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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2025

OR

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

OR

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

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

For the transition period from_____to_____

Commission file number: 001-40858

XORTX Therapeutics Inc.

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

British Columbia, Canada

(Jurisdiction of Incorporation or Organization)

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

(Address of Principal Executive Offices)

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

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

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

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

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

None

(Title of Class)

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

None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 6,962,218

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

☐Yes ☒No

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

☐Yes ☒No

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

☒Yes ☐No

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

☒Yes ☐No

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

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

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

☐

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

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

☐

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

☐

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

☐Yes ☐No

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

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

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

☐ Item 17 ☐ Item 18

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

☐Yes ☒No

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

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

☐Yes ☐No

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GENERAL MATTERS

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

Unless otherwise indicated, financial information in this Annual Report on Form 20-F (the "**Annual Report**") has been prepared in accordance with International Financial Reporting Standards ("**IFRS**") as issued by the International Accounting Standards Board ("**IASB**"). Unless otherwise noted herein, all references to "$," or "dollars", "United States dollars" or "U.S. dollars" are to the currency of the United States, the Company's functional currency effective January 1, 2023, and references to "Canadian dollars," or "CAD" are to the currency of Canada.

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

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

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

In particular, forward-looking statements in this Annual Report include, but are not limited to, statements about:

- our ability to obtain additional financing;
- the accuracy of our estimates regarding expenses, costs associated with clinical trials, regulatory and commercial activities, future revenues and capital requirements;
- the success and timing of our preclinical studies and clinical trials;
- our ability to obtain and maintain regulatory approval of XORLO™, XORTX's proprietary formulation of oxypurinol, for use in the Company's XRx-026 program to treat gout, its XRx-008 program to treat autosomal dominant kidney disease ("**ADPKD**"), its XRx-101 program to treat AKI associated with respiratory virus infection, its XRx-225 program to treat diabetic nephropathy and any other product candidates we may develop, and the labeling under any approval we may obtain;
- regulatory approvals and discussions and other regulatory developments in the United States, the EU and other countries;
- the performance of third-party manufacturers and contract research organizations;
- our plans to develop and commercialize our product candidates, if they are approved;
- our plans to advance research in other kidney disease applications;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the possibility of regaining compliance with the minimum bid price requirements of the Nasdaq Stock Market LLC ("Nasdaq");
- the use of proceeds from capital raising activity;
- the successful development of our sales and marketing capabilities;
- the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available; and
- the loss of key scientific or management personnel.

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

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

We believe there is a reasonable basis for our expectations and beliefs, but they are inherently uncertain. We may not realize our expectations, and our beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements.

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

RISK FACTORS SUMMARY

The following is a summary of the uncertainties and factors (including those set forth under "Risk Factors"), that could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements.

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 and we will require substantial additional funding, which may not be available to us on acceptable terms, or at all, if we are to continue operations. Raising additional capital may cause dilution to shareholders and require us to relinquish certain rights. Our limited operating history may make it difficult 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, one of which is still in preclinical development. If we do not obtain regulatory approval of one or more of our product candidates, or experience delays in doing so, our business will be materially adversely affected.

In order for us to develop and bring our product candidates to market, we must conduct clinical trials. Clinical trials are expensive, time consuming and difficult to design and implement and involve uncertain outcomes that may not support regulatory approval. 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. In addition, 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. Meanwhile, 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. Clinical trials also require support from government agencies, which owing to political instability have in recent years seen their ability conduct inspections and carry on operations subject to interruption and delay. Furthermore, our product candidates may have undesirable adverse events that may delay or prevent marketing approval or, if approval is obtained, require them to be taken off the market, to include contraindications, warnings and precautions, limitations of use, or otherwise limit their sales.

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 are delayed 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. Additionally, 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 nature of clinical trials means that 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.

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. Such products may also face competition sooner than anticipated and may not find market acceptance. There is also no guarantee that our product candidates would obtain approval or commercialization across jurisdictions, which would limit their full market potential. Furthermore, even if we receive regulatory approvals, 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.

We operate in a highly competitive environment, and our competitors may develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted. 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. We also may not be successful in our efforts to use and expand our therapeutic platforms to build a pipeline of product candidates.

A variety of external factors could also impact our ability to successfully commercialize our products. Healthcare legislation and regulations could alter market dynamics; regulatory actions could materially and adversely affect our future financial condition and business operations; product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business; we may need to have in place increased product liability coverage when or if we begin the commercialization of our product candidates, if approved; 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; and we are exposed to foreign currency and currency fluctuation risks. Additionally, macroeconomic trends may negatively impact our operations, including fluctuations in interest rates, political instability, and barriers to trade.

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 revenue.

Risks Related to Our Securities

The price of our common shares has been and is likely to be volatile and may drop. There is no public market for our convertible securities. An investment in our securities could result in the loss of your investment and we have not, and do not plan to, pay dividends. We incur significant costs as a result of operating as a public company and our management is required to devote substantial time to corporate governance standards. As a public company we are subject to the requirements of the exchanges on which we are listed and could be subject to delisting for failure to meet exchange standards. Additionally, 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 “foreign private issuer” we have disclosure obligations that and 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. We also are subject to reduced reporting requirements as we are an “emerging growth company.” We are governed by the corporate laws of Canada which in some cases have a different effect on shareholders than the corporate laws of the United States.

Risks Related to Our Dependence on Third Parties

We 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 in some cases. We also rely on strategic partnerships to advance our business and product candidates. These relationships existing and future strategic partnerships and third party relationships are important to our business. If we are unable to maintain these relationships, if such relationships are not successful, or if we fail to foster such relationships in the future, our business could be adversely affected. Our business also depends upon our employees and personnel.

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 and on our ability to successfully protect and defend our own intellectual property, as we believe this provides us with important competitive advantages. Protecting our intellectual property could be challenging and expensive and a failure to do so could negatively impact our operations. However, intellectual property protections may still not entirely protect our intellectual property.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

1.A. Directors and Senior Management

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

Name	Position with the Company
Allen Davidoff	President and Chief Executive Officer and Director
Michael Bumby	Chief Financial Officer
Stacy Evans	Chief Business Officer
Stephen Haworth	Chief Medical Officer
Anthony J. Giovinazzo	Non-Executive Chair
Krysta Davies Foss	Director
Raymond Pratt	Director
Paul Van Damme	Director

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

1.B. Advisers

Not required.

1.C. Auditors

Davidson & Company LLP ("Davidson & Company"), of Vancouver, Canada, serves as the Company's auditor. Davidson & Company has served as the Company's auditor since January 16, 2025.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not required.

ITEM 3. KEY INFORMATION

3.A.

[Reserved]

3.B. Capitalization and Indebtedness

Not required.

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

Not required.

3.D. Risk Factors

Following is a list of risks that the Company faces in its normal course of business. The risks and uncertainties set out below are not the only ones the Company is facing, but is designed to highlight what we believe are the material factors to consider when evaluating our business and expectations. There are additional risks and uncertainties that the Company does not currently know about or that the Company currently considers immaterial which may also impair the Company's business operations and cause the price of the common shares, without par value of the Company (the "**Common Shares**") to decline. References to past events and risks are provided as examples only and are not intended to be a complete listing or representation as to whether any such risk factor presented has occurred in the past or the likelihood of it occurring in the future. If any of the following risks actually occur, the Company's business may be harmed and the Company's financial condition and results of operations may suffer significantly.

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

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a clinical-stage biotechnology company. We have incurred significant losses since our inception. Our net losses for the years ended December 31, 2023, 2024 and 2025 were US$2,158,065, US$3,313,346 and US$2,656,304 respectively. As of December 31, 2025, our accumulated deficit was approximately US$23,824,557. 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 Food and Drug Administration ("**FDA**") to perform trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates.

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

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

We are currently advancing two of our product candidates through preclinical and clinical development as well as other potential product candidates through discovery. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials for each indication for each of these product candidates. We will continue to require additional funding to complete the development and commercialization of our product candidates and to continue to advance the development of our other product candidates and such funding may not be available on acceptable terms or at all.

As the 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, if approved;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing strategic partnerships, and any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements.

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

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

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

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. The XRx-026 program for the treatment of gout, is the Company's most advanced program and closest to generating revenue. However, this program will need additional funding, approval of a NDA by the FDA, as well, market access and acceptance will be required in order to be able to generate revenue, none of which can be assured. While the XRx-008 (a product candidate in development for ADPKD) and XRx-101 (product candidate in development for AKI associated with respiratory virus infections) product candidate programs are advancing towards Phase 3 clinical trials, these programs will require additional preclinical studies or clinical development as well as regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We face significant development risk as our product candidates advance further through clinical development. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- successful and timely FDA approval and market access of the XRx-026 program;
- timely completion of our preclinical studies and our current and future clinical trials, which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to complete Investigational New Drug ("IND") application-enabling studies and successfully submit INDs or comparable applications to allow us to initiate clinical trials for our current or any future product candidates;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities the safety, efficacy, and acceptable risk-to-benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential adverse events 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, if approved;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current Good Manufacturing Practices ("**cGMP**") requirements;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; and
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, if approved, 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, one of which is still in preclinical development. If we do not obtain regulatory approval of one or more of our product candidates, or experience significant delays in doing so, our business will be materially adversely affected.

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

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

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

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

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

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

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

Subject to further discussions with FDA, clinical activities related to our programs XRx-026, XRx-008 and XRx-101 continue to evolve. The current priority of the Company is to advance the XRx-026 development program for the treatment of gout. The XRx-026 program is in planning stage for a bridging pharmacokinetic clinical trial. With respect to the XRx-008 program for the treatment of ADPKD - a Phase 3 “registration” clinical trial is planned, and in addition a Phase 3 clinical trial for XRx-101 product candidate program in the treatment of acute kidney injury (“AKI”) associated with respiratory virus infections. Clinical activities are costly, and the Company may not be successful in raising funding. We may experience delays in our ongoing or future clinical trials, and we do not know whether future clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement or completion of these planned clinical trials could be substantially delayed or prevented by many factors, including:

- inability to generate satisfactory preclinical, toxicology or other in vivo or in vitro data capable of supporting the initiation or continuation of clinical trials;
- further discussions with the FDA or other regulatory agencies regarding the scope or design of our clinical trials;
- the limited number of, and competition for, suitable sites to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- any delay or failure to obtain approval or agreement from regulatory authorities to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required to finance a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient supplies of the product candidate for our clinical trials;

- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or Clinical Research Organizations ("**CROs**"), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delay or failure to obtain institutional review board ("**IRB**") approval to conduct a clinical trial at each prospective clinical trial site;
- slower than expected trial subject rates of patient recruitment and enrollment, or other failures to recruit and enroll subjects, which could be particularly challenging for our trials relating to AKI in respiratory virus infection patients;
- failure of subjects to complete the clinical trial;
- the inability to enroll a sufficient number of subjects in studies as required by the FDA to ensure adequate statistical power to detect statistically significant treatment effects, in particular, as we are developing certain of our product candidates for the treatment of rare diseases, we may face more limited pools of patients from which to draw for clinical testing and an 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;
- unforeseen safety issues, including severe or unexpected drug-related adverse events experienced by clinical trial subjects, including possible deaths;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of subjects or clinical investigators to follow our clinical trial protocols;
- inability to monitor subjects adequately during or after treatment by us or our CROs;
- our CROs, clinical study sites or investigators failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing; and
- our clinical trials may be suspended or terminated upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future strategic partners that have responsibility for the clinical development of any of our product candidates.

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

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

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

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

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

In particular, we are developing certain of our product candidates 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 granted 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, if approved.

Our product candidates may be associated with have undesirable adverse events 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, or limitations of use in labeling, or otherwise limit their sales.

Our products are in varied stages of development ranging from preclinical to late-stage clinical trial development. All of our product candidates are required to undergo ongoing safety testing in humans through well-designed and IRB-approved clinical trials. However, not all adverse events associated with product candidates can be predicted or anticipated. Unforeseen adverse events 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 adverse events, 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 adverse events caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications and limitations of use to the approved product's label or the dissemination of safety alerts to physicians, pharmacies, and patients;
- we may be required to change the way the product is administered, conduct additional clinical trials or develop a REMS ("**Risk Evaluation and Mitigation Strategy**") for the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

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

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

For our clinical trials that we may conduct at sites outside the United States, particularly in countries that may have ongoing economic, social, political or health related issues, in addition to the risks listed above, we may experience adverse impacts.

Clinical trials conducted outside of the United States carry certain risks, including:

- 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, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- the refusal of the FDA and Health Canada and other regulatory agencies to accept data from clinical trials in these affected geographies.

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

There are a number of incentive programs administered by the FDA and other regulatory bodies to facilitate development of drugs in areas of unmet medical need, such as fast track designation and breakthrough therapy designation. Our product candidates may not qualify for or maintain designations under these or any of the other of FDA's existing or future programs to expedite drug development in areas of unmet medical need. Our inability to fully take advantage of these incentive programs may require us to run larger trials, incur delays, lose opportunities that may not otherwise be available to us, lose marketing exclusivity for which we would otherwise be eligible and incur greater expense in the development of our product candidates. Even if a product candidate qualifies for one of these programs, it may not receive approval on an expedited basis or at all. In addition, the regulatory body may later decide that the product candidate no longer meets the criteria for designation and revoke it.

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

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

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

Disruptions at the FDA and other government agencies caused by reductions in force, funding shortages, government shutdowns internal policy changes, 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, sufficient staffing, 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, political instability has led the U.S. government to shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Ongoing changes in government policies and practices on matters of public health may adversely impact our development and commercialization efforts. Decisions about the development of product candidates are often based on interactions with FDA and regulatory guidance provided by the agency following such interactions. If FDA does not agree with our decisions resulting from such interactions and guidance or there are subsequent policy changes, review and approval of our product candidates may be delayed or not occur at all.

Separately, in response to global pandemics or public health emergencies, the FDA or other regulatory authorities may adopt policy measures that restrict or delay inspections or clinical trials.

If these issues prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

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

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

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

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

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

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

Risks Related to 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 needed 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 is associated with undesirable or unintended adverse events, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval for the product or that limit or restrict its commercial use, if approved.

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 policies, statutes or regulations, changes in regulatory review for each submitted product application, or reductions in personnel needed to review product applications, may cause delays in the approval or rejection of an application. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

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

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

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

- our inability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authority that any of our product candidates are safe and effective for their proposed indications;

- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocols, trial designs or implementation of the trials;

- the FDA or similar foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or similar foreign regulatory authorities for marketing approval, or that regulatory agencies may require us to include a larger number of patients than we anticipated;
- upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate or may identify other current good clinical practices ("**GCP**") deficiencies related to the trials;
- the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies may fail to meet the requirements of the FDA or comparable foreign regulatory authorities;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates, including any potential companion diagnostics, may be insufficient or inadequate;
- the medical standard of care or the approval policies or regulations of the FDA or similar foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for marketing approval; or
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a new drug application or other comparable marketing submissions in foreign jurisdictions or to obtain approval of our product candidates in the United States or elsewhere.

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

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

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

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

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

Specifically, there are a large number of companies developing or marketing treatments for gout, polycystic kidney disease, AKI, respiratory virus infections, 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 are developing new treatments for gout, cardiovascular, kidney disease or diabetes that may affect the progression of acute, intermittent or chronic kidney disease.

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

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

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

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

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

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

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

Our product candidates that are in preclinical and clinical development may never be approved and/or be commercially successful. Even when available on the market following approval, 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, if approved, 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 events, or the prevalence and severity of adverse events;
- sales, marketing and distribution support;
- availability of coverage and reimbursement amounts from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the cost-effectiveness of our approved products;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products; the extent to which the product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular diseases;
- whether the product can be used effectively with other therapies to achieve higher response rates;
- adverse publicity about our approved products or favorable publicity about competitive products;
- relative convenience, ease of use, ease of administration and other perceived advantages of our products over alternative products; and
- potential product liability claims.

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

FDA has granted the Company's Orphan Drug Designation request for XRx-008. We will continue to seek orphan drug status for one or more of our product candidates, including in jurisdictions outside the U.S., but even where it is granted, we may be unable to maintain any benefits associated with orphan drug status, including market exclusivity for any of the product candidates that we are developing. If our competitors are able to obtain orphan product exclusivity for their products in specific indications, we may not be able to have competing product candidates approved in those indications by the applicable regulatory authority for a significant period of time.

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

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

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

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

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

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

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

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the negotiated "maximum fair prices" for ten selected Part D drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional Part D drugs for the second cycle of negotiations. The negotiated prices for this second group will be effective on January 1, 2027. While there had been some questions about the Trump Administration's position on this program, on September 30, 2025, CMS issued final guidance for the third negotiation cycle. On January 27, 2026, CMS announced its selection of 15 additional drugs (covered under either Part B or Part D) for the third cycle of negotiations. The negotiated prices for this third group will be effective on January 1, 2028. CMS also selected one previously negotiated drug for the program's first renegotiations.

In April 2025, President Trump signed an Executive Order with the goal of lowering prescription drug prices in the United States. The Order includes directives to various government agencies to take steps to achieve this goal. The Department of Health and Human Services is to propose guidance for the Medicare Drug Negotiation Program aimed at increasing transparency, prioritizing high-cost drugs, and minimizing negative effects on pharmaceutical innovation. Additional areas of focus, reflected in the Executive Order, include reforming the pharmaceutical supply chain, accelerating approvals of generics and biosimilars, streamlining reclassification of some prescription drugs to OTC status, steps to simplify and expand the importation of prescription drugs, and reducing anti-competitive behavior by pharmaceutical companies, including patent abuse and market manipulation. The success of these efforts is uncertain and the impact on our business and the pharmaceutical industry in general is not yet known.

In May 2025, President Trump issued an executive order implementing the concept of most-favored nation pricing. Under this order, the Department of Health and Human Services, in coordination with other federal agencies, is directed to take actions to ensure that the price of prescription drugs paid by federal health insurers, including Medicare and Medicaid, is in line with the prices paid in comparably developed nations.

As an alternative to the Affordable Care Act, President Trump recently announced the Great Healthcare Plan. As presented, the plan is intended to lower drug prices by increasing competition and benchmarking U.S. drug prices to other countries, reduce insurance premiums by redirecting subsidies from insurers to individuals, increase accountability and transparency from insurers, and promote consumer choice by giving individuals more direct control over how healthcare dollars are spent. Legislative and regulatory action will be required to fully implement the plan. It is unclear how these proposed changes will impact our business and the pharmaceutical industry in general.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters, Form 483s, 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. Changes in government policies and practices in the U.S. under the new presidential administration, including reductions in staffing at FDA, are ongoing. These changes may adversely impact our development and commercialization efforts. 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 testing of our product candidates or commercialization of our product candidates, if approved.

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 share price;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates, if approved.

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

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

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

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

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

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure and that of any third-party billing and collections provider we use may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such the federal privacy rules for health information promulgated under the Health Insurance Portability and Accountability Act of 1996, as amended ("**HIPAA**") or state securities laws, and regulatory penalties. We are in the process of implementing security measures to prevent unauthorized access to our valuable trade secrets, patient data, and other confidential information, there is no guarantee that we can continue to protect our systems from breach. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or providers, process claims and appeals, conduct research and development activities, collect, process and prepare company financial information, provide information about any future products, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

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

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

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

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

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

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

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

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

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, including as a result of trade barriers and the imposition of tariffs. 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.

Of note, in April 2025, President Trump signed an Executive Order with the goal of lowering prescription drug prices in the United States. The Order includes directives to various government agencies to take steps to achieve this goal. The Department of Health and Human Services is to propose guidance for the Medicare Drug Negotiation Program aimed at increasing transparency, prioritizing high-cost drugs, and minimizing negative effects on pharmaceutical innovation. Additional areas of focus, reflected in the Executive Order, include reforming the pharmaceutical supply chain, accelerating approvals of generics and biosimilars, streamlining reclassification of some prescription drugs to OTC status, steps to simplify and expand the importation of prescription drugs, and reducing anti-competitive behavior by pharmaceutical companies, including patent abuse and market manipulation. The success of these efforts is uncertain and the impact on our business and the pharmaceutical industry in general is not yet known.

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, trade barriers and tariffs, 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 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 approved. 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 approved product ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of any products for which we receive approval.

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.

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

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

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

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

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

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

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

Risks Related to Our Securities

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

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

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.

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

The Company has received a notice of non-compliance from Nasdaq relating to the minimum bid price requirement set forth in Nasdaq Rule 5550(a)(2) that requires a minimum bid price of at least US$1.00 for 30 consecutive business days (the "**Minimum Bid Requirement**") and is working to regain compliance within the prescribed period (see Item 4). The Company has until April 13, 2026 to meet the Minimum Bid Requirement. If we are unable to achieve and maintain compliance with such listing standards or other Nasdaq listing requirements in the future, our Common Shares could be delisted from Nasdaq. Even if we cure the deficiency and meet the Minimum Bid Requirement discussed in this Annual Report our securities may fail to meet the continued listing requirements to be listed on Nasdaq. If Nasdaq delists our Common Shares from trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a determination that our Common Shares are 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.

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 incur significant costs as a result of operating as a public company and our management is required to devote substantial time to corporate governance standards.

We are currently listed on the TSX Venture Exchange ("**TSXV**") and Nasdaq under the trading symbol "XRTX" and on each of the Frankfurt, Munich, Berlin, and Stuttgart Stock Exchanges under the trading symbol "ANU". As a public company in these jurisdictions, we incur significant legal, accounting, administrative and other expenses.

As a result of being a public company, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and the related rules and regulations implemented by the Securities and Exchange Commission (the "**SEC**"), the applicable Canadian securities regulators, and Nasdaq, have increased legal and financial compliance costs and have made some compliance activities more time consuming. We are investing resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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", as such term is defined in Rule 405 under the Securities Act of 1933, as amended (the "**Securities Act**"), and 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 principal shareholders are currently exempt from the insider reporting and short-swing profit recovery requirements in Section 16 of the U.S. Exchange Act of 1934, as amended (the "**Exchange Act**"), while our officers, directors and are exempt from such requirements through an exemption available to Canadian organized entities. Accordingly, our shareholders may not know on as timely a basis as with U.S. domestic issuers when our officers, directors and principal shareholders purchase or sell their Common Shares, as the reporting deadlines under the corresponding Canadian insider reporting requirements are longer (we have four days to report). As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) which, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. As a result of such varied reporting obligations, shareholders should not expect to receive the same information at the same time as information provided by U.S. domestic companies.

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

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

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

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not "emerging growth companies," including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 ("**Section 404**"). We could be an "emerging growth company" for up to five years following the completion of the US IPO Offering, although, if we have more than US$1.235 billion in annual revenue, if the market value of our Common Shares held by non-affiliates exceeds US$700 million as of June 30 of any year, or we issue more than US$1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an "emerging growth company" as of the following December 31. Investors could find our Common Shares less attractive if we choose to rely on these exemptions. If some investors find our Common Shares less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our Common Shares and our share price may be more volatile. We have elected not to take advantage of the extended transition period allowed for emerging growth companies for complying with new or revised accounting guidance as allowed by Section 107 of the JOBS Act and Section 7(a)(2)(B) of the Securities Act.

We have identified a material weakness in our internal controls over financial reporting. If our remediation efforts to address the material weakness are not effective, or if we experience additional material weaknesses or otherwise 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.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with the applicable accounting standards, which for us, is IFRS. 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 we conduct in connection with Section 404 or any subsequent testing by our independent registered public accounting firm if required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our Common Shares.

In connection with the preparation of our financial statements for the fiscal year ended December 31, 2025, our management continued to identify material weakness related to a material weakness in the period end closing process and related management review controls, that was first identified for the fiscal year ended December 31, 2024. While the Company has implemented enhanced control activities to remediate previously identified material weaknesses, such remedial activities have been determined to not yet be operating effective as of December 31, 2025 and that the material weakness remains. As part of these remediation efforts, our management conducted a comprehensive review of the Company's internal control framework in accordance with the criteria set forth in the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO Criteria"). During this process, our management, determined that certain remediation activities require additional time and resources to complete, including controls that are currently being implemented or that require a sufficient period of operation before management can conclude on their operating effectiveness.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to the material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. We cannot assure you that all of our existing material weaknesses have been identified, or that we will not in the future identify additional material weaknesses. If we fail to maintain the adequacy of our internal control over financial reporting in accordance with the COSO Criteria, as may be modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404.

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

There is no public market for our convertible securities.

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

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

Our Common Shares are listed on the TSXV, Nasdaq and we also trade over the counter on the Frankfurt Borse. 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 our Common Shares when desired, or the trading prices that you may obtain for your Common Shares.

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

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

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

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

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

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

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

The rules governing "passive foreign investment companies," ("**PFICs**") can have adverse effects on U.S. Holders (as defined below in "*Material U.S. Federal Income Tax Considerations for U.S. Holders*") of the Company's shares for U.S. federal income tax purposes. Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets (generally, using a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income (including cash), we would be characterized as a PFIC for U.S. federal income tax purposes. The determination of whether we are a PFIC, which must be made annually after the close of each taxable year, depends on the particular facts and circumstances and may also be affected by the application of the PFIC rules, which are subject to differing interpretations. Our status as a PFIC will depend on the composition of our income and the composition and value of our assets (including goodwill and other intangible assets), which will be affected by how, and how quickly, we spend any cash that is raised in an offering or in any other subsequent financing transaction. Moreover, our ability to earn specific types of income that will be treated as non-passive for purposes of the PFIC rules is uncertain with respect to future years. We believe we were classified as a PFIC during the taxable year ended December 31, 2025. Based on current business plans and financial expectations, we may be a PFIC for our taxable year ending December 31, 2026, or future taxable years, and we cannot provide any assurances regarding our PFIC status for any current or future taxable year.

If we are a PFIC, a U.S. Holder would be subject to adverse U.S. federal income tax consequences, such as ineligibility for certain preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. Investors should consult their own tax advisors regarding the potential consequences if we were or were to become a PFIC, including the availability, and advisability, of, and procedure for making certain tax elections that may in certain circumstances mitigate possible adverse U.S. federal income tax consequences that may result from PFIC status.

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

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

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

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

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

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

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

Negative macroeconomic and geopolitical trends or other events outside our control could harm our future revenue and financial condition, our ability to access capital, and increase our costs and expenses.

There can be no assurance that the Company's business (or that of our CROs, contract manufacturing organizations and other contractors and consultants) and corresponding financial performance will not be adversely affected by general negative economic or consumer trends or events, including pandemics, public health crises, weather catastrophes, acts of terrorism, war, trade disputes, and political instability. In particular, global economic markets have seen extensive volatility over the past few years owing to the outbreak of the COVID-19 pandemic, interest-rate volatility and inflation, the war between Russia and Ukraine, conflict in the Middle East, the war against Iran, including potential disruption to energy markets, and political instability, including shutdowns of the U.S. government.

These events, including responses to such events, have created, and may continue to create, significant disruption of the global economy, supply chains and distribution channels, and financial and labor markets. If such conditions continue, recur or worsen, this may have a material adverse effect on the Company's business and financial condition, its ability to conduct clinical trials, and its ability to access capital on favorable terms, or at all, could be negatively impacted as a result of such conditions and consequences. Additionally, our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these events or the impacts of any macro event could disrupt our business and harm our operations and financial condition and increase our costs and expenses. Furthermore, such economic conditions have produced downward pressure on share prices and on the availability of credit while also driving up interest rates, further complicating borrowing and lending activities. If current levels of market disruption and volatility continue or increase, the Company might experience reductions in business activity, increases in funding costs, decreases in asset values, additional write-downs and impairment charges and lower profitability.

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 strategic partnerships with other companies that we believe can provide such capabilities, and we may enter into similar such arrangements in the future, including as a result of the Vectus Acquisition (as defined herein). Our existing strategic partnerships, and any future strategic partnerships we enter, 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, if approved, 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 the risks relating to product development, regulatory approval and commercialization described in this AIF also apply to the activities of our program strategic partners.

Additionally, subject to its contractual obligations to us, if one of our strategic partners is involved in a business combination, the partner might deemphasize or terminate the development or commercialization efforts 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 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 strategic partnerships and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our therapeutic platforms and our business may be materially and adversely affected.

We rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates. We may not be able to obtain regulatory approval for our product candidates or commercialize any products that may result from our development efforts, and for which we receive approval, if we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us.

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

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

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

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

Part of our reliance and partnerships with CROs includes reliance on third-party doctors, nurses or healthcare workers in our clinical trials. Fraud caused by third party errors or omissions, including intentional or unintentional failure to administer drugs as whole, failure to administer in a timely fashion, failure to accurately record data or complete the assigned measures or tests 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 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 have relied 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 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, relating to supply chain issues or changes in government policies, including trade barriers and the impact of tariffs, 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 to produce 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.

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, Michael Bumby, our Chief Financial Officer, Dr. Stephen Haworth, our Chief Medical Officer, Dr. Stacy Evans, our Chief Business Officer, as well as other members of our senior management, scientific and clinical team. We currently do not maintain "key person" insurance coverage for Dr. Davidoff and Michael Bumby. 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 20-F, we had two full-time employees, one part-time employee and 14 consultants. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. Additionally, as our product candidates enter and advance through preclinical studies and any clinical trials, we will need to expand our development, manufacturing, regulatory sales and marketing capabilities or contract with other organizations to provide these capabilities for us. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity amongst remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected and our ability to generate or grow revenue could be reduced, prohibiting us from implementing 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 have been a party to license agreements to which we in-license key patent and patent applications for use in one or more of our product candidates. Such agreements can be important to our business and can 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.

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 protection of our intellectual property could result in 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all 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 will lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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

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

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

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

Composition-of-matter patents on the active pharmaceutical ingredient, or API, in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because such patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. We currently have granted U.S. patents with claims to the use of uric acid lowering agents to treat insulin resistance or diabetic nephropathy, and patent applications filed in the U.S., EU and under the Patent Cooperation Treaty with similar claims for the treatment of metabolic syndrome, diabetes, fatty liver disease as well as a composition of matter patent for formulations of xanthine oxidase inhibitors. In addition, we have received grant composition/formulation patents from the USPTO, and the European patent office.

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.

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.

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

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

We are generally also subject to all 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.

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.

ITEM 4. INFORMATION ON THE COMPANY

4.A. History and Development of the Company

Name, Address and Incorporation

The Company was incorporated to carry on business under the *Business Corporations Act* (British Columbia) (the "**BCBCA**") as "APAC Resources Inc." on May 31, 2011 and with registration number BC0911882. XORTX Pharma Corp. ("**XORTX Pharma**") was incorporated under the laws of Alberta, Canada on August 24, 2012 under the name ReVasCor Inc. and was continued under the Canada Business Corporations Act on February 27, 2013 under the name of XORTX Pharma Corp. XORTX Pharma completed a reverse take-over transaction on January 10, 2018 (the "**RTO**") with the Company. As part of this transaction, the Company changed its name to its current name: "XORTX Therapeutics Inc." XORTX Pharma remains as a wholly owned subsidiary of the Company and is the Company's only subsidiary.

Our registered office is located at 250 Howe Street, 20th Floor, Vancouver, British Columbia, V6C 3R8. Our operations office and mailing address is 3710 – 33rd Street NW, Calgary, Alberta, T2L 2M1 and our telephone number is (403) 455-7727. Our website address is www.xortx.com. The information contained on, or that can be accessed through, our website is not a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

General Development of the Business of the Company

Recent Developments

On February 4, 2026, the Company announced that it entered into an extension agreement with Vectus Biosystems Limited ("Vectus") to extend the time available to complete Vectus Acquisition (as defined herein). The agreement extends the time available to the Company and Vectus to close the Vectus Acquisition until March 31, 2026, to provide additional time for transfer of intellectual property. The Vectus Acquisition is subject to finalization of closing documentation and the satisfaction of typical closing conditions, including receipt of all regulatory approvals, and compliance with applicable stock exchange requirements and securities laws.

On February 4, 2026, the Company disclosed that in connection with the appointment of Krysta Davies Foss to the Board of Directors, it granted Ms. Davies Foss 20,000 options to purchase Common Shares at an exercise price of CAD $0.69 for a period of five years, in accordance with the Company's Stock Option Plan.

On March 5, 2026, the Company announced that it had filed its notice of meeting, management information circular (the "Circular") and related documents with the securities regulators in connection with its upcoming Annual and Special Meeting of shareholders to be held March 24, 2026 (the "Meeting"). At the Meeting, shareholders will to vote to: (1) to fix the number of directors to be elected at the Meeting at five; (2) to elect directors of the Company; (3) to appoint Davidson & Company as the auditor of the Company for the ensuing year and to authorize the directors of the Company to fix the remuneration of the auditor; (4) to confirm and approve the Company's Stock Option Plan; and (5) to consider and vote on an ordinary resolution to amend the Company's articles to provide for a consolidation of the Company's Common Shares on the basis of up to five (5) pre-consolidation Common Shares for every one (1) post-consolidation Common Shares (the "2026 Share Consolidation") as more particularly described in the Circular.

On March 13, 2026, the Company announced that the independent proxy advisory firm, Institutional Shareholder Services ("ISS") recommended Shareholders vote FOR on the 2026 Share Consolidation at the March 24, 2026 shareholder Meeting. In relation to the share consolidation, ISS recommended voting FOR this resolution stating: "…the stock consolidation should have no direct impact on shareholder value and could enhance the long-term growth prospects of the Company by broadening its financing alternatives." ISS is an independent proxy voting and corporate governance advisory firm whose shareholder voting recommendations and analysis are subscribed to, and are relied upon, by many pension funds, investment managers, mutual funds and other institutional shareholders.

On March 18, 2026, the Company announced that it was substituting its slate of nominees to the Company's board of directors at the March 24, 2026 shareholder meeting. The company announced that it would be nominating Messrs. George Scorsis, Richard Grieve and Mika Grasso (collectively, the "New Nominees") for election to the Company's board of directors (the "Board") instead of Ms. Krysta Davies Foss and Messrs. Raymond Pratt and Paul Van Damme. The Company is currently in negotiations with respect to a significant financing initiative and it is a condition of that financing that the New Nominees be added to the Board in place of the three existing nominees. In the event that the financing is not completed, the New Nominees will resign from the Board with those vacancies to be filled in due course by the Company. The financing is subject to the approval of the TSXV Venture Exchange.

Three Year History

The three year history of the Company and its business are outlined below. Please note that the details below have been adjusted to reflect the consolidation of the Company's Common Shares on the basis of one post-consolidation Share for every nine pre-consolidation Common Shares, effective November 9, 2023 (the "**2023 Share Consolidation**").

2023

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

On January 19, 2023, the Company issued 328,777 Common Shares for the exercise of pre-funded warrants at US$0.0009 per share in the amount of US$296.

On January 19, 2023, the Company announced positive topline results from the XRX-OXY-101 – Bridging Pharmacokinetics Clinical Trial characterizing the pharmacokinetics of the Company's proprietary formulation of oral oxypurinol, XORLO™. Results showed that XORLO™ was well tolerated across the various dosing regimens. No safety issues were identified in any of the four parts of the study on the 88 subjects who received the drug. Results from the four parts of the study showed (i) a substantial increase in the bioavailability of oxypurinol with the XORLO™ formulation platform; (ii) increased dose proportionality compared to non-formulated oxypurinol; (iii) a multiple dosing regimen that achieved therapeutic target values; and (iv) confirmation of the innovations claimed in the recently granted US and EU patents regarding the Company's unique proprietary formulations of oxypurinol.

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

On March 14, 2023, the Company announced submission of a Type D meeting request to the FDA and a response setting the date for a virtual meeting on May 1, 2023.

On April 21, 2023, the Company announced the FDA granted ODD for oxypurinol – "orphan-drug designation request of oxypurinol is granted for treatment of autosomal dominant polycystic kidney disease".

On May 4, 2023, the Company announced completion of a Type D meeting with the FDA, which resulted in the identification of additional clinical endpoints potentially available for accelerated approval and further understanding of the FDA expectations for the accelerated approval of XORLO™ for the treatment of ADPKD.

On May 23, 2023 the Company announced that Nasdaq granted the Company's request for a 180-day extension (until November 20, 2023) to regain compliance with Nasdaq's minimum bid price requirement of US$1.00 per share. The Company was first notified by Nasdaq of its failure to comply with the Minimum Bid Requirement on November 22, 2022, and was given until May 22, 2023 to regain compliance.

On June 6, 2023, the Company announced that it would present scientific data supporting the recent ODD at the PKD Foundation – "PKD Connect" meeting held June 22-24, 2023, in Denver, Colorado. The studies presented were conducted by Dr. Charles Edelstein of the University of Colorado and represent the seminal research leading to the FDA ODD grant that was announced by the Company on April 21, 2023.

On June 29, 2023, the Company announced the results of its annual and special meeting of shareholders held Wednesday, June 28, 2023. Approximately 41.6% of the total number of Common Shares of the Company issued and outstanding were represented at the meeting. All matters presented for approval at the Meeting were duly authorized and approved by shareholders, including election of all six management nominees to the Board of Directors of the Company, the appointment of Smythe LLP as auditors of the Company for the ensuing year and authorization of the directors to fix their remuneration, and re-approval of the Stock Option Plan.

On August 4, 2023, the Company announced the appointment of James Fairbairn as Chief Financial Officer to replace Amar Keshri, who left the Company's employ effective July 31, 2023. James Fairbairn was appointed Interim Chief Financial Officer effective June 29, 2023.

On August 29, 2023, the Company announced that it submitted an ODD application for XORLO™ to the EMA.

On September 7, 2023, the Company announced its participation in the Kidney Foundation's "Kidney March", in support of the almost 4 million Canadians who have chronic kidney disease.

On September 28, 2023, the Company announced the acceptance of an abstract submitted to the American Society of Nephrology. The abstract entitled, "*The Effect of Lowering Uric Acid with a Xanthine Oxidase Inhibitor on PKD in Mice,*" was reviewed by the ASN review panel for scientific merit and novel discoveries.

On October 27, 2023, the Company announced the results of its special meeting of shareholders held on the same date. A total of 8,453,229 Common Shares (2023 Share Consolidation) of the Company were represented at the Meeting, representing approximately 47% of the total number of Common Shares of the Company issued and outstanding. The sole item of business of the meeting, being shareholder approval of the consolidation resolution was duly authorized and approved.

On November 2, 2023, the Company announced the presentation of new research findings at the American Society of Nephrology meeting being held November 3, 2023 in Philadelphia.

On November 8, 2023, the Company announced that the Board of Directors approved the 2023 Share Consolidation.

On November 10, 2023, the Company announced that the 2023 Share Consolidation was completed. The Company's shares began trading on a post-consolidation basis on the TSXV and the Nasdaq on Tuesday, November 14, 2023.

On November 29, 2023, the Company announced receipt of a letter of compliance from the Nasdaq Listing Qualifications Department in connection with the Minimum Bid Requirement. To regain compliance, the Company's Common Shares were required to trade at or above US$1.00 per share for at least 10 consecutive trading days. Following implementation of the 2023 Share Consolidation, this requirement was met on November 28, 2023 and the Company received the compliance letter from Nasdaq on such date. As a result, the deficiency in Nasdaq's Minimum Bid Requirement was cured.

On November 30, 2023, the Company announced that it entered into an At The Market Offering Agreement with H.C. Wainwright & Co., LLC ("**Wainwright**"), pursuant to which the Company, at its discretion, may offer and sell, from time to time, through Wainwright, Common Shares without par value having an aggregate offering price of up to US$3,701,931 (the "**ATM Offering**"). A cash commission of 3.0% on the aggregate gross proceeds raised under the ATM Offering will be paid to Wainwright in connection with its services.

2024

On January 2, 2024, the Company announced the appointment of Patrick Treanor to the Board of Directors and announced the resignation of Ian Klassen, both effective December 31, 2023.

On January 3, 2024, the Company announced submission of a new patent for the treatment of chronic kidney disease ("**CKD**"). The patent is designed to protect new discoveries and strategies for the treatment of individuals with varied degrees of kidney function in the setting of CKD. Importantly, this patent entitled "*Oral and Sublingual Formulations of Xanthine Oxidase Inhibitors and Methods of Treating Disease*," outlines new formulations and methods for safer and more effective the use of XOI in the setting of CKD in particular ADPKD, diabetic nephropathy ("**DN**"), IgA nephropathy, lupus nephritis and focal segmental glomerulosclerosis.

On February 1, 2024, the Company provided details on a consulting agreement entered between the Company and Plutus Bridge Capital Inc. ("**Plutus**"). XORTX retained Plutus pursuant to an amended and restated consulting agreement made as of January 27, 2024 (the "**Plutus Agreement**") to provide social media marketing and related services in accordance with TSXV policies. Plutus is an independently owned public relations and capital markets consultancy firm based in Vancouver, British Columbia. Plutus will use commercially reasonable efforts to increase public awareness of the Company and its products, services, and securities through online advertising campaigns.

On February 15 and March 4, 2024, the Company closed two tranches of a non-brokered offering of 899,717 common share units at a price of CAD $3 per common share unit for aggregate gross proceeds of US$2,000,549 (CAD $2,699,151). Each common share unit consisted of one common share and one warrant to purchase one common share at CAD $4.50 per common share for a period of two years. The warrants were immediately exercisable and may be exercised for two years from the date of issuance, provided however that, if the Common Shares on the TSXV trade at greater than CAD $6.00 for ten (10) or more consecutive trading days, the warrants will be accelerated and the warrants will expire on the 30th business day following notice. In connection with the non-brokered offering, the Company paid finder's fees of US$97,241 (CAD $132,551), representing a 5% finder's fee on certain subscriptions to qualified finders.

On March 11, 2024, the Company announced an amendment to the terms of an aggregate of 1,101,433 outstanding common share purchase warrants, as follows:

- In connection with 231,746 warrants issued pursuant to the private placement that closed on February 9, 2021 and which had an original exercise price of CAD $42.26 per share (CAD $0.40 per share, adjusted to reflect the 2021 share consolidation and 2023 Share Consolidation), to amend the exercise price from CAD $42.26 to US$5.00.

- In connection with 286,355 warrants issued pursuant to the prospectus offering that closed on October 15, 2021 and which had an original exercise price of US$42.93 per share (US$4.77 per share, adjusted to reflect the 2023 Share Consolidation) to amend the exercise price from US$42.93 to US$5.00.

- In connection with 583,332 warrants issued pursuant to the prospectus offering that closed on October 7, 2022 and which had an original exercise price of US$10.98 per share (US$1.22 per share, adjusted to reflect the 2023 Share Consolidation) to amend the exercise price from US$10.98 to US$5.00.

Pursuant to the polices of the TSXV the terms of the warrants, as amended, are subject to an acceleration expiry provision such that if for any ten consecutive trading dates (the "**Premium Trading Days**") during the unexpired term of the warrants, the closing price of the Company's shares on the TSXV exceeds US$6.50 (approximately CAD $8.7562), the exercise period of the warrants would be reduced to 30 days, starting seven days after the last Premium Trading Day. The Company will announce any such accelerated expiry date by press release. All other terms of the warrants remained unchanged.

On March 19, 2024, the Company summarized its achievements in 2023 noting it was year of substantial clinical, technological and regulatory progress. Key milestones included: 1) the grant of U.S. ODD for the XRx-008 program for ADPKD that is being developed under the US FDA 505(b)(2) rules; and 2) ongoing discussions with the FDA have aligned our endpoints and other Phase 3 clinical trial elements to make XORLO™ the Company's proprietary oxypurinol formulation, eligible for accelerated approval.

On March 27, 2024, the Company announced the appointment of Dr. Ronald Perrone, MD to its Clinical Advisory Board. Dr. Perrone is Professor of Medicine at Tufts University School of Medicine in Boston, Massachusetts. Dr. Perrone is board certified in Nephrology. He did his Internal Medicine residency at Grady Memorial Hospital in Atlanta and Nephrology fellowship at Boston University Medical Center. Dr. Perrone's research involves clinical investigations focused on kidney disease with a special emphasis on polycystic kidney disease (**"PKD"**). He is heavily involved in clinical research in ADPKD clinical trials and works with regulatory agencies such as the FDA to contribute to the development of database assessment tools to validate total kidney volume as a biomarker for PKD progression. Dr. Perrone's focus on translational clinical trial interventions in ADPKD includes trials for Sanofi, Reata, Palladio Biosciences, HALT-PKD, the TAME PKD Metformin trial, TEMPO and REPRISE trials for Tolvaptan. Dr. Perrone also initiated a PKD Database Consortium in 2007 which led to the creation of the PKD Outcomes Consortium in 2009. The PKD Outcomes Consortium, comprising contributors from academia, the pharmaceutical industry, National Institute of Health ("**NIH**"), FDA, the Clinical Data Interchange Standards Consortium ("**CDISC**"), and the Critical Path Institute ("**C-Path**"), is creating the groundwork for validation of for biomarkers and clinical trial and regulatory endpoints in ADPKD. This work is ongoing and involves frequent interactions with the FDA and the European Medicines Agency ("**EMA**"). Dr. Perron has co-authored over 100 peer-reviewed publications on a variety of kidney diseases, including many on PKD.

On April 8, 2024, the Company announced the appointment of Abigail Jenkins, a biotech industry veteran with deep experience with the commercialization of therapies for renal and cardiovascular disease, to its Board of Directors. Ms. Jenkins brings over 20 years of leadership experience in the biopharmaceutical industry delivering life-enhancing therapies from research to commercialization for patients in need. Ms. Jenkins is the current President, CEO and a Director of Gamida Cell, a Nasdaq listed company. Ms. Jenkins holds a Master of Science in biotechnology and biotech business enterprise from Johns Hopkins University, a Bachelor of Arts in psychology and biology from Indiana University, and a certificate of achievement in General Management as a Kellogg Executive Scholar. She was recognized in 2022 as one of the PharmaVoice 100, one of the industry's 100 Most Inspiring Leaders, Disrupter category, for change agents who define excellence in leadership in biopharma.

On April 22, 2024, the Company announced a research paper titled, "*Raising serum uric acid with a uricase inhibitor worsens PKD in rat and mouse models*," was accepted for publication in the peer-reviewed *American Journal of Physiology-Renal Physiology and published online April 19, 2024*. The study reported health consequences associated with increasing serum uric acid ("**SUA**") in mice or rat models of ADPKD, specifically the effects of increasing SUA on cyst growth and kidney size. This study showed, for the first time, that chronically increased SUA can significantly increase cyst index and increase kidney size in ADPKD. Independent of the modifying effects of chronically increased SUA, a fundamental new discovery from this study was that over expression of xanthine oxidase ("**XO**") in kidney tissue was present, suggesting aberrant purine metabolism may be present in ADPKD and suggesting a possible role of XO in disease progression. Inhibition of XO using XORLO™, XORTX's proprietary formulation of oxypurinol, substantially lowered uric acid concentrations, attenuated the effects of chronically increased SUA on cyst index and kidney size in the RC/RC mouse model of ADPKD in this study.

On April 30, 2024, the Company announced that it received TSXV approval to amend the terms of 1,024,099 outstanding common share purchase warrants. The exercise price of the warrants was adjusted to US$5.00 per share, down from higher original prices, following a series of private placements in 2021 and 2022.

On May 17, 2024, the Company announced that it received approval from the TSXV to amend the terms of 910,000 outstanding common share purchase warrants issued on October 15, 2021. The exercise price was reduced to US$5.00 per share, down from the previous adjusted price of US$42.93 per share following a 9:1 consolidation. This re-pricing completed a previously announced adjustment and included an acceleration provision.

On June 4, 2024, the Company announced that it will participate in the BIO International Convention 2024, held from June 3-6, 2024. Dr. Allen Davidoff, the CEO, will present an overview of the Company, covering its progress and upcoming regulatory and clinical activities.

On August 20, 2024, the Company announced that its abstract, titled "*Xanthine oxidase in rats, mice, and humans with polycystic kidney disease*," was accepted by the American Society of Nephrology ("**ASN**"). The study, conducted at the University of Colorado under Dr. Charles Edelstein's independent lab, will be presented during the session on "Genetic Diseases: Cystic - Therapeutic Investigations and Prognosis."

On August 29, 2024, the Company reported that recent peer-reviewed research highlights genetic factors linked to the over-expression of XO, playing a role in kidney disease and other conditions. These findings support XORTX's approach of inhibiting XO to treat kidney and other diseases.

On September 12, 2024, the Company refiled its management's discussion and analysis ("**MD&A**") for the financial year ended December 31, 2023, and the interim period ended June 30, 2024, following a review by the Alberta Securities Commission. The amended MD&A includes the full definition of Disclosure Controls and Procedures and additional details on the use of funds and estimated costs for the Company's product candidates. The amended MD&A was reviewed by the Audit Committee and approved by the Board of Directors.

On September 13, 2024, the Company announced that it held its annual and special meeting on September 12, 2024, with 31% of the Company's shares represented. All resolutions were approved, including the election of seven management nominees to the Board of Directors, the appointment of Smythe LLP as auditors, authorization for directors to fix their remuneration, and the re-approval of the Stock Option Plan. Detailed voting results can be found in the Report of Voting Results on the Company's SEDAR+ profile.

On October 9, 2024, the Company announced that it launched a precision medicine program, building on recent peer-reviewed research that links genetic factors to the over-expression of XO, contributing to kidney disease and other conditions. This innovative approach combines genetic diagnostics and XO inhibition to target individuals most in need, expanding the Company's therapeutic programs for kidney disease and related diseases like sepsis.

On October 18, 2024, the Company closed a registered direct offering and concurrent private placement for the purchase and sale of 810,810 Common Shares (or pre-funded warrants in lieu thereof) (the "**October 2024 Offering**"). At closing, through the registered direct offering, the company sold: (i) 320,000 Common Shares at a price of US$1.85 per share. and (ii) 490,810 pre-funded warrants at a price of US$1.8499 per pre-funded unit, with each pre-funded unit consisting of one pre-funded warrant to purchase one common share (the "**October 2024 Pre-Funded Warrants**"). The October 2024 Pre-Funded Warrants have an exercise price of US$0.00001 per share and will terminate once exercised in full. As at the date of this Annual Report, all October 2024 Pre-Funded Warrants have been exercised. In addition, through the concurrent private placement, the Company sold 810,810 common share purchase warrants (the "**October 2024 Common Warrants**"), with an exercise price of US$2.18 per Common Warrant Share, exercisable immediately upon issuance with a term of five years from the date of issuance. Aggregate gross proceeds amounted to US$1,499,993. The Company used the net proceeds from the offering for working capital and general corporate purposes.

On October 24, 2024, the Company announced the acceptance of an abstract titled "*Xanthine oxidase in rats, mice, and humans with polycystic kidney disease*," by the American Society of Nephrology. The study was conducted at the University of Colorado and sponsored by XORTX. Key findings included:

- In rat or mouse models of Polycystic Kidney Disease (PKD), increasing uric acid worsened cyst growth, while using the XO inhibitor Oxypurinol reduced both uric acid levels and cyst growth.

- Clinical results from the Halt Clinical Trial showed that elevated serum uric acid was linked to increased kidney volume, faster PKD progression, and earlier onset of high blood pressure in patients.

On December 12, 2024, the Company announced that Dr. Davidoff would present at the Rare and Genetic Kidney Disease Summit in Boston on December 12, 2024. His presentation, titled "*Autosomal Dominant Polycystic Kidney Disease - Genetic and Environmental Factors → Evidence for Aberrant Purine Metabolism as a Second Hit Determining Disease Progression*," highlighted XORTX's recent discoveries, including research showing that genetic factors influencing XO over-expression may play a significant role in the progression of ADPKD by impacting purine metabolism.

On December 19, 2024, Dr. Michael Bumby, a biotech/pharma industry veteran, joined the Company as its Chief Financial Officer replacing James Fairbairn, the Company's then current Chief Financial Officer.

2025

On January 6, 2025, the Company announced the launch of a new late-stage program, XRx-026, to treat gout. This program is focused on developing a treatment for individuals who are intolerant to allopurinol, a common medication used to manage gout.

On January 17, 2025, the Company announced that it changed its auditor from Smythe LLP to Davidson & Company, effective January 16, 2025. The Board of Directors accepted the resignation of Smythe LLP and appointed Davidson & Company as the Company's auditor, to hold office until the Company's next annual general meeting. There were no reservations in Smythe LLP's audit reports, and no reportable events occurred between the Company and its former auditor.

On January 29, 2025, the Company participated in the Microcap Conference hosted by DealFlow Events in Atlantic City, where the Company updated investors on its gout program, XRx-026, and its plans to advance the program through a New Drug Application ("**NDA**") filing. The presentation also covered the progress of XRx-008, the program for ADPKD, including preparations for registration clinical trials.

On February 24, 2025, the Company submitted a Type C meeting request to the FDA regarding its XRx-026 program for the treatment of gout. This request follows the advancement of XORLO™, the Company's proprietary drug formulation of oxypurinol, to a stage where discussion with the FDA was necessary to effectively continue advancement of the development program. The purpose of the meeting was to review the XRx-026 program and assess its readiness for submitting an NDA through the FDA's 505(b)(2) development pathway for gaining marketing approval for XORLO™ in the US.

On March 19, 2025, the Company provided an update regarding communications with the FDA. The Company prepared a broad Type B meeting review at the FDA's request, including review of chemistry, manufacturing, pharmacology, toxicology and clinical evidence regarding the Company's XRx-026 program for the treatment of gout. The purpose of the Type B meeting will be to review the XRx-026 program and its readiness for submission of an NDA to gain marketing approval for XORLO™ in the US using the FDA 505(b)(2) development pathway. The Company believes that a Type B meeting will facilitate a broader discussion toward market approval.

On April 17, 2025, the Company received a notification from the Nasdaq that it was not in compliance with the Minimum Bid Requirement While the failure to met the Minimum Bid Price does not have an immediate impact on the Company's listing, in accordance with Listing Rule 5810(c)(3)(A), the Company has 180 calendar days from the date of notification to regain compliance with the Minimum Bid Requirement, during which time the shares will continue to trade on the Nasdaq Capital Market. If at any time before the end of the 180 calendar day period, the bid price of the shares closes at or above US$1.00 per share for a minimum of 10 consecutive business days (subject to Nasdaq's discretion to extend this 10 day period under Rule 5810(c)(3)(H)), and the Company continues to meet the other listing requirements, Nasdaq will provide written notification that the Company has achieved compliance with the Minimum Bid Requirement and will consider such deficiency resolved. The notification letter does not affect the Company's compliance status with its TSXV listing. The Company will evaluate all options to resolve the deficiency and regain compliance with the Minimum Bid Requirement.

On April 28, 2025, the Company announced receipt of notification that the European Patent office will grant the Company a patent "Xanthine Oxidase Inhibitor Formulations." The patent covers compositions and methods of formulating using XORTX's proprietary formulations of xanthine oxidase inhibitors ("XOI") for the treatment of the health consequences of chronically high uric acid, gout, renal, cardiovascular and other diseases where aberrant purine metabolism has been implicated in disease progression.

On April 30, 2025, the Company announced that it had received responses from the FDA on its Type B Meeting Package related to the development of XRX-026 for the treatment of gout. The responses clarified the remaining steps for submission of an NDA. Under the IND planned for submission, additional data will be provided to the FDA including support for the 505(b)2 development pathway, and a proposed two-part bridging clinical study will be conducted with the first part characterizing the pharmacokinetics of XORTX's commercial form of oxypurinol tablet and the second part evaluating the therapeutic equivalence between allopurinol in gout patients and XORTX's commercial form of oxypurinol.

On May 19, 2025, the Company announced a non-brokered private placement to raise up to US$3,000,000 through the issuance of up to 3,409,090 units of the Company at a price of US$0.88 per unit, with each unit will be comprised of one Common Share and one Common Share purchase warrant (the "**May 2025 Offering**"). On July 22, 2025, the Company announced that the May 2025 Offering would not proceed.

On July 22, 2025, the Company closed a non-brokered private placement of units (the "**July 2025 Units**"), whereby it issued 1,267,123 units at a price of US$0.73 per unit for aggregate gross proceeds of US$925,000 pursuant to the listed issuer financing exemption under Part 5A of National Instrument 45-106 — Prospectus Exemptions (the "**Listed Issuer Financing Exemption**," such offering the "**July 2025 Offering**"). Each July 2025 Unit consisted of one Common Share one common share purchase warrant (the "**July 2025 Warrants**"). Each July 2025 Warrant entitles the holder thereof the right to purchase one additional Common Share at a price of US$1.20 for a period of sixty (60) months following the date of issuance; provided, however, that if the closing price of the Common Shares on Nasdaq is greater than US$2.00 for ten or more consecutive trading days, the July 2025 Warrants will accelerate and expire on the 30th business day following the date of the notice of such period. Because the July 2025 offering was completed pursuant to the Listed Issuer Financing Exemption, the securities issued were not be subject to a hold period pursuant to applicable Canadian securities laws. The Company used the proceeds of the July 2025 Offering for gout programs, general corporate and working capital purposes. In connection with the July 2025 offering, the Company paid an aggregate of US$12,264 in finder's fees and issued, in aggregate, 16,800 finder's warrants (the "**July 2025 Finder's Warrants**").

On August 7, 2025, the Company provided a corporate update on its 2025 progress and strategic goals for 2026, indicating that the first half of 2025 was marked by intense focus and significant advancement, solidifying a robust plan to accelerate the lead gout program towards a NDA filing, aiming to propel technology toward revenue generation and foster substantial shareholder value. It was noted that the XRx-026 program was approximately 12 months from filing a NDA with the FDA for XORLO™ marketing approval, targeting an estimated US$700 million per year market opportunity (considering the inflation-adjusted Febuxostat peak sales). Key objectives outlined included: IND application; XRX-OXY-102 clinical trial; chemistry, manufacturing and controls; commercialization preparations; and European market strategy.

On August 8, 2025, the Company closed a non-brokered private placement of 156,849 units at a price of US$0.73 (the "**August 2025 Units**"), for aggregate gross proceeds of US$114,500 (the "**August 2025 Private Placement**"). Each August 2025 Unit consisted of one Common Share and one Common Share purchase warrant (the "**August 2025 Warrants**"), with each warrant entitling the holder thereof the right to purchase one additional Common Share at a price of US$1.20 for a period of sixty (60) months following the date of issuance; provided, however, that if the closing price of the Common Shares on Nasdaq is greater than US$2.00 for ten (10) or more consecutive trading days, the August 2025 Warrants will accelerate and expire on the 30th business day following the date of the notice of such period. The securities issued in the August 2025 Private Placement were subject to a four month and a day hold. No finder's fees were paid.

On September 3, 2025, the Company announced the initiation of IND preparation for its lead program, XRx-026, focused on the treatment of gout. In support of this milestone, the Company engaged Allucent (formerly, Cato Research Canada Inc.), a global contract research organization specializing in regulatory and clinical development, pursuant to the 2017 master services agreement. Preparation of the IND will include a comprehensive review of non-clinical, pharmacologic, toxicological, and regulatory progress, and will incorporate the clinical development plan and protocol for a pharmacologic characterization study of XORLO™, the Company's proprietary formulation of oxypurinol, in fed and fasted states.

On October 15, 2025, the Company entered into a binding term sheet to acquire a renal anti-fibrotic therapeutic program from Vectus Biosystems Limited ("**Vectus**"), an Australian company (the "**Vectus Acquisition**"). The renal anti-fibrotic therapeutic program includes a novel new chemical entity, VB4-P5, along with its associated intellectual property, regulatory documentation, and manufacturing data. The program is currently at the pre-IND stage of development and targets both rare and prevalent forms of kidney disease. Under the terms XORTX will acquire intellectual property specifically related to the VB4-P5 compound and the data generated by Vectus from its work on the VB4-P5 small molecule and related assets in exchange for US$3.0 million, payable in Common Shares or Common Share equivalents of XORTX at a deemed issue price of US$0.86 per Common Share Equivalent (the "**Vectus Issue Price**"), with the Vectus Issue Price subject to adjustment in certain circumstances provided, however, that the Vectus Issue Price will not be lower than the Discounted Market Price (as defined in the policies of the TSXV) on October 16, 2025. The Vectus Acquisition was to occur no later than 90 days post signing, being January 13, 2026. As, detailed above, on January 13, 2026, the Company entered into an extension agreement with Vectus to extend the closing date to March 31, 2026, and as of the date of the Form 20-F, the transaction is in the final stages of closing.

On October 20, 2025, the Company announced that it received a notice from the Nasdaq Stock Market LLC granting the Company's request for an 180-day extension to regain compliance with the minimum bid price requirement of US$1.00 per share under the Nasdaq Rule 5550(a)(2). The Company was first notified by Nasdaq that it was non-compliant with this requirement on April 17, 2025, and was given until October 14, 2025 to regain compliance. The Company now has until April 13, 2026 to meet the requirement. The Company is working to resolve this issue.

On October 29, 2025, the Company announced that it had closed its registered direct offering for the purchase and sale of 1,750,000 Common Shares or pre-funded warrants in a registered direct offering at a purchase price of US$0.63 per common share. In connection with the offering, an institutional investor acquired 572,470 Common Shares and 1,177,530 Pre-Funded Warrants. Each Pre-funded Warrant will entitle the holder to acquire one common share at an exercise price of US$0.0001 per share. The gross proceeds from the offering were US$1,102,500, before deducting placement agent fees and other offering expenses payable by the Company. D. Boral Capital LLC acted as sole placement agent for the offering, and was issued 87,500 agent warrants, each exercisable into one Common Share of the Company at an exercise price of US$0.69 commencing 181 days following their issuance, and having a term of 18 months from the closing date. D. Boral Capital LLC was also paid a cash commission of US$77,175, equal to 7% of the gross proceeds of the Offering.

On December 31, 2025, the Company announced recent peer-reviewed, independent, published research reports that expand current knowledge that genetic factors are linked to the over-expression of xanthine oxidase ("XO"), high chronic uric acid concentrations in the blood and gout.

Also on December 31, 2025, the Company announced appointment of Krysta Davies Foss as a director and the resignation of Bill Farley, Abigail Jenkins and Patrick Treanor reducing the Board of Directors to five members. Ms. Davies Foss is a seasoned biotechnology executive with more than 25 years of experience advising pharmaceutical and biotechnology companies on development strategy, commercialization, and market preparedness across a broad range of therapeutic areas. She currently serves as Chief Executive Officer of Triad Strategic Services, a leading pharma and biotech strategy consulting firm. In addition to her executive role, Ms. Davies Foss serves on multiple boards, including the Canadian Organization for Rare Disorders (CORD), and has provided strategic intelligence and advisory services to organizations ranging from incubators and early-stage startups to large multinational pharmaceutical companies. Her experience spans the full product development lifecycle, from early innovation through global commercialization.

Significant Acquisitions During 2025

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

Additional Information

Additional information relating to the Company can be found on the SEDAR+ website at www.sedarplus.ca and on the SEC website at www.sec.gov. The SEC's website contains reports, information statements, and other information regarding issuers that file electronically with the SEC. We also maintain a website at www.xortx.com. Information contained in, or accessible through, our website is not a part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference.

4.B. Business Overview

Overview

XORTX Therapeutics is a late clinical-stage biotechnology company focused on identifying, developing and potentially commercializing therapies to treat diseases modulated by aberrant purine and uric acid metabolism in indications such as gout, autosomal dominant polycystic kidney disease ("ADPKD") an orphan (rare) disease and larger, more prevalent type 2 diabetic nephropathy ("T2DN") as well as acute kidney injury ("AKI") associated with respiratory virus infection.

Our focus is on developing unique therapeutic products to:

- treat gout patients, specifically those that have shown an intolerance to treatment with allopurinol;
- slow or reverse the progression of chronic kidney disease in patients at risk of end stage kidney failure;
- address the immediate need of individuals facing AKI associated with respiratory virus infection; and
- Treat patients with type 2 diabetic nephropathy.

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

We believe that our technology is underpinned by well-established research and insights into the underlying biology of aberrant purine metabolism, chronically high serum uric acid and its health consequences. Our aim is to advance a novel proprietary formulation of oxypurinol, a uric acid lowering agent that works by effectively inhibiting xanthine oxidase. We are developing innovative product candidates that include new or existing drugs that we believe can be adapted to address different disease indications where aberrant purine metabolism and/or elevated uric acid is a common denominator, including gout, polycystic kidney disease, pre-diabetes, insulin resistance, metabolic syndrome, diabetes, diabetic nephropathy, and infection. We are focused on building a pipeline of assets to address the unmet medical needs of patients with a variety of serious or life-threatening diseases using our innovative formulations of oxypurinol, and in combination with uric acid lowering agents - a pipeline-in-a-product strategy supported by our intellectual property, established exclusive manufacturing agreements, and proposed clinical trials with experienced clinicians.

Our four current unique product development programs are:

- XRx-026, a program for the treatment of gout;

- XRx-008, a program for the treatment of ADPKD;
- XRx-101, a program to treat AKI associated with respiratory virus infection, AKI and associated health consequences; and
- XRx-225, a program for the treatment of T2DN.

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

Our Proprietary Therapeutic Platforms

Our expertise and understanding of the pathological effects of aberrant purine metabolism combined with our understanding of uric acid lowering agent structure and function, has enabled the development of our proprietary therapeutic platforms. These are a complementary suite of therapeutic formulations designed to provide unique solutions for acute and chronic disease. We believe our therapeutic platforms can be used alone, or in combination, with synergistic activity for a tailored approach to a variety of disease entities that can address disease in multiple body systems through management of chronic or acute hyperuricemia, immune modulation, and metabolic disease. We continue to leverage these therapeutic platforms to expand our pipeline of novel and next generation drug-based product candidates that we believe could represent significant improvements to the standard of care in multiple acute and chronic cardiovascular and renal diseases.

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

Highly modular and customizable

We believe our platforms can be combined in multiple ways and we believe this synergy can be applied to address acute, intermittent or chronic disease progression. For example, our XRx-026 and XRx-008 programs are designed for longer term stable chronic oral dosing of XOI, decreasing production of uric acid. We believe that our formulation technology allow us to manage the unique challenges of cardiovascular and renal disease by modulating purine metabolism and its negative health consequences on the body. Our XRx-101 program for AKI associated with respiratory virus infection is designed to produce rapid suppression of hyperuricemia then maintain purine metabolism at a low level during viral infection and target management of acute organ injury. Our XRx-008 program is designed for longer term stable chronic oral dosing of xanthine oxidase inhibitors. We believe the capabilities of our formulation technology allow us to manage the unique challenges of cardiovascular and renal disease by modulating, purine metabolism, inflammatory and oxidative state.

Fit-for-purpose

We believe our platforms can 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(s) with a design that enhances their anti-inflammatory activity. The capability of tailoring the potential therapeutic benefit of this class of new agents permits us to identify targets and diseases that may respond to treatment. Through rational design, we can further optimize those small molecules and proprietary formulations to maximize their clinical potential and importantly their therapeutic effects, while minimizing potential adverse events.

Readily scalable and transferable

We believe our in-house small molecule and formulations design expertise are intended to create a steady succession of drug product candidates that are scalable, efficient to manufacture and produce large scale, high purity active pharmaceutical drug product. We believe this will provide a competitive advantage, new intellectual property and the opportunity to provide first-in-class products that target unmet medical needs and meaningful improvements to quality of life.

Our team's expertise with the development of uric acid lowering agents, specifically regarding the development and use of xanthine oxidase inhibitors, has enabled the development of our therapeutic product candidates to treat the symptoms of, and potentially reduce gout attacks, delay the progression of ADPKD, AKI due to respiratory virus infection, and T2DN. There is no guarantee that the FDA will approve our proposed uric acid lowering agent(s) and product candidates for the treatment of gout, kidney disease or the health consequences of diabetes.

Product Candidate Pipeline

Our product candidates include XRx-026, XRx-008, XRx-101, and XRx-225. Our lead program, XRx-026 is designed to treat gout. This program has recently been prioritized by XORTX in our development efforts as we believe it represents a near-term opportunity for marketing approval and revenue generation. Under the IND planned for submission, additional data will be provided to the FDA including support for the 505(b)(2) development pathway, and a proposed two-part bridging clinical study will be conducted with the first part characterizing the pharmacokinetics of XORTX's commercial form of oxypurinol tablet and the second part evaluating the therapeutic equivalence between allopurinol in gout patients and XORTX's commercial form of oxypurinol. Additionally, manufacture of a GMP commercial drug supply to address the US gout market is required.

The Company's second program, XRx-008, has reported results for the XRX-OXY-101 Bridging Pharmacokinetic Study of XORLO™ (the "**XRX-OXY-101 PK Clinical Trial**") in advance of initiating Phase 3 registration clinical trial testing, the last stage of clinical development before application for FDA approval. In a May 2023 Type D meeting, FDA stated that it was open to considering accelerated approval based on the effects on eGFR at one year as a reasonably likely surrogate endpoint with eGFR at two years as the confirmatory endpoint. Our reported pharmacokinetic bridging study XRX-OXY-101 is intended to support both the XRx-008 and XRx-101 programs. Future late-stage clinical studies targeting attenuation or reversal of AKI in hospitalized individuals with respiratory virus infection are planned. XRx-225 is a non-clinical stage program advancing new chemical entities toward the clinical development stage.

Products

With respect to the Company's lead and most advanced development program, XRx-026, the FDA has provided responses to the Company's Type B Meeting Package clarifying the remaining steps needed for submission of an NDA through the Section 505(b)(2) regulatory pathway for the treatment of gout. Under the IND planned for submission, additional data will be provided to the FDA including support for the 505(b)(2) development pathway, and a proposed two-part bridging clinical study will be conducted with the first part characterizing the pharmacokinetics of XORTX's commercial form of oxypurinol tablet and the second part evaluating the therapeutic equivalence between allopurinol in gout patients and XORTX's commercial form of oxypurinol. The company intends to use the data generated under the IND to support a future NDA submission. XORTX intends to advance this drug to marketing approval pending favorable study results and its FDA discussions. A commercial drug supply is also required. The Company believes that peak net sales revenue for this product could reach more than US$500 million per year.

XRx-008 is XORTX's late clinical stage program focused on demonstrating the potential of its novel product candidate for ADPKD. XRx-008 is the development name given to XORTX's therapeutics program and associated proprietary oral formulation of oxypurinol, appropriate for use in individuals with progressively decreasing kidney filtering capacity.

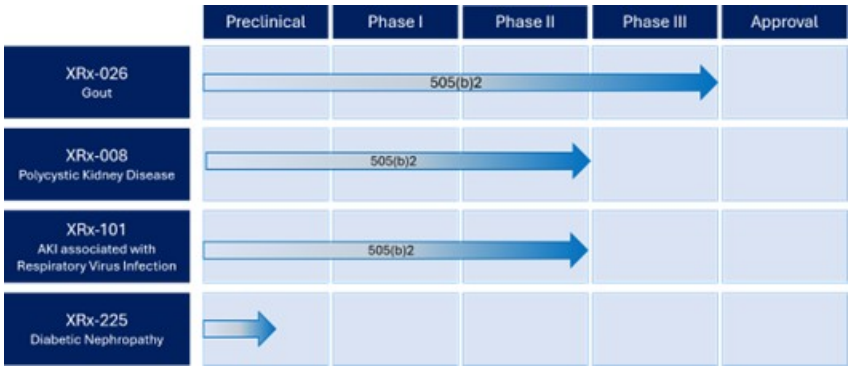
XORTX is also developing a drug product combination therapy that includes both intravenous uric acid lowering therapy combined with an oral anti-hyperuricemic xanthine oxidase inhibitor, XRx-101, for use in treating patients with AKI associated with respiratory virus infection including co-morbidities such as acute cardiac injury and sepsis.

XORTX is currently evaluating novel XOI candidates for its XRx-225 program to treat T2DN as well as developing new chemical entities to address other orphan and large market disease patients with unmet medical needs.

Patents

XORTX wholly owns composition of matter patents and applications for unique proprietary formulations of xanthine oxidase inhibitors. To date, three patents have been granted: one in the U.S. and two in Europe. XORTX has also submitted two patent applications to cover the use of uric acid lowering agents for the treatment of the health consequences of respiratory virus infection. Recently, XORTX filed a third provisional patent application covering formulations and methods of dosing xanthine oxidase inhibitors in individuals with kidney disease.

XORTX Therapeutics Pipeline:



The interpretation by XORTX based upon FDA discussions is that the 505(b)(2) pathway and right of reference to the former NDA provide XORTX the ability to rely upon previous Phase 1 and Phase 2 clinical studies and/or conduct its own additional Phase 1 and Phase 2 studies for the XRx-026, XRx-008 and XRx-101 programs. However, we may elect to conduct our own Phase 1 and Phase 2 studies as necessary or required to further support and gain marketing approval in the aforementioned programs. XORTX believes that the XRx-008 program will be eligible for accelerated review.

Our Strategy

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

1. Subject to discussions with US FDA, under the IND planned for submission, additional data will be provided to the FDA including support for the 505(b)(2) development pathway, and a proposed two-part bridging clinical study will be conducted with the first part characterizing the pharmacokinetics of XORTX's commercial form of oxypurinol tablet and the second part evaluating the therapeutic equivalence between allopurinol in gout patients and XORTX's commercial form of oxypurinol. We plan to then submit an NDA to the FDA, for the XRx-026 product candidate program, which we believe will address an unmet medical need for gout.

2. Subject to discussions with FDA, following the successful completion of the Phase 3 clinical registration trial of XRx-008 product candidate program submit an NDA to the FDA, requesting review under the Accelerated Approval program status. We believe introduction of this class of drug could establish a new standard of care for ADPKD.

3. Maximize the potential of the XRx-026 and XRx-008 product candidate programs, if approved, through independent commercialization and through opportunistic collaborations with third parties.

4. Leverage our pipeline-in-a-product strategy and experience, developing additional proprietary formulations of xanthine oxidase inhibitor and/or uric acid lowering agents to treat select rental indications and complement our activities 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 purines and nutrients within the circulation. 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 the development of gout, kidney stones, cardiovascular disease, 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.

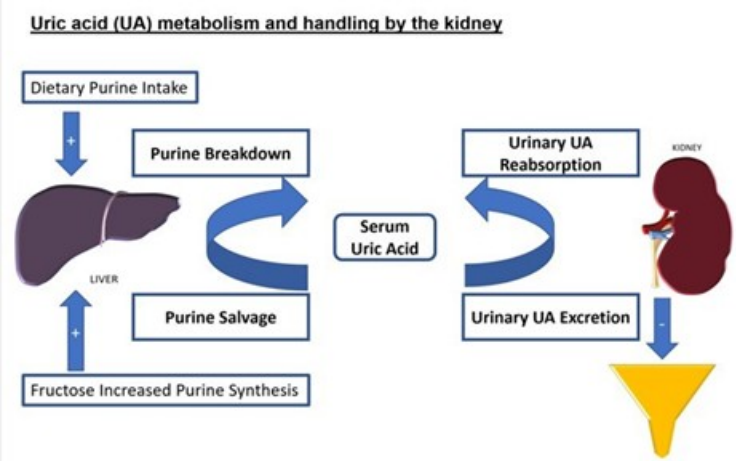


Figure 1: Dietary sources of purines such as yeast, shellfish, organ meats can lead to chronically increased nucleic acids and purines in the circulation. Both are broken down by the liver into uric acid for excretion. Fructose stimulates the liver to produce endogenous purines and can lead to increased 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. In addition, recent epidemiologic studies have reported that certain genetic factors predispose some individuals to chronically high levels of uric acid and secondary disease.

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 chronically high SUA, including gout and the rare kidney disease - ADPKD.

Gout is a miserable disease. Acute gout attacks are extremely painful, but fortunately short-lived. Chronic gout can have a very negative impact on quality of life and can be both disabling and deforming. The incidence of gout increases with age, and it is largely a disease of older men and postmenopausal women. Patients with gout frequently have other chronic diseases, particularly kidney disease, obesity, and diabetes. Patients with chronic gout usually benefit significantly from allopurinol treatment. Gout flares are reduced or eliminated, tophaceous deposits are reabsorbed and renal complications are reversed. Unfortunately, approximately 3-5% of patients treated with allopurinol develop a rash or other adverse reaction to allopurinol and must discontinue the medication. These allopurinol-intolerant patients are often without an effective alternate treatment that will lower serum uric acid (SUA) and control their chronic gout symptoms and complications. This small population of patients with chronic gout and intolerance to allopurinol has an unmet medical need and limited therapeutic alternatives. Oxypurinol treatment has the potential to benefit approximately 70-75% of these patients. The population of individuals who are intolerant of allopurinol and that could potentially benefit is estimated to number 120,000 to 150,000 patients in the US. Oxypurinol is the active metabolite of allopurinol and like allopurinol, it is a xanthine oxidase inhibitor.

Physiologically, SUA would appear to be a natural measure of therapeutic effectiveness in chronic gout. Uric acid precipitates at approximately 7 mg/dL at 37ºC. Elevated SUA is an important diagnostic measure in chronic gout and a clinical measure that can be monitored during the management of the disease and guide therapy. Observational studies have demonstrated that chronic gout patients have fewer acute gout symptoms when SUA levels are maintained at < 6 mg/dL and that tophi resolve more quickly when SUA is maintained at lower levels.

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

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

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

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

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

Current Therapies and Treatments in Development

Currently, allopurinol is the first in line drug of choice for treating individuals with gout. However, ~3-5% of individuals cannot tolerate this drug. An alternative drug, Febuxostat, has a side effect profile that limits its use in patients. The XRx-026 program aims to provide a safe, effective and well tolerated alternative therapy for individuals with chronically high serum uric acid levels that cause gout attacks.

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

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

Prior FDA Review of Oxypurinol

Oxypurinol was developed as an alternative therapy to allopurinol in gout patients who were intolerant of allopurinol. Oxypurinol is an active metabolite of allopurinol. In 2003, a third-party company Cardiome Pharma Corp. ("**Cardiome**") filed an NDA for the orphan indication of allopurinol intolerant gout. Cardiome announced via a press release dated June 24, 2004 that it had received an approvable letter from the FDA for oxypurinol for allopurinol intolerant hyperuricemia(the "**Prior FDA Review**"). The press release stated that "prior to final marketing approval, the FDA requires additional clinical and manufacturing data from Cardiome." Oxypurinol has never been approved for the treatment of gout.

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 with a lower risk of adverse events. Furthermore, we believe our proprietary small molecule discovery and formulation program innovations and engineering capabilities uniquely enable us to develop the next generation of kidney therapeutics, including new molecular entities with secondary pharmacologic effects, to help address this treatment gap. Our proprietary pipeline-in-a-product strategy uniquely allows us to utilize all of the above approaches in our mission to allow patients to manage and control the negative symptoms and progression of kidney disease.

XORTX Competitive Advantage

We are led by an experienced and dedicated management team whose average experience exceeds 15 years in the pharmaceutical industry, including several leading pharmaceutical companies. Our Board of Directors includes highly qualified researchers, pharmaceutical senior executives and experts in the fields of drug development, corporate development and pharmaceutical commercialization. We are supported by a highly regarded network of leading experts within the field of hyperuricemia, gout and 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 for the XRx-026 and XRx-008 programs, could become a significant treatment option for patients suffering from gout and ADPKD, respectively.

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-026 for the treatment of gout

Overview

The XRx-026 program is designed to decrease the chronically high serum uric acid concentration in the blood (SUA) by inhibiting the production of uric acid by the xanthine oxidase enzyme by administering a xanthine oxidase inhibitor – oxypurinol. Common symptoms that accompany chronically increased SUA are gout, prevalence of kidney stones, systemic inflammation, rheumatoid arthritis, endothelial dysfunction, metabolic syndrome, diabetes and kidney disease in patients. Many individuals with high uric acid – hyperuricemia – and gout take a xanthine oxidase inhibitor on a daily basis. For individuals who cannot tolerated allopurinol, therapeutic options are limited.

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

Potential Advantages of XORLO™ formulation from the XRx-026 program for gout

XORLO™ from the XRx-026 program, under our granted formulation patent, is a product candidate intended to be administered once daily to inhibit the xanthine oxidase enzyme and thereby decrease uric acid production consequently decreasing chronic injury associated with hyperuricemia and decrease the frequency of gout attacks, tophi and kidney stone development.

We believe our proprietary formulation of xanthine oxidase inhibitor, XORLO™ from the XRx-026 program, could become a significant treatment option for patients suffering from gout. We believe the proprietary formulation of oxypurinol – XORLO™ can increase the bioavailability of oxypurinol substantially and have reported clinical findings with this result. So far, based upon the results of publicly available third-party clinical trials, over 700 patients have been treated clinically with oxypurinol, and results have shown that the rate of adverse events such as rash and liver enzyme elevation is substantially reduced, suggesting that oxypurinol may be superior in terms of tolerability to allopurinol. The XORLO™ product candidate includes the addition of L-Arginine as bioavailability enhancer and a nephron-protective effect has been observed. Therefore, we believe our patented formulation of oxypurinol may provide an additional benefit compared to allopurinol alone. A therapeutic intervention to reduce uric acid could provide a treatment modality that ultimately reduces inflammation and modifies the underlying disease pathology. There have been no adverse events reported that are unique to oxypurinol. Importantly, in this group of over 700 patients exposed to oxypurinol, no serious adverse events related to Stevens-Johnson Syndrome have been reported.

Clinical experience with oxypurinol is extensive and it has been administered in clinical studies to patient with gout, endothelial dysfunction, and congestive heart failure. Results of those clinical trials and other clinical and non-clinical results suggest that hyperuricemia may play a pathological role in obesity, hypertension, metabolic syndrome, polycystic kidney disease, sepsis, heart disease and other disease, as yet not rigorously tested in clinical trials. Patients with congestive heart failure, hypertension are often simultaneously treated with a number of drugs plus allopurinol.

Anticipated clinical development of XORLO™

Oxypurinol, a significant pharmaceutically active ingredient of the XORLO™ product candidate, is not yet approved for marketing anywhere in the world, though it was previously reviewed by the FDA between 2003 and 2005 as sponsored by a third-party, Cardiome but it did not receive FDA marketing approval. Under the IND planned for submission, additional data will be provided to the FDA including support for the 505(b)(2) development pathway, and a proposed two-part bridging clinical study will be conducted with the first part characterizing the pharmacokinetics of XORTX's commercial form of oxypurinol tablet and the second part evaluating the therapeutic equivalence between allopurinol in gout patients and XORTX's commercial form of oxypurinol.to support our application for FDA approval of XORLO™.

We believe XORLO™ and the XRx-026 development program may utilize the FDA 505(b)(2) developmental pathway to support an application for approval of a reformulation of oxypurinol with increased bioavailability and potentially superior tolerability compared to allopurinol. We also plan to pursue the hybrid application of the EU Centralized Procedure, a procedure for the authorization of medicines, where there is a single application, a single evaluation and a single authorization throughout the European Union pursuant to article 10(3) of Directive 2001/83/EC, for the approval of this product candidate.

Based upon this strategy, the XRx-026 program has completed a bridging pharmacokinetic study – XRX-OXY-101 – designed to describe the bioavailability of the unique proprietary formulation and characterize the oral dosing for the Company's planned Marketing application for gout. Based upon discussions with the FDA, we believe an additional pharmacokinetics bridging study, with circulating oxypurinol levels in the presence of food, using the commercial formulation of tablet, should be sufficient to characterize the range of uric acid lowering in the fasted and fed state.

XRx-008

Overview

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

Current treatment of diseases

Only one therapeutic is currently approved to treat ADPKD – tolvaptan (Jynarque). This therapy has been reported to slow the progression of total kidney volume in individuals with ADPKD and decline of kidney function. Its use is limited by an adverse event profile that includes a black box warning for liver toxicity and other lesser adverse events. Together, this adverse event profile limits the use of this drug to approximately 5% of individuals diagnosed with ADPKD.

The XRx-008 program is developing a unique proprietary formulation of oxypurinol design to address the therapeutic needs of those individuals with progressing kidney disease, whose disease appears to be accelerated by the presence of hyperuricemia.

Despite it's advanced clinical stage of development, Oxypurinol has not been approved for marketing in the U.S. or elsewhere in the world.

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

The unique proprietary formulation of oxypurinol for the XRx-008 program differs from the XRx-026 program, though under our granted formulation patent, is a product candidate intended to be administered once daily to inhibit the xanthine oxidase enzyme and thereby decrease uric acid production consequently decreasing chronic injury associated with progressing kidney disease in patients 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 cardiovascular disease progression and decreases 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, from the XRx-008 program, could become a significant treatment option for patients suffering from ADPKD. We believe this formulation can increase the bioavailability of oxypurinol substantially and have reported clinical findings with this result. So far, based upon the results of publicly available third-party clinical trials, over 700 patients have been treated clinically with oxypurinol, and results have shown that the rate of adverse events such as rash and liver enzyme elevation is substantially reduced, suggesting that oxypurinol may be superior in terms of tolerability to allopurinol. The unique formulation of oxypurinol product candidate includes the addition of L-Arginine as bioavailability enhancer and a nephron-protective effect has been observed. Therefore, we believe our patented formulation of oxypurinol may provide an additional benefit compared to allopurinol alone. A therapeutic intervention to reduce uric acid could provide a treatment modality that ultimately reduces inflammation and modifies the underlying disease pathology. There have been no adverse events reported that are unique to oxypurinol. Importantly, in this group of over 700 patients exposed to oxypurinol, no serious adverse events related to Stevens-Johnson Syndrome have been reported.

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

Anticipated clinical development

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

Based upon this strategy, the XRx-008 program has completed a bridging pharmacokinetic study – XRX-OXY-101 – designed to describe the bioavailability of the unique proprietary formulation and characterize the oral dosing for the Company's planned Phase 3 clinical trial to slow or reverse progression of kidney disease in subjects with ADPKD. Subject to discussions with the FDA the Phase 3 registration trial's primary endpoint will characterize the benefit of uric acid lowering on the rate of total kidney volume expansion and secondarily measure glomerular filtration rate decline. Secondary endpoints will include change proteinuria and inflammatory markers. In a May 2023 Type D meeting, FDA stated that it was open to considering accelerated approval based on the effects on eGFR at one year as a reasonably likely surrogate endpoint with eGFR at two years as the confirmatory endpoint.

XRx-101

Overview

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

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

Current treatment of diseases

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

Potential Advantages of XRx-101

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

Anticipated clinical development of XRx-101

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

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

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

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

XRx-225

Overview

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

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

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

Current treatment of diseases

Major therapeutic interventions to treat T2DN include near-normal blood glucose control, antihypertensive treatment, and restriction of dietary proteins. Drug classes employed include hormones (such as insulin), sulfonylureas, biguanides, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, GLP-1 receptor agonists, SGLT2 inhibitors, 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

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

Anticipated clinical development of XRx-225

XRx-225 is in non-clinical development stages, and we have not conducted any clinical trials to date. XORTX is in the process of manufacturing XRx-225 in preparation for non-clinical pharmacology, toxicology, and pharmacokinetic animal testing, and then contemplates advancing to Phase 1 clinical testing, and thereafter further clinical development, subject to discussions with FDA. As the XRx-225 product candidate includes oxypurinol, we plan to leverage 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 in support of the product candidate's potential FDA approval.

Intellectual Property

Our business success will depend significantly on our ability to:

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

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

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

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

Patent Family No.	Patent Family Name	XRx-101	XRx-008 or XRx-026	XRx-225	Additional Potential Candidates
1	Xanthine Oxidase Inhibitor Formulation Patents - Kidney, Cardiovascular, Neurological	X	X	X	Other indications such as gout, 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.
Xrx-008 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 Diagnosis, Treatment, and Prevention of Kidney Disease	X		X	
5	Oral and Sublingual Formulation of Xanthine Oxidase Inhibitors and Methods of Treating Disease	X	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 and includes a pending PCT, application. XORTX-owned Patent Family Member No. 3 includes a pending PCT application. These three families relate to our key product candidates and programs including XRx-026, XRx-101, XRx-008 and XRx-225 and our therapeutic platform technology, described elsewhere in this Annual Report, and also for additional potential product candidates. Family Member No. 4 includes a provisional patent application. Family Member No. 5 includes a provisional patent application.

The XORTX owned patent family members include claims to cover AKI, and other acute organ injury due to respiratory virus infection - a program which could ultimately be expanded to a larger patient population with unmet medical needs including other viral and sepsis patients. The value of patents for reformulation or repurposed drugs is additive as is the case of orphan programs given that FDA grant of orphan drug status would provide the Company with a seven-year marketing exclusivity in the U.S. which would be more than adequate to generate acceptable rewards, given the premium pricing environment available to rare disease opportunities. Notably, this exclusivity is 10 years in Europe and Japan.

XORTX neither owns nor licenses oxypurinol, our technology is based upon proprietary formulations of oxypurinol that improve oral bioavailability. Increased bioavailability improve the drugs ability to address the therapeutic range and utility.

Manufacturing

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

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

Competition

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

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

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

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

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

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

- *XRx-026*: XORLO™ from the XRx-026 program is intended to treat patients with gout. Currently, first line gout therapy is allopurinol, marketed by several manufacturers. Febuxostat is a secondary xanthine oxidase inhibitor marketed by Takeda.

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

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

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

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

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

Government Regulation

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

U.S. Small Molecule Drug Product Development Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA, pursuant to the FDCA. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, untitled letters, Form 483s, voluntary product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

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

- completion of nonclinical laboratory tests, animal studies and formulation studies conducted according to good laboratory practices ("**GLPs**") and other applicable regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to GCPs, to establish the safety and efficacy of the proposed product for its intended use;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced to assess readiness for commercial manufacturing and conformance to the manufacturing-related elements of the application, to conduct a data integrity audit, and to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

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

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

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

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

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

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

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

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

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

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

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

U.S. Review and Approval Process

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with detailed descriptions of the product's chemistry, manufacturing, and controls, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently over US$4.6 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$400,000. 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 that provide a treatment where no adequate therapy exists. The review process for both standard and priority reviews may be extended by FDA for three additional months to consider additional, late-submitted information, or information intended to clarify information already provided in the submission in response to FDA review questions.

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

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter ("**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 ("**ETASU**"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, restricted distribution requirements, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS plan. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy as described as post marketing commitments or requirements included in the approval letter. Once granted, product approvals may be withdrawn if compliance with regulatory requirements and commitments is not maintained or problems are identified following initial marketing. Moreover, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Hatch-Waxman Act and New Drug Marketing Exclusivity

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

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

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

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

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

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

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

Patent Term Extension

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

Pediatric Clinical Trials and Exclusivity

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

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

Orphan Drug Designation and Orphan Product Exclusivity

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

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

Expedited Development and Review Programs

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

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

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

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

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

Accelerated Approval

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

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

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

FDA Commissioner's National Priority Review Voucher (CNPV) Pilot Program

In June 2025, the FDA announced the CNPV pilot program which was designed to accelerate the development and review of certain drugs and biologics that are aligned with U.S. national health priorities, such as addressing a U.S. public health crisis, developing more innovative cures for the American people, addressing a large unmet medical need, onshoring drug development and manufacturing to advance the health interests of Americans and strengthen U.S. supply chain resiliency, and increasing affordability. The FDA has stated that voucher recipients will receive a decision with respect to an application on an accelerated basis, as well as enhanced communication with review staff throughout the review process. The FDA expects the CNPV program to accelerate the application review timeline from 10-12 months to 1-2 months by convening a multidisciplinary team of physicians and scientists for a team-based review, interacting frequently with the sponsor of the application to clarify questions, and completing review of the application concurrently. The FDA retains full discretion to extend the review window if the data or application components submitted are insufficient or incomplete, if the results of the pivotal trial(s) are ambiguous, or if the review is particularly complex. The FDA has indicated the CNPV program does not change the FDA's rigorous safety and efficacy standards for review and approval. In late 2025, FDA began issuing approvals for drugs with CNPVs within the 1-2 month review timeframe. The CNPV program is new, limited in scope, and subject to evolving guidance, and available FDA resources. The FDA retains broad discretion to modify the criteria, processes, or benefits of the program and may rescind participation or alter timelines or the intended benefits at any time. Adding to the uncertainty, concerns have been raised regarding the legality of the CNPV program.

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, untitled letters, Form 483s or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; and
- mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("**PDMA**"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act ("**DSCSA**") was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. 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. Ongoing changes to policies and practices, including staffing cuts at FDA, under the new presidential administration may adversely impact our development and commercialization efforts.

Additional Regulation

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

Anti-Corruption Laws

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

Data Privacy and the Protection of Personal Information

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

State laws protecting health and personal information are becoming increasingly stringent. For example, California has implemented the California Confidentiality of Medical Information Act that imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information, and California has recently adopted the CCPA. The CCPA mirrors a number of the key provisions of the European Union's General Data Protection Regulation ("**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, the California Privacy Rights Act ("**CPRA**"), was approved by California voters in the election on November 3, 2020. The CPRA modifies 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. As of January 1, 2026, 18 other states (Colorado, Connecticut, Delaware, Indiana, Iowa, Kentucky, Maryland, Minnesota, Nebraska, New Hampshire, New Jersey, Oregon, Rhode Island, Tennessee, Texas, Utah, and Virginia) have also passed substantially similar laws to the CCPA, hereafter referred to as comprehensive consumer privacy laws. These comprehensive consumer privacy laws provide individuals with rights to: (i) request access, correction, and deletion of their personal information; (ii) opt out of certain personal information sharing, processing activities; and (iii) receive detailed information about how their personal information is used and shared. Individuals also may be required to consent to certain processing activities, such as activities with sensitive categories of personal information in certain circumstances. They laws also include notice obligations when using personal data for training on large language models, and additional obligations to perform various types of personal information processing assessments, both related to general privacy risks to individuals, but also security risks and risks unique to artificial intelligence or automated decision making technologies.

Government Regulation Outside of the United States

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

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

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

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

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

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medical 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 ("**MRP**") for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the European Union. Basically, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products and is based on the principle of recognition of an already existing national marketing authorization by one or more member states. In the MRP, a marketing authorization for a drug already exists in one or more member states of the EU and subsequently marketing authorization applications are made in other European Union member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states. After a product assessment is completed by the reference member state, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations within individual member states shall be granted within 30 days after acknowledgement of the agreement.

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

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

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

Europe - Data Privacy

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will continue to 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, including as a result of staffing cuts at the FDA. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Moreover, among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

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

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

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the negotiated "maximum fair prices" for ten selected Part D drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs became effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional Part D drugs for the second cycle of negotiations. The negotiated prices for this second group will be effective on January 1, 2027. While there had been some questions about the Trump Administration's position on this program, on September 30, 2025, CMS issued final guidance for the third negotiation cycle. On January 27, 2026, CMS announced its selection of 15 additional drugs (covered under either Part B or Part D) for the third cycle of negotiations. The negotiated prices for this third group will be effective on January 1, 2028. CMS also selected one previously negotiated drug for the program's first renegotiations.

In April 2025, President Trump signed an Executive Order with the goal of lowering prescription drug prices in the United States. The Order includes directives to various government agencies to take steps to achieve this goal. The Department of Health and Human Services is to propose guidance for the Medicare Drug Negotiation Program aimed at increasing transparency, prioritizing high-cost drugs, and minimizing negative effects on pharmaceutical innovation. Additional areas of focus, reflected in the Executive Order, include reforming the pharmaceutical supply chain, accelerating approvals of generics and biosimilars, streamlining reclassification of some prescription drugs to OTC status, steps to simplify and expand the importation of prescription drugs, and reducing anti-competitive behavior by pharmaceutical companies, including patent abuse and market manipulation. The success of these efforts is uncertain and the impact on our business and the pharmaceutical industry in general is not yet known.

In May 2025, President Trump issued an executive order implementing the concept of most-favored nation pricing. Under this order, the Department of Health and Human Services, in coordination with other federal agencies, is directed to take actions to ensure that the price of prescription drugs paid by federal health insurers, including Medicare and Medicaid, is in line with the prices paid in comparably developed nations.

As an alternative to the Affordable Care Act, President Trump recently announced the Great Healthcare Plan. As presented, the plan is intended to lower drug prices by increasing competition and benchmarking U.S. drug prices to other countries, reduce insurance premiums by redirecting subsidies from insurers to individuals, increase accountability and transparency from insurers, and promote consumer choice by giving individuals more direct control over how healthcare dollars are spent. Legislative and regulatory action will be required to fully implement the plan. It is unclear how these proposed changes will impact our business and the pharmaceutical industry in general.

At the state level, legislatures have 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. We expect that additional federal, state and foreign 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, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Other Healthcare Laws and Compliance Requirements

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

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

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

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

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

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

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

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

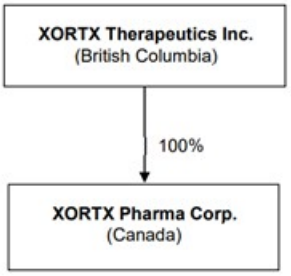
- State laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of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

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

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

4.C. Organizational Structure

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



4.D. Property, Plant and Equipment

Not applicable.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The management's discussion and analysis of the Company for the year ended December 31, 2025 is included in this Annual Report in Exhibit 15.1.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

6.A Directors and Senior Management

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

Name, Province / State and Country of Residence	Age	Position with the Company	Date Became a Director / Officer	Experience and Qualifications
Allen Davidoff, Alberta, Canada	65	President and Chief Executive Officer and Director	January 9, 2018	Current President and Chief Executive Officer of the Company since January 9, 2018 and its predecessor company, XORTX Pharma Corp. since July 2012; former Chief Scientific Officer and co-founder, Stem Cell Therapeutics Inc (Trillium Therapeutics). (November 2004 to December 2011). Ph.D. in Cardiovascular Physiology and Biophysics from the University of Calgary.
Michael Bumby, Ontario, Canada	62	Chief Financial Officer	December 18, 2024	Current Chief Financial Officer of the Company since December 18, 2024; current Director and Audit Committee Chair, MediPharm Labs since April 2023; former Chief Financial Officer, VIVO Cannabis Inc. (December 2017 to April 2023). Doctor of Veterinary Medicine degree from the University of Guelph; MBA from the University of Toronto.
Stacy Evans, California, United States	52	Chief Business Officer	November 16, 2022	Over 20+ years' experience in business development in the biopharmaceutical industry with leading biopharmaceutical companies. Current Chief Business Officer of the Company since November 16, 2022 and independent industry consultant since 2015. M.D. from McGill University; Executive MBA from Columbia University.
Krysta Davies Foss,[1][2] Ontario, Canada	52	Director	December 31, 2025	Over 25 years of experience advising pharmaceutical and biotechnology companies on development strategy, commercialization, and market preparedness across a broad range of therapeutic areas. Current Chief Executive Officer, Triad Strategic Services, a leading pharma and biotech strategy consulting firm and Director, Canadian Organization for Rare Disorders. BA from Simon Fraser University; Masters of Intelligence and International Relations, university of Salford, Mancheter, UK.
Anthony J. Giovinazzo,[1][2] Ontario, Canada	69	Non-Executive Chair	June 3, 2022	Director, Conavi Medical Inc. (formerly Titan Medical Inc.) since September 2020; Executive Chair, Kalgene Inc., a private company since July 2021; Director, Cosciens Biopharma Inc. since May 2026; former Director and CEO (November 2009 to March 2017), Cynapsus Therapeutics Inc., a TSX and Nasdaq listed company, that was acquired in an all-cash transaction with Sunovion Pharmaceuticals Inc. for US$841 million. Former Director, ProMIS Neurosciences Inc. (March 2017 to September 2020), Pond Technologies Holdings Inc. (October 2020 to June 2021); and Microbix Biosystems Inc. (December 2020 to March 2022). Master's of Business Administration from IMD, Geneva, Switzerland; Graduate Certificate Studies in Canadian Law from Osgoode Hall Law School, York University, Toronto, Ontario; Bachelor of Arts in Economics and Accounting from McMaster University.
Stephen Haworth, Pennsylvania, United Sates	75	Chief Medical Officer	July 1, 2021	Current Chief Medical Officer of the Company; Principal Consultant, Haworth Biopharmaceutical Consulting Services Inc. since July 2013; former Executive Medical Director, Cormedix Inc. (2017 to 2018); former Vice President, VaxInnate Corporation (2015). Medical degree from University College Hospital Medical School, University of London, with Honors.
Raymond Pratt,[2] Maryland, United States	75	Director	December 20, 2021	Current Principal, RDP Pharma Consulting since April 2022; Chief Medical Officer, Savara Inc. since October 2023; former Chief Development Officer and former Chief Medical Officer, Rockwell Medical, Inc. (2012 to March 2022).
Paul Van Damme,[1] Ontario, Canada	76	Director	January 25, 2018	Former Director, OncoQuest Inc., a subsidiary of Quest PharmaTech Inc. (November 2015 to February 2020) and former Chief Financial Officer, Mind Medicine (MindMed) Inc. (now Definium Therapeutics Inc.) (August 2019 to April 2020). B.Comm. from the University of Toronto; MBA from the Rotman School of Management; Chartered Professional Accountant.

(1) Member of the Audit Committee

(2) Member of the Compensation, Governance and Nominating Committee

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

6.B. Compensation

Introduction

The following section describes the significant elements of our executive and director compensation program. Our named executive officers for the year ended December 31, 2025 include our principal executive officer, our principal accounting officer, our principal medical officer and our principal business officer. See Item 6.C. Board Practices, of this Annual Report for a discussion of any contracts for service that we have with our directors.

Overview

Compensation Philosophy

The goal of our compensation program is to attract, retain and motivate our employees and executives. The Compensation Committee in conjunction with the Board of Directors is responsible for setting our executive compensation and establishing corporate performance objectives. In considering executive compensation, the Compensation Committee 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. The Compensation Committee is committed to ensuring fair and equitable compensation for our executives and Board of Directors. To achieve this, the Compensation Committee regularly engages independent external compensation consultants, such as Aon Radford, to conduct thorough benchmark analyses against a defined peer group. This ongoing process allows us to align compensation practices with market standards and ensure that our compensation programs attract, retain, and motivate top talent while serving the best interests of our shareholders. For additional details regarding the relevant education and experience of each member of our Compensation Committee see Item 6.A. above. Our named executive officers and directors are not permitted to purchase financial instruments, including, for greater certainty, prepaid variable forward contracts, equity swaps, collars, or units of exchange funds that are designed to hedge or offset a decrease in market value of equity securities granted as compensation or held, directly or indirectly, by the named executive officer or director.

Components of Compensation Package

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

Determining Compensation

Our Board of Directors is responsible for ensuring that the Company has in place an appropriate plan for executive compensation ensuring that total compensation paid to all executive officers is fair and reasonable and is consistent with the Company's compensation philosophy and in line with industry practice. Our Compensation Committee assists our Board of Directors in its oversight of executive compensation.

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

Other Compensation

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

Director Compensation

In addition to the granting of options, during the period ended December 31, 2025, the non-executive directors of the Company received compensation of CAD $3,000 per quarter for director services, which amount was increased effective April 1, 2025 to US$5,000 per quarter and CAD $300 per committee meeting, with the Chair of each committee receiving CAD $700 per committee meeting. Anthony Giovinazzo, Chair of the Company, receives annual compensation of US$125,000.

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

Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers and our non-executive directors for the years ended December 31, 2025, 2024 and 2023 after giving effect to the 2023 Share Consolidations. 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 (US$)					
Name and Position	**Year**	**Salary, Consulting Fee, Retainer or Commission ($)**	**Bonus ($)**	**Committee or Meeting Fees ($)**	**Value of Stock Option ($)**	**Value of All Other Compensation ($)**	**Total Compensation**
Allen Davidoff. PhD. *CEO*	2025	324,738	—	—	5,640	—	330,378
	2024	343,505	48,150	—	25,334	—	416,989
	2023	337,794	—	—	40,642	—	378,436
Michael Bumby, [1] DVM, MBA *Chief Financial Officer ("**CFO**")*	2025	160,980	—	n/a	6,326	—	167,306
	2024	6,515	—	n/a	207	—	6,722
	2023	n/a	n/a	n/a	n/a	n/a	n/a
Stacy Evans MD, MBA, *Chief Business Officer ("**CBO**")*	2025	150,000	—	—	—	—	150,000
	2024	157,500	—	—	—	—	157,500
	2023	280,000	—	n/a	—	—	280,000
Dr. Stephen Haworth, MB BS, MRCP, *Chief Medical Officer ("**CMO**")*	2025	96,000	—	n/a	2,593	—	98,593
	2024	96,000	14,445	n/a	9,748	—	120,193
	2023	200,229	—	n/a	15,041	—	215,270
Krysta Davies Foss [2], *Director*	2025	n/a	n/a	n/a	n/a	n/a	n/a
	2024	n/a	n/a	n/a	n/a	n/a	n/a
	2023	n/a	n/a	n/a	n/a	n/a	n/a
William Farley [3], BSc *Former Director*	2025	17,502	—	1,092	—	—	18,594
	2024	8,662	—	2,195	5,353	—	16,210
	2023	8,970	—	1,455	—	—	10,425
Anthony Giovinazzo, MBA, CSC, BA *Director*	2025	124,976	—	—	—	—	124,976
	2024	123,133	—	—	6,799	—	129,932
	2023	133,967	—	—	—	—	133,967
Abigail Jenkins [4], MSc *Former Director*	2025	17,293	—	220	—	—	17,513
	2024	6,495	—	438	21,218	—	28,151
	2023	n/a	n/a	n/a	n/a	n/a	n/a
Dr. Raymond Pratt, MD FACP *Director*	2025	17,084	—	219	—	—	17,303
	2024	8,662	—	—	5,353	—	14,015
	2023	8,970	—	794	—	—	9,764
Patrick Treanor [5], BSc, MBA *Former Director*	2025	17,571	—	513	—	—	18,084
	2024	8,713	—	2,058	—	—	10,771
	2023	—	—	—	12,900	—	12,900
Paul Van Damme, B Comm, CPA, MBA *Director*	2025	17,571	—	1,526	—	—	19,097
	2024	8,662	—	3,221	5,353	—	17,236
	2023	8,970	—	1,895	—	—	10,865

Notes:

(1) Michael Bumby was appointed CFO on December 18, 2024. The amounts included for 2024 reflect the period from December 18, 2024 to December 31, 2024.

(2) Krysta Davies Foss was appointed as a director on December 31, 2025.

(3) William Farley resigned effective December 31, 2025.

(4) Abigail Jenkins was appointed as a director on April 8, 2024 and resigned effective December 31, 2025.

(5) Patrick Treanor was appointed as a director on December 31, 2023 and resigned effective December 31, 2025.

Outstanding Equity Awards at 2025 Fiscal Year End

Name and Position	Type of Compensation Security	Number of Compensation Securities, Number of underlying Securities and Percentage of Class	Date of Issue or Grant	Issue, Conversion or Exercise Price[1][2]	Closing Price of Security or Underlying Security on Date of Grant ($)[1]	Expiry Date
Allen Davidoff *CEO & Director*	Stock option	2,222	Jan12-22	$ 22.86	$ 20.97	Jan12-27
	Stock option	10,535	Jun06-22	$ 14.40	$ 17.55	Jun06-27
	Stock option	6,666	Mar04-24	$ 4.50	$ 4.66	Mar04-29
		15.0 %				
Michael Bumby *CFO*	Stock option	13,000	Dec18-24	$ 1.75	$ 1.62	Dec18-29
		10.0 *%*				
William Farley, *Former Director*	Stock option	2,366	May12-21	$ 16.91	$ 17.43	Mar31-26
	Stock option	1,522	Dec21-21	$ 22.86	$ 20.97	Mar31-26
	Stock option	3,333	Jun06-22	$ 14.40	$ 14.40	Mar31-26
	Stock option	2,222	Mar04-24	$ 4.50	$ 4.66	Mar31-26
		7.3 %				
Anthony Giovinazzo, *Director*	Stock option	16,666	Jun06-22	$ 14.40	$ 17.55	Jun06-27
	Stock option	2,822	Mar04-24	$ 4.50	$ 4.66	Mar04-29
		15.0 %				
Dr. Stephen Haworth, *CMO*	Stock option	2,366	Jul14-21	$ 21.66	$ 22.72	Jul14-26
	Stock option	1,111	Jan12-22	$ 22.86	$ 20.97	Jan12-27
	Stock option	2,222	Nov25-22	$ 12.42	$ 12.42	Nov25-27
	Stock option	3,333	Mar04-24	$ 4.50	$ 4.66	Mar04-29
		7.0 %				
Abigail Jenkins, *Former Director*	Stock option	8,000	Apr08-24	$ 5.00	$ 5.11	Mar31-26
		6.2 %				
Dr. Raymond Pratt, *Director*	Stock option	3,333	Dec21-21	$ 22.86	$ 20.97	Dec21-26
	Stock option	3,333	Jun06-22	$ 14.40	$ 17.55	Jun06-27
	Stock option	2,222	Mar04-24	$ 4.50	$ 4.66	Mar04-29
		6.8 %				
Patrick Treanor, *Former Director*	Stock option	8,000	Dec31-23	$ 2.90	$ 2.90	Mar31-26
		6.2 %				
Paul Van Damme, *Director*	Stock option	2,407	Dec21-21	$ 22.86	$ 20.97	Dec21-26
	Stock option	3,333	Jun06-22	$ 14.40	$ 17.55	Jun06-27
	Stock option	2,222	Mar04-24	$ 4.50	$ 4.66	Mar04-29
		6.1 %				

Notes:

(1) CAD $

(2) Pricing of options is based on the closing price of securities on the day before grant in accordance with TSXV policies.

6.C. Board Practices

All of our directors are elected at the annual general meeting of our shareholders and each holds such office until his or her successor is elected or appointed, unless his or her office is earlier vacated by way of the director's resignation or death or under any of the relevant provisions of our Articles or the BCBCA. For information about the period during which each of our directors and senior management has served in their respective offices, see "Item 6.A. - Directors and Senior Management."

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

The Company employs its director Dr. Allen Davidoff as its President and Chief Executive Officer at an annual salary of US$321,000, pursuant to an Employment Agreement dated November 1, 2021, 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 termination due to a change of control, as defined in the Davidoff Agreement, the Davidoff Agreement provides for a lump sum payment equal to 12 times his monthly base salary amount in effect at the time. Also, in accordance with the Company's Stock Option Plan, all unvested options then held by Dr. Davidoff shall be deemed to have vested upon any such termination due to a change in control. In addition, the Board of Directors has determined a discretionary bonus of up to 75% for Allen Davidoff of his annual compensation.

The Company entered into a consulting agreement on December 16, 2024 with Michael Bumby, the Company's Chief Financial Officer that provides for a monthly fee of CAD $18,750.00 (CAD $225,000 per annum) (the **"Bumby Agreement**"). The Bumby Agreement provides for a discretionary bonus up to 40% of the annual compensation, contains standard confidentiality clauses and has an indefinite term. The Bumby Agreement can be terminated by Mr. Bumby or the Company by providing 90 days' notice with no additional termination fees. In the case of a change of control, as defined in the Bumby Agreement, the Bumby Agreement provides for a lump sum payment equal to 12 times his monthly base salary amount in effect at the time plus an amount equal to the maximum performance bonus payable thereunder.

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 a consultant to act in the capacity as chief medical officer, pursuant to which Haworth Biopharmaceutical Consulting Services Inc. is entitled to compensation for the provision of such services of base fees of US$20,062.50 per month, with a discretionary bonus of up to 30% of the total value of the contract, subject to the discretion of the Compensation Committee. This agreement may be terminated at any time and for any reason by either party with 30 days' notice or by the Company with no notice but payment of one month's fee for services.

The Company entered into a contract with Stacy Evans, dated September 1, 2022 and effective September 1, 2022 for a one-year term expiring September 1, 2023, by and between the Company and Stacy Evans, for consulting services to the Company. On November 16, 2022, the Company appointed Stacy Evans to act in the capacity as chief business officer, pursuant to which he is entitled to compensation for the provision of such services of base fees of US$20,000 per month for the first 90 days and US$25,000 thereafter, such amount to be reduced should the Company engage an external party. Stacy Evans is also entitled to a transaction bonus of 0.75% or 1.25%, calculated on the value of strategic partnerships, for consummation of a transaction, with 0.75% being paid on a transaction that originated as a Company lead and 1.25% being paid on a transaction that originated as a lead from Dr. Evans, such 1.25% amount to be reduced to 0.75% should a broker-dealer be entitled to a success fee. This agreement may be terminated at any time and for any reason by either party with 30 days' notice or by the Company with no notice but payment of one month's fee for services. Effective May 1, 2024, the Company and Stacy Evans entered into an Amended and Restated Consulting Agreement for a one-year term that provides for monthly compensation of $12,500 with all other terms in the September 1, 2022 contract remaining. During the year ended December 31, 2025, Stacy Evans was paid $12,500 per month.

The Company does not have 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, although certain employment and compensation agreements that the Company has entered do contain provisions that would provide compensation as a result of a change of control of the Company, as described above.

Audit Committee

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

Audit Committee Terms of Reference

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

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

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

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

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

In performing such duties, the Audit Committee is responsible for the review and approval of financial information, oversight of the external auditor (including the sole responsibility for recommending the appointment or dismissal of the external auditor), and monitoring related party transactions, expense accounts, whistleblower complaints, and monitoring compliance with the Company's Code of Business Conduct and Ethics. The Company has a written charter which sets out the duties and responsibilities of its Audit Committee. The Audit Committee Charter is attached hereto as Exhibit 15.2.

Audit Committee Composition

The Audit Committee's charter requires that the Audit Committee consist of at least three members, all of whom shall be independent and with such members to be appointed annually by the Board. The Company's Audit Committee is comprised of three directors, each of whom the Board has determined to be independent: Krysta Davies Foss, Anthony Giovinazzo and Paul Van Damme (Chair). The Audit Committee must meet at least four times per year on a quarterly basis.

Relevant Education and Experience

Paul Van Damme (Chair) – Paul Van Damme is a Chartered Professional Accountant with over 45 years business experience. He holds a Bachelor of Commerce degree from the University of Toronto and an MBA from the Rotman School of Management. He is an experienced accountant having worked for PricewaterhouseCoopers in their Toronto and London, UK offices and he has held the position of CFO with a number of Canadian and US private and public companies including Allelix Biopharmaceuticals Inc., Vasogen Inc. and Structural Genomics Consortium, a UK-based charity. Mr. Van Damme is financially literate and an independent director of the Company for the purpose of NI 52-110 and Rule 10A-3 under the Exchange Act. Mr. Van Damme is also an "audit committee financial expert" as defined by Form 20-F.

Krysta Davies Foss – Krysta Davies Foss has 25+ years of experience advising pharmaceutical and biotechnology companies on development strategy, commercialization, and market preparedness across a broad range of therapeutic areas. She currently serves as Chief Executive Officer of Triad Strategic Services, a leading pharma and biotech strategy consulting firm. In addition to her executive role, Ms. Davies Foss serves on multiple boards, including the Canadian Organization for Rare Disorders (CORD), and has provided strategic intelligence and advisory services to organizations ranging from incubators and early-stage startups to large multinational pharmaceutical companies. Her experience spans the full product development lifecycle, from early innovation through global commercialization. Krysta Davies Foss is financially literate and an independent director of the Company for the purpose of NI 52-110 and Rule 10A-3 under the Exchange Act.

Anthony Giovinazzo – Anthony Giovinazzo is the former Chief Executive Officer and Director of Cynapsus Therapeutics, a Nasdaq listed specialty pharmaceutical company. 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 Masters 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. Mr. Giovinazzo is financially literate and an independent director of the Company for the purpose of NI 52-110 and Rule 10A-3 under the Exchange Act.

Pre-Approval Policies and Procedures

All audit and non-audit services performed by our auditors for the twelve-month period ended December 31, 2025 were pre-approved by our Audit Committee. It is our policy that all audit and non-audit services performed by our auditors will continue to be pre-approved by our Audit Committee.

Compensation, Governance and Nominating Committee

The Compensation, Governance and Nominating Committee (the **"CGN Committee"**) has the responsibility of assisting the Board of Directors with oversight of executive and director compensation and assisting the Board of Directors in fulfilling its corporate governance responsibilities under applicable law, to promote a culture of integrity throughout the Company.

Without limiting the generality of the foregoing, the CGN Committee has the following responsibilities relating to oversight of executive and director compensation:

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

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

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

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

Without limiting the generality of the foregoing, the Corporate Governance & Nominating Committee has the following responsibilities:

(a) recommending suitable candidates for nominees for election or appointment as directors and specifying which of the criteria, listed in the charter of the CGN Committee, governing the overall composition of the Board of Directors 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 of Directors ensuring that qualifications required under any applicable laws and governance policies are maintained and advise the Chairman of the Board of Directors 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 Chairman of the Board of Directors 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 of Directors at the annual meeting of the Directors, the allocation of Board of Directors members to each of the Board of Directors Committees. Where a vacancy occurs at any time in the membership of any Board of Directors Committee, recommending to the Board of Directors 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 of Directors, its Committees and Board of Directors members and making recommendations to the Board of Directors; and

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

The CGN Committee is composed of three independent directors, Krysta Davies Foss, Anthony Giovinazzo and Raymond Pratt. The Chair of the CGN Committee is Anthony Giovinazzo. 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.

6.D. Employees

As at December 31, 2025, we had two full-time employees, one part–time employee 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 and consultants to be good.

6.E. Share Ownership

The following table indicates information as of March 19, 2026, regarding the beneficial ownership of our Common Shares, 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 March 19, 2026, 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 March 19, 2026, we had 16 record holders of our Common Shares, with six record holders in the United States, representing 55.8% of our outstanding Common Shares, nine record holders in Canada, representing 44.1% of our outstanding Common Shares and one record holder in Japan, representing 0.1% of our outstanding Common Shares.

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

Name and Address of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% and Greater Shareholders:		
None	Nil	* %
Directors and Named Executive Officers:		
Davidoff, Allen (1)	152,025	2.1 %
Bumby, Michael (2)	3,250	*
Evans, Stacy	Nil	*
Davies Foss, Krysta (3)	22,770	*
Farley, William (4)	9,443	*
Giovinazzo, Anthony (5)	29,113	1.0 %
Haworth, Stephen (6)	8,321	*
Jenkins, Abigail (7)	8,000	*
Pratt, Raymond (8)	8,888	*
Treanor, Patrick (9)	8,000	*
Van Damme, Paul (10)	8,285	*
All executive officers and directors as a group (10 persons)	258,095	3.7 %

* Indicates beneficial ownership of less than 1%.

Notes:

(1) Consists of 126,448 Common Shares, warrants exercisable for 8,191 Common Shares and options exercisable for 17,386 Common Shares within 60 days of March 19, 2026, held personally by Mr. Davidoff.

(2) Consists of options exercisable for 3,250 Common Shares within 60 days of March 19, 2026, held personally by Mr. Bumby.

(3) Consists of 2,770 Common Shares and 20,000 options exercisable for 20,000 Common Shares within 60 days of March 19, 2026, held personally by Ms. Davies Foss.

(4) Consists of options exercisable for 9,443 Common Shares within 60 days of March 19, 2026, held personally by Mr. Farley.

(5) Consists of 9,625 Common Shares and options exercisable for 19,488 Common Shares within 60 days of March 19, 2026, held personally by Mr. Giovinazzo.

(6) Consists of options exercisable for 8,321 Common Shares within 60 days of March 19, 2026, held personally by Mr. Haworth.

(7) Consists of options exercisable for 8,000 Common Shares within 60 days of March 19, 2026, held personally by Ms. Jenkins.

(8) Consists of options exercisable for 8,888 Common Shares within 60 days of March 19, 2026, held personally by Mr. Pratt.

(9) Consists of options exercisable for 8,000 Common Shares within 60 days of March 19, 2026, held personally by Mr. Treanor.

(10) Consists of 323 Common Shares and options exercisable for 7,962 Common Shares within 60 days of March 19, 2026, held personally by Mr. Van Damme.

Share Compensation Plan

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

The Plan authorizes the issuance of Options up to an aggregate of 10% of the issued Common Shares from time to time. There are currently 6,962,218 Common Shares of the Company issued and outstanding, and therefore the current 10% threshold is 696,222 Common Shares available for Options grants under the Plan. Options may be granted under the Plan with a maximum exercise period of up to ten (10) years, as determined by the Board of Directors of the Company.

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

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

A copy of the Plan is attached as Exhibit 4.15 to this Annual Report.

6.F. Market for Securities

Our common shares are listed in Canada on the TSXV and in the United States on Nasdaq under the trading symbol XRTX. Our common shares also trade over the counter on the Frankfurt Burse under the trading symbol ANUA.

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

	TSXV			Nasdaq		
Month	**High**	**Low**	**Volume**	**High**	**Low**	**Volume**
January 2025	2.49	1.26	137,656	1.79	0.85	5,685,440
February	1.82	1.18	202,471	1.25	0.82	1,780,527
March	1.55	1.20	129,066	1.10	0.85	364,886
April	1.59	1.15	94,377	1.19	0.85	1,251,719
May	1.51	1.26	45,763	1.12	0.95	706,529
June	1.32	1.08	64,517	0.98	0.80	697,195
July	1.40	0.98	82,211	1.03	0.72	4,898,378
August	1.27	0.91	51,978	0.93	0.70	1,907,266
September	1.24	1.07	26,050	0.90	0.76	729,224
October	1.97	0.86	498,903	1.41	0.60	121,387,172
November	0.88	0.76	40,528	0.70	0.52	2,196,068
December	0.85	0.70	157,601	0.67	0.51	997,187
January 2026	0.83	0.63	34,690	0.62	0.46	636,749
February	0.77	0.49	76,805	0.58	0.37	7,033,638
March (1)	0.64	0.485	44,638	0.49	0.36	603,319

Note:
(1) For the period March 1, 2026 to March 18, 2026, the date of this Form 20-F.

6.G. Prior Sales

The following table sets forth the securities not listed but issued by the Company during the financial year ended December 31, 2025 and outstanding as at December 31, 2025.

Date of Issuance	Type of Security	Number of Securities Issued	Issuance/ Exercise Price per Security ($)
July 21, 2025	Warrants	1,283,923	US$1.20
August 8, 2025	Warrants	156,849	US$1.20
October 23, 2025	Warrants	87,500	US$0.69

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

Not applicable.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

7.A. Major Shareholders

Not Applicable.

7.B. Related Party Transactions

Other than as described below, since January 1, 2025, no director or executive officer of the Company or any person or company who beneficially owns, or controls or directs, directly or indirectly more than 10% of the outstanding Common Shares or any known associate or affiliate of such persons, has or has had any material interest direct or indirect, in any transaction or in any proposed transaction that has materially affected or is reasonably expected to materially affect the Company.

Since the year beginning January 1, 2025, the Company entered into various transactions with related parties. All related party transactions were measured at the amount of consideration established and agreed to by the related parties. All amounts payable to related parties are unsecured, non-interest bearing and have no fixed terms of repayment.

The Company entered into the following during the year ended December 31, 2025:

- Wages and benefits were paid or accrued to Allen Davidoff, CEO, in the amount of $324,738.
- Professional fees were paid or accrued to Michael Bumby, CFO, in the amount of $160,980.
- Research and development fees were paid or accrued to Haworth Biopharmaceutical, a company owned by Stephen Haworth, CMO of the Company in the amount of $96,000.
- Consulting fees were paid or accrued to Stacy Evans, CBO of the Company in the amount of $150,000.
- Directors' fees were paid or accrued to the directors of the Company in the amount of $215,568. The amount includes a director's fee payment of $128,877 for the year ended December 31, 2025, to Anthony Giovinazzo, Chairman of the Company.
- As of December 31, 2025, $10,730 was payable to directors of the Company, $28,044 was payable or accrued to the CFO of the Company for CFO services, $16,000 was payable and accrued to the CMO of the Company for consulting services, and $37,500 was payable and accrued to the CBO of the Company for consulting services. The balances are unsecured, non-interest bearing, and have no fixed terms of repayment.

The Company's management compensation transactions for the fiscal years ending December 31, 2023 – 2025 are summarized as follows:

	Short-term employee benefits	Directors' fees	Share-based payments	Total
	$	$	$	$
Year ended December 31, 2023				
Directors and officers	974,240	182,675	77,779	1,234,694
Year ended December 31, 2024				
Directors and officers	815,935	172,229	85,680	1,073,844
Year ended December 31, 2025				
Directors and officers	731,718	215,568	14,559	961,845

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

7.C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

The audited consolidated financial statements for the years ended December 31, 2025, 2024, and 2023 can be found under "Item 18. Financial Statements".

8.B. Significant Changes

We are not aware of any significant change that has occurred since December 31, 2025, the date of the audited consolidated financial statements included in this Annual Report, and that has not been disclosed elsewhere in this Annual Report.

ITEM 9. THE OFFER AND LISTING.

9.A. Offer and Listing Details

The Common Shares are listed and posted for trading on each of the TSXV and Nasdaq under the trading symbol "XRTX." Our shares also trade over the counter on the Frankfurt Borse under the trading symbol "ANU".

9.B. Plan of Distribution

Not applicable.

9.C. Markets

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

9.D. Selling Shareholders

Not applicable.

9.E. Dilution

Not applicable.

9.F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

10.A. Share Capital

Not applicable.

10.B. Memorandum and Articles of Association

1. The Company was incorporated to carry on business without restrictions under the BCBCA as "APAC Resources Inc." on May 31, 2011 and with registration number BC0911882.

   ReVasCor, Inc. was incorporated under the laws of Alberta, Canada on August 24, 2012 and was continued under the Canada Business Corporations Act on February 27, 2013 under the name of XORTX Pharma Corp. ("**XORTX Pharma**"). XORTX Pharma completed a reverse take-over transaction on January 10, 2018 (the "**RTO**") with the Company. As part of this transaction, the Company changed its name to its current name: "XORTX Therapeutics Inc." XORTX Pharma remains as the wholly owned subsidiary of the Company.

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

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

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

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

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

The Company, if authorized by the directors, may:

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

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

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

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

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

3. The authorized share capital of the Company consists of an unlimited number of Common Shares, each without par value. We have no preferred shares authorized under our Articles.

   As of the date hereof, our authorized share capital consists of an unlimited number of Common Shares, each without par value, of which 6,962,218 are issued and outstanding. In addition, we have 149,761 Common Shares issuable pursuant to outstanding stock options, and 3,309,880 Common Shares issuable upon the exercise of outstanding Common Share purchase warrants. We had 16 holders of record and approximately 2,566 beneficial owners of our Common Shares as of March 19, 2026.

   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 choose.

   Subject to priority rights that may be applicable to any then outstanding shares, and the applicable provisions of the BCBCA, holders of our Common Shares are entitled to receive dividends, as and when declared by our Board of Directors, in their sole discretion as they see fit.

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

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

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

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

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

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

i) decrease the par value of those shares; or

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

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

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

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

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

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

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

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

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

and alter its Notice of Articles and Articles accordingly.

5. Unless an annual general meeting is deferred or waived in accordance with the BCBCA, the Company must hold an annual general meeting at least once in each calendar year and not more than 15 months after the last annual reference date at such time and place as may be determined by the directors.

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

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

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

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

b) otherwise, 10 days.

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

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

b) otherwise, 10 days.

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

The directors may set a date as the record date for the purpose of determining shareholders entitled to vote at any meeting of shareholders. The record date must not precede the date on which the meeting is to be held by more than two months or, in the case of a general meeting requisitioned by shareholders under the BCBCA, by more than four months. If no record date is set, the record date is 5 p.m. on the day immediately preceding the first date on which the notice is sent or, if no notice is sent, the beginning of the meeting.

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

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

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

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

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

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

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

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

i) past services performed for the Company;

ii) property;

iii) money; and

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

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

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

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

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

10.C. Material Contracts

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

1. Employment Agreement, dated November 1, 2021 by and between the Company and Allen Davidoff, pursuant to which the Company employed Allen Davidoff as President and Chief Executive Officer for an indefinite term, and providing for an annual salary of $300,000, to be annually reviewed, plus reimbursement for reasonable expenses. Additionally, in the event of Mr. Davidoff's termination upon notice by the corporation after the first year of employment, he is entitled to a severance payment equal to twelve times his-then current monthly salary. Furthermore, if following a change of control (as defined in the agreement) Mr. Davidoff is terminated within 30 days he will be entitled to a cash payment equal to 12 times his then-current monthly salary.

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

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

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

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

6. Master Services Agreement dated July 20, 2017 between the Company and Cato Research Canada Inc. (now Allucent) to manage future regulatory and clinical trial programs.

7. Sponsored Research Agreement between the Regents of the University of Colorado ("**UC**") and the Company dated May 27, 2021 pursuant to which the UC has agreed to provide certain research services to the Company.

8. Amended and Restated Consulting Agreement, dated May 1, 2024 by and between the Company and Stacy Evans to extend the provision of services to the Company by Dr. Evans for a term of 12 months at a monthly compensation of $12,500, subject to certain adjustments as outlined in the agreement, plus expenses and certain bonus opportunities. Additionally, the agreement provided for the grant of 8,000 fully vested options exercisable for a term of five years from the effective date of the agreement at the closing price of the Company's stock as reported on Nasdaq and the day prior to the effective date of the agreement. Further, the agreement provides for certain success fees upon the consummation of transactions, as described in the agreement.

9. Consulting Agreement, dated as of December 16, 2024 between the Company and Michael Bumby (the "**Bumby Consulting Agreement**") providing for a monthly fee to Mr. Bumby of CAD$18,750. The Bumby Consulting Agreement will continue until the earlier termination by either party upon 90 days' advanced notice or breach. Additionally, the Bumby Consulting Agreement granted Mr. Bumby 13,000 stock options with an exercise price of CAD$1.75, vesting 25% on the one year anniversary of the grant date and 25% each successive anniversary of the grant date, provides for an annual performance bonus, payment of expenses, and certain payments upon a change in control of the Company.

10. On October 17, 2025, the Company entered into a binding term sheet to acquire a renal anti-fibrotic therapeutic program from Vectus. On January 13, 2026, the Company entered into an extension agreement with Vectus to extend the closing date to March 31, 2026.

10.D. Exchange Controls

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

10.E. Taxation

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

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

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

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

Scope of this Summary

Authorities

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

U.S. Holders

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

- a citizen or individual resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate whose income is subject to U.S. federal income taxation regardless of its source; or

- a trust that (1) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons for all substantial decisions or (2) has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

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

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

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

Passive Foreign Investment Company Rules

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

We believe we were classified as a PFIC during the taxable year ended December 31, 2025. Based on current business plans and financial expectations, we may be a PFIC for our taxable year ending December 31, 2026 or future taxable years. No opinion of legal counsel or ruling from the IRS concerning our status as a PFIC has been obtained or is currently planned to be requested. The determination of whether any corporation was, or will be, a PFIC for a tax year depends, in part, on the application of complex U.S. federal income tax rules, which are subject to differing interpretations. In addition, whether any corporation will be a PFIC for any tax year depends on the assets and income of such corporation over the course of each such tax year and, as a result, our PFIC status for the current year and future years cannot be predicted with certainty as of the date of this document. Accordingly, there can be no assurance that the IRS will not challenge any PFIC determination made by us (or by one of our subsidiaries). Each U.S. Holder should consult its own tax advisor regarding our status as a PFIC and the PFIC status of each non-U.S. subsidiary.

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

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

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

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

Default PFIC Rules Under Section 1291 of the Code

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

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

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

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

QEF Election

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

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

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

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

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

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

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

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

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

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

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 Common Shares 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 Common Shares 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 may apply with respect to a U.S. Holder if the Company is 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 Common Shares as security for a loan will, except as may be provided in Treasury Regulations, be treated as having made a taxable disposition of such Common Shares.

In addition, a U.S. Holder who acquires Common Shares from a decedent will not receive a "step up" in tax basis of such Common Shares 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 its own tax advisors 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 Common Shares.

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

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

Distributions on the Common Shares.

A U.S. Holder that receives a distribution with respect to a Common Share will be required to include the amount of such distribution in gross income as a dividend (without reduction for any Canadian income tax withheld from such distribution) to the extent of our current and accumulated "earnings and profits", as computed under U.S. federal income tax principles. A dividend generally will be taxed to a U.S. Holder at ordinary income tax rates if we are a PFIC for the tax year of such distribution or the preceding tax year. To the extent that a distribution exceeds our current and accumulated "earnings and profits," such distribution will be treated first as a tax-free return of capital to the extent of a U.S. Holder's tax basis in such Common Shares and thereafter as gain from the sale or exchange of such Common Shares (see "Sale or Other Taxable Disposition of the Common Shares" below). However, we may not maintain the calculations of earnings and profits in accordance with U.S. federal income tax principles, and each U.S. Holder may be required to assume that any distribution by us with respect to such Common Shares will constitute ordinary dividend income. Dividends received on such Common Shares generally will not be eligible for the "dividends received deduction" generally applicable to corporations.

Dividends paid by a "qualified foreign corporation" are eligible for taxation in the case of non-corporate U.S. Holders at a reduced long-term capital gains rate rather than the marginal tax rates generally applicable to ordinary income provided that certain requirements are met. Each non-corporate U.S. Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate on dividends with regard to its particular circumstances.

A non-U.S. corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on common shares that are readily tradable on an established securities market in the United States. We believe that we qualify as a resident of Canada for purposes of, and are eligible for the benefits of, the Canada-United States Income Tax Convention (1980) as amended (the "Treaty"), which the IRS has determined is satisfactory for purposes of the qualified dividend rules and that it includes an exchange of information provision, although there can be no assurance in this regard. Further, our common shares will generally be considered to be readily tradable on an established securities market in the United States if they remain listed on the Nasdaq. Therefore, subject to the discussion below under "— Passive Foreign Investment Company Rules", if the Treaty is applicable, or if the common shares are readily tradable on an established securities market in the United States, dividends paid by us will generally be "qualified dividend income" in the hands of non-corporate U.S. Holders, provided that certain conditions are met, including conditions relating to holding period and the absence of certain risk reduction transactions.

Sale or Other Taxable Disposition of the Common Shares

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

Additional Tax Considerations

Receipt of Foreign Currency

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

Foreign Tax Credit

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

Information Reporting; Backup Withholding Tax

Under U.S. federal income tax laws certain categories of U.S. Holders must file information returns with respect to their investment in, or involvement in, a foreign corporation. For example, U.S. return disclosure obligations (and related penalties) are imposed on U.S. Holders that hold certain specified foreign financial assets in excess of certain threshold amounts. The definition of specified foreign financial assets includes not only financial accounts maintained in foreign financial institutions, but also, unless held in accounts maintained by a financial institution, any stock or security issued by a non-U.S. person, any financial instrument or contract held for investment that has an issuer or counterparty other than a U.S. person, and any interest in a non-U.S. entity. U. S. Holders may be subject to these reporting requirements unless the Common Shares are held in an account at certain financial institutions. Penalties for failure to file certain of these information returns are substantial. U.S. Holders should consult their own tax advisors regarding the requirements of filing information returns, including the requirement to file IRS Form 8938. In addition, U.S. Holders should consult with their own tax advisors regarding the requirements of filing information returns, and, if applicable, filing obligations relating to the PFIC rules, including possible reporting on an IRS Form 8621.

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

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

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

10.F. Dividends and Paying Agents

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

10.G. Statement by Experts

Not applicable.

10.H. Documents on Display

Documents concerning the Company referred to in this Annual Report may be viewed by appointment during normal business hours at our registered and records office at 250 Howe Street, 20th Floor, Vancouver, British Columbia, V6C 3R8.

10.I. Subsidiary Information

Not applicable.

10.J. Annual Report to Security Holders

Not applicable

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company's financial instruments consist of cash and cash equivalents, accounts payable and accrued liabilities, lease obligation, and derivative warrant liability. The fair values of cash and cash equivalents and accounts payable and accrued liabilities approximate their carrying values at December 31, 2025, due to their short-term nature. The lease liability is classified as level 2 in the fair value hierarchy as the fair value is determined based on market interest rates.

The following table presents the Company's financial instruments, measured at fair value on the consolidated statements of financial position as at December 31, 2025 and 2024 and categorized into levels of the fair value hierarchy:

		December 31, 2025		December 31, 2024	
	Level	Carrying Value	Estimated Fair Value *	Carrying Value	Estimated Fair Value *
		$	$	$	$
FVTPL					
Cash and cash equivalents	1	864,514	864,514	2,473,649	2,473,649
Financial liabilities at amortized cost					
Accounts payable and accrued liabilities	1	553,784	553,784	147,205	147,205
Lease liability	2	37,287	37,287	38,785	38,785
FVTPL					
Derivative warrant liability	3	8,000	8,000	572,000	572,000

There were no transfers for levels of change in the fair value measurements of financial instruments for the years ended December 31, 2025 and 2024.

Risk management is carried out by the Company's management team with guidance from the Board of Directors. The Company's financial instruments were as follows:

a) Credit risk

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

	December 31, 2025	December 31, 2024
	$	$
Cash and cash equivalents	864,514	2,473,649

All of the Company's cash is held with major financial institutions in Canada and management believes the exposure to credit risk with such institutions is minimal. The Company considers the risk of material loss to be significantly mitigated due to the financial strength of the major financial institutions where cash is held. The Company's maximum exposure to credit risk as at December 31, 2025 and 2024 is the carrying value of its financial assets.

b) Liquidity risk

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

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

The contractual maturities of these financial liabilities as at December 31, 2025 and 2024 are summarized below:

	Payments due by period as of December 31, 2025			
	Total	Less than 3 months	Between 3 months and 1 year	1-3 years
	$	$	$	$
Accounts payable and accrued liabilities	553,784	553,784	—	—
Lease liability	37,287	22,230	15,057	—
	591,071	576,014	15,057	—

	Payments due by period as of December 31, 2024			
	Total	Less than 3 months	Between 3 months and 1 year	1-3 years
	$	$	$	$
Accounts payable and accrued liabilities	147,205	147,205	—	—
Lease liability	38,785	23,124	15,661	—
	185,990	170,329	15,661	—

c) Market Risk

i) Interest Rate Risk

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

ii) Foreign Currency Risk

As at December 31, 2025, the Company is exposed to currency risk on the following financial assets and liabilities denominated in CAD Dollars ("**CAD**"), British Pounds ("**GBP**"), and European Euro ("**EUR**"). The sensitivity of the Company's net earnings due to changes in the exchange rate between the CAD, GBP and EUR against the U.S. dollar is included in the table below in U.S. dollar equivalents:

	CAD	GBP amount	EUR	Total
	$	$	$	$
Cash	345,475	—	—	345,475
Accounts payable and accrued liabilities	(332,506)	—	—	(332,506)
Net exposure	12,969	—	—	12,969
Effect of +/- 10% change in currency	1,297	—	—	1,297

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

There have been no changes in any risk management policies since December 31, 2025.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

12.A. Debt Securities

Not applicable.

12.B. Warrants and Rights

Not applicable.

12.C. Other Securities

Not applicable.

12.D. American Depositary Shares

Not applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

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

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

On March 11, 2024, the Company amended the terms of an aggregate of 1,101,433 outstanding common share purchase warrants as follows:

- In connection with 231,746 warrants issued February 9, 2021 with an original exercise price of CAD $42.26 per share (CAD $0.40 per share, as adjusted to reflect the 2021 and 2023 Share Consolidations), the Company amended the exercise price from CAD $42.26 to $5.00.
- In connection with 286,355 warrants issued on October 15, 2021 with an original exercise price of $42.93 per share ($4.77 per share, as adjusted to reflect the 2023 Share Consolidation), the Company amended the exercise price from $42.93 to $5.00.
- In connection with 583,332 warrants issued on October 7, 2022 with an original exercise price of $10.98 per share ($1.22 per share, as adjusted to reflect the 2023 Share Consolidation), the Company amended the exercise price from $10.98 to $5.00.

Pursuant to the polices of the TSXV the terms of the warrants, as amended, are subject to an acceleration expiry provision such that if for any ten consecutive trading dates (the "**Premium Trading Days**") during the term of the warrants, the closing price of the Company's shares on the TSXV exceeds $6.50 (approximately CAD $8.7562), the exercise period of the warrants will be reduced to 30 days, starting seven days after the last Premium Trading Day. The Company will announce any such accelerated expiry date by press release. All other terms of the warrants remain unchanged.

On April 30, 2024, the Company received TSXV approval to amend the terms of 1,024,099 outstanding common share purchase warrants. The exercise price of the warrants was adjusted to US$5.00 per share, down from higher original prices, following a series of private placements in 2021 and 2022.

On May 17, 2024, the Company received approval from the TSXV to amend the terms of 910,000 outstanding common share purchase warrants issued on October 15, 2021. The exercise price was reduced to US$5.00 per share, down from the previous adjusted price of US$42.93 per share following a 9:1 consolidation.

ITEM 15. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

At the end of the period covered by this Annual Report, an evaluation of the effectiveness of the design and operation of the Company's "disclosure controls and procedures" (as such term is defined in Rules 13a-15(e) under the Exchange Act) was carried out by the Company's CEO and CFO. Based upon that evaluation, the Company's CEO and CFO have concluded that the Company's disclosure controls and procedures were not effective due to a material weakness in internal controls over financial reporting related to the closing process and related management review controls for the period ended December 31, 2025.

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

Management Report on Internal Control Over Financial Reporting & Auditor Attestation

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

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

Management conducted an evaluation of the effectiveness of the Corporation's internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("**COSO**").

Based on this evaluation, management identified a material weakness in the period end closing process and related management review controls and concluded that the Corporation's internal control over financial reporting was not effective as of December 31, 2025. While the Company has implemented enhanced control activities to remediate the identified material weakness in the closing process and related management review controls, such remedial activities have been determined to not yet be operating effectively. The Company is committed to the continuous development of processes to address the material weakness and mitigate any associated risks moving forward. Readers of this Annual Report and associated financial statements should take this into consideration. A material weakness is a deficiency or a combination of control deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Because of their inherent limitations, internal controls over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Furthermore, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Attestation Report of Independent Auditor

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

Changes in Internal Control over Financial Reporting

Other than the work done to address the identified material weakness discussed above, during the year ended December 31, 2025, there were no changes in the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

The Company's Audit Committee, which consists exclusively of independent directors in accordance with Nasdaq listing requirements, is comprised of Krysta Davies Foss, Anthony Giovinazzo and Paul Van Damme. Paul Van Damme is the Chair of the Audit Committee. The Board of Directors has determined that Krysta Davies Foss, Anthony Giovinazzo and Paul Van Damme each meet the independence requirements for directors, including the heightened independence standards for members of the audit committee under Rule 10A-3 under the Exchange Act. The Board has determined that Paul Van Damme is "financially literate" within the meaning of Nasdaq listing requirements and an "audit committee financial expert" as defined by Form 20-F. For a description of the education and experience of each member of the Audit Committee, see "Item 6A. Directors, Senior Management and Employees."

ITEM 16B. CODE OF ETHICS

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

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

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

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

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth information regarding the amount billed and accrued to the Company by its auditor, Davidson & Company, for the fiscal years ended December 31, 2025 and 2024:

	Year Ended December 31,	
Services	**2025**	**2024**
Audit Fees[(1)]	$ 99,376	$ 70,329
Audit-Related Fees[(2)]	—	121
Tax Fees[(3)]	—	3,987
Other Fees[(4)]	19,396	6,550
Total	$ 118,772	$ 80,987

Notes:

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

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

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

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

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

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

Not Applicable.

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

Not Applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

We engaged Smythe to audit our consolidated financial statements for the fiscal years ended December 31, 2023 and 2022. Smythe advised the Company they wished to discontinue services due to a change in their policies and resigned effective January 16, 2025.
Effective January 16, 2025, we engaged Davidson & Company as our independent auditor to audit our consolidated financial statements for the fiscal year ended December 31, 2024. The change of independent auditor was approved by our Audit Committee of the Board of Directors.

Smythe's audit report relating to the financial statements of the Company as of and for the fiscal years ended December 31, 2023 and 2022 did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles.

During Smythe's engagement and up to the interim period before Smythe's resignation, there had been no disagreements between Smythe and the Company on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement(s), if not resolved to the satisfaction of Smythe, would have caused it to make reference to the subject matter of the disagreement(s) in connection with its report. Additionally, during the two most recent fiscal years there had been no "reportable events" as defined under Item 16F(a)(1)(v) of Form 20-F that would require disclosure.

We provided a copy of this disclosure to Smythe and requested it to furnish us with a letter addressed to the SEC stating whether it agrees with the above statements, and if not, stating the respects in which it does not agree. A letter from Smythe is attached as Exhibit 15.5, which is incorporated herein by reference.

During 2023 and 2022 and the subsequent interim periods prior to the engagement of Davidson & Company effective January 16, 2025, neither we nor any person on our behalf consulted with Davidson & Company regarding either (i) the application of accounting principles to a specific completed or contemplated transaction, or the type of audit opinion that might be rendered on our financial statements and no written or oral advice provided by Davidson & Company was an important factor considered by us in reaching a decision as to any accounting, auditing or financial reporting issue, or (ii) any matter that was the subject of a disagreement or reportable event as defined in Form 20-F.

ITEM 16G. CORPORATE GOVERNANCE

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

Quorum Requirement

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

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

Shareholder Approval Exemption

Nasdaq Listing Rule 5635 sets forth circumstances under which shareholder approval is required prior to certain types of security issuances. Pursuant to the Nasdaq Stock Market Rules, a company must receive prior shareholder approval for non-public offerings involving the sale, issuance or potential issuance by a listed company of its common shares (or securities convertible into or exercisable for its common shares), which alone or together with sales by officers, directors, or substantial shareholders, is equal to 20% or more of the company's common shares or 20% or more of the voting power outstanding before the issuance, at less than the price that is the lower of: (i) the Nasdaq official closing price immediately preceding the signing of the binding agreement; or (ii) the average Nasdaq official closing price of the common shares for the five trading days immediately preceding the signing of the binding agreement. In the event of an issuance meeting the criteria set forth above, we may not be required to seek prior shareholder approval under applicable Canadian law and the rules of the TSXV.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

We have adopted insider trading policies and procedures governing the purchase, sale, and other dispositions of our securities by directors, senior management, and employees that are reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and listing standards applicable to us. Our Insider Trading and Blackout Period Policy has been filed as Exhibit 11.2 to this Annual Report.

ITEM 16K. CYBERSECURITY

Our information technology tries to identify, assess and manage our cybersecurity threats and risks. Depending on the environment, various technical, physical, and organizational measures, and processes may help mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example, vulnerability management, disaster recovery and business continuity planning, system monitoring, data encryption and access controls.

There can be no assurance that the Company's cybersecurity risk management measures and processes, including its controls or procedures, will be fully implemented, complied with or effective in protecting the Company's systems and information. The Company has not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents that have materially affected the Company, including its operations, business strategy, results of operations, or financial condition. The Company faces risks from cybersecurity threats that, if realized, could but are not likely materially affect it at this stage. Many of the laws and regulations regarding cybersecurity, information security, privacy and data protection applicable to the Company are subject to change and uncertain interpretation, and any failure or perceived failure to comply with such laws and regulations could result in negative publicity, legal proceedings, suspension or disruption of operations, increased cost of operations, or otherwise harm the business of the Company.

Cybersecurity Governance

Responsibility for the oversight and management of cybersecurity risks and the Company's cybersecurity policy rests with the Board of Directors, which has the responsibility for ensuring that the Company has adequate procedures in place to prevent and mitigate cybersecurity incidents. In the event of a cybersecurity incident, the CEO will immediately notify the Board of Directors about the incident and provide a detailed Cyber Incident Report that discloses relevant information about the date and time of the incident, as well as description of the attack, affected systems, actions taken, and further recommendations, which may be adjusted as additional details become now.

XORTX's cybersecurity program is overseen and implemented by a third-party company, Integrated Data Solutions, a company with more than 20 years of experience in software development, IT infrastructures and business cybersecurity. In the event of cybersecurity incident, the Company will take immediate action to mitigate such an event and assess current and future impacts and will prepare the Cyber Incident Report to be delivered to the Board of Directors, which will then review and analyze the situation and will provide their feedback on the mitigation and prevention measures to avoid events in the future.

PART III

ITEM 17: FINANCIAL STATEMENTS

Refer to Item 18. Financial Statements.

ITEM 18: FINANCIAL STATEMENTS

Financial Statements Filed as Part of this Annual Report:

Audited Annual Financial Statements for the years ended December 31, 2025, 2024 and 2023:

Independent Auditor's Report of Davidson & Company LLP (PCAOB ID: 731), dated February 25, 2026;

Independent Auditor's Report of Smythe LLP (PCAOB ID: 955), dated April 1, 2024;

Consolidated Statements of Financial Position as at December 31, 2025 and 2024;

Consolidated Statements of Loss and Comprehensive Loss for the years ended December 31, 2025, 2024 and 2023;

Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2025, 2024 and 2023;

Consolidated Statements of Cash Flows for the years ended December 31, 2025, 2024 and 2023;

Notes to the Consolidated Financial Statements.

ITEM 19. EXHIBITS

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

Exhibit Number	Description
1.1	Articles and Notice of Articles of the Company (incorporated by reference to Exhibit 3.1 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021)
2.1	Securities Purchase Agreement dated October 17, 2024 between the Company and the Purchasers thereto (incorporated by reference to Exhibit 99.3 to the Company's Form 6-K filed October 18, 2024)
2.2	Form of October 2024 Warrant (incorporated by reference to Exhibit 99.5 to the Company's Form 6-K filed October 18, 2024)
2.3	Form of October 2024 Pre-Funded Warrant (incorporated by reference to Exhibit 99.4 to the Company's Form 6-K filed October 18, 2024)
4.1#	Employment Agreement dated November 1, 2021, by and between the Company and Allen Davidoff (incorporated by reference to Exhibit 4.2 of the Company's Form 20-F filed May 12, 2025)
4.2	Master Services Agreement dated July 20, 2017 between the Company and Cato Research Canada Inc. (incorporated by reference to Exhibit 10.3 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021)
4.3†	Master Service and Technology Agreement, dated February 25, 2019, by and between the Company and Prevail InfoWorks, Inc. (incorporated by reference to Exhibit 10.6 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021)
4.4†	Side Letter to Master Service and Technology Agreement, dated February 24, 2020, by and between the Company and Prevail InfoWorks, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021)
4.5#	Consulting Amending Agreement, dated as of January 27, 2022, by and between the Company and Stephen Haworth (incorporated by reference to Exhibit 4.26 to the Company's Form 20-F filed May 3, 2022)
4.6#	Stock Option Plan (incorporated by reference as Schedule B to Exhibit 99.2 to the Company's Form 6-K filed on November 23, 2021.)
4.7†	Sponsored Research Agreement dated May 27, 2021 between the Regents of the University of Colorado and the Company (incorporated by reference to Exhibit 4.19 to the Company's Form 20-F filed May 3, 2022)
4.8#	Amended and Restated Consulting Agreement between the Company and Stacy Evans, dated May 1, 2024 (incorporated by reference to Exhibit 4.31 to the Company's Form 20-F filed May 10, 2024)
4.9#	Consulting Agreement, dated as of December 16, 2024 between the Company and Michael Bumby (incorporated by reference to Exhibit 4.32 to the Company's Form 20-F filed May 12, 2025)
4.10*	Summary of Terms for an Asset Acquisition Between Vectus Biosystems Limited and XORTX Therapeutics Inc. dated October 15, 2025
4.11*	Extension Agreement, among Vectus Biosystems Limited and the Company dated January 13, 2026
8.1	Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021)
11.1	Code of Conduct (incorporated by reference to Exhibit 11.1 to the Company's Form 20-F filed April 28, 2023)
11.2	Insider Trading and Blackout Period Policy (incorporated by reference to Exhibit 11.2 to the Company's Form 20-F filed May 12, 2025)
12.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
12.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
13.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1	Management Discussion and Analysis of the Company for the year ended December 31, 2024 (incorporated by reference to Exhibit 99.2 to the Form 6-K filed February 27, 2026)
15.2	Audit Committee Charter (incorporated by reference to Exhibit 15.2 to the Company's Form 20-F filed April 28, 2023)
15.3*	Consent of independent registered public accounting firm, Davidson & Company LLP (PCAOB ID: 731)
15.4*	Consent of independent registered public accounting firm, Smythe LLP (PCAOB ID: 995)
15.5	Letter from Smythe LLP, as the Company's former independent registered public accountant (incorporated by reference to Exhibit 15.5 to the Company's Form 20-F filed May 12, 2025)
97.1	Clawback policy (incorporated by reference to Exhibit 97.1 to the Company's Form 20-F filed May 10, 2024)
101	The following materials from the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2025, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Statements of Financial Position as of December 31, 2025 and 2024; (ii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2025, 2024 and 2023; (iii) Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2025, 2024 and 2023; (iv)

	Consolidated Statements of Cash Flows for the years ended December 31, 2025, 2024 and 2023; and (v) Notes to Consolidated Financial Statements
104	Cover Page Interactive Data File (formatted as Inline eXtensible Business Reporting Language (iXBRL) and contained in Exhibit 101)

* Filed herewith.

\# Indicates management contract or compensatory plan.

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

SIGNATURES

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

XORTX THERAPEUTICS INC.

/s/ Michael Bumby

By: Michael Bumby
Title: Chief Financial Officer

Date: March 20, 2026

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CONSOLIDATED FINANCIAL STATEMENTS

AS AT AND FOR THE YEARS ENDED DECEMBER 31, 2025, 2024 AND 2023
(Expressed in U.S. Dollars)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Directors of
XORTX Therapeutics Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statement of financial position of XORTX Therapeutics Inc. (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of loss and comprehensive loss, changes in shareholders' equity, and cash flows for the year ended December 31, 2025 and 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years ended December 31, 2025 and 2024 in conformity with IFRS Accounting Standards as issued by the International Accounting Standards Board ("IFRS Accounting Standards").

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company will have to finance its research and development activities and if the Company is unsuccessful in obtaining adequate financing in the future, research activities will be postponed. These circumstances and conditions indicate the existence of a material uncertainty that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

DAVIDSON & COMPANY LLP | 1200 – 609 Granville Street, PO BOX 10372, Pacific Centre, Vancouver, BC V7Y 1G6 | 604 687 0947 | **davidson-co.com**

We have served as the Company's auditor since 2025.

/s/ DAVIDSON & COMPANY LLP

Chartered Professional Accountants — Vancouver, Canada

February 25, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

TO THE SHAREHOLDERS AND DIRECTORS OF XORTX THERAPEUTICS INC.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statements of loss and comprehensive loss, changes in shareholders' equity and cash flows of Xortx Therapeutics Inc. and its subsidiaries (the "Company") for the year ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements, present fairly, in all material respects, the results of operations and cash flows of the Company for the year ended December 31, 2023, in conformity with IFRS Accounting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

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

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

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

SMYTHE LLP | **smythecpa.com**

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Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that

(1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

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

Smythe LLP

Chartered Professional Accountants
Vancouver, Canada
April 1, 2024

XORTX THERAPEUTICS INC.
Consolidated Statements of Financial Position
(Expressed in U.S. Dollars)

	Note	December 31, 2025	December 31, 2024
		$	$
Assets			
Current			
Cash	**5**	864,514	2,473,649
Accounts receivable		80,172	17,637
Prepaid expenses	**6**	22,609	185,412
Deferred acquisition costs	**19**	293,803	—
Total Current Assets		**1,261,098**	**2,676,698**
Non-current			
Contract payments	**7**	1,200,000	1,200,000
Intangible assets	**8**	185,367	183,108
Property and equipment	**9**	37,065	34,721
Total Assets		**2,683,530**	**4,094,527**
Liabilities			
Current			
Accounts payable and accrued liabilities	**10,13**	553,784	147,205
Derivative warrant liability	**12(h)**	8,000	572,000
Lease obligation	**11**	37,287	38,785
Total Liabilities		**599,071**	**757,990**
Shareholders' Equity			
Share capital	**12**	20,183,547	18,493,571
Reserves	**12**	5,778,074	6,039,078
Obligation to issue shares	**8(c)**	—	24,746
Accumulated other comprehensive loss		(52,605)	(52,605)
Accumulated deficit		(23,824,557)	(21,168,253)
Total Shareholders' Equity		**2,084,459**	**3,336,537**
Total Liabilities and Shareholders' Equity		**2,683,530**	**4,094,527**

Nature of operations and going concern (Note 1)
Commitments (Note 17)
Subsequent event (Note 19)

/s/ "Allen Davidoff"
Director

/s/ "Paul Van Damme"
Director

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

XORTX THERAPEUTICS INC.
Consolidated Statements of Loss and Comprehensive Loss
For the years ended December 31, 2025, 2024 and 2023
(Expressed in U.S. Dollars)

	Note	2025 $	2024 $	2023 $
Expenses				
Research and development	**13**	574,935	183,830	2,418,715
Consulting, wages and benefits	**13**	1,000,587	1,055,247	1,037,558
Directors' fees	**13**	215,568	168,143	179,406
Investor relations		595,838	1,360,170	919,490
Professional fees	**13**	349,328	616,859	514,263
General and administrative		241,032	320,949	375,505
Public company costs		120,335	141,404	170,184
Travel		21,121	31,916	170,187
Amortization of property and equipment	**9**	85,730	86,204	73,062
Amortization of intangible assets	**8**	26,385	31,070	66,632
Impairment of intangible assets	**8**	1,833	—	—
Share-based payments	**12(g),13**	25,155	122,527	120,984
Loss before other items		**(3,257,847)**	**(4,118,319)**	**(6,045,986)**
Fair value adjustment on derivative warrant liability	**12(h)**	564,000	1,035,105	3,641,403
Foreign exchange loss		(4,327)	(73,009)	(7,025)
Interest income		41,870	121,908	253,543
Transaction costs on derivative warrant liability	**12(b)**	—	(279,031)	—
Total loss and comprehensive loss for the year		**(2,656,304)**	**(3,313,346)**	**(2,158,065)**
Basic and diluted loss per common share		(0.56)	(1.15)	(1.09)
Weighted average number of common shares outstanding - Basic and diluted		4,734,633	2,878,514	1,981,734

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

XORTX THERAPEUTICS INC.
Consolidated Statements of Changes in Shareholders' Equity
For the years ended December 31, 2025, 2024 and 2023
(Expressed in U.S. Dollars)

	Number of common shares	Share capital $	Reserves $	Obligation to issue shares $	Accumulated deficit $	Accumulated other comprehensive loss $	Total $
Balance, December 31, 2022	**1,670,071**	**16,524,354**	**6,197,158**	**24,746**	**(15,696,842)**	**(52,605)**	**6,996,811**
Reclassification of derivative warrant liability	—	—	(318,000)	—	—	—	(318,000)
Pre-funded warrants exercised	328,777	532,181	(531,885)	—	—	—	296
Share-based payments	—	—	120,984	—	—	—	120,984
Comprehensive loss for the year	—	—	—	—	(2,158,065)	—	(2,158,065)
Balance, December 31, 2023	**1,998,848**	**17,056,535**	**5,468,257**	**24,746**	**(17,854,907)**	**(52,605)**	**4,642,026**
Shares issued pursuant to private placement	1,219,717	1,387,549	—	—	—	—	1,387,549
Pre-funded warrants issued	—	—	907,994	—	—	—	907,994
Reclassification of derivative warrant liability	—	—	123,651	—	—	—	123,651
Share issuance costs	—	(331,541)	(224,140)	—	—	—	(555,681)
Pre-funded warrants exercised	257,810	359,214	(359,211)	—	—	—	3
Warrants exercised	5,000	21,814	—	—	—	—	21,814
Share-based payments	—	—	122,527	—	—	—	122,527
Comprehensive loss for the year	—	—	—	—	(3,313,346)	—	(3,313,346)
Balance, December 31, 2024	**3,481,375**	**18,493,571**	**6,039,078**	**24,746**	**(21,168,253)**	**(52,605)**	**3,336,537**
Shares issued pursuant to at-the-market offering	73,871	113,547	—	—	—	—	113,547
Shares issued pursuant to private placement	1,996,442	1,400,156	—	—	—	—	1,400,156
Pre-funded warrants issued	—	—	741,832	—	—	—	741,832
Share issuance costs	—	(547,288)	(304,444)	—	—	—	(851,732)
Pre-funded warrants exercised	1,410,530	723,561	(723,547)	—	—	—	14
Reversal of obligation to issue shares upon termination of agreement	—	—	—	(24,746)	—	—	(24,746)
Share-based payments	—	—	25,155	—	—	—	25,155
Comprehensive loss for the year	—	—	—	—	(2,656,304)	—	(2,656,304)
Balance, December 31, 2025	**6,962,218**	**20,183,547**	**5,778,074**	**—**	**(23,824,557)**	**(52,605)**	**2,084,459**

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

XORTX THERAPEUTICS INC.
Consolidated Statements of Cash Flows
For the years ended December 31, 2025, 2024 and 2023
(Expressed in U.S. in Dollars)

	2025	2024	2023
	$	$	$
Cash provided by (used in):			
Operating activities			
Net loss for the year	(2,656,304)	(3,313,346)	(2,158,065)
Items not affecting cash:			
Amortization	112,115	117,274	139,694
Fair value adjustment on derivative warrant liability	(564,000)	(1,035,105)	(3,641,403)
Impairment of intangible assets	1,833	—	—
Share-based payments	25,155	122,527	120,984
Transaction costs on derivative warrant liability	—	279,031	—
Unrealized foreign exchange (gain) loss	(23,739)	34,178	(13,634)
Changes in non-cash operating assets and liabilities:			
Accounts receivable	(62,535)	43,074	21,041
Prepaid expenses	162,803	208,166	142,654
Accounts payable and accrued liabilities	235,949	(134,447)	(1,194,436)
	(2,768,723)	(3,678,648)	(6,583,165)
Investing activities			
Acquisition of intangible assets	(55,223)	(38,924)	(42,052)
Acquisition of equipment	—	—	(4,311)
Deferred acquisition costs	(239,730)	—	—
	(294,953)	(38,924)	(46,363)
Financing activities			
Pre-funded warrants and warrants exercised	14	16,573	296
Payment of lease obligation	(89,572)	(69,723)	(66,089)
Cash share issuance costs	(738,433)	(667,883)	(295,251)
Proceeds from issuance of equity instruments	2,255,535	3,500,542	—
	1,427,544	2,779,509	(361,044)
Effect of foreign exchange loss (gain) on cash	26,997	(35,953)	4,041
Decrease in cash	(1,609,135)	(974,016)	(6,986,531)
Cash, beginning of year	2,473,649	3,447,665	10,434,196
Cash, end of year	864,514	2,473,649	3,447,665
Supplemental Cash Flow and Non-Cash Investing and Financing Activities Disclosure			
Fair value of agent's warrants	38,484	—	—
Derivative warrant liability reclassified to share capital on exercise of warrants	—	5,244	—
Recognition of right-of-use asset	88,074	96,998	—
Deferred financing costs reclassified to share capital and transaction costs on derivative warrant liability	—	166,344	—
Share issuance costs in accounts payable	113,299	—	—
Deferred acquisition costs in accounts payable	54,073	—	—

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

XORTX THERAPEUTICS INC.
Notes to the Consolidated Financial Statements
For the years ended December 31, 2025, 2024 and 2023
(Expressed in U.S. Dollars)

1. Nature of operations and going concern

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

XORTX is a public company listed on the TSX Venture Exchange (the "TSXV") and on the Nasdaq Stock Market ("Nasdaq") under the symbol "XRTX". The Company's operations and mailing address is 3710 – 33rd Street NW, Calgary, Alberta, Canada T2L 2M1 and its registered address is located at 550 Burrard Street, Suite 2900, Vancouver, British Columbia, V6C 0A3. The Company has received a notice of non-compliance from Nasdaq relating to the minimum bid price requirement and is working to regain compliance within the prescribed period.

XORTX is a late - stage clinical pharmaceutical company focused on developing innovative therapies to treat gout and progressive kidney disease modulated by aberrant purine and uric acid metabolism in orphan disease indications such as allopurinol intolerant gout and autosomal dominant polycystic kidney disease, as well as more prevalent type 2 diabetic nephropathy, and fatty liver disease. The Company's current focus is on developing products to slow and/or reverse the progression of these diseases.

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

2. Basis of preparation

Statement of Compliance

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

Basis of Measurement and Presentation

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

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

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

These consolidated financial statements were approved for issue by the Board of Directors on February 25, 2026.

3. Material accounting policies

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

Financial Instruments

a) Classification

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

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

The following are the Company's financial instruments as at December 31, 2025 and 2024:

	Classification
Cash	Amortized cost
Accounts receivable	Amortized cost
Contract payments	Amortized cost
Accounts payable and accrued liabilities	Amortized cost
Derivative warrant liability	FVTPL
Lease obligations	Amortized cost

b) Measurement

Financial assets at FVTOCI

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

Financial assets and liabilities at amortized cost

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

Financial assets and liabilities at FVTPL

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

3. Material Accounting policies (continued)

Financial Instruments (continued)

Impairment of financial assets at amortized cost

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

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

c) Derecognition

Financial assets

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

Financial liabilities

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

Cash

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

Equipment

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

Computer equipment	3 years

Leases

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

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

3. Material Accounting policies (continued)

Leases (continued)

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

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

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

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

Research and development costs

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

Intangible assets

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

Government assistance

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

3. Material Accounting policies (continued)

Impairment of long-lived assets

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

Derivative warrant liabilities

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

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

The Company uses the Black-Scholes option pricing model to estimate fair value at each period end date. The key assumptions used in the model are described in Note 12 (h).

Share-based payments

The Company has a stock option plan that is described in Note 12 and grants share options to acquire common shares of the Company to directors, officers, employees and consultants. Share-based payments to employees are measured at the fair value of the instruments granted. Share-based payments to non-employees are measured at the fair value of the goods or services received or the fair value of the equity instruments issued as calculated using the Black-Scholes option pricing model if the fair value of the goods or services cannot be reliably measured. The offset to the recorded expense is to reserves.

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

Share capital

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

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

3. Material Accounting policies (continued)

Share capital (continued)

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

Earnings (loss) per common share

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

Foreign currency translation

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

Income taxes

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

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

New and recent accounting pronouncements

In April 2024, IASB issued IFRS 18, Presentation and Disclosure in Financial Statements to replace IAS 1, Presentation of Financial Statements. The aim of IFRS 18 is to set out requirements for presentation and disclosure of financial statements to ensure the entity provides relevant and accurate information about its assets, liabilities, equity, income and expenses. IFRS 18 is effective for the Company as of January 1, 2027. The Company is assessing the impact of this standard on the consolidated financial statements.

4. Critical accounting judgments and estimates

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

Revisions to accounting estimates are recognized in the period in which the estimate is revised and may affect both the period of revision and future periods. Information about critical accounting judgments in applying accounting policies that have the most significant risk of causing material adjustment to the carrying amounts of assets and liabilities recognized in the consolidated financial statements within the next financial year are discussed below:

Share-based payment transactions and warrant liabilities

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Warrant liabilities are accounted for as derivative liabilities if the proceeds from exercise are either not fixed, denominated in a currency other than the functional currency, or can be settled on a net basis, and therefore do not meet the fixed for fixed criteria. Estimating fair value for share-based transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the instrument. This estimate also requires determining the most appropriate inputs to the valuation model including the expected life of the share option or warrant, volatility and dividend yield and making assumptions about them.

Classification of contract payments

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

Impairment of intangible assets

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

Determination of functional currency

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

Treatment of research and development costs

Costs to develop products are capitalized to the extent that the criteria for recognition as intangible assets in IAS 38 Intangible Assets are met. Those criteria require that the product is technically and economically viable, the Company has the intention and ability to use the asset, and how the asset will generate future benefits. Management assessed the capitalization of development costs based on the attributes of the development project, perceived user needs, industry trends and expected future economic conditions. Management considers these factors in aggregate and applies significant judgment to determine whether the product is feasible. The Company has not capitalized any development costs as at December 31, 2025.

(Expressed in U.S. Dollars)

4. Critical accounting judgments and estimates (continued)

Leases

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

Classification of pre-funded warrants

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

Current and deferred taxes

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

5. Cash

The Company's cash consists of cash held and interest-bearing deposits with the Company's bank and brokerage accounts. The current annual interest rate earned on these deposits is 2.10% to 3.50% (2024 – 3.62%).

	December 31, 2025	December 31, 2024
	$	$
Cash	244,022	53,686
Interest-bearing deposits	620,492	2,419,963
	864,514	2,473,649

6. Prepaid expenses

The Company's prepaid expenses relate to the following:

	December 31, 2025	December 31, 2024
	$	$
Research and development	—	1,167
Insurance	2,582	158,007
Investor relations conferences and services	12,464	19,490
Administrative services and other	7,563	6,748
	22,609	185,412

(Expressed in U.S. Dollars)

7. Contract payments

During the year ended December 31, 2020, the Company entered into an agreement with Prevail InfoWorks Inc. As part of the agreement, the Company paid $1,200,000 through the issuance of units in the private placement that closed February 28, 2020, to be applied to future regulatory and clinical trial programs. The 108,590 units issued were measured by reference to their fair value on the issuance date, which is equal to CAD $14.76 per unit.

8. Intangible assets

Cost	Total
	$
Balance, December 31, 2023	336,803
Additions	38,924
Balance, December 31, 2024	**375,727**
Additions	55,223
Disposal	(26,579)
Balance, December 31, 2025	**404,371**

Accumulated amortization	Total
	$
Balance, December 31, 2023	161,549
Amortization	31,070
Balance, December 31, 2024	**192,619**
Amortization	26,385
Balance, December 31, 2025	**219,004**

Carrying values	Total
	$
At December 31, 2024	183,108
At December 31, 2025	**185,367**

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

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

The Company will also pay the Licensor royalties on the cumulative net revenues from the sale or sublicense of the product covered under the patent license until the later of (i) the expiration of the last patent right covering the product; and (ii) the expiration of ten years from the date of the first commercial sales of a product. As of December 31, 2025, no royalties have been accrued or paid.

b) In December 2012, the Company entered into an agreement to license certain intellectual property relating to the use of all uric acid lowering agents to improve the treatment of metabolic syndrome. Under this patent rights purchase agreement, between the Company and Dr. Richard Johnson and Dr. Takahiko Nakagawa (the "Vendors"), the Company will pay the Vendors a royalty based on the cumulative net revenues from the sale or sublicense of the product covered under the licensed intellectual property until the later of (i) the expiration of the last patent right covering the product; and (ii) the expiration of 10 years from the date of the first commercial sales of a product. As of December 31, 2025, no royalties have been accrued or paid.

(Expressed in U.S. Dollars)

8. Intangible assets (continued)

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

i) An annual license fee of $1,000;
ii) Reimburse UFRF for United States and/or foreign costs associated with the maintenance of the licensed patents;
iii) The issuance to UFRF of 180,397 shares of common stock of the Company. 160,783 have been issued to UFRF as at December 31, 2025 and December 31, 2024. The remaining shares to be issued are included in obligation to issue shares ($24,746);
iv) Milestone payments of $500,000 upon receipt of FDA approval to market licensed product in the United States of America and $100,000 upon receipt of regulatory approval to market each licensed product in each of other jurisdictions;
v) Royalty payments of up to 1.5% of net sales of products covered by the license until the later of (i) the expiration of any patent claims; or (ii) 10 years from the date of the first commercial sale of any covered product in each country. Following commencement of commercial sales, the Company will be subject to certain annual minimum royalty payments that will increase annually to a maximum of $100,000 per year. As at December 31, 2025, no royalties have been accrued or paid; and
vi) UFRF is entitled to receive a royalty of 5% of amounts received from any sub-licensee that are not based directly on product sales, excluding payments received for research and development or purchases of the Company's securities at not less than fair market value. As at December 31, 2025, no royalties have been accrued or paid.

On October 12, 2025, UFRF terminated the agreement as the Company did not achieve the specified milestones. There were no outstanding financial obligations under the agreement at the termination date. Accordingly, the previously recognized license asset of $26,579 and the related obligation to issue shares of $24,746, which had been recorded within equity, were derecognized upon termination.

9. Property and equipment

Cost	Right-of-use asset	Equipment	Total
	$	$	$
Balance, December 31, 2023	114,588	23,344	137,932
Additions	96,998	—	96,998
Balance, December 31, 2024	**211,586**	**23,344**	**234,930**
Additions	88,074	—	88,074
Balance, December 31, 2025	**299,660**	**23,344**	**323,004**

Accumulated amortization	Right-of-use asset	Equipment	Total
	$	$	$
Balance, December 31, 2023	103,675	10,330	114,005
Amortization	78,525	7,679	86,204
Balance, December 31, 2024	**182,200**	**18,009**	**200,209**
Amortization	80,763	4,967	85,730
Balance, December 31, 2025	**262,963**	**22,976**	**285,939**

(Expressed in U.S. Dollars)

9. Property and equipment (continued)

Carrying values	Right-of-use asset	Equipment	Total
	$	$	$
At December 31, 2024	29,386	5,335	34,721
At December 31, 2025	**36,697**	**368**	**37,065**

The Company entered into an office lease during the year ended December 31, 2022 for which a right-of-use asset was recognized (Note 11). During the year ended December 31, 2025, the Company extended its office lease. A $88,074 right - of - use asset addition was recognized with a corresponding $88,074 increase to the lease liability.

10. Accounts payable and accrued liabilities

	December 31, 2025	December 31, 2024
	$	$
Trade payables	395,539	84,020
Accrued liabilities	158,245	63,185
Total	553,784	147,205

11. Lease obligation

The Company has entered into an office lease expiring in 2026, with an imputed interest rate of 8% per annum. A reconciliation of the outstanding lease obligation as at December 31, 2025 is as follows:

	$
Balance, December 31, 2023	11,510
Additions	96,998
Lease payments	(69,723)
Balance, December 31, 2024	38,785
Additions	88,074
Lease payments	(89,572)
Balance, December 31, 2025	**37,287**

The $88,074 lease obligation addition recognized in the year ended December 31, 2025 relates to an extension of the office lease to May 31, 2026. The $96,998 lease obligation recognized in the year ended December 31, 2024 relates to an extension of the office lease to May 31, 2025.

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

	December 31, 2025	December 31, 2024
	$	$
2025	—	39,535
2026	38,008	—
Total minimum lease payments	38,008	39,535
Less: imputed interest	(721)	(750)
Total present value of minimum lease payments	37,287	38,785
Less: current portion	(37,287)	(38,785)
Non-current portion	—	—

12. Share capital and reserves

a) Authorized and issued

Unlimited common shares – 6,962,218 issued at December 31, 2025 (2024 – 3,481,375, 2023 – 1,998,848).

b) Issuances

Year ended December 31, 2025:

On January 15, 2025, the Company issued 73,871 common shares in an at-the-market offering for gross proceeds of $113,547. In connection with the offering, the Company incurred issuance costs of $19,064. The costs were recorded as a reduction of equity.

On January 15, 2025, the Company issued 233,000 common shares for the exercise of pre-funded warrants at US$0.00001 per share in the amount of $2. An amount of $324,643 was transferred from reserves to share capital as a result.

On July 22, 2025, the Company closed a non-brokered private placement of 1,267,123 units at a price of $0.73 per unit for aggregate gross proceeds of $925,000. Each unit consists of one common share and one common share purchase warrant. Each warrant entitles the holder to purchase one common share at a price of $1.20 for a period of sixty months following the date of issuance provided, however, that if the closing price of the common shares on the Nasdaq is greater than $2.00 for ten or more consecutive trading days, the warrants will be accelerated and will expire on the 30th business day following the date of such notice. In connection with the offering, the Company paid an aggregate of $12,264 in finder's fees and issued, in aggregate, 16,800 finder's warrants. Each finder's warrant has terms equal to those of the common share purchase warrants. The Company incurred additional cash issuance costs of $305,604. The 16,800 finder's warrants were determined to have a fair value of $11,560.

On August 8, 2025, the Company closed a non-brokered private placement of 156,849 units at a price of $0.73 per unit for aggregate gross proceeds of $114,500. Each unit consisted of one common share and one common share purchase warrant. Each warrant entitles the holder to purchase one common share at a price of $1.20 for a period of sixty months following the date of issuance provided, however, that if the closing price of the common shares on the Nasdaq is greater than $2.00 for ten or more consecutive trading days, the warrants will be accelerated and will expire on the 30th business day following the date of such notice. The Company incurred cash issuance costs of $32,075.

On October 23, 2025, the Company closed its registered direct offering for the purchase and sale of 572,470 common shares at a price of $0.63 per common share, and 1,177,530 pre-funded warrants at a price of $0.62999 per pre-funded warrant for aggregate gross proceeds of $1,102,488. Each pre-funded warrant entitles the holder to acquire one common share at an exercise price of $0.00001 per share. In connection with the offering, the Company paid an aggregate of $77,175 in finder's fees and issued 87,500 agent warrants, each exercisable into one common share of the Company at an exercise price of $0.69 commencing 181 days following issuances with a term of eighteen months from the closing date. The Company incurred additional cash issuance costs of $405,550 and were recorded as a reduction of equity. The 87,500 finder's warrants were determined to have a fair value of $26,924.

Concurrently with the closing of the offering, the Company issued 1,177,530 common shares for the exercise of the pre-funded warrants at $0.00001 per share in the amount of $12. An amount of $398,904 was transferred from reserves to share capital as a result.

Year ended December 31, 2024:

On February 15 and March 4, 2024, the Company closed two tranches of a non-brokered offering of 899,717 common share units at a price of CAD $3.00 per common share unit for aggregate gross proceeds of $2,000,549 (CAD $2,699,151). Each common share unit consists of one common share and one warrant to purchase one common share at CAD $4.50 per common share for a period of two years, provided, however that, if, the common shares on the TSXV trade at greater than CAD $6.00 for 10 or more consecutive trading days, the warrants will be accelerated and the warrants will expire on the 30th business day following the date of notice.

(Expressed in U.S. Dollars)

12. Share capital and reserves (continued)

The proceeds were allocated $1,205,

000 to the derivative warrant liability (Note 12(h)) and the residual $795,549 was allocated to common shares.

In connection with the offering, the Company paid finder's fees of $97,241, representing a 5% finder's fee on certain subscriptions to qualified finders. The Company incurred additional cash share issuance costs of $367,195 including $166,344 deferred at December 31, 2023. The costs were allocated between common shares and derivative warrant liability in proportion to their initial carrying amounts with $185,405 recorded as a reduction of equity and $279,031 recorded as transaction costs on derivative warrant liability.

On March 25, 2024, the Company issued 5,000 common shares for the exercise of warrants at CAD $4.50 per share in the amount of $16,570 (CAD $22,500). An amount of $5,244 was transferred from derivative warrant liability to share capital as a result.

On October 18, 2024, the Company closed its registered direct offering and concurrent private placement for the purchase and sale of: (i) 320,000 common share units at a price of $1.85 per unit, with each unit consisting of one common share and one warrant to purchase one common share; and (ii) 490,810 pre-funded warrant units at a price of $1.84999 per pre-funded unit, with each pre-funded unit consisting of one pre-funded warrant to purchase one common share and one warrant to purchase one common share. Aggregate gross proceeds amounted to $1,499,993. The pre-funded warrants have an exercise price of $0.00001 per share and will terminate once exercised in full. The unit warrants are exercisable at an exercise price of $2.18 are immediately exercisable and expire five years from issuance.

In connection with the private placement, the Company incurred issuance costs of $370,276. The costs were recorded as a reduction of equity.

On November 21, 2024, the Company issued 257,810 common shares for the exercise of pre-funded warrants at US$0.00001 per share in the amount of $3. An amount of $359,211 was transferred from reserves to share capital as a result.

Year ended December 31,2023:

On January 19, 2023, the Company issued 328,777 common shares for the exercise of pre-funded warrants at $0.0009 per share in the amount of $296. An amount of $531,885 was transferred from reserves to share capital as a result.

c) Diluted Weighted Average Number of Common Shares Outstanding

	Year ended		
	December 31, 2025	December 31, 2024	December 31, 2023
Basic weighted average shares outstanding	**4,734,633**	2,878,514	1,981,734
Effect of outstanding securities	—	—	—
Diluted weighted average shares outstanding	**4,734,633**	2,878,514	1,981,734

During the years ended December 31, 2025, 2024 and 2023, the Company had a net loss, as such, the diluted loss per share calculation excludes any potential conversion of options and warrants that would decrease loss per share.

(Expressed in U.S. Dollars)

12. Share capital and reserves (continued)

d) Common Share Purchase Warrants

A summary of the changes in warrants for the years ended December 31, 2025, 2024 and 2023 is presented below:

	Number of Warrants	Weighted Average Exercise price	
Balance, December 31, 2023 and 2022	**1,125,210**	**$ 22.31**	
Granted – February 9, 2024	824,767	3.13	(1)
Granted – February 23, 2024	74,950	3.13	(1)
Granted – October 18, 2024	810,810	2.18	
Exercised	(5,000)	3.13	(1)
Balance, December 31, 2024	**2,830,737**	**$ 3.60**	
Granted – July 21, 2025	1,267,123	1.20	
Granted – August 8, 2025	156,849	1.20	
Balance, December 31, 2025	**4,254,709**	**$ 2.82**	

(1) Exercise price of CAD $4.50.

During the year ended December 31, 2024, the Company amended the exercise price of 1,125,210 common share purchase warrants that were issued pursuant to private placements that closed in February 2021, October 2021 and October 2022. Pursuant to the polices of the TSXV the terms of the warrants, as amended, will be subject to an acceleration expiry provision such that if for any 10 consecutive trading dates during the unexpired term of the warrants, the closing price of the Company's shares on the exchange exceeds $6.50, the exercise period of the warrants will be reduced to 30 days, starting seven days after the last premium trading day. All other terms of the warrants remain unchanged.

At December 31, 2025, the weighted average contractual remaining life of the unexercised warrants was 2.58 years (2024 – 2.58 years).

The following table summarizes information on warrants outstanding at December 31, 2025:

Exercise Price	Number Outstanding		Expiry date	Remaining Contractual Life
$5.00	198,333	(1)	February 9, 2026	0.11 years
$5.00	270,211		October 15, 2026	0.79 years
$5.00	101,111		October 15, 2026	0.79 years
$5.00	555,555		October 7, 2027	1.77 years
CAD $4.50	819,767	(1)	February 9, 2026	0.11 years
CAD $4.50	74,950	(1)	February 23, 2026	0.15 years
$2.18	810,810		October 18, 2029	3.80 years
$1.20	1,267,123		July 21, 2030	4.56 years
$1.20	156,849		August 8, 2030	4.61 years
Total	4,254,709			2.58 years

(1) Expired unexercised subsequent to December 31, 2025.

(Expressed in U.S. Dollars)

12. Share capital and reserves (continued)

e) Pre-Funded Warrants

A summary of the changes in pre-funded warrants for the years ended December 31, 2025, 2024 and 2023 is presented below:

	Number of Warrants	Weighted Average Exercise price
Balance, December 31, 2022	328,777	$ 0.0009
Exercised	(328,777)	0.0009
Balance, December 31, 2023	—	—
Granted – October 18, 2024	490,810	0.00001
Exercised	(257,810)	0.00001
Balance, December 31, 2024	**233,000**	**$ 0.00001**
Granted – October 23, 2025	1,177,530	0.00001
Exercised	(1,410,530)	0.00001
Balance, December 31, 2025	—	—

f) Finders' and Underwriters Warrants

A summary of the changes in finders' and underwriters warrants for the years ended December 31, 2025, 2024 and 2023 is presented below:

	Number of Warrants	Weighted Average Exercise price
Balance, December 31, 2024, 2023 and 2022	**50,298**	**$ 23.57**
Granted – July 21, 2025	16,800	1.20
Granted – October 23, 2025	87,500	0.69
Balance, December 31, 2025	**154,598**	**$ 8.25**
Exercisable, December 31, 2025	**67,098**	**$ 18.11**

At December 31, 2025, the weighted average contractual remaining life of the unexercised finders' and underwriters' warrants was 1.64 years(2024 – 2.24 years).

The following table summarizes information on finders' and underwriters' warrants outstanding at December 31, 2025:

Exercise Price	Number Outstanding	Expiry date	Remaining Contractual Life
CAD$42.30	6,377	(1) February 9, 2026	0.11 years
$42.93	16,144	October 15, 2026	0.79 years
$10.98	27,777	October 7, 2027	1.77 years
$1.20	16,800	July 21, 2030	4.56 years
$0.69	87,500	April 23, 2027	1.31 years
Total	154,598		1.64 years

(1) Expired unexercised subsequent to December 31, 2025.

The fair value of the finders' warrants issued on July 21, 2025 was estimated at $11,560 on the date of grant using the Black-Scholes option pricing model. The exercise price of the unit of $1.20; expected life of 5 years; expected volatility of 100%; risk free rate of 2.99%; and expected dividend yield of 0%.

(Expressed in U.S. Dollars)

12. Share capital and reserves (continued)

f) Finders' and Underwriters Warrants (continued)

The fair value of the finders' warrants issued on October 23, 2025 was estimated at $26,924 on the date of grant using the Black-Scholes option pricing model. The exercise price of the unit of $0.69; expected life of 18 months; expected volatility of 87%; risk free rate of 2.39%; and expected dividend yield of 0%.

g) Stock Options

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

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

	2024	2023
Dividend yield	Nil	Nil
Annualized volatility	100 %	100 %
Share price	CAD $3.82	CAD $2.90
Risk-free interest rate	3.47 %	3.25 %
Expected life	5 years	5 years

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

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

During the year ended December 31, 2025, the Company recorded share-based expenses of $25,155 (2024 - $122,527; 2023 - $120,984), in respect of the vesting of options issued in prior years.

A summary of the changes in stock options for the years ended December 31, 2025, 2024 and 2023 is presented below:

	Number of Options	Weighted Average Exercise price (CAD)
Balance, December 31, 2022	128,240	$ 21.75
Granted – December 31, 2023	8,000	2.90
Expired	(32,318)	33.65
Balance, December 31, 2023	**103,922**	**$ 16.60**
Granted – March 4, 2024	39,483	4.50
Granted – April 8, 2024	8,000	5.00
Granted – December 18, 2024	13,000	1.75
Expired	(16,642)	22.22
Balance, December 31, 2024	**147,763**	**$ 10.80**
Expired	(18,002)	12.86
Balance, December 31, 2025	**129,761**	**$ 10.51**
Vested and exercisable, December 31, 2025	**109,596**	**$ 11.86**

12. Share capital and reserves (continued)

g) Stock Options (continued

The weighted average contractual remaining life of the unexercised options was 2.27 years (2024 - 3.02 years).

The following table summarizes information on stock options outstanding at December 31, 2025:

Exercise Price (CAD$)	Number Outstanding	Number Exercisable	Expiry Date	Remaining Contractual Life
16.92	2,366	2,366	May 12, 2026	0.36 years
21.69	4,732	4,732	July 14, 2026	0.53 years
22.86	7,262	7,262	December 21, 2026	0.97 years
22.86	9,163	9,163	January 12, 2027	1.03 years
14.40	37,200	37,200	June 6, 2027	1.43 years
12.42	5,554	5,554	November 25, 2027	1.90 years
2.90	8,000	8,000	December 31, 2028	3.00 years
4.50	34,484	24,069	March 4, 2029	3.18 years
5.00	8,000	8,000	April 8, 2029	3.27 years
1.75	13,000	3,250	December 18, 2029	3.97 years
	129,761	**109,596**		

h) Derivative Warrant Liability

During the years ended December 31, 2024, 2022 and 2021, the Company issued warrants which were recorded as derivative financial liabilities as the exercise price was denominated in a currency other than the functional currency of the Company and in certain situations allow the holder to exercise the warrants on a cashless basis and therefore may be settled other than by the exchange of a fixed amount of cash. Under the cashless exercise option, the holders of these warrants may elect to settle the warrants on a cashless basis if the common shares are not subject to an effective registration statement at the time the holder wishes to exercise them. A contract that may be settled by a single net payment (generally referred to as net cash settled or net equity settled) is a financial liability and not an equity instrument.

These warrants are revalued at each reporting period and any gain or loss is recorded in profit or loss.

The fair value of the warrants issued during the year ended December 31, 2025 with an exercise price denominated in CAD was estimated at $nil (2024 - $1,205,000) on the date of grant using the Black-Scholes option pricing model with the following data and assumptions:

	2024
Dividend yield	Nil
Annualized volatility	130-135 %
Share price	CAD$3.03 – CAD$3.40
Risk-free interest rate	4.28% – 4.33 %
Expected life	2 years

(Expressed in U.S. Dollars)

12. Share capital and reserves (continued)

h) Derivative Warrant Liability (continued)

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

Balance at December 31, 2022	**$**	**3,854,403**
Reclassified from reserves		318,000
Fair value adjustment		(3,641,403)
Balance at December 31, 2023	**$**	**531,000**
Warrants issued February 9, 2024		1,102,000
Warrants issued February 23, 2024		103,000
Warrants exercised		(5,244)
Reclassified to reserves		(123,651)
Fair value adjustment		(1,035,105)
Balance at December 31, 2024	**$**	**572,000**
Fair value adjustment		(564,000)
Balance at December 31, 2025	**$**	**8,000**

Significant assumptions used in determining the fair value of the derivative warrant liabilities at December 31, 2025, 2024 and 2023 are as follows:

	December 31, 2025	December 31, 2024	December 31, 2023
Share price	**$ 0.56**	**$ 1.13**	**$ 2.31**
Risk-free interest rate	**2.55 %**	**2.92 %**	**3.25%-3.91 %**
Dividend yield	**0 %**	**0 %**	**0 %**
Expected volatility	**78%-127 %**	**94%-134 %**	**100 %**
Remaining term (in years)	**0.1–1.8**	**1.1-2.8**	**2.1-3.8**

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

(Expressed in U.S. Dollars)

13. Related party transactions

All related party transactions were measured at fair value. All amounts due from/payable to related parties are unsecured, non-interest bearing and have no fixed terms of repayment.

During the year ended December 31, 2025, the Company incurred the following transactions with related parties:

a) Wages and benefits and professional fees were paid or accrued to Allen Davidoff, the Chief Executive Officer ("CEO"), in the amount of $324,738 (2024 - $391,655; 2023 - $337,794).

b) Fees were paid or accrued to Michael Bumby, the Chief Financial Officer ("CFO") of the Company in the amount of $160,980 (2024 - $156,335 (paid or accrued to the former and current CFO; 2023 - $156,217 (paid or accrued to the former CFO)).

c) Research and development fees were paid or accrued to Haworth Biopharmaceutical Consulting Services Inc., a company owned by Stephen Haworth, the Chief Medical Officer ("CMO") of the Company in the amount of $96,000 (2024 - $110,445; 2023 - $200,229).

d) Consulting fees were paid or accrued to Stacy Evans, the Chief Business Officer ("CBO") of the Company in the amount of $150,000 (2024 - $157,500; 2023 - $280,000).

e) Directors' fees were paid or accrued to the directors of the Company in the amount of $215,568 (2024 - $172,229; 2023 - $182,675). The amount includes director fees payment of $128,877 for the year ended December 31, 2025 (2024 - $123,133; 2023 - $133,967) to Anthony Giovinazzo, Chairman of the Company.

f) As at December 31, 2025, $10,730 (2024 - $11,120) was payable to directors of the Company, $28,044 (2024 - $7,705) was payable and accrued to the CFO of the Company for CFO services, $16,000 (2024 - $8,000) was payable and accrued to the CMO of the Company for consulting services,and $37,500 (2024 - $12,500) was payable and accrued to the CBO of the Company for consulting services. The balances are unsecured, non-interest bearing, and have no fixed terms of repayment.

g) Management and directors' key management compensation transactions for the years ended December 31, 2025, 2024, and 2023 are summarized as follows:

	Management Compensation	Directors' fees	Share-based payments	Total
	$	$	$	$
Year ended December 31, 2023				
Directors and officers	974,240	182,675	77,779	1,234,694
Year ended December 31, 2024				
Directors and officers	815,935	172,229	85,680	1,073,845
Year ended December 31, 2025				
Directors and officers	**731,718**	**215,568**	**14,559**	**961,845**

(Expressed in U.S. Dollars)

14. Income taxes

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

	2025	2024	2023
	$	$	$
Net loss for the year	(2,656,304)	(3,313,346)	(2,158,065)
Statutory tax rate	27 %	27 %	27 %
Expected income tax recovery	**(717,000)**	**(895,000)**	**(583,000)**
Decrease to income tax recovery due to:			
Non-deductible permanent differences	(145,000)	(246,000)	45,000
Temporary differences	(549,000)	312,000	(25,000)
(Over) under provided in prior years	—	(1,099,000)	(559,000)
Change in tax assets not recognized	1,411,000	1,928,000	1,122,000
Income tax recovery	—	—	—

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

	December 31, 2025	December 31, 2024
	$	$
Share issuance costs	292,000	292,000
Cumulative eligible capital	108,000	95,000
Operating losses carried forward	8,104,000	6,706,000
Total deferred tax assets	8,504,000	7,093,000
Deferred tax assets not recognized	(8,504,000)	(7,093,000)
	—	—

The realization of income tax benefits related to these deferred potential tax deductions is not probable. Accordingly, no deferred income tax assets have been recognized for accounting purposes. The Company has Canadian non-capital losses carried forward of approximately CAD $41,443,000 that may be available for tax purposes. The losses expire as follows:

Expiry date	CAD$
2032	44,000
2033	748,000
2034	325,000
2035	286,000
2036	365,000
2037	618,000
2038	1,089,000
2039	554,000
2040	1,116,000
2041	3,648,000
2042	12,628,000
2043	8,084,000
2044	6,534,000
2045	5,404,000
Total	41,443,000

(Expressed in U.S. Dollars)

15. Financial instruments and risk management

The Company's financial instruments consist of cash, accounts receivable, contract payments, accounts payable and accrued liabilities, lease obligation and derivative warrant liability. The fair values of cash and accounts payable and accrued liabilities and lease liability approximate their carrying values at December 31, 2025, due to their short-term nature. Derivative warrant liability is carried at fair value and is classified within Level 3 of the fair value hierarchy.

The following table presents the Company's financial instruments, measured at fair value on the consolidated statements of financial position as at December 31, 2025 and 2024 and categorized into levels of the fair value hierarchy:

		December 31, 2025		December 31, 2024	
	Level	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
		$	$	$	$
FVTPL					
Derivative warrant liability	3	8,000	8,000	572,000	572,000

There were no transfers for levels of change in the fair value measurements of financial instruments for the years ended December 31, 2025, 2024 and 2023.

Risk management is carried out by the Company's management team with guidance from the Board of Directors. The Company's risk exposures and their impact on the Company's financial instruments were as follows:

a) Credit risk

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

	December 31, 2025	December 31, 2024
	$	$
Cash	864,514	2,473,649

All of the Company's cash is held with major financial institutions in Canada and management believes the exposure to credit risk with such institutions is minimal. The Company considers the risk of material loss to be significantly mitigated due to the financial strength of the major financial institutions where cash is held. The Company has no exposure to the ongoing banking crisis. The Company's maximum exposure to credit risk as at December 31, 2025 and 2024 is the carrying value of its financial assets.

b) Liquidity risk

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

The Company's financial assets are comprised of its cash, accounts receivable, contract payments and the financial liabilities are comprised of its accounts payable and accrued liabilities, and lease liability.

15. Financial instruments and risk management (continued)

b) Liquidity risk (continued)

The contractual maturities of these financial liabilities as at December 31, 2025 and 2024 are summarized below:

	Payments due by period as of December 31, 2025			
	Total	Less than 3 months	Between 3 months and 1 year	1-3 years
	$	$	$	$
Accounts payable and accrued liabilities	553,784	553,784	—	—
Lease liability	37,287	22,230	15,057	—
	591,071	576,014	15,057	—

	Payments due by period as of December 31, 2024			
	Total	Less than 3 months	Between 3 months and 1 year	1-3 years
	$	$	$	$
Accounts payable and accrued liabilities	147,205	147,205	—	—
Lease liability	38,785	23,124	15,661	—
	185,990	170,329	15,661	—

c) Market risk

i) Interest Rate Risk

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

ii) Foreign Currency Risk

As at December 31, 2025, the Company is exposed to currency risk on the following financial assets and liabilities denominated in Canadian Dollars ("CAD"). The sensitivity of the Company's net earnings due to changes in the exchange rate between the CAD against the U.S. dollar is included in the table below in U.S. dollar equivalents:

	CAD
	$
Cash	345,475
Accounts payable and accrued liabilities	(332,506)
Net exposure	12,969
Effect of +/- 10% change in currency	1,297

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

There have been no changes in any risk management policies since December 31, 2024.

(Expressed in U.S. Dollars)

16. Capital management

The Company defines capital that it manages as shareholders' equity. The Company manages its capital structure in order to have funds available to support its research and development and sustain the future development of the business. When managing capital, the Company's objective is to ensure the entity continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders. Management adjusts the capital structure as necessary in order to support its activities.

Since inception, the Company's objective in managing capital is to ensure sufficient liquidity to finance its research and development activities, general and administrative expenses, expenses associated with intellectual property protection, and its overall capital expenditures. There were no changes during the year ended December 31, 2025. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

17. Commitments

The Company has long-term arrangements with commitments that are not recognized as liabilities as at December 31, 2025 and December 31, 2024 are as follows:

a) Employment Agreements

	December 31, 2025	December 31, 2024
	$	$
Management services – officers	321,000	321,000

The President, CEO, and a director of the Company has a long-term employment agreement with the Company. The agreement has a termination clause whereby he is entitled to the equivalent of 12 times his then current monthly salary which, as of December 31, 2025 and 2024, equated to an annual salary of $321,000.

b) Payments

In the normal course of business, the Company has committed to payments totaling $131,199 (December 31, 2024 - $323,000) related to its clinical trial, and manufacturing, activities, and other regular business activities excluding management and director compensation which are expected to occur over the next 12 months.

18. Segmented information

The Company operates in one reportable operating segment: the development and commercialization of therapies to treat hyperuricemia related diseases. As the operations comprise a single reporting segment, amounts disclosed also represent segment amounts. All long-term assets of the Company are located in Canada.

19. Subsequent event

On October 15, 2025, the Company entered into a binding term sheet (the "Term Sheet") to acquire a Renal Anti-Fibrotic Therapeutic Program from Vectus Biosystems Limited, an Australian Securities Exchange listed company ("Vectus"). The program includes a novel new chemical entity, VB4-P5, along with its associated intellectual property, regulatory documentation, and manufacturing data. The Term Sheet provides for the Company to acquire from Vectus the intellectual property specifically related to the VB4-P5 compound and the data generated by Vectus from its work on the VB4-P5 small molecule and related assets. The consideration receivable by Vectus is $3,000,000, payable in common shares of the Company at a deemed issue price of $0.86 per common share (the "Issue Price"), with the Issue Price subject to adjustment in certain circumstances. The Company has agreed to pay a cash finders' fee of the greater of 5% of the transaction value or $250,000.

The Term Sheet is subject to finalization of closing documentation, satisfaction of conditions that are typical for a transaction of this type including receipt of all regulatory approvals, and compliance with applicable stock exchange requirements and applicable securities laws. Closing of the acquisition will occur no more than 90 days from the execution of the Term Sheet. If the Term Sheet is terminated or closing does not occur, other than as a result of a breach of the Term Sheet by Vectus, then the Company shall issue to Vectus $50,000 of common shares at the Issue Price.

Pursuant to the binding term sheet that was entered into between XORTX and Vectus, closing is to occur no later than 90 days post signing, being January 13, 2026.

On January 13, 2026, the Company entered into an extension agreement with Vectus to extend the closing date to March 31, 2026.

As of December 31, 2025, the Company had incurred $293,803 of deferred acquisition costs in connection with this transaction, which includes $200,000 towards the finders' fee.

On February 4, 2026, the Company issued 20,000 options to purchase common shares of the Company to a director. The options are exercisable at a price of CAD $0.69 per common share and expire five years from the date of grant.

Exhibit 4.10

Execution Copy

SUMMARY OF TERMS FOR AN ASSET ACQUISITION BETWEEN

Vectus Biosystems Limited

(ASX: VBS)

AND

XORTX Therapeutics Inc.

(Nasdaq: XRTX and TSXV: XRTX)

*This Summary of Terms (the "**Term Sheet**") sets forth the understanding with regard to a proposed asset acquisition (the "**Asset Acquisition**") between XORTX Therapeutics Inc. (the "**Buyer**") and Vectus Biosystems Limited (the "**Seller**"), whereby the Buyer will acquire the Assets (as defined below) in exchange for common shares of the Buyer that are listed for trading on Nasdaq and the TSX Venture Exchange (or common share equivalents, such as pre-funded warrants) (the "**Issued Securities**"). This Term Sheet is to be considered a binding agreement of the parties. Notwithstanding, the parties may determine and agree to enter into a further definitive agreement for the Asset Acquisition (the "**Definitive Agreement**"), but are not obligated to do so. In the event a Definitive Agreement is not entered into by and between the parties, this Term Sheet shall constitute the binding definitive agreement of the parties.*

Purchased Assets	All of the Seller's right, title and interest in and to the Assets, namely the Seller's stand-alone sole **VB4-P5 Renal Antifibrotic Therapeutic Treatment and Program** (the "**Program**") including: 1. All Program Data, Inventory and Rights: a. all chemistry, manufacturing, basic non-clinical and clinical data for the specific Program in the Seller's possession including data regarding kidney disease and specifically fibrosis in relation to the activity of the VB4-P5 small molecule; b. the Seller's remaining stand-alone sole VB4-P5 inventory (i.e. non-GMP supply on an "as is" basis); c. all regulatory documentation and communications with the FDA and other international equivalent organizations with regard to the stand-alone sole VB4-P5 Program, including all regulatory filings (e.g. IND, NDA, etc.); d. all intellectual property rights and documentation related to the, and necessary for, Program, including under all patents, trade secrets, know-how, molecules,

	peptides, amino acids, research data, clinical trial results and information materially relating to or forming part of the specific Program as well as under any license agreement or otherwise; e. any other assets owned by the Seller and not listed above that materially relate to, and are necessary for, the Program; and f. all master drug files relating to the Program and the rights to manufacture all drugs in connection with the Program, (collectively defined herein as the "**Assets**").
Form of Transaction:	The Buyer to acquire complete and unencumbered title to 100% of Assets from the Seller in exchange for the Issued Securities. The Asset Acquisition will be structured in a tax effective manner for both the Seller and the Buyer pursuant applicable tax laws.
Purchase Price:	USD $3.0 million (the "**Purchase Price**"), payable through the issuance of the Issued Securities by the Buyer to the Seller at a deemed issue price that, in the aggregate, shall equal the Purchase Price. The deemed issue price (the "**Issue Price**") shall at all times be determined by the parties in accordance with the rules and policies of the TSX Venture Exchange (the "**TSXV**"). Subject to the foregoing sentence, unless the parties otherwise agree in writing, the Issue Price shall be USD$0.86 per common share, or such lower price at which common shares of the Buyer (if any) are offered, issued or sold pursuant to the Registration Statement proposed to be filed and issued by the Buyer or, if lower, such price which is the VWAP for common stock of the Buyer sold in the five business days prior to Closing, provided that such lower price is not lower than the Discounted Market Price (as defined in the rules and policies of TSVX) as of the last trading day before the issuance of a press release by the Buyer announcing the Asset Acquisition or the filing of a Form 5C with the TSXV by the Buyer in respect of the Asset Acquisition.
Definitive Agreement:	If they so choose, the Buyer and the Seller may work together collaboratively to prepare, negotiate and complete the Definitive Agreement in an expeditious manner. In such instance, the Buyer's legal counsel will prepare the first draft of the Definitive Agreement. In the event a Definitive Agreement is not entered into by and between the parties, this Term Sheet shall constitute the binding definitive agreement of the parties.

Closing:	At the closing of the Asset Acquisition (the "**Closing**"), the Purchase Price will be paid by the issuance by the Buyer of the Issued Securities at the Issue Price. The proportion of common shares and pre-funded warrants comprising the Issued Securities will be negotiated between the parties, subject to applicable stock exchange rules and applicable securities laws and, unless the parties otherwise agree in writing, shall be: a. such number of common shares issued at the Issue Price and that comprise 9.9% of issued and outstanding common shares of the Buyer as at Closing (the "**Closing Common Shares**"); and b. such number of pre-funded warrants, in respect of which, the underlying common shares, when issued, will be issued at the Issue Price that, in combination with the Closing Common Shares, equates to USD 3.0 million in value in the aggregate. At the Closing, (i) Buyer will own complete and unencumbered title to 100% of the Assets free and clear of any liens, charges or security interests, and (ii) Seller will own USD $3.0 million fully paid of Issued Securities of the Buyer registered in the name of the Seller. Prior to the Closing, the Buyer will continue its due diligence into the Assets. Prior to the Closing, the Seller will continue its due diligence into the Buyer. Unless the parties otherwise agree in writing, the Closing shall be no more than 90 days from the execution of this Term Sheet.
Cash	No cash consideration will be paid as part of the Asset Acquisition.
Post-Closing Share Ownership of the Buyer by the Seller:	The Buyer and the Seller agree that by utilizing both common shares of the Buyer and pre-funded warrants of the Buyer, it is intended that at or after Closing, the Seller shall not own more than 9.9% of issued and outstanding common shares of the Buyer. If requested by the Seller in writing after the Closing, the Buyer will use its resonable commercial efforts to register all of the Issued Securities with the SEC to allow such Issued Securitites to be freely traded and sold, subject to the lock up agreement referred to below.
Closing Documentation:	At the Closing, the parties will enter into and deliver all necessary additional agreements and closing documentation customary for the

	type of transaction contemplated by this Term Sheet and the type of Assets to be purchased and sold pursuant to the Asset Acquisition. The Seller will enter into a lockup agreement with the Buyer that provides, among other things, that: a. at any future shareholder meeting of the Buyer for a period of one year from Closing or such other period as agreed by the parties, the Seller will vote any common shares of the Buyer that it holds in accordance with the voting recommendations of the Buyer's management; and b. the Seller may not sell any of the Closing Common Shares until the 45th day after the Closing Date and may not sell any prefunded warrants or common shares issued upon exercise of such warrants which are issued to the Seller until after the 180th day after the Closing Date, subject to any applicable stock exchange rules or applicable securities laws.
Shareholder Approval:	Subject to applicable stock exchange rules and applicable securities laws, the Buyer and the Seller intend to structure the Asset Acquisition in a manner that avoids shareholder approval for each of the Buyer and the Seller.
Conditions:	The Closing is expected to be subject to the satisfaction of customary conditions to Closing for a transaction of this type, including, but not limited to: (i) the Buyer being satisfied with that status of its due diligence in connection with the Assets; (ii) the Seller being satisfied, at that time, with that status of its due diligence in connection with the Buyer; (iii) satisfactory negotiation of the terms of the Definitive Agreement, including customary provisions for a transaction of this nature in the event that the parties determine to enter into a Definitive Agreement; (iv) approval by Boards of Directors of each of the Buyer and the Seller; (v) the satisfactory negotiation and completion of all relevant closing documents; (vi) the absence of a material adverse change with respect to the Assets or either party; (vii) the absence of a governmental restraint on consummation of the Asset Acquisition; (viii) receipt of all required regulatory or other approvals, including from the TSX Venture Exchange, Nasdaq and the ASX; and (ix) the Buyer continuing as a going concern at all times from the date of execution of this Term Sheet to the end of the lock up period and the Seller receiving confirmation of this in a form satisfactory to the Seller (acting reasonably).

	If this Term Sheet is terminated or Closing does not occur, other than as a result of a breach of this Term Sheet by the Seller, then the Buyer shall issue to the Seller USD $50,000 of common shares at the Issue Price. From the time of the execution of this Term sheet until the Closing and subject to applicable securities laws, the Buyer will keep the Seller informed of any significant transaction, capital raising, or dilutionary events which the Seller agrees to keep confidential subject to the applicable regulatory requirements. From the time of the execution of this Term sheet until the Closing and subject to applicable securities laws, the Seller will keep the Buyer informed of any significant transaction, events or material facts or changes in connection with the Program and the Assets which the Buyer agrees to keep confidential subject to the applicable regulatory requirements.
Normal Course Operation of the Seller's Business:	From the date of this Term Sheet and until completion of the Closing, the Seller shall continue to operate its business with respect to, and protect, the Assets in the normal course.
Representations & Warranties, Covenants and Deal Protections:	Any Definitive Agreement will contain representations, warranties, closing conditions and covenants customary for a transaction of this nature.
Fees and Expenses:	Except as otherwise agreed upon, each party shall each be responsible for its own costs and expenses incurred in connection with this Term Sheet and any Definitive Agreement.
Confidentiality:	The existence and terms of this Term Sheet will be treated as strictly confidential information pursuant to the mutual confidentiality agreement entered into between the Buyer and the Seller subject to any disclosure required by applicable stock exchange rules and applicable securities laws. The parties agree that the entering into of this Term Sheet constitutes a material fact or material change with respect to the Buyer and Seller, and will require disclosure in accordance with applicable securities laws and stock exchange rules.
Miscellaneous:	By their signatures below, each party represents and warrants that they have full power and authority to execute and deliver this Term Sheet and perform their respective obligations contained herein. The parties agree that this Term Sheet and any Definitive Agreement will be governed by and construed under the laws of the Province of Alberta. Each of the parties irrevocably agrees that any legal action or proceeding arising out of or relating to this Term Sheet or any

	Definitive Agreement shall be brought and determined in the Courts of the Province of Alberta. SIGNED Terms are VALID until 11:59 PM (Calgary time) on Monday, October 15, 2025.

This Term Sheet is executed and made effective as of the last date set forth below:

XORTX Therapeutics Inc.

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

Date: _____

By: _____
Name:
Title:

Date: _____

By: _____
Name:
Title:

Date: _____

Vectus Biosystems Limited

By: */s/ Ron Shnier*
Name: Dr Ron Shnier
Title: Chairman

Date: _____

By: */s/ Linda Waters*
Name: Linda Waters
Title: Director

Date: _____

By: */s/ Maurie Stang*
Name: Maurie Stang
Title: Director

Date: _____

Exhibit 4.11

EXTENSION AGREEMENT

This extension agreement (this "**Agreement**") is dated the 13th day of January, 2026 (the "**Effective Date**").

AMONG:

VECTUS BIOSYSTEMS LIMITED
("**Vectus**")

- and -

XORTX THERAPEUTICS INC.
(the "**Company**")

(Collectively, the "**Parties**", and as to each, a "**Party**")

WHEREAS:

A. On October 15, 2025 the Parties entered into a term sheet (the "**Term Sheet**") regarding the Company's proposed purchase of, *inter alia,* Vectus' VB4-P5 Renal Antifibrotic Therapeutic Treatment and Program (the "**Proposed Transaction**");

B. Under the Term Sheet, the Parties agreed, *inter alia,* that Closing shall be completed by a date that is no more than ninety (90) days from the execution of the Term Sheet (the "**Closing Date**"); and

C. The Parties have now agreed to extend the Closing Date until March 31, 2026, subject to the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. The Parties hereby acknowledge and declare that the foregoing recitals are true and correct in substance and in fact.

2. The Parties hereby agree to extend the Closing Date until on or before March 31, 2026.

3. Except as amended by this Agreement, the Term Sheet shall continue in full force and effect, the intention being that this Agreement shall be read in conjunction with and as an amendment to the Term Sheet.

4. Words capitalized in this Agreement (including the recitals hereof) and not otherwise defined herein shall have the meanings ascribed to such words in the Term Sheet.

5. If any provision of this Agreement or its application to any Party or circumstance is determined to be illegal, invalid or unenforceable by an arbitrator or a court of competent jurisdiction, it will be ineffective only to the extent of its illegality, invalidity or

unenforceability without affecting the validity or the enforceability of the remaining provisions of this Agreement and without affecting its application to other Parties or circumstances.

6. This Agreement shall enure to the benefit of and be binding upon each of the Parties and their respective successors and permitted assigns.

7. This Agreement may be executed and delivered in one or more counterparts, and by facsimile or other electronic communication, each of which, when executed and delivered, will be deemed an original, and all of which will constitute one and the same document.

[Remainder of Page Left Intentionally Blank — Signature Page to Follow]

IN WITNESS WHEREOF the Parties have duly executed and delivered this Agreement, effective as of the date first above written.

VECTUS BIOSYSTEMS LIMITED

Per: */s/ Maurie Stang*
Name: Mr. Maurie Stang
Title: Non Executive Director

XORTX THERAPEUTICS INC.

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

[Signature Page to the Extension Agreement]

Exhibit 12.1

CERTIFICATION
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Allen Davidoff, certify that:

1. I have reviewed this annual report on Form 20-F of XORTX Therapeutics Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the issuer as of, and for, the periods presented in this report;

4. The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the issuer and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: March 20, 2026

/s/ Allen Davidoff
Name: Allen Davidoff
Title: President and Chief Executive Officer
(principal executive officer)

Exhibit 12.2

CERTIFICATION
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Bumby, certify that:

1. I have reviewed this annual report on Form 20-F of XORTX Therapeutics Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the issuer as of, and for, the periods presented in this report;

4. The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the issuer and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting.

5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: March 20, 2026

/s/ Michael Bumby
Name: Michael Bumby
Title: Chief Financial Officer
(principal financial officer)

Exhibit 13.1

CERTIFICATION
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, as the Chief Executive Officer of XORTX Therapeutics Inc. certifies that, to the best of his knowledge and belief, the annual report on Form 20-F for the fiscal year ended December 31, 2025, which accompanies this certification, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and the information contained in the annual report on Form 20-F for the fiscal year ended December 31, 2025 fairly presents, in all material respects, the financial condition and results of operations of XORTX Therapeutics Inc. at the dates and for the periods indicated. The foregoing certification is made pursuant to § 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350) and shall not be relied upon for any other purpose. The undersigned expressly disclaims any obligation to update the foregoing certification except as required by law.

Date: March 20, 2026

/s/ Allen Davidoff
Allen Davidoff
President and Chief Executive Officer
(principal executive officer)

Exhibit 13.2

CERTIFICATION
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, as the Chief Financial Officer of XORTX Therapeutics Inc. certifies that, to the best of his knowledge and belief, the annual report on Form 20-F for the fiscal year ended December 31, 2025, which accompanies this certification, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and the information contained in the annual report on Form 20-F for the fiscal year ended December 31, 2025 fairly presents, in all material respects, the financial condition and results of operations of XORTX Therapeutics Inc. at the dates and for the periods indicated. The foregoing certification is made pursuant to § 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350) and shall not be relied upon for any other purpose. The undersigned expressly disclaims any obligation to update the foregoing certification except as required by law.

Date: March 20, 2026

/s/ Michael Bumby
Michael Bumby
Chief Financial Officer
(principal financial officer)

Exhibit 15.3

DAVIDSON

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form F-3 (File No. 333-269429), and the Registration Statement on Form S-8 (File No. 333-268034), of XORTX Therapeutics Inc. (the "Company") of our report dated February 25, 2026, on the consolidated statements of financial position of the Company as of December 31, 2025 and 2024, and the related consolidated statements of loss and comprehensive loss, changes in shareholders' equity, and cash flows for the years ended December 31, 2025 and 2024, included in the Company's Annual Report on Form 20-F filed with the Securities and Exchange Commission.

/s/ DAVIDSON & COMPANY LLP

Chartered Professional Accountants Vancouver, Canada

March 20, 2026

Exhibit 15.4

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form F-3 (File No. 333-269429), and the Registration Statement on Form S-8 (File No. 333-268034) of XORTX Therapeutics Inc. (the "Company") of our report dated April 1, 2024, relating to the consolidated financial statements of the Company for the year ended December 31, 2023, appearing in the Company's Annual Report on Form 20-F for the year ended December 31, 2025, filed with the Securities and Exchange Commission.

/s/ Smythe LLP
Smythe LLP
Chartered Professional Accountants
Vancouver, Canada
March 20, 2026