale, sold, transferred or assigned without our consent. There is currently no trading market for the Warrants.

Exchange Listing

There is no trading market available for the Warrants on any securities exchange or nationally recognized trading system. We do not intend to list the Warrants on any securities exchange or nationally recognized trading system.

Right as a Shareholder

Except as otherwise provided in the Warrants or by virtue of such holder's ownership of Warrant Shares, the holders of the Warrants do not have the rights or privileges of holders of our common shares, including any voting rights, until they exercise their Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Warrants and generally including any reorganization, recapitalization or reclassification of our common shares, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common shares, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common shares, the holders of the Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Warrants immediately prior to such fundamental transaction.

Options to Purchase Shares

The following table sets forth the aggregate number of options to purchase our common shares upon completion of this offering:

Category	Number of Options to Acquire Common Shares	Exercise Price ($)[1]	Expiration Date
All of Our Executive Officers and All of Our Directors, as a Group (10 in total)	807,399	$1.60 to 5.87	From March 19, 2023 to January 11, 2026

(1) Represents the weighted-average exercise price of all outstanding options to purchase our common shares, whether vested or unvested.

Prior Sales

The following table summarizes issuances of our common shares and securities convertible or exchangeable into common shares during the 12-month period preceding the date of this prospectus.

Date of Issuance	Type of Security	Number of Securities Issued	Issuance/ Exercise Price per Security ($)
July 14, 2021	Options	63,882	2.41
October 15, 2021	Shares	2,906,000	5.11 (US$4.13)
October 15, 2021	Warrants	2,906,000	5.90 (US$4.77)
December 21, 2021	Options	86,496	2.54
January 12, 2022	Options	127,500	2.54
June 6, 2022	Options	394,822	1.60

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of our common shares in the public market could adversely affect prevailing market prices and could impair our ability to raise equity capital in the future. Sales of substantial numbers of our shares in the public market could adversely affect prevailing market prices of our common shares.

Rule 144

In general, under Rule 144 of the Securities Act as currently in effect, an "affiliate" who has beneficially owned our shares for a period of at least six months is entitled to sell within any three-month period a number of shares that does not exceed the greater of either 1% of the then outstanding shares or the average weekly trading volume of our shares on Nasdaq the four calendar weeks preceding the filing with the SEC of a notice on Form 144 with respect to such sale. Such sales under Rule 144 of the Securities Act are also subject to prescribed requirements relating to the manner of sale, notice and availability of current public information about us.

Under Rule 144, a person who is not deemed to have been an affiliate of ours at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior holder other than an affiliate, is entitled to sell such shares without restriction, provided we have been in compliance with our reporting requirements under the Exchange Act for 90 days preceding such sale. To the extent that our affiliates sell their shares, other than pursuant to Rule 144 or a registration statement, the purchaser's holding period for the purpose of effecting a sale under Rule 144 commences on the date of transfer from the affiliate. In addition, under Rule 144, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares without regard to whether current public information about us is available.

Rule 701

In general, under Rule 701 of the Securities Act as currently in effect, each of our employees or directors who acquire our common shares from us in connection with a compensatory stock plan or other written agreement executed prior to the closing of our initial public offering is eligible to resell such shares in reliance on Rule 144, but without compliance with some of the restrictions, including the holding period, contained in Rule 144.

Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act.

Canadian Resale Restrictions

Any sale of any of our shares which constitutes a "control distribution" under Canadian securities laws (generally a sale by a person or a group of persons holding more than 20% of the voting rights attached to our outstanding voting securities) will be subject to restrictions under applicable Canadian securities laws in addition to those restrictions noted above, unless the sale is qualified under a prospectus filed with Canadian securities regulatory authorities or if prior notice of the sale is filed with the Canadian securities regulatory authorities at least seven days before any sale and there has been compliance with certain other requirements and restrictions regarding the manner of sale, payment of commissions, reporting and availability of current public information about us and compliance with applicable Canadian securities laws.

Lock-up Agreements

For a description of the lock-up arrangements that we, our directors, officers, and certain of our shareholders have entered into in connection with this offering, see "*Underwriting*."

TAXATION

Material Canadian Federal Income Tax Considerations

The following is, as of the date of this prospectus, a general summary of the principal Canadian federal income tax considerations under the Income Tax Act (Canada) (the "**Canadian Tax Act**"), generally applicable to an investor who acquires Common Share Units or Pre-Funded Warrant Units pursuant to this offering 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 underwriter, is not affiliated with the Company or the underwriter and who acquires and holds the Shares, Pre Funded Warrants, or Warrants as capital property, or a Holder. Generally, the Shares, Pre-Funded Warrants, and Warrants will be considered to be capital property to a Holder thereof provided that the Holder does not use the Shares, Pre-Funded Warrants, or Warrants 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 Shares, Pre-Funded Warrants, and Warrants. Such Holders should consult their own tax advisors with respect to the consequences of acquiring Units or Pre-Funded 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 Units or Pre-Funded Warrants, controlled by a non-resident person (or a group of non-resident persons that do not deal at arm's length with each other for purpose of the Tax Act) 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 Units or Pre-Funded Warrants.

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, nor does it 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 Units pursuant to this offering. **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 Shares, Pre-Funded Warrants, 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.

Allocation of Cost

Holders will be required to allocate on a reasonable basis their cost of each Unit between the Share and the Warrant comprising the Unit in order to determine their respective costs for purposes of the Canadian Tax Act. For its purposes, the Corporation intends to allocate $ to each Share and $ to each Warrant. Although the Corporation believes that its allocation is reasonable, it is not binding on the CRA or the Holder and the Corporation expresses no opinion with respect to such allocation. Holders are encouraged to consult their own tax advisors in this regard.

Exercise of Warrants or Pre-Funded Warrants

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

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 (a "**Canadian Resident Holder**"). Certain Canadian Resident Holders whose 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 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 election is not available in respect of the Warrants or Pre-Funded Warrants. Canadian Resident Holders should consult their own tax advisors regarding this election.

Expiry of Warrants or Pre-Funded Warrants

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

Dividends

Dividends received or deemed to be received on the 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. There may be limitations on the ability of the Company to designate dividends as eligible dividends.

Dividends received or deemed to be received by a corporation that is a Canadian Resident Holder on the 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 an additional tax on

dividends received or deemed to be received on the Shares to the extent such dividends are deductible in computing taxable income. Such additional tax may be refundable in certain circumstances.

Dispositions of Common Shares, Warrants or Pre-Funded Warrants

Upon a disposition (or a deemed disposition) of a Share, Pre-Funded Warrant or a Warrant (which does not include the exercise of a Warrant or Pre-Funded Warrant and excluding a disposition arising on the expiry of a Warrant or Pre-Funded Warrant), 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 Share, Warrant, or Pre-Funded Warrant, net of any reasonable costs of disposition, are greater (or are less) than the adjusted cost base of such Share, Warrant, or Pre-Funded Warrant, as the case may be, to the Canadian Resident Holder. The 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 Share acquired pursuant to this offering 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 one-half of the amount of any capital gain (a "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 one-half of the amount of any capital loss (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 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 directly or indirectly through a partnership or a trust. 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" or a "substantive CCPC" 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.

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 Shares, Warrants, or Pre-Funded Warrants, 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 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, or 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 or Pre-Funded Warrants

In the event of the expiry of an unexercised Warrant or Pre-Funded Warrant, a Non-Canadian Holder will be considered to have disposed of such Warrant or Pre-Funded Warrant for nil proceeds and will accordingly realize a capital loss equal to the Canadian Resident Holder's adjusted cost base of such Warrant or Pre-Funded 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 Shares, Pre-Funded Warrants, or Warrants*", below.

Dispositions of Shares, Warrants or Pre-Funded 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 Share, Warrant or Pre-Funded Warrant nor will capital losses arising therefrom be recognized under the Canadian Tax Act, unless the Share, Pre-Funded Warrant, or Warrant or Pre-Funded 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 Shares, Warrants or Pre-Funded Warrants acquired pursuant to this offering will not be "taxable Canadian property" to a Non-Canadian Holder if the Shares are listed on a "designated stock exchange", as defined in the Canadian Tax Act (which currently includes 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. 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 Shares, Warrants, or Pre-Funded 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 Shares, Warrants or Pre-Funded Warrants*" and "*Residents of Canada — Capital Gains and Capital Losses*".

Non-Canadian Holders whose Shares, Warrants, or Pre-Funded Warrants 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 Shares acquired pursuant to this offering and exercise, disposition, and lapse of Warrants acquired pursuant to this offering, the acquisition, ownership, and disposition of the Shares received upon exercise of such Warrants (the "Warrant Shares"), the ownership, exercise and disposition of Pre-Funded Warrants acquired pursuant to this offering and the Shares received upon the exercise of such Pre-Funded Warrants (the "Pre-Funded Warrant Shares") as the case may be. The term "**securities**" as used in this summary includes the Shares, Pre-Funded Warrants, Warrants, Warrant Shares and Pre-Funded Warrant Shares, as applicable.

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 securities pursuant to this offering. 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 securities. 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 securities.

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 securities acquired pursuant to this offering 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 securities as part of a straddle, hedging transaction, conversion transaction, constructive sale, or other integrated transaction; (f) acquired the securities in connection with the exercise of employee stock options or otherwise as compensation for services; (g) hold the securities 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 securities.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds the securities, 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 securities.

U.S. Federal Income Tax Consequences of the Acquisition of a Common Share Unit or Pre-Funded Warrant Unit

The acquisition of a Common Share Unit or Pre-Funded Warrant Unit, as the case may be, should be treated for U.S. federal income tax purposes as the acquisition of a Share or a Pre-Funded Warrant, as applicable, and a Warrant. The purchase price for each Common Share Unit or Pre-Funded Warrant Unit, as the case may be, will be allocated between a Share or a Pre-Funded Warrant, as applicable, and a Warrant in proportion to their relative fair market values at the time such securities are issued to the U.S. Holder. This allocation of the purchase price for each such Common Share Unit or Pre-Funded Warrant Unit, as the case may be, will establish a U.S. Holder's initial tax basis for U.S. federal income tax purposes in the Share or Pre-Funded Warrant, as applicable, and of the Warrant that comprise each such Common Share Unit or Pre-Funded Warrant Unit. For this purpose, we will allocate US$ of the purchase price to the Share or Pre-Funded Warrant, as applicable, and US$ of the purchase price to the Warrant.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, we believe a Pre-Funded Warrant should be treated as a separate class of Shares for U.S. federal income tax purposes and a U.S. Holder of Pre-Funded Warrants and Pre-Funded Warrant Shares should generally be taxed in the same manner as a holder of Shares except

as described below. Accordingly, no gain or loss should be recognized upon the exercise of a Pre-Funded Warrant and, upon exercise, the holding period of a Pre-Funded Warrant should carry over to the Pre-Funded Warrant Shares received. Similarly, the tax basis of the Pre-Funded Warrant should carry over to the Pre-Funded Warrant Shares received upon exercise, increased by the exercise price of US$0.0001 per share. However, such characterization is not binding on the IRS, and the IRS may treat the Pre-Funded Warrant as warrants to acquire Shares. If so, the amount and character of a U.S. Holder's gain with respect to an investment in Pre-Funded Warrants could change, and a U.S. Holder may not be entitled to make the "QEF Election" or "Mark-to-Market Election" described below to mitigate PFIC consequences in the event that we are classified as a PFIC. Accordingly, each U.S. Holder should consult its own tax advisor regarding the risks associated with the acquisition of a Pre-Funded Warrant pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes

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 securities.

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 securities 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 securities.

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 securities 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 Shares, Pre-Funded Warrants, the Warrant Shares, or Pre-Funded Warrant 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 securities and (b) any excess distribution received on the securities. 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 securities, if shorter).

Under Section 1291 of the Code, any gain recognized on the sale or other taxable disposition of the securities of a PFIC (including an indirect disposition of shares of a Subsidiary PFIC), and any excess distribution received on such securities (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 securities. 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 securities, 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 Shares, Pre-Funded Warrants, Warrant Shares, and the Pre-Funded Warrant 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 securities were sold on the last day of the last tax year for which we were a PFIC. No such election, however, may be made with respect to the Warrants.

Under proposed Treasury Regulations, if a U.S. Holder has an option, warrant, or other right to acquire stock of a PFIC (such as the Warrants), such option, warrant or right is considered to be PFIC stock subject to the default rules of Section 1291 of the Code. Under rules described below, the holding period for the Warrant Shares will begin on the date a U.S. Holder acquires the related Warrant. This will impact the availability of the QEF Election and Mark-to-Market Election with respect to the Warrant Shares. Thus, a U.S. Holder will have to account for the Warrant Shares, Pre-Funded Warrant Shares, Shares, and Pre-Funded Warrants under the PFIC rules and the applicable elections differently.

QEF Election

A U.S. Holder that makes a QEF Election for the first tax year in which its holding period of its Shares or Pre-Funded Warrants begins generally will not be subject to the rules of Section 1291 of the Code discussed above with respect to its Shares or Pre-Funded Warrants. 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 Shares or Pre-Funded Warrants 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 Shares or Pre-Funded Warrants.

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 Shares or Pre-Funded Warrants 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.

As discussed above, under proposed Treasury Regulations, if a U.S. Holder has an option, warrant or other right to acquire stock of a PFIC (such as the Warrants), such option, warrant or right is considered to be PFIC stock subject to the default rules of Section 1291 of the Code. However, a U.S. Holder of an option, warrant or other right to acquire stock of a PFIC may not make a QEF Election that will apply to the option, warrant or other right to acquire PFIC stock. In addition, under proposed Treasury Regulations, if a U.S. Holder holds an option, warrant or other right to acquire stock of a PFIC, the holding period with respect to shares of stock of the PFIC acquired upon exercise of such option, warrant or other right will include the period that the option, warrant or other right was held.

Consequently, under the proposed Treasury Regulations, if a U.S. Holder of the Shares or Pre-Funded Warrants makes a QEF Election, such election generally will not be treated as a timely QEF Election with respect to Warrant Shares and the rules of Section 1291 of the Code discussed above will continue to apply with respect to such U.S. Holder's Warrant Shares. However, a U.S. Holder of Warrant Shares should be eligible to make a timely QEF Election if such U.S. Holder makes a "purging" or "deemed sale" election to recognize gain (which will be taxed under the rules of Section 1291 of the Code discussed above) as if such Warrant Shares were sold for fair market value. As a result of the "purging" or "deemed sale" election, the U.S. Holder will have a new basis and holding period in the Warrant Shares acquired upon the exercise of the Warrants for purposes of the PFIC rules. In addition, gain recognized on the sale or other taxable

disposition (other than by exercise) of the Warrants by a U.S. Holder will be subject to the rules of Section 1291 of the Code discussed above. Each U.S. Holder should consult its own tax advisor regarding the application of the PFIC rules to the securities.

Upon the exercise of a Pre-Funded Warrant, a U.S. Holder may be required to make a new QEF Election with respect to the Pre-Funded Warrant Shares received. Each U.S. Holder should consult its own tax advisor regarding the application of the QEF Election rules to the Pre-Funded Warrants and Pre-Funded Warrant Shares.

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 securities, 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 Shares, Warrant Shares, and Pre-Funded Warrant Shares only if such shares are marketable stock. The Shares, Warrant Shares, and Pre-Funded Warrant Shares generally will be "marketable stock" if the Shares, Warrant Shares and Pre-Funded Warrant 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 Shares, Warrant Shares and Pre-Funded Warrant 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 Shares will be "regularly traded" in subsequent calendar quarters. U.S. Holders should consult their own tax advisors regarding the marketable stock rules. A Mark-to-Market Election will likely not be available with respect to the Warrants and Pre-Funded Warrants. Accordingly, each U.S. Holder should consult its own tax advisor regarding the availability of a Mark-to-Market Election with respect to the Warrants and Pre-Funded Warrants. The balance of this discussion generally assumes that a Mark-to-Market Election may be made with respect a Pre-Funded Warrant.

A U.S. Holder that makes a Mark-to-Market Election with respect to its Shares or Pre-Funded Warrants generally will not be subject to the rules of Section 1291 of the Code discussed above with respect to such Shares, Warrant Shares, Pre-Funded Warrant Shares, or Pre-Funded Warrants. 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 Shares or Pre-Funded Warrants 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 Shares and Pre-Funded Warrants.

Any Mark-to-Market Election made by a U.S. Holder for the Shares or Pre-Funded Warrants will also apply to such U.S. Holder's Warrant Shares and Pre-Funded Warrant Shares. As a result, if a Mark-to-Market Election has been made by a U.S. Holder with respect to its Shares, any Warrant Shares received will

automatically be marked-to-market in the year of exercise. Because, under the proposed Treasury Regulations, a U.S. Holder's holding period for Warrant Shares includes the period during which such U.S. Holder held the Warrants, a U.S. Holder will be treated as making a Mark-to-Market Election with respect to its Warrant Shares after the beginning of such U.S. Holder's holding period for the Warrant Shares unless the Warrant Shares are acquired in the same tax year as the year in which the U.S. Holder acquired its securities. Consequently, the default rules under Section 1291 described above generally will apply to the mark-to-market gain realized in the tax year in which Warrant Shares are received. However, the general mark-to-market rules will apply to subsequent tax years.

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 Shares, Pre-Funded Warrants, and any Warrant Shares or Pre-Funded Warrant Shares as of the close of such tax year over (b) such U.S. Holder's tax basis in such securities. 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 Shares, Pre-Funded Warrants, and any Warrant Shares or Pre-Funded Warrant Shares, over (ii) the fair market value of such securities (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 Shares, Pre-Funded Warrants, Warrant Shares, and Pre-Funded Warrant 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 securities, 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 securities 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 Shares, Pre-Funded Warrants, Warrant Shares, and Pre-Funded Warrant 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.

Because the U.S. federal income tax characterization of the Pre-Funded Warrants is unclear, U.S. Holders of Pre-Funded Warrants should consult with their tax advisors as to the availability of a QEF Election or Mark-to-Market election with respect to the Pre-Funded Warrants.

Other PFIC Rules

Under Section 1291(f) of the Code, the IRS has issued proposed Treasury Regulations that, subject to certain exceptions, would cause a U.S. Holder that had not made a timely QEF Election to recognize gain (but not loss) upon certain transfers of securities that would otherwise be tax-deferred (e.g., gifts and exchanges pursuant to corporate reorganizations). However, the specific U.S. federal income tax consequences to a U.S. Holder may vary based on the manner in which the securities are transferred.

If finalized in their current form, the proposed Treasury Regulations applicable to PFICs would be effective for transactions occurring on or after April 1, 1992. Because the proposed Treasury Regulations have not yet been adopted in final form, they are not currently effective, and there is no assurance that they will be adopted in the form and with the effective date proposed. Nevertheless, the IRS has announced that, in the absence of final Treasury Regulations, taxpayers may apply reasonable interpretations of the Code provisions applicable to PFICs and that it considers the rules set forth in the proposed Treasury Regulations to be reasonable interpretations of those Code provisions. The PFIC rules are complex, and the

implementation of certain aspects of the PFIC rules requires the issuance of Treasury Regulations which in many instances have not been promulgated and which, when promulgated, may have retroactive effect. U.S. Holders should consult their own tax advisors about the potential applicability of the proposed Treasury Regulations.

Certain additional adverse rules will apply with respect to a U.S. Holder if we are a PFIC, regardless of whether such U.S. Holder makes a QEF Election. For example, under Section 1298(b)(6) of the Code, a U.S. Holder that uses the securities as security for a loan will, except as may be provided in Treasury Regulations, be treated as having made a taxable disposition of such securities.

In addition, a U.S. Holder who acquires securities from a decedent will not receive a "step up" in tax basis of such securities to fair market value.

Special rules also apply to the amount of foreign tax credit that a U.S. Holder may claim on a distribution from a PFIC. Subject to such special rules, foreign taxes paid with respect to any distribution in respect of stock in a PFIC are generally eligible for the foreign tax credit. The rules relating to distributions by a PFIC and their eligibility for the foreign tax credit are complicated, and a U.S. Holder should consult with their own tax advisor regarding the availability of the foreign tax credit with respect to distributions by a PFIC.

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 securities.

U.S. Federal Income Tax Consequences of the Exercise and Disposition of Warrants

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

Exercise of Warrants

A U.S. Holder should not recognize gain or loss on the exercise of a Warrant and related receipt of a Warrant Share (unless cash is received in lieu of the issuance of a fractional Warrant Share). A U.S. Holder's initial tax basis in the Warrant Share received on the exercise of a Warrant should be equal to the sum of (a) such U.S. Holder's tax basis in such Warrant plus (b) the exercise price paid by such U.S. Holder on the exercise of such Warrant. It is unclear whether a U.S. Holder's holding period for the Warrant Share received on the exercise of a Warrant would commence on the date of exercise of the Warrant or the day following the date of exercise of the Warrant. If we are a PFIC, a U.S. Holder's holding period for the Warrant Share for PFIC purposes will begin on the date on which such U.S. Holder acquired its Warrant.

If the acquisition of a Pre-Funded Warrant is not treated as an acquisition of Shares for U.S. federal income tax purposes as described above in under the heading "*Treatment of Pre-Funded Warrants*", then the foregoing rules described in this paragraph would also apply to the exercise of a Pre-Funded Warrant.

Disposition of Warrants

A U.S. Holder will recognize gain or loss on the sale or other taxable disposition of a Warrant in an amount equal to the difference, if any, 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 the Warrant sold or otherwise disposed of. Subject to the PFIC rules discussed above, any such gain or loss generally will be a capital gain or loss, which will be long-term capital gain or loss if the Warrant is held for more than one year. Deductions for capital losses are subject to complex limitations under the Code.

Expiration of Warrants Without Exercise

Upon the lapse or expiration of a Warrant, a U.S. Holder will recognize a loss in an amount equal to such U.S. Holder's tax basis in the Warrant. Any such loss generally will be a capital loss and will be long-term

capital loss if the Warrants are held for more than one year. Deductions for capital losses are subject to complex limitations under the Code.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of Warrant Shares that will be issued on the exercise of the Warrants, or an adjustment to the exercise price of the Warrants, may be treated as a constructive distribution to a U.S. Holder of the Warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in the "earnings and profits" or our assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to the shareholders). Adjustments to the exercise price of Warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the Warrants should generally not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. (See more detailed discussion of the rules applicable to distributions made by us at "*Distributions on the Shares, Pre-Funded Warrants, Warrant Shares, and Pre-Funded Warrant Shares*" below).

General Rules Applicable to U.S. Federal Income Tax Consequences of the Acquisition, Ownership, and Disposition of the Shares, Pre-Funded Warrants, Warrant Shares and Pre-Funded Warrant Shares

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

Distributions on the Shares, Pre-Funded Warrants, Warrant Shares, and Pre-Funded Warrant Shares

A U.S. Holder that receives a distribution, including a constructive distribution, with respect to a Share, Pre-Funded Warrant, Warrant Share or Pre-Funded Warrant Share (as well as any constructive distribution on a Warrant as described above) 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 securities and thereafter as gain from the sale or exchange of such securities (see "*Sale or Other Taxable Disposition of the Shares, Pre-Funded Warrants Warrant Shares and/or Pre-Funded Warrant 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 securities will constitute ordinary dividend income. Dividends received on such securities 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 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 Shares, Pre-Funded Warrants, Warrant Shares and/or Pre-Funded Warrant Shares

Upon the sale or other taxable disposition of the Shares, Pre-Funded Warrants, Warrant Shares, or Pre-Funded Warrant 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 securities 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 securities 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 securities 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 securities (or with respect to any constructive dividend on the Warrants) 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 securities 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 securities 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 SECURITIES. U.S. HOLDERS SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO THE TAX CONSIDERATIONS APPLICABLE TO THEM IN THEIR OWN PARTICULAR CIRCUMSTANCES.

UNDERWRITING

A.G.P./Alliance Global Partners is acting as the representative of the underwriter and the sole book-running manager in this offering. We have entered into an underwriting agreement dated , 2022 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally and not jointly agreed to purchase from us, at the respective public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, our Units listed next to its name in the following table:

Underwriter	Number of Common Share Units	Number of Pre-Funded Warrant Units	Total
A.G.P./Alliance Global Partners			
Total			

The underwriter is committed to purchase all the securities we are offering other than those covered by the over-allotment option to purchase additional securities described below, if they purchase any Units. The obligations of the underwriter may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriter's obligations are subject to customary conditions and representations and warranties contained in the underwriting agreement, such as receipt by the underwriter of officers' certificates and legal opinions.

We have agreed to indemnify the underwriter against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriter may be required to make in respect thereof.

The underwriter is offering the Pre-Funded Warrant Units and Common Share Units, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-allotment Option to Purchase Additional Securities

Pursuant to the underwriting agreement, we have granted the underwriter an option, exercisable for up to 45 days from the date of this prospectus, to purchase up to 731,707 additional Shares and/or Warrants (15% of the Shares and Shares underlying the Pre-Funded Warrants and accompanying Warrants sold in this offering) at the public offering price set forth on the cover page hereto, less the underwriting discounts and commissions. The underwriter may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional Shares and accompanying Warrants are purchased pursuant to the over-allotment option, the underwriter will offer these Shares and accompanying Warrants on the same terms as those on which the other securities are being offered. If this over-allotment option is exercised in full, the total gross proceeds will be approximately US$6.9 million and the total net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses, to us will be approximately US$5.55 million.

Discounts, Commissions and Expense Reimbursement

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriter of its over-allotment option to purchase additional securities.

	Per Common Share Unit	Per Pre-Funded Warrant Unit	Total Without Over-Allotment	Total With Over-Allotment
Public offering price				
Underwriting discounts and commissions (7.0%)				
Proceeds, before expenses, to us.				

The underwriter proposes to offer the Common Share Units or Pre-Funded Warrant Units offered by us to the public at the public offering price per respective Unit set forth on the cover of this prospectus. In addition, the underwriter may offer some of the Units to other securities dealers at such price less a concession of up to US$ per Common Share Unit and US$ per Pre-Funded Warrant Unit.

If all of the Units offered by us are not sold at the respective public offering prices per Unit, the underwriter may change the offering price per Common Share Unit or Pre-Funded Warrant Unit and other selling terms by means of a supplement to this prospectus.

We have also agreed to reimburse certain of the representative's accountable expenses not to exceed US$100,000 in the aggregate, and non-accountable expenses not to exceed 1.0% of the aggregate gross proceeds of this offering.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discounts, commissions and underwriter expense reimbursements, will be approximately US$688,267.44.

Lock-Up Agreements

For a period of 90 days after the date of this prospectus, subject to certain exceptions, we have agreed with the underwriter not to offer for sale, issue or sell, or register for offer or sale, any of our common shares or any other shares of our capital stock or file or cause to be filed with the SEC any registration statement relating to the offering of any of our securities. In addition, all of our directors and executive officers have entered into lock-up agreements with the representative prior to the commencement of this offering pursuant to which each of these persons, for a period of 90 days from the closing date of this offering, without the prior written consent of the representative, agree not to (1) offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, any of our common shares or any securities convertible into or exercisable or exchangeable for our common shares whether now owed or hereafter acquired or with respect to which the director or executive officer has or hereafter acquires the power of disposition; (2) enter into any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of such securities; or (3) engage in any short selling of such securities.

Underwriter Warrants

Upon closing of this offering, we will issue to A.G.P./Alliance Global Partners a compensation warrant ("**Compensation Warrant**") entitling A.G.P./Alliance Global Partners or its designees to purchase shares of our common shares (equal to up to 5.0% of the aggregate number of the Shares or Shares issuable upon the exercise of Pre-Funded Warrants that we issue in this offering), subject to any reductions necessary to comply with the rules and regulations of the Financial Industry Regulatory Authority, Inc. ("**FINRA**"). The Compensation Warrants will be exercisable at any time and from time to time, in whole or in part, during the four and a half-year period commencing six months from the effective date of the registration statement of which this prospectus forms a part, at a price per common share equal to 100% of the public offering price per Common Share Unit. The Compensation Warrants will provide for registration rights for the shares underlying the Compensation Warrants, pursuant to FINRA Rule 5110(f)(2)G), including a one-time demand registration right and unlimited piggyback rights, as well as contain customary anti-dilution provisions. The demand registration rights shall expire five years from the effective date of this registration statement and the piggyback registration rights shall expire seven years from the effective date of this registration statement. Pursuant to FINRA Rule 5110(g), the Compensation Warrants and any shares issued upon exercise of the Compensation Warrants shall not be 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 the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the underwriter or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members

in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the website maintained by the underwriter or selling group members, if any, participating in this offering and the underwriter participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of Units to the underwriter and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriter and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Stock Exchanges

Our common shares are listed on the TSXV and Nasdaq under the symbol “XRTX”. We do not intend to apply for listing of the Units, Pre-Funded Warrants, and/or Warrants on any securities exchange or other nationally recognized trading system.

Stabilization

In connection with this offering, the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales. Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.

Over-allotment transactions involve sales by the underwriter of shares in excess of the number of shares the underwriter are obligated to purchase. This creates a syndicate short position that may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriter may close out any short position by exercising their option to purchase additional Shares and accompanying Warrants or Pre-Funded Warrants and accompanying Warrants and/or purchasing Shares in the open market.

Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the over-allotment option. If the underwriter sells more shares than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common shares or preventing or retarding a decline in the market price of our common shares. As a result, the price of our common shares in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriter makes any representation or prediction as to the effect that the transactions described above may have on

the price of our common shares. These transactions may be effected on Nasdaq, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, the underwriter and selling group members may engage in passive market making transactions in our common shares on Nasdaq in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Certain Relationships

The underwriter and its affiliates have in the past and may in the future provide various investment banking, commercial banking, financial advisory, brokerage, and other services to us and have and may receive customary fees and expense reimbursement.

The underwriter and its affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriter and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of our company. The underwriter and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Offer Restrictions Outside the United States

This prospectus does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the securities or possession or distribution of this prospectus or any other offering or publicity material relating to the securities in any country or jurisdiction (other than the United States) where any such action for that purpose is required. Accordingly, the underwriter has undertaken that it will not, directly or indirectly, offer or sell any securities offered hereby or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with any applicable laws and regulations and all offers and sales of securities by it will be made on the same terms.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "**Relevant Member State**") an offer to the public of any securities may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to legal entities which are qualified investors as defined under the Prospectus Directive;
- by the underwriter to fewer than 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriter for any such offer; or

- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of our common shares shall result in a requirement for us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, (1) the expression an "offer of common shares to the public" in relation to any common shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for the common shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, (2) the expression "**Prospectus Directive**" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive), and includes any relevant implementing measure in each Relevant Member State and (3) the expression "**2010 PD Amending Directive**" means Directive 2010/73/EU.

United Kingdom

This prospectus has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000 (the "**FSMA**")) as received in connection with the issue or sale of the common shares in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to the common shares in, from or otherwise involving the United Kingdom.

Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriter is not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "**Corporations Act**"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the securities may only be made to persons (the "**Exempt Investors**"), who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the securities without disclosure to investors under Chapter 6D of the Corporations Act.

The securities applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where

disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring securities must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances and, if necessary, seek expert advice on those matters.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("**SIX**"), or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the securities have been or will be filed with or approved by any Swiss regulatory authority. This document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("**CISA**"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

Dubai International Financial Centre

This prospectus relates to an "Exempt Offer" in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("**DFSA**"). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents relating to Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The securities to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this prospectus, you should consult an authorized financial advisor.

Hong Kong

The securities have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the securities has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or

indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "**Japanese Person**" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus may be distributed only to, and is directed only at, investors listed in the first addendum (the "**Addendum**"), to the Israeli Securities Law, consisting primarily of joint investment in trust funds; provident funds; insurance companies; banks; portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange Ltd., underwriters, each purchasing for their own account; venture capital funds; entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors. Qualified investors shall be required to submit written confirmation that they fall within the scope of the Addendum.

EXPENSES RELATED TO THIS OFFERING

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the offer and sale of our Shares in this offering. All amounts listed below are estimates.

Itemized expense	Amount
SEC registration fee	667.44
Nasdaq listing fee	40,000
FINRA filing fee	2,600
Printing and engraving expenses	30,000
Transfer agent and registrar fees	40,000
Legal fees and expenses	500,000
Accounting fees and expenses	75,000
Total	688,267.44

LEGAL MATTERS

The validity of the securities being offered by this prospectus and other legal matters concerning this offering relating to Canadian law will be passed upon for us by Fasken Martineau DuMoulin LLP. Certain legal matters in connection with this offering relating to U.S. law will be passed upon for us by Troutman Pepper Hamilton Sanders LLP. Certain legal matters in connection with this offering relating to Canadian law will be passed upon for the underwriter by TingleMerrett LLP. Certain legal matters in connection with this offering relating to U.S. law will be passed upon for the underwriter by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

EXPERTS

The consolidated financial statements of XORTX as of and for the year ended December 31, 2021, have been audited by Smythe LLP, independent registered public accounting firm, as set forth in their report thereon. Smythe LLP is independent with respect to us within the meaning of the Rules of Professional Conduct of the Institute of Chartered Professional Accountants of British Columbia and under all relevant U.S. professional and regulatory standards, including Public Company Accounting Oversight Board Rule 3520. We have included our financial statements in this prospectus and in this registration statement in reliance on the report of Smythe LLP given on their authority as experts in accounting and auditing.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to our directors, officers or persons controlling us, we have been advised that it is the SEC's opinion that such indemnification is against public policy as expressed in such act and is, therefore, unenforceable.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act, including relevant exhibits and schedules, with respect to the securities to be sold in this offering. This prospectus, which constitutes a part of the registration statement, does not contain all of the information contained in the registration statement. You should read the registration statement and its exhibits for further information with respect to us and the securities. Some of these exhibits consist of documents or contracts that are described in this prospectus in summary form. You should read the entire document or contract for the complete terms. The SEC maintains an internet website at www.sec.gov, from which you can electronically access the registration statement and its exhibits.

We are subject to the reporting requirements of the Exchange Act applicable to foreign private issuers. As a foreign private issuer, the SEC's rules do not require us to deliver proxy statements or to file quarterly reports on Form 10-Q, among other things. However, we plan to produce quarterly financial reports and furnish them to the SEC not later than 45 days after the end of each of the first three quarters of our fiscal year and to file our annual report on Form 20-F not later than 90 days after the end of our fiscal year. In addition, our "insiders" are not subject to the SEC's rules regarding insider reporting and prohibiting short-swing trading under Section 16 of the Exchange Act.

We will also be subject to the full informational requirements of the securities commissions in Alberta, British Columbia, and Ontario. You are invited to read and copy any reports, statements or other information, other than confidential filings, that we intend to file with the Canadian provincial and territorial securities commissions. These filings are also electronically available from SEDAR (http://www.sedar.com), the Canadian equivalent of the SEC's Electronic Document Gathering And Retrieval System. Documents filed on SEDAR are not, and should not be considered, part of this prospectus.

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

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with the SEC. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be part of this prospectus.

We incorporate by reference the documents listed below:

- our Annual Report on Form 20-F for the fiscal year ended December 31, 2021 filed with the SEC on May 3, 2022;
- our Report on Form 6-K filed with the SEC on August 11, 2022 and
- the description of the securities contained in our Amendment No. 1 to the registration statement on Form 8-A filed with the SEC on October 4, 2021 (File No. 001-40858) pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), together with all amendments and reports filed for the purpose of updating that description.

We will provide, free of charge upon written or oral request, to each person to whom this prospectus is delivered, including any beneficial owner of the securities, a copy of any or all of the information that has been incorporated by reference into this prospectus, but which has not been delivered with the prospectus. The information contained on or linked to or from our website is not incorporated by reference into this prospectus and should not be considered part of this prospectus. Requests for such information should be made to us at the following address:

Suite 2900 — 550 Burrard Street
Vancouver, British Columbia
Canada
V6C 0A3
1 (403) 455-7727

You should assume that the information appearing in this prospectus and any accompanying prospectus supplement, as well as the information we previously filed with the SEC and incorporated by reference, is accurate as of the dates on the front cover of those documents only. Our business, financial condition and results of operations and prospects may have changed since those dates.

4,878,048 Common Share Units
and Pre-Funded Warrant Units consisting of
4,878,048 Common Shares
Pre-Funded Warrants to Purchase Common Shares and
Warrants to Purchase 4,878,048 Common Shares

PROSPECTUS

, 2022

A.G.P.

Through and including , 2022 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 6. Indemnification of Directors and Officers

Under the BCBCA, we may indemnify an individual who:

(a) is or was our director or officer;

(b) is or was a director or officer (y) at our request, or (z) of another corporation at the time when such corporation is or was an affiliate of ours; or

(c) at our request, is or was, or holds or held a position equivalent to that of a director or officer of a partnership, trust, joint venture or other unincorporated entity,

against a judgment, penalty or fine awarded or imposed in, or an amount paid in settlement of, any legal proceeding or investigative action, whether current, threatened, pending or completed, in which such eligible party is involved because of that association with us or other entity.

However, indemnification is prohibited under the BCBCA if:

(a) such eligible party did not act honestly and in good faith with a view to our best interests (or the other entity, as the case may be);

(b) in the case of a proceeding other than a civil proceeding, such eligible party did not have reasonable grounds for believing that such person's conduct was lawful;

(c) the indemnity or payment is made under an earlier agreement to indemnify or pay expenses and, at the time that the agreement to indemnify or pay expenses was made, the Company was prohibited from giving the indemnity or paying the expenses by its articles; or

(d) the indemnity or payment is made otherwise than under an earlier agreement to indemnify or pay expenses and, at the time that the indemnity or payment is made, the Company was prohibited from giving the indemnity or paying the expenses by its articles.

We may not indemnify or pay the expenses of an eligible party in respect of an action brought against an eligible party by or on behalf of us.

The BCBCA allows us to pay, as they are incurred in advance of a final disposition of a proceeding, the expenses actually and reasonably incurred by the eligible party, provided that we receive from such eligible party an undertaking to repay the amounts advanced if it is ultimately determined that such payment is prohibited. Following the final disposition of an eligible proceeding, the BCBCA requires us to pay the expenses actually and reasonably incurred by the eligible party in respect of that proceeding if the eligible party has not been reimbursed for those expenses and is wholly successful, on the merits or otherwise, in the outcome of the proceeding, or is substantially successful on the merits in the outcome of the proceeding.

Despite the foregoing, on application by us or an eligible party, a court may:

(a) order us to indemnify an eligible party in respect of an eligible proceeding;

(b) order us to pay some or all of the expenses incurred by an eligible party in an eligible proceeding;

(c) order enforcement of or any payment under an indemnification agreement;

(d) order us to pay some or all of the expenses actually and reasonably incurred by a person in obtaining the order of the court; and

(e) make any other order the court considers appropriate.

The BCBCA provides that we may purchase and maintain insurance for the benefit of an eligible party (or their heirs and personal or other legal representatives of the eligible party) against any liability that may be incurred by reason of the eligible party being or having been a director or officer, or in an equivalent position of ours or that of an associated corporation.

Our articles provide that, subject to the BCBCA, we must indemnify our directors, former directors or alternate directors and his or her heirs and legal personal representatives against all judgments, penalties or fines awarded or imposed in, or an amount paid in settlement of, all legal proceedings, investigative actions or other eligible proceedings (whether current, threatened, pending or completed) to which such person is or may be liable, and we must, after the final disposition of a legal proceeding, investigative action or other eligible proceeding, pay the expenses (which includes costs, charges and expenses, including legal and other fees but does not include judgments, penalties, fines or amounts paid in settlement of a proceeding) actually and reasonably incurred by such person in respect of that proceeding.

We have entered into indemnity agreements with our directors and certain officers which provide, among other things, that we will indemnify him or her to the fullest extent permitted by law from and against all liabilities, costs, charges and expenses incurred as a result of his or her actions in the exercise of his or her duties as a director or officer.

Prior to completion of this offering, we intend to enter into new indemnification agreements with each of our current directors and officers. The indemnification agreements will generally require that we indemnify and hold the indemnitees harmless to the greatest extent permitted by law for liabilities arising out of the indemnitees' service to us as directors and officers, if the indemnitees acted honestly and in good faith with a view to the best interests of the Company and, with respect to criminal and administrative actions or other non-civil proceedings that are enforced by monetary penalty, if the indemnitee had reasonable grounds to believe that his or her conduct was lawful. The indemnification agreements will also provide for the advancing of defense expenses to the indemnitees by us.

At present, we are not aware of any pending or threatened litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification would be required or permitted.

The proposed form of Underwriting Agreement filed as Exhibit 1.1 to this Registration Statement provides for indemnification of our officers and directors by the underwriter against certain liabilities.

Item 7. Recent Sales of Unregistered Securities

Set forth below is information regarding all securities issued by us without registration under the Securities Act during the past three years after giving effect to the Share Consolidation. The information presented below does not give effect to our corporate reorganization as described in the prospectus forming part of this Registration Statement. We believe that each of such issuances was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Rule 701 and/or Regulation S under the Securities Act. No underwriter or underwriting discount or commission was involved in any of the transactions set forth in this Item 7.

Common Share Issuances

- On February 28, 2020, we issued 1,555,317 of our common shares in a private placement, at a price of $1.64 per share, for an aggregate offering price of $2,556,320.
- On February 9, 2021, we issued 2,085,687 of our common shares in a private placement, at a price of $2.935 per share, for an aggregate offering price of $6,121,572.
- Since January 1, 2019, we have issued 651,566 of our common shares pursuant to the exercise of warrants, with exercise prices ranging from $1.64 to $4.70 per share, for aggregate consideration of $2,430,083.
- On February 1, March 1, and March 31, 2021, we issued an aggregate of 25,551 of our common shares at a price of $3.35 per share, in exchange for services performed.
- On October 15, 2021 and November 8, 2021, we issued 3,261,000 of our common shares in connection with the underwritten US IPO Offering (the "**US IPO Offering**"). 2,906,000 common shares were issued at closing on October 15, 2021 and 355,000 were issued in connection with a partial over-allotment exercise on November 8, 2021) at $5.11 a price per unit (US$4.13 at the October 15, 2021 Bank of Canada Daily Exchange Rate of US$1.00 = $1.2379), with each unit consisting of one common and one common share purchase warrant ("**IPO Common Share Purchase Warrant**") for

aggregate gross proceeds of $16,663,710. A.G.P./Alliance Global Partners acted as the representative of the underwriter and the sole book-running manager for the US IPO Offering.

Stock Option Grants

- Since January 1, 2019, we have granted our employees, consultants and advisors options to purchase an aggregate of 941,005 options to acquire common shares under our equity compensation plans at exercise prices ranging from $1.64 to $3.29 per share.

Warrants

- On February 28, 2020, we issued warrants to purchase an aggregate of 1,567,213 common shares for exercise prices ranging between $1.64 to $2.94 per share, in connection with the common share issuance of the same date referenced above. As of the date of this registration statement, all of the warrants have either been exercised or have expired.
- On February 9, 2021, we issued warrants to purchase an aggregate of 2,144,005 common shares for an exercise price of $4.70 per share, in connection with the common share issuance of the same date referenced above. As of the date of this registration statement, none of the warrants have been exercised.
- On October 15, 2021, we issued IPO Common Share Purchase Warrants to purchase an aggregate of 3,341,900 common shares for an exercise price of $5.90 (U.S. $4.77 at the October 15, 2021 Bank of Canada Daily Exchange Rate) per share, in connection with the underwritten US IPO Offering. We issued 2,906,000 IPO Common Share Purchase Warrants in connection with the U.S. IPO Offering units and an additional 435,900 Common Share Purchase Warrants in connection with A.G.P./Alliance Global Partners' exercise of its option for the purchase of up to 435,900 additional Common Share Purchase Warrants that same day.

Other than the issuances in connection with the U.S. IPO Offering on October 15, 2021, none of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Item 8. Exhibits and Financial Statement Schedules

The exhibits listed in the exhibits index, appearing elsewhere in this Registration Statement, have been filed as part of this Registration Statement.

All schedules have been omitted because they are not required, are not applicable or the information is otherwise set forth in the financial statements and related notes thereto.

EXHIBIT INDEX

Exhibit Number	Description
1.1**	Form of Underwriting Agreement
3.1**	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)
4.1**	Specimen common share certificate (incorporated by reference to Exhibit 2.1 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
4.2**	Form of Warrant
4.3**	Form of Pre-Funded Warrant
4.4**	Form of Compensation Warrant
4.5**	Form of Private Placement Warrant (incorporated by reference to Exhibit 4.4 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021).
4.6**	Form of IPO Common Share Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021).
4.7**	Form of IPO Compensation Warrant (incorporated by reference to Exhibit 4.4 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021).
5.1**	Opinion of Fasken Martineau DuMoulin LLP
5.2**	Opinion of Troutman Pepper Hamilton Sanders LLP
10.1%**	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)
10.2#**	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)
10.3**	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)
10.4#%**	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)
10.5**	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)
10.6%**	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)
10.7%**	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)
10.8%**	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)
10.9#**	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 Registration Statement on Form F-1 filed on July 21, 2021)

Exhibit Number	Description
10.10%**	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)
10.11#**	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 Registration Statement on Form F-1 filed on July 21, 2021)
10.12%**	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)
10.13**	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)
10.14**	Form of Warrant Agency Agreement
10.15#**	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)
10.16#**	Consulting Services Agreement, dated effective December 20, 2021, by and between the Company, W.B. Rowlands & Co. Ltd., and William Bruce Rowlands (incorporated by reference to Exhibit 4.15 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
10.17#**	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)
10.18%**	Patent Rights Purchase Agreement dated effective May 26, 2014 between Dr. Richard Johnson, Dr. Takahiko Nakagawa and the Company (incorporated by reference to Exhibit 4.17 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
10.19%**	Equity Agreement dated effective June 23, 2014 between the Company and the University of Florida Research Foundation, Inc. (incorporated by reference to Exhibit 4.18 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
10.20%**	Sponsored Research Agreement dated May 27, 2021 between the Regents of the University of Colorado and the Company (incorporated by reference to Exhibit 4.19 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
10.21%**	Combined Master Services Agreement made on July 19, 2021 between the Company and Quotient Sciences Limited (incorporated by reference to Exhibit 4.20 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
10.22**	Development and Clinical Manufacturing Services Agreement dated effective August 17, 2021 between the Company and Lonza Ltd. (incorporated by reference to Exhibit 4.21 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
10.23**	Global Master Services Agreement between Altasciences Company Inc., (a contract research organization) and the Company dated effective December 22, 2021 (incorporated by reference to Exhibit 4.22 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
10.24**	Proposal for XORTX Therapeutics Inc., dated February 21, 2022, by and between the Company and Covar Pharmaceuticals Inc. (incorporated by reference to Exhibit 4.23 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
10.25**	Proposal for XORTX Therapeutics Inc., dated December 6, 2021, by and between the Company and Covar Pharmaceuticals Inc. (incorporated by reference to Exhibit 4.24 to the Company's Annual Report on Form 20-F filed on May 3, 2022)

Exhibit Number	Description
10.26%**	Proposal, dated as of March 29, 2022, by and between the Company and Curia Spain, S.A.U. (incorporated by reference to Exhibit 4.25 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
10.27#**	Consulting Amending Agreement, dated as of January 27, 2022, by and between the Company and Stephen Haworth (incorporated by reference to Exhibit 4.26 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
10.28#**	Agreement, dated as of November 1, 2021, by and between the Company and Amar Keshri (incorporated by reference to Exhibit 4.27 to the Company's Annual Report on Form 20-F filed on May 3, 2022)
21.1**	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)
23.1*	Consent of independent registered public accounting firm (Smythe LLP)
23.2**	Consent of Fasken Martineau DuMoulin LLP (included in Exhibit 5.1)
23.3**	Consent of Troutman Pepper Hamilton Sanders LLP (included in Exhibit 5.2).
24.1**	Powers of Attorney (included on signature page to the registration statement)
107*	Filing Fee Table

* Filed herewith.

** Previously filed.

% Portions of this Exhibit have been omitted from the document because it is both not material and the type of information that the Registrant treats as private or confidential.

# Indicates management contract or compensatory plan.

Item 9. Undertakings

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions described in Item 6 hereof, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes:

- To provide the underwriter specified in the underwriting agreement, at the closing, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- That for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4), or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
- That for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this Amendment No. 2 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Calgary, Provice of Alberta, Canada, on September 21, 2022.

XORTX Therapeutics Inc.

By: /s/ Allen Davidoff
Name: Allen Davidoff
Title: President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 2 to the Registration Statement has been signed by the following persons in the capacities and on September 21, 2022.

Signatures	Title
/s/ Allen Davidoff Allen Davidoff	President and Chief Executive Officer and Director (Principal Executive Officer)
/s/ Amar Keshri Amar Keshri	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
* William Farley	Director
* Anthony Giovinazzo	Director
* Ian Klassen	Director
* Jacqueline Le Saux	Director
* Raymond Pratt	Director
* Paul Van Damme	Director

*By: /s/ Allen Davidoff
Name: Allen Davidoff
Title: Attorney-in-fact

AUTHORIZED REPRESENTATIVE

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned certifies that it is the duly authorized United States representative of the registrant and has duly caused this Amendment No. 2 to the Registration Statement on Form F-1 to be signed by the undersigned, thereunto duly authorized, on September 21, 2022.

PUGLISI & ASSOCIATES

By: /s/ Donald J. Puglisi

Name: Donald J. Puglisi
Title: Managing Director

Exhibit 23.1

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in this Registration Statement on Form F-1 of Xortx Therapeutics Inc. of our auditors' report dated April 7, 2022, relating to the consolidated financial statements for the years ended December 31, 2021 and 2020, 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.

We also consent to the reference to us as experts in matters of accounting and audit in this registration statement.

/s/ Smythe LLP

Smythe LLP
Chartered Professional Accountants

Vancouver, Canada
September 21, 2022

Exhibit 107

Calculation of Filing Fee Tables
FORM F-1

(Form Type)

XORTX THERAPEUTICS INC.

(Exact Name of Registrant as Specified in its Charter)

N/A

(Translation of Registrant's Name into English)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price (1)(2)	Fee Rate	Amount of Registration Fee
Newly Registered Securities								
Fees Previously Paid	Equity	Common Share Units, each Common Share Unit consisting of one common share, no par value, and one warrant, each to purchase one common share(3)	Rule 457(o)			$ 6,900,000(6)	$92.70 per $1,000,000	$ 639.63
Fees Previously Paid	Equity	Common shares included in the Common Share Units(3)	Rule 457(g)					
Fees Previously Paid	Equity	Warrants included in the Common Share Units(3)	Rule 457(g)					
Fees Previously Paid	Equity	Pre-Funded Warrant Units, each Pre-Funded Warrant Unit consisting of one pre-funded warrant to purchase one common share, no par value, and one warrant, each to purchase one common share(3)(4)	Rule 457(o)					
Fees Previously Paid	Equity	Common shares underlying the pre-funded warrants included in the Pre-Funded Warrant Units(3)	Rule 457(o)					
Fees Previously Paid	Equity	Warrants included in the Pre-Funded Warrant Units(3)	Rule 457(g)					
Fees Previously Paid	Equity	Warrants to be issued to the Underwriters(5)	Rule 457(g)			$ 300,000	$92.70 per $1,000,000	$ 27.81
Fees Previously Paid	Equity	Common shares underlying Warrants to be issued to the Representative(5)	Rule 457(o)					
Fees Previously Paid	-	-	-	-	-	-	-	-
		Total Offering Amounts				$ 7,200,000		$ 667.44
		Total Fees Previously Paid						$ 1,112.40
		Total Fee Offsets						$ 667.44
		Net Fee Due						$ -

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933 (the "**Securities Act**"). Includes the offering price attributable to additional shares that the underwriters have the option to purchase to cover over-allotments, if any.

(2) The registration fee is calculated in accordance with Rule 457(o) under the Securities Act, based on an estimate of the proposed maximum aggregate offering price.

(3) In accordance with Rule 416(a), we are also registering an indeterminate number of additional common shares that shall be issuable pursuant to Rule 416 to prevent dilution resulting from share splits, share dividends or similar transactions.

(4) The proposed maximum aggregate offering price of the common shares proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the aggregate offering price of the pre-funded warrants offered and sold in the offering (plus the aggregate exercise price of the common shares issuable upon exercise of the pre-funded warrants), and as such the proposed aggregate maximum offering price of the common shares and pre-funded warrants (including the common shares issuable upon exercise of the pre-funded warrants), if any, is $6,900,000.

(5) The Registrant will issue to the underwriters warrants to purchase a number of common shares equal to an aggregate of 5.0% of the common shares and/or pre-funded warrants sold in the offering. The exercise price of the underwriters' warrants is equal to 100% of the offering price of the common shares and/or pre-funded warrants offered hereby. The underwriters' warrants are exercisable beginning six months from the effective date of the offering, from time to time, in whole or in part, within five years commencing from the effective date of the offering.

(6) Includes up to $900,000 of common shares and/or common share purchase warrants that are subject to the underwriter's option to purchase additional securities.