

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

FORM 20-F/A
(Amendment No. 1)

(Mark One)

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

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2021

OR

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

OR

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

Date of event requiring this shell company report

For the transition period from ____ to ____

Commission file number: 001-40858

XORTX Therapeutics Inc.

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

British Columbia, Canada

(Jurisdiction of Incorporation or Organization)

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

(Address of Principal Executive Offices)

Amar Keshri, Chief Financial Officer

Telephone: 1-403-455-7727

E-mail: akeshri@xortx.com

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

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

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

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

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

None

(Title of Class)

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

None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 12,989,678

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

Yes No

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

Yes No

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

x 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)

x Yes No

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

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

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

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

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

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

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

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

Item 17 Item 18

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

Yes No

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court Yes No

Auditor Name Auditor Location Auditor Firm ID
Smythe LLP Vancouver, Canada 00995

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EXPLANATORY NOTE

This Amendment on Form 20-F/A (the “Amendment”) amends the Annual Report on Form 20-F of XORTX Therapeutics Inc. (“XORTX” or the “Company”) for the year ended December 31, 2021, as filed with the Securities and Exchange Commission on May 3, 2022 (the “Original Form 20-F”). This Amendment is being filed solely for the purpose of including disclosure that the Company inadvertently omitted from Item 5 of the Original Form 20-F relating to Use of Proceeds of the US IPO Financing (as defined in Item 5), a breakdown of R&D expenditures, a comparative analysis of the 12 months ended December 31, 2021, and disclosure of related party names.

This Amendment does not reflect events occurring after the filing of the Original Form 20-F and does not modify or update the disclosure therein in any way other than as required to reflect the amendments described herein and reflected below. No other changes have been made to the Original Form 20-F. The filing of this Amendment should not be understood to mean that any statements contained herein are true or complete as of any date subsequent to the date of the original filing of the Original Annual Report. Accordingly, this Amendment should be read in conjunction with our filings made with the Securities and Exchange Commission subsequent to the filing of the Original Form 20-F.

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 Amended Annual Report has been prepared in accordance with IFRS as issued by the IASB. Unless otherwise noted herein, all references to “\$,” “Canadian dollars,” or “dollars” are to the currency of Canada and “US\$,” “United States dollars,” or “U.S. dollars” are to the currency of the United States.

We are an “emerging growth company” as defined in the JOBS Act, and as such, we have elected to comply with certain reduced U.S. public company reporting requirements.

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

Unless otherwise indicated, the Company has obtained the market and industry data contained in this Amended 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 Amended Annual Report, such data involves risks and uncertainties and are subject to change based on various factors, including those described under “Cautionary Statement Regarding Forward-Looking Information and Statements” and “Item 3.D. Risk Factors”.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the intentions, plans and future actions of the Company;
- statements relating to the business and future activities of the Company;
- anticipated developments in operations of the Company;
- market position, ability to compete and future financial or operating performance of the Company;
- the timing and amount of funding required to execute the Company’s business plans;
- capital expenditures;
- the effect on the Company of any changes to existing or new legislation or policy or government regulation;
- the availability of labor;
- requirements for and availability to us of additional capital;
- goals, strategies and future growth;
- the adequacy of financial resources;
- expectations regarding revenues, expenses and anticipated cash needs;
- the impact of the COVID-19 pandemic on the business and operations of the Company; and

- general market conditions and macroeconomic trends driven by the COVID-19 pandemic and/or geopolitical conflicts, including supply chain disruptions, market volatility, inflation, and labor challenges, among other factors.

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

GLOSSARY

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

“**ACA**” means the Patient Protection and Affordable Care Act;

“**ADPKD**” means autosomal dominant polycystic kidney disease;

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

“**AKI**” means acute kidney injury;

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

“**ANDA**” means abbreviated new drug applications;

“**Annual Report**” means the Annual Report on Form 20-F for the year ended December 31, 2021, as filed with the Securities and Exchange Commission on May 3, 2022;

“**Amended Annual Report**” means this Amendment No. 1 to the Annual Report

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

“**articles**” means our articles of incorporation;

“**ASP**” means average sales price;

“**Audit Committee**” means the Audit Committee of the Company;

“**Audit Committee Charter**” means the Audit Committee Charter of the Audit Committee;

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

“**Board of Directors**” or “**Board**” means the Board of Directors of the Company;

“**BPCA**” means the Best Pharmaceuticals for Children Act;

“**bylaws**” means our amended and restated bylaws;

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

“**Cardiome**” means Cardiome Pharma Corp.;

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

“**CCPA**” means the California Consumer Privacy Act;

“**CEO**” means the Company’s principal executive officer;

“**CFO**” means the Company’s principal financial officer;

“**Compensation Committee**” means the Compensation Committee of the Company;

“**GCP**” means current good clinical practices;

“**cGMP**” means current Good Manufacturing Practices;

“**CHMP**” means Committee for Medicinal Products for Human Use;

“**CJEU**” means the Court of Justice of the European Union;

“**CMC**” means chemistry manufacturing and control;

“**CMOs**” means contract manufacturing organization;

“**CMS**” means Centers for Medicare & Medicaid Services;

“**CNS**” means central nervous system;

“**Code of Conduct**” means our Code of Business Conduct and Ethics;

“**Common Shares**” means common shares of the Company;

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

“**CPRA**” means the California Privacy Rights Act;

“**CRA**” means the Canada Revenue Agency;

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

“**CRL**” means a complete response letter;

“**CROs**” means contract research organizations;

“**CRP**” means Creatinine Reactive Protein;

“**CSE**” means the Canadian Securities Exchange;

“**CTA**” means clinical trial application;

“**CTO**” means Chief Technology Officer;

“**Cures Act**” means the 21st Century Cures Act;

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

“**DGCL**” means the Delaware General Corporation Law;

“**DHHS**” means the Department of Health and Human Services;

“**DSCSA**” means the Drug Supply Chain Security Act;

“**EMA**” means the European Medicines Agency;

“**ESRD**” means end stage renal disease;

“**ETASU**” means elements to assure safe use;

“**EU**” means the European Union;

“**EUA**” means the FDA Emergency Use Authorization;

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

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

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

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

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

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

“**GCPs**” means good clinical practices;

“**GDPR**” means the European Union General Data Protection Regulation;

“**GLPs**” means good laboratory practices;

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

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

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

“**Holder**” means a holder of the Company’s shares;

“**IASB**” means International Accounting Standards Board;

“**ICU**” means intensive care units;

“**IFRS**” means International Financial Reporting Standards;

“**IL-6**” means interleukin-6;

“**IMM**” means irreversible morbidity or mortality;

“**IND**” means Investigational New Drug application;

“**IRB**” means institutional review board;

“**IRS**” means the Internal Revenue Service;

“**JAMA**” means the Journal of the American Medical Association;

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

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

“**MAA**” means marketing authorization application;

“**MRP**” means mutual recognition procedure;

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

“**Nasdaq**” means the Nasdaq Stock Market;

“**Nasdaq Rules**” means the Nasdaq Stock Market LLC Rules;

“**NDA**” means New Drug Application;

“**NIH**” means the United States National Institutes of Health;

“**ODD**” means orphan drug designation;

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

“**PBMs**” means pharmaceutical benefit managers;

“**PCAOB**” means the Public Company Accounting Oversight Board;

“**PCT**” means Patent Cooperation Treaty;

“**PDMA**” means the Prescription Drug Marketing Act;

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

“**PREA**” means the Pediatric Research Equity Act;

“**pre-IND**” means pre-investigational new drug application;

“**Prevail**” means Prevail Partnerships LLC;

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

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

“**PSP**” means the Pediatric Study Plan;

“**R&D**” means research and development;

“**Regulations**” the regulations under the Tax Act;

“**REMS**” means risk evaluation and mitigation strategies;

“**RLD**” means reference listed drug;

“**Rowlands**” means William Bruce Rowlands, an individual;

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

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

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

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

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

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

“**Securities Act**” means the Securities Act of 1933, as amended;

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

“**Share Consolidation**” means the Company’s consolidation of its shares on a one (1) post-consolidated share for 11.74 pre-consolidated shares basis which took effect on September 23, 2021;

“**SPA**” means special protocol assessment;

“**SUA**” means a serum uric acid;

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

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

“**T2DN**” means type 2 diabetic nephropathy;

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

“**TSX**” means Toronto Stock Exchange;

“**TSXV**” means TSX Venture Exchange;

“**UK**” means United Kingdom;

“**UR**” means uric acid;

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

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

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

“**UofC**” means University of Colorado;

“**U.S.**” means United States;

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

“**USPTO**” means United States Patent and Trademark Office;

“**Vendors**” means Dr. Richard Johnson and Dr. Takahiko Nakagawa;

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

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

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

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

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

PART I

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The amended management's discussion and analysis of the Company for the year ended December 31, 2021 is included in this Amended Annual Report as Exhibit 15.1.

PART III

ITEM 19. EXHIBITS

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

| Exhibit Number | Description |
|-----------------------|---|
| 1.1 | Articles and Notice of Articles of the Company (incorporated by reference to Exhibit 3.1 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 2.1** | Specimen common share certificate |
| 2.2 | Form of Common Share Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021) |
| 2.3 | Form of pre-funded warrant (incorporated by reference to Exhibit 4.2 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021) |
| 2.4** | Form of Underwriter's Warrant Agreement |
| 4.1% | Investigator Initiated-Clinical Trial Agreement, dated August 3, 2020, by and between the Company and Icahn School of Medicine at Mount Sinai (incorporated by reference to Exhibit 10.1 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.2# | Employment Agreement, dated August 1, 2021, by and between the Company and Allen Davidoff (incorporated by reference to Exhibit 10.2 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021) |
| 4.3% | Master Services Agreement, dated July 20, 2017, by and between the Company and Cato Research Canada Inc. (incorporated by reference to Exhibit 10.3 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.4#% | Consulting Agreement, dated February 1, 2021, by and between the Company and David Sans (incorporated by reference to Exhibit 10.4 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.5# | Consulting Agreement, dated March 1, 2021, by and between the Company and 1282803 Ontario Inc. (incorporated by reference to Exhibit 10.5 to the Company's Amendment No. 2 to the Registration Statement on Form F-1 filed on October 4, 2021) |
| 4.6% | Master Service and Technology Agreement, dated February 25, 2019, by and between the Company and Prevail InfoWorks, Inc. (incorporated by reference to Exhibit 10.6 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.7% | Side Letter to Master Service and Technology Agreement, dated February 24, 2020, by and between the Company and Prevail InfoWorks, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.8% | Subscription Agreement, dated February 28, 2020, by and between the Company and Prevail Partners LLC (incorporated by reference to Exhibit 10.8 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 4.9# | Consulting Agreement, dated July 1, 2021, by and between the Company and Next Level Consultants Inc. (incorporated by reference to Exhibit 10.10 to the Company's Amendment No. 1 to the Draft Registration Statement on Form F-1 filed on July 21, 2021) |

| | |
|--------------------------|--|
| 4.10% | Standard Exclusive License Agreement with Know How dated effective as of June 23, 2014, by and between the Company and the University of Florida Research Foundation, Inc. (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form F-1 Filed on August 12, 2021) |
| 4.11# | Consulting Agreement, dated July 1, 2021, by and between the Company and Haworth Biopharmaceutical Consulting Services Inc. (incorporated by reference to Exhibit 10.12 to the Company's Amendment No. 1 to the Draft Registration Statement on Form F-1 filed on July 21, 2021) |
| 4.12% | Patent Rights Purchase Agreement, dated effective as of December 5, 2012, by and between Dr. Richard Johnson, Dr. Takahiko Nakagawa, and Revascor Inc. (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form F-1 filed on August 12, 2021) |
| 4.13 | Form of Warrant Agency Agreement with Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 10.14 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021) |
| 4.14 | Consulting Agreement, dated March 1, 2018, by and between the Company and W.B. Rowlands & Co. Ltd. (incorporated by reference to Exhibit 10.15 to the Company's Amendment No. 1 to the Registration Statement on Form F-1 filed on September 16, 2021) |
| 4.15**# | Consulting Services Agreement, dated effective December 20, 2021, by and between the Company, W.B. Rowlands & Co. Ltd., and William Bruce Rowlands |
| 4.16# | Stock Option Plan (incorporated by reference as Schedule B to Exhibit 99.2 to the Company's Form 6-K filed on November 23, 2021.) |
| 4.17**0% | Patent Rights Purchase Agreement dated effective May 26, 2014 between Dr. Richard Johnson, Dr. Takahiko Nakagawa and the Company. |
| 4.18**0% | Equity Agreement dated effective June 23, 2014 between the Company and the University of Florida Research Foundation, Inc. |
| 4.19**0% | Sponsored Research Agreement dated May 27, 2021 between the Regents of the University of Colorado and the Company |
| 4.20**0% | Combined Master Services Agreement made on July 19, 2021 between the Company and Quotient Sciences Limited |
| 4.21** | Development and Clinical Manufacturing Services Agreement dated effective August 17, 2021 between the Company and Lonza Ltd. |
| 4.22** | Global Master Services Agreement between Altasciences Company Inc., (a contract research organization) and the Company dated effective December 22, 2021 |
| 4.23** | Proposal for XORTX Therapeutics Inc., dated February 21, 2022, by and between the Company and Covar Pharmaceuticals Inc. |
| 4.24** | Proposal for XORTX Therapeutics Inc., dated December 6, 2021, by and between the Company and Covar Pharmaceuticals Inc. |
| 4.25**0% | Proposal, dated as of March 29, 2022, by and between the Company and Curia Spain, S.A.U. |
| 4.26**# | Consulting Amending Agreement, dated as of January 27, 2022, by and between the Company and Stephen Haworth |
| 4.27**# | Agreement, dated as of November 1, 2021, by and between the Company and Amar Keshri |
| 8.1 | Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Draft Registration Statement on Form F-1 filed on May 26, 2021) |
| 11.1** | Code of Conduct |
| 12.1* | Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer |
| 12.2* | Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer |
| 13.1** | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 13.2** | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 15.1* | Amended Management Discussion and Analysis of the Company for the year ended December 31, 2021 |
| 15.2** | Audit Committee Charter |
| 15.3** | Consent of independent registered public accounting firm (Smyth LLP) |
| 101** | The following materials from the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2021, formatted in eXtensible Business Reporting Language (XBRL): |

- (i) Consolidated Financial Statements for the Years Ended December 31, 2021, 2020 and 2019;
- (ii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2021, 2020 and 2019;
- (iii) Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2021, 2020 and 2019;
- (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2021, 2020 and 2019; and
- (v) Notes to Consolidated Financial Statements for the Years Ended December 31, 2021, 2020 and 2019

104* Cover Page Interactive Data File (formatted as Inline eXtensible Business Reporting Language (iXBRL) and contained in Exhibit 101)

* Filed herewith.

** Previously filed with the Company's Annual Report on Form 20-F for the year ended December 31, 2021 (File No. 001-40858), filed with Securities and Exchange Commission on May 3, 2022.

Indicates management contract or compensatory plan.

% Portions of this exhibit (indicated by asterisks) have been omitted as the Company has determined that (1) the omitted information is not material and (2) the omitted information would likely cause competitive harm to the Company if publicly disclosed.

SIGNATURES

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

XORTX THERAPEUTICS INC.

/s/ Amar Keshri

By: Amar Keshri
Title: Chief Financial Officer

Date: January 26, 2023

CERTIFICATION

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Allen W. Davidoff, certify that:

1. I have reviewed this annual report on Form 20-F/A 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; and
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;

Date: January 26, 2023

/s/ Allen W. Davidoff

Name: Allen W. Davidoff

Title: Chief Executive Officer
(principal executive officer)

CERTIFICATION

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Amar Keshri, certify that:

1. I have reviewed this annual report on Form 20-F/A 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; and
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;

Date: January 26, 2023

/s/ Amar Keshri

Name: Amar Keshri

Title: Chief Financial Officer
(principal financial officer)



MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE YEAR ENDED DECEMBER 31, 2021

NOTE TO READER:

This MD&A amends and restates and supersedes, the Company's MD&A filed on April 12, 2022, which now includes disclosure relating to Use of Proceeds of the US IPO Financing (as defined in the MD&A), a breakdown of R&D expenditures, a comparative analysis of the 12 months ended December 31, 2021, and disclosure of the related party names. For this reason, the April 12, 2022 MD&A should not be relied upon and readers should refer only to the June 29, 2022 document.

XORTX THERAPEUTICS INC.
Management Discussion and Analysis
For the year ended December 31, 2021

This management discussion and analysis of financial position and results of operations (“**MD&A**”) is prepared as at April 12, 2022 and should be read in conjunction with the audited consolidated financial statements and related notes thereto of XORTX Therapeutics Inc. (the “**Company**” or “**XORTX**”) for the year ended December 31, 2021, which have been prepared in accordance with International Financial Reporting Standards (“**IFRS**”) as issued by the International Accounting Standards Board (“**IASB**”) and interpretations of the International Financial Reporting Interpretations Committee (“**IFRIC**”). All dollar amounts included therein and in the following MD&A are expressed in Canadian dollars except where noted.

In this discussion, unless the context requires otherwise, references to “we” or “our” are references to XORTX Therapeutics Inc.

CORPORATE INFORMATION

XORTX was incorporated under the laws of Alberta, Canada on August 24, 2012, under the name ReVasCor Inc. and continued under the Canada Business Corporations Act on February 27, 2013, under the name of XORTX Pharma Corp. Upon completion of a reverse take-over transaction on January 10, 2018, with APAC Resources Inc., a company incorporated under the laws of British Columbia, the Company changed its name to “XORTX Therapeutics Inc.” and XORTX Pharma Corp. became a wholly-owned subsidiary. The Company’s principal executive offices are located at Suite 4000, 421 – 7th Avenue SW, Calgary, Alberta, Canada T2P 4K9. The Company’s shares trade on the TSX Venture Exchange (“**TSXV**”), on the Nasdaq Stock Exchange (“**Nasdaq**”) under the symbol “**XRTX**”, and on the Börse Frankfurt under the symbol “**ANU**”.

FORWARD LOOKING STATEMENTS

This MD&A contains certain statements, other than statements of historical fact that are forward-looking statements, which reflect the current view of the Company with respect to future events including corporate developments, financial performance and general economic conditions which may affect the Company.

All statements other than statements of historical fact contained in this MD&A, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our ability to obtain additional financing;
 - the accuracy of our estimates regarding expenses, future revenues and capital requirements;
 - the success and timing of our preclinical studies and clinical trials;
 - our ability to obtain and maintain regulatory approval of XORLO and any other product candidates we may develop, and the labeling under any approval we may obtain;
 - regulatory approvals and other regulatory developments in the United States and other countries;
 - the performance of third-party manufacturers and contract research organizations;
 - our plans to develop and commercialize our product candidates;
 - our ability to obtain and maintain intellectual property protection for our product candidates;
-

- the successful development of our sales and marketing capabilities;
- the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available; and
- the loss of key scientific or management personnel.

XORTX relies on certain key expectations and assumptions in making the forecasts, projections, predictions or estimations set out in forward-looking information. These factors and assumptions are based on information available at the time that the forward-looking information is provided. These include, but are not limited to, expectations and assumptions concerning:

- the availability of capital to fund planned expenditures;
- prevailing regulatory, tax and environmental laws and regulations; and
- the ability to secure necessary personnel, equipment and services.

Undue reliance should not be placed on forward-looking information because a number of risks and factors may cause actual results to differ materially from those set out in such forward-looking information. These include:

- incorrect assessments of the value of acquisitions, licenses and development programs;
- technical, manufacturing and processing problems;
- actions by governmental authorities, including increases in taxes;
- the availability of capital on acceptable terms;
- fluctuations in foreign exchange, currency, or interest rates and stock market volatility;
- failure to realize the anticipated benefits from licenses or acquisitions;
- the other factors specifically identified as risk factors in this MD&A; and
- potential labour unrest.

Readers are cautioned that the foregoing list of factors should not be construed as exhaustive. Further information relating to risks is included in this MD&A under Risks Related to the Business.

Except as may be required by applicable law or stock exchange regulation, XORTX undertakes no obligation to update publicly or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events. Accordingly, readers should not place undue reliance on forward-looking statements. If XORTX does update one or more forward-looking statements, no inference should be drawn that additional updates will be made with respect to those or other forward-looking statements. Additional information relating to the Company is available by accessing the SEDAR website at www.sedar.com.

BUSINESS OVERVIEW

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

Our focus is on developing three therapeutic products to:

- 1/ slow or reverse the progression of chronic kidney disease in patients at risk of end stage kidney failure;
 - 2/ address the immediate need of individuals facing coronavirus induced AKI; and
 - 3/ the identification of other opportunities where our existing and new intellectual property can be leveraged to address health issues.
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We believe that our technology is underpinned by well-established research and insights into the underlying biology of aberrant purine metabolism, its health consequences and of oxypurinol, a uric acid lowering agent that works by effectively inhibiting xanthine oxidase. We develop therapeutic products that include new or existing drugs that can be adapted to address different disease indications where aberrant purine metabolism and/or elevated uric acid is a common denominator, including polycystic kidney disease, pre-diabetes, insulin resistance, metabolic syndrome, diabetes, diabetic nephropathy, and infection. We are focused on building a pipeline of assets to address the unmet medical needs for patients with a variety of serious or life-threatening diseases using our innovative formulation of oxypurinol, and our proprietary pipeline-in-a-product strategy supported by our intellectual property, established exclusive manufacturing agreements, and proposed clinical trials with experienced clinicians.

Our three lead product candidates are XRx-008, for the treatment of ADPKD; XRx-101, to treat AKI associated with Coronavirus / COVID-19 infection, AKI and associated health consequences; and XRx-225, for the treatment of T2DN. At XORTX, we aim to redefine the treatment of kidney diseases by developing medications to improve the quality-of-life of patients with life-threatening diseases by modulating aberrant purine and uric acid metabolism, including lowering elevated uric acid as a therapy.

Our Proprietary Therapeutic Platforms

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

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

Highly Modular and Customizable

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

Fit-for-purpose

Our platforms can also be utilized to engineer new chemical entities and formulations of those agents that have enhanced properties. For example, our XRx-225 product candidate program, some of the intellectual property for which we license from third parties, represents a potential new class of xanthine oxidase inhibitor(s) with a targeted design to enhance anti-inflammatory activity. The capability of tailoring the therapeutic benefit of this class of new agents permits us to identify targets and disease that we wish to exploit and then, through formulation design, optimize those small molecules and proprietary formulations to maximize clinically meaningful therapeutic effect.

Readily scalable and transferable

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

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

Product Candidate Pipeline

Our lead product candidates are XRx-008, XRx-101, and XRx-225. The XRx-008 program is currently screening subjects for bridging pharmacokinetic characterization before initiating a Phase 3 registration clinical trial, the last stage of clinical development before United States Food and Drug Administration ("FDA") approval. Similarly, a second "pharmacokinetic" study is planned to support both the XRx-008 and XRx-101 program and future late-stage clinical studies targeting attenuation or reversal of acute kidney disease in hospitalized individuals with COVID-19. XRx-225 is at the non-clinical stage and advancing toward the clinical development stage.

Products

The Company's most advanced development program, XRx-008, is a late clinical stage program focused on demonstrating the potential of our novel therapy for ADPKD. XRx-008 is the development name given to XORTX's proprietary oral formulation of oxypurinol. This proprietary formulation of oxypurinol has shown increased oral bioavailability and the potential for an enhanced therapeutic range. XORTX is also developing a second oral formulation of oxypurinol, XRx-101, for use in treating patients with AKI due to respiratory virus infection and/or associated co-morbidities including sepsis.

XORTX is currently evaluating xanthine oxidase inhibitor candidates for the XRx-225 program to treat T2DN as well as developing new chemical entities to address the large unmet medical need.

Patents

XORTX is the exclusive licensee of two U.S. granted patents with claims to the use of all uric acid lowering agents to treat insulin resistance or diabetic nephropathy. Counterparts for some of these patent applications have also been submitted in Europe. In both the US and Europe, XORTX has been granted patents for unique proprietary formulations of xanthine oxidase inhibitors. In addition, XORTX has also submitted two patent applications to cover the use of uric acid lowering agents for the treatment of the health consequences of coronavirus infection, as well as a new provisional patent for novel therapeutics to treat polycystic kidney disease.

OUR STRATEGY

The Company's goal is to apply our interdisciplinary expertise and pipeline-in-a-product strategy to further identify, develop and commercialize novel treatments in orphan indications, with an initial focus on renal and significant unmet medical needs.

Our ability to implement our business strategy is subject to numerous risks.

These risks include, among others (see “Risks Related to the Business”):

- we have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future;
- we will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to alter, delay, scale back, or cease our product development programs or operations;
- we have not generated any revenue to date and may never be profitable;
- we have a limited number of product candidates, all of which are still in preclinical or clinical development, and we may fail to obtain regulatory approval or experience significant delays in doing so;
- our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales;
- we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements, and the denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations;
- security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation;
- the COVID-19 pandemic may materially and adversely affect our business and financial results;
- our existing strategic partnerships are important to our business, and future strategic partnerships may also be important to us; if we are unable to maintain any of these strategic partnerships, or if these strategic partnerships are not successful, we may not realize the anticipated benefits of our strategic partnerships and our business could be adversely affected;
- we rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates;
- our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties;
- our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged;
- if we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed; and
- if we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

Funding Requirements

The Company has not generated any revenue from product sales to date and does not expect to do so until such time as XORTX obtains regulatory approval for and commercializes one or more of our product candidates. As the Company is currently in clinical and preclinical stages of development, it will be some time before we expect to achieve this and it is uncertain that we ever will. We expect that we will continue to increase our operating expenses in connection with ongoing clinical trials and preclinical activities and the development of product candidates in our pipeline. We also expect to continue our strategic partnerships and we continue to seek additional collaboration opportunities. Further, we expect to continue our efforts to pursue additional grants and refundable tax credits from the Canadian government in order to further our research and development. Although it is difficult to predict our funding requirements, based upon our current operating plan, the Company anticipates that our existing cash and cash equivalents as of December 31, 2021, combined with the net proceeds of future financings, will enable us to advance the clinical development of XRx-008 and XRx-101 product candidates. XORTX may also be eligible to receive certain research, development and commercial milestone payments in the future. However, because successful development of our product candidates and the achievement of milestones by our strategic partners is uncertain, we are unable to estimate the actual funds we will require to complete the research, development and commercialization of product candidates.

RECENT DEVELOPMENTS

Consolidation and Exchange Uplistings

On September 20, 2021, the Company announced that further to receipt of shareholder approval at the special meeting of shareholders held September 2, 2021 (announced on August 13, 2021), the Company would complete a share consolidation of the issued and outstanding common shares of the Company on the basis of 11.74 pre-consolidation common shares for each one (1) post-consolidation common share. On September 24, 2021, the share consolidation was affected resulting in consolidated shares outstanding on that date of 9,528,687.

On October 13, 2021, the Company announced that it had received approval to list its common shares on the Nasdaq under the symbol “XRTX”.

On November 2, 2021, the Company announced that it had received final approval to list its common shares on the TSXV under the symbol “XRTX”. The Company’s shares were de-listed from trading on the Canadian Securities Exchange effective November 4, 2021 and trading on the TSXV commenced on November 5, 2021.

Public Offering and Private Placement

On October 15, 2021, the Company closed an underwritten public offering in the U.S. of 2,906,000 units, with each unit consisting of one common share and one warrant to purchase one common share at US\$4.13 per unit, for aggregate gross proceeds of approximately US\$12 million, prior to deducting underwriting discounts and other offering expenses (the “**US IPO Offering**”). The USD IPO Offering was undertaken by A.G.P. / Alliance Global Partners (“**A.G.P.**”) who acted as sole book-running manager. The warrants are exercisable at US\$4.77 per share and have a term of five years. In addition, the Company granted A.G.P. a 45-day option to purchase up to an additional 435,900 common shares and warrants to purchase up to an additional 435,900 common shares at US\$4.13 less underwriting discounts. On closing, A.G.P. exercised its option to purchase additional warrants to purchase up to an additional 435,900 common shares. On November 8, 2021, A.G.P. partially exercised its 45-day option to purchase 355,000 common shares at US\$4.13 per share, resulting in additional gross proceeds to the Company of approximately US\$1.47 million which increased the US IPO Offering to 3,261,000 common shares and 3,341,900 warrants.

In January and February 2021, 350,204 warrants that were issued in connection with the February 2020 private placement were exercised. Of the warrants exercised, 339,801 were exercised at \$2.94 per common share and 10,703 were exercised at \$1.64 per common share in respect to certain finder’s warrants that were issued in relation to that private placement.

On February 9, 2021, the Company closed a private placement with the issuance of 2,085,687 units at a subscription price of \$2.935 per unit for gross proceeds of \$6,121,572 (the “**Private Placement**”). Each unit comprised one common share and one common share purchase warrant. Each warrant entitles the holder, on exercise, to purchase one additional common share in the capital of the Company, at a price of \$4.70 for a period of five years from the issuance of the units; provided, however, that, if, at any time following the expiry of the statutory four month hold period, the closing price of the common shares is greater than \$14.09 (adjusted to reflect the share consolidation of 11.74:1 effected on September 24, 2021) for 10 or more consecutive trading days, the warrants will be accelerated upon notice and the warrants will expire on the 30th calendar day following the date of such notice. In addition, the warrants were also subject to a ratchet provision that provided for an adjustment in the exercise price in the event the Company issued or sold common shares or securities convertible into common shares at a price (or conversion price, as applicable) less than the exercise price such that the exercise price would be amended to match such lower price. With the US IPO Offering being undertaken at a higher price than the Private Placement, the ratchet provision terminated on October 15, 2021.

In connection with the Private Placement, the Company paid \$116,216 in cash commissions and issued 58,288 finders' warrants. Each finders' warrant is exercisable into one common share at a price of \$4.70 and having the same expiry, acceleration and anti-dilution provisions as the warrants included in the Private Placement.

As at the date of this MD&A, the Company has used approximately CAD\$3,000,000 of the proceeds of the US IPO Offering for funding operations and general corporate purposes, which included further research and development, clinical trials, and manufacture of active pharmaceutical ingredients and drug product to support clinical trials. The Company intends to use the remaining net proceeds of the US IPO Offering, together with existing cash, for funding operations and general corporate purposes, which may include further research and development, clinical trials, manufacture of active pharmaceutical ingredients and drug product to support clinical trials.

Patent Advancements

On December 29, 2020, the Company announced the receipt of notification that the patent "Formulations of Xanthine Oxidase Inhibitors" will be granted for XRx-225 by the European Patent Office. The patent covers compositions and methods of using XORTX's proprietary formulations of xanthine oxidase for, renal and other diseases where aberrant purine metabolism has been implicated in disease progression. On September 1, 2021, the Company announced the grant of the patent titled "EPO National Stage of PCT International Application for Compositions and Methods for Treatment and Prevention of Hyperuricemia Related Health Consequences".

On March 16, 2020, XORTX announced the filing of a provisional patent application covering the potential use of any uric acid lowering agent, and more specifically a xanthine oxidase inhibitor XRx-101 (we believe a novel formulation of oxypurinol), to treat respiratory, kidney disease and multi-organ injury related to patients infected with SARS-COV-2 or other respiratory viruses COVID-19.

On December 20, 2021, the Company filed a provisional patent for polycystic kidney disease entitled "Compositions and Methods for Diagnosis, Treatment of and Prevention of Kidney Disease". This provisional patent filing was based upon findings of two independent investigator led studies that: (1) studied the role of aberrant purine metabolism in ADPKD kidney tissue, the results showing that xanthine oxidase enzyme expression and activity in kidney tissue in ADPKD is increased substantially and significantly, potentially revealing a new mechanism of injury in ADPKD; and (2) explored the health consequences of high uric acid in a mouse model of autosomal dominant polycystic kidney disease that successfully demonstrated that increased levels of serum uric acid can accelerate structural and functional changes in kidneys of patients with ADPKD.

On March 23, 2022, the Company announced the submission of a Patent Cooperation Treaty ("PCT") patent application seeking international patent protection for the patent entitled "Compositions and Methods for Enhancing Anti-Viral Therapies". This patent is based on retrospective clinical data from XORTX scientific partners suggesting that an important therapeutic opportunity lies with addressing aberrant purine metabolism combined with hyperuricemia in patients most at risk to severe COVID-19 outcome. Since the advent of COVID-19 and during 2020, accumulating evidence suggests that individuals most at risk for more severe health consequences fall within a group that includes individuals with obesity, hypertension, metabolic syndrome, insulin resistance, pre-diabetes, diabetes or chronic kidney disease have a higher incidence of hyperuricemia and endothelial dysfunction. Low grade systemic inflammation associated with these disease states and pre-existing vascular injury may suppress an individual's ability to respond with a sufficiently robust response to fight infection and leaves the individual more prone to excessive pro-inflammatory and pro-coagulative state. This new patent filing proposes compositions and methods for enhancing anti-viral therapies for the treatment of individuals most at risk.

On April 7, 2022, the Company announced receipt of notification that the patent “Formulations of Xanthine Oxidase Inhibitors” will be granted by the United States Patent Office. The patent covers compositions for, and methods of using XORTX’s proprietary formulations of xanthine oxidase inhibitors for renal and other diseases where aberrant purine metabolism has been implicated in disease progression.

Regulatory Advancements

On March 14, 2022, the Company announced the submission of its clinical trial application (“CTA”) with Health Canada for a XRX-OXY-101 bridging pharmacokinetics study. The study is an important first clinical step in the Company’s 505(b)2 clinical and regulatory plan for 2022 and will support the XRX-008 program for ADPKD as well as the planned phase 3 registration trial.

On March 31, 2022, the Company announced the filing of an IND application with the FDA. This IND filing is in support of the Company’s XRX-008 program for treatment of progressing kidney disease due to ADPKD and contains the protocol for the bridging pharmacokinetics study – XRX-OXY-101 discussed below.

On April 12, 2022, the Company announced receipt of a no objection letter from Health Canada regarding the Company’s upcoming XRX-OXY101 clinical bridging pharmacokinetics study. The XRX-OXY-101 study has been designed with three important objectives: 1) to determine which of XORTX’s novel formulations results in the best circulating oxypurinol concentrations; 2) to determine the effect of food on the bioavailability of this formulation; and 3) to determine the safety and pharmacokinetics of multiple doses of this selected formulation. Knowledge gained during the conduct of this trial will provide guidance regarding the future oral dosing of oxypurinol formulations in support of the Company’s planned phase 3 registration trial in ADPKD. Additionally, this study will provide data to support future New Drug Application (“NDA”) marketing submissions to the FDA and the European Medicines Agency (“EMA”).

Partnership with Icahn School of Medicine

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

On October 14, 2021, the Company announced that the results of the study provide support for the Company’s provisional patent applications for XRX-101 with the conclusion of the study indicating, *“In patients admitted to the hospital for COVID-19, higher uric acid levels were independently associated with major adverse kidney events and mortality in a dose-dependent manner. In addition, hyperuricemia was associated with higher procalcitonin and troponin levels.”*

Appointment of LONZA Group as Manufacturer

On April 30, 2020, the Company announced the appointment of LONZA Group as the manufacturer of GMP oxypurinol for the XRX-008 and XRX-101 clinical trial programs. The launch of oxypurinol manufacturing for both XRX-008 and XRX-101 is the first step to advance these programs toward clinical testing. Lonza is a leading global supplier to the pharmaceutical, biotech and specialty ingredients markets.

Appointment of Altasciences as Contract Research Organization

On December 2, 2021, the Company announced the appointment of Altasciences Company Ltd., a contract research organization (“CRO”) for its planned Bridging pharmacokinetic study in support of the XRX-008 program for ADPKD and XRX-101 for AKI associated with Coronavirus / COVID-19 infection. The goal of the planned bridging pharmacokinetics study – XRX-OXY-101, is to characterize the increased bioavailability of oxypurinol in humans and follows successful results in two animal models where increased bioavailability was demonstrated for this formulation.

Changes in officers, directors and advisory board members

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

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

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

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

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

On December 20, 2021, Raymond Pratt was elected to the Board of Directors to replace Bruce Rowlands who resigned effective that date.

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

FUTURE PLANS AND OUTLOOK

XORTX intends to grow its business by developing three programs focused on kidney disease.

For the balance of 2022, the Company anticipates a number of advancements and changes in its business.

In 2022, XORTX is focused on advancing XRx-008 into a clinical trial, the submission of an Orphan Drug Designation application, initiation of special protocol assessment discussions with the FDA and continuing formulation development for other kidney disease applications. To achieve these objectives, XORTX's action plan includes:

1. **Initiate XRX-OXY-101 Bridging Study.** This study is a three-part, single-dose; fed or fasted; then, multi-dose crossover comparative bioavailability and pharmacokinetic study in healthy volunteers. It is designed to permit XORTX to characterize the safety and relative bioavailability of the XRx-008 formulation. Knowledge gained during the conduct of this trial will provide guidance regarding the oral dose of XRx-008 for our planned registration trial in ADPKD. Additionally, this study will provide data to support future **NDA** submissions to the FDA and the EMA. This study is planned to start in the second quarter of 2022.
 2. **Initiate XRX-OXY-102 Bridging Study.** This study is a multi-dose crossover comparative bioavailability and pharmacokinetic study in healthy volunteers. It is designed to permit XORTX to characterize the safety and relative bioavailability of the XRx-101 formulation options. Knowledge gained during the conduct of this trial will provide guidance regarding the oral dose of XRx-101 for future clinical and commercial planning. Additionally, this study will provide data to support future **NDA** submissions to the FDA and EMA. This study is planned to start in the second quarter of 2022.
 3. **Complete Orphan Drug Designation.** Current research being conducted will be used to file for orphan drug designation in 2022.
 4. **Commence XRX-OXY-301 Registration trial in ADPKD.** XRX-OXY-301 is a multi-site, multi-national, placebo controlled, study in ADPKD patients with progressing stage 2 or 3 kidney disease. The objective of this study is to evaluate the safety and effectiveness of XRx-008 over a 24-month period and study the ability of xanthine oxidase inhibition to decrease the rate of decline of glomerular filtration rate. An estimated 350 patients will be enrolled. This study is planned to start in the second half of 2022, subject to SPA negotiations with the FDA.
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5. **Ongoing CMC Work.** In parallel to the XRX-OXY-101 and XRX-OXY-102 studies, XORTX will be focused on performing the necessary scale-up, process validation and stability as part of the CMC requirements for the filing of the IND, as well as future clinical and commercial supplies. All development will be performed according to current GMP methodology. This work will be ongoing throughout 2022 and 2023.
6. **Preparation of 505(b)(2) IND.** In parallel with initiation of XRX-OXY-101 a 505(b)2 based IND is expected to be submitted in the second quarter of 2022 for the XRX-008 program.
7. **Activities Related to Potential Commercial Launch.** In preparation for a possible NDA filing in 2025 in the U.S. for XRX-008, XORTX is planning to conduct additional commercialization studies, including nephrologist, patient, payer, pricing and/or reimbursement studies, as well as product brand name selection and filings, and plans for launch. This work will be ongoing from 2022 to 2025.
8. **Activities Related to European Registration.** XORTX intends to establish guidance from the European Union for path to approval in the European Union, including required clinical studies and reimbursement conditions. This work will be ongoing from 2022 to 2025.

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

SUMMARY OF QUARTERLY RESULTS

The table below sets forth unaudited quarterly results prepared by management for the eight previous quarters to December 31, 2021:

| (unaudited) | 2021 Q4 | 2021 Q3 | 2021 Q2 | 2021 Q1 |
|---|--------------|-------------|-----------|-------------|
| Amortization of Intangible Assets | 4,739 | 4,526 | 4,373 | 4,244 |
| Foreign Exchange (gain) loss | (346,716) | 12,242 | 7,336 | 387 |
| Consulting | 368,662 | 109,269 | 94,480 | 151,861 |
| Directors' fees | 22,700 | 39,500 | - | - |
| General and administrative | 146,012 | 6,263 | 13,012 | 10,812 |
| Interest | 1,669 | 1,382 | 665 | 1,882 |
| Investor Relations | 134,543 | 118,947 | 60,251 | 204,874 |
| Listing fees | 148,487 | 36,858 | 36,903 | 14,553 |
| Professional Fees | 71,246 | (402,676) | 491,552 | 112,821 |
| Research and Development | 430,948 | 381,967 | 26,423 | 13,786 |
| Share Based Payments ² | 143,496 | 62,221 | 90,451 | 202,990 |
| Travel | 239 | - | - | 2,100 |
| Wages and Benefits | 137,678 | 48,000 | 48,000 | 52,412 |
| Transaction costs on derivative warrant liability | 1,537,948 | - | - | 85,732 |
| (Gain) loss on derivative warrant liability | (11,895,882) | 7,936,114 | (655,000) | 1,315,000 |
| Total Comprehensive Income (loss) | 9,094,231 | (8,354,613) | (218,446) | (2,173,454) |
| Earnings (loss) per Share | 0.74 | (0.89) | (0.02) | (0.26) |

| (unaudited) | 2020 Q4 | 2020 Q3 | 2020 Q2 | 2020 Q1 |
|---|-----------|-----------|-----------|-----------|
| Accretion | - | - | 425 | 421 |
| Amortization of Intangible Assets | 5,140 | 5,154 | 5,095 | 5,050 |
| Foreign Exchange loss (gain) | 7,006 | 42,230 | 90,907 | (143,104) |
| Consulting | 39,172 | 15,000 | 33,708 | 15,000 |
| General and administrative | 1,933 | 1,742 | 3,445 | 2,396 |
| Interest | 815 | 839 | 2,525 | 8,487 |
| Investor Relations | 109,973 | 52,848 | 40,081 | 38,275 |
| Listing fees | 15,510 | 10,802 | 14,063 | 11,763 |
| Professional Fees | 75,000 | 37,819 | 22,785 | 26,976 |
| Research and Development | 142,548 | 120,033 | 12,452 | 2,422 |
| Share Based Payments ¹ | 6,748 | 90,443 | 189,524 | 6,728 |
| Travel | - | - | - | 8,460 |
| Wages and Benefits | 79,808 | 48,000 | 49,740 | 50,357 |
| Impairment of intangible assets | 64,562 | - | - | - |
| Recovery of provision for patent acquisition ² | (95,490) | - | - | - |
| Forgiveness of debt | - | - | (91,014) | - |
| Total Comprehensive Loss | (452,725) | (424,910) | (373,736) | (33,231) |
| Loss per Share | (0.07) | (0.06) | (0.05) | (0.01) |

Notes:

(1) Share based payments relate to the vesting of options over the period.

(2) The provision for patent acquisition relates to a patent rights acquisition of US\$75,000 paid in 2012. During the year ended December 31, 2020, the Company determined that the purchase was no longer feasible; therefore, the provision was reversed.

Three months ended December 31, 2021

The Company earned comprehensive income of \$9,094,231 (\$0.22 per share) for the three months ended December 31, 2021, compared to a loss of \$452,725 (\$0.07 per share) in the three months ended December 31, 2020.

Variances within the loss items are as follows:

Foreign Exchange (Gain) Loss – gain of \$346,716 (2020 – loss of \$7,006) – Our foreign exchange gain was \$346,716 for the three months ended December 31, 2021 as compared to loss of \$7,006 primarily due to an unrealized translation gain on the U.S. dollar denominated cash balance.

Consulting - \$368,662 (2020 - \$39,172) – Consulting expenses increased during the three months ended December 31, 2021, as more consultants were engaged during 2021 due to an increase in Company activity with respect to corporate development.

Directors' fees - \$22,700 (2020 - \$nil) – Directors' fees expenses increased during the three months ended December 31, 2021, as the Company began paying annual and meeting fees to its independent directors on July 1, 2021.

General and administrative - \$146,012 (2020 – \$1,933) General and administrative costs increased significantly mostly due to an increase in the director and officer insurance premium.

Listing fees - \$148,487 (2020 - \$15,510) – Listing fees increased during the three months ended December 31, 2021 due to costs related to the Company's listings on the TSXV and Nasdaq stock exchanges.

Research and development - \$430,948 (2020 - \$142,548) – Research and development expenses increased in the three months ended December 31, 2021, as detailed in the following table.

The table below presents combined research and development costs for XRx-008, XRx-101, and XRx-225 as the Company's projects are presently run concurrently and in combination.

| | Q4 2021 | Q4 2020 | Change \$ | Change % |
|---|------------|------------|------------|----------|
| Manufacturing and related process expenses ¹ | 115,295 | 142,022 | (26,727) | (19)% |
| Intellectual property expenses ² | 10,371 | - | 10,371 | - |
| Translational science expenses ³ | 196,632 | - | 196,632 | - |
| External consultants expenses ⁴ | 108,650 | 525 | 108,125 | 20595% |
| Other related expenses | - | - | - | - |
| Total Research and development | \$ 430,948 | \$ 142,547 | \$ 288,401 | 202% |

Notes:

- (1) Manufacturing and related process expenses includes third party direct manufacturing costs, quality control testing and packaging costs. In Q4 2021, manufacturing costs primarily related to the Company's oxypurinol manufacturing, feasibility study and chemical compound studies. The decrease in manufacturing and related process expenses in Q4 2021 as compared to Q4 2020 relates to a timing difference as fiscal 2021 manufacturing and related expenses overall were higher than yearly 2020 costs geared towards the start of bridging study and registration trial in ADKPD planned for 2022.
- (2) Intellectual property expenses include legal and filing fees associated with our patent portfolio. The increase in intellectual property expenses in Q4 2021 as compared to Q4 2020 relate to increased legal fees as the Company expanded its patent portfolio.
- (3) Translational science expenses include various research studies conducted to expand our intellectual knowledge base related to oxypurinol and our proprietary formulations of oxypurinol, pharmacokinetic testing, non-clinical bioavailability studies, pharmacology and toxicology testing and identify potential licensing opportunities. The translational science expense in Q4 2021 related to sponsored research work at the University of Denver, Colorado and Mount Sinai Hospital, New York. No such activity was undertaken in 2020.
- (4) External consultants' expenses include third party consultants engaged in the activities of research and development, including chemistry, manufacturing, drug product development, regulatory, non-clinical and clinical study execution. The increase in external consultants' expenses in Q4 2021 as compared to Q4 2020 was attributed to increased activity focused on to initiation of the Company's bridging study and thereafter a single registration trial associated to the XRx-008 program in individuals with ADKPD planned for 2022.

Share-based payments - \$143,496 (2020 - \$6,748) – The share-based payment expense increased in the three months ended December 31, 2021, as more options were granted that vested over the period.

Gain on derivative warrant liability - \$11,895,882 (2020 – nil). This gain relates to the warrants included in the units issued under the Private Placement and IPO. The Private Placement warrants were classified as a derivative financial liability as they contained a ratchet provision that provided for an adjustment in the exercise price of the warrants if shares or securities convertible to shares were sold at a price lower than the exercise price. The IPO warrants have an exercise price in US dollars and have a derivative financial liability as the exercise price is in a different currency than the functional currency of the entity. The warrants are initially recognized at fair value and subsequently measured at fair value with changes recognized through profit or loss. Of this amount, a gain of \$9,068,213 relates to the Private Placement warrants and was recognized as the ratchet provision on the warrants described above ended, thereby resulting in the derecognition of the derivative warrant liability during the quarter. A gain of \$2,827,669 relates to the IPO warrants and the derivative liability recognized. Gains and losses resulting from the revaluation of the derivative warrants are non-cash and do not impact our cash flows.

Selected Annual Financial Information

The financial information reported here in has been prepared in accordance with IFRS. The Company uses the Canadian dollar as its presentation currency.

Selected Statement of Operations Data

| | 2021 | 2020 | 2019 |
|-------------------------------------|--------------|--------------|------------|
| Revenue | \$ Nil | \$ Nil | \$ Nil |
| Comprehensive loss for the year | \$ 1,652,282 | \$ 1,284,602 | \$ 629,576 |
| Weighted average shares outstanding | 9,847,641 | 6,664,025 | 5,359,429 |
| Loss per share, basic and diluted | \$ 0.17 | \$ 0.19 | \$ 0.12 |

Selected Statement of Financial Position Data

| | Dec. 31, 2021 | Dec. 31, 2020 | Dec. 31, 2019 |
|----------------------------------|---------------|---------------|---------------|
| Cash and cash equivalents | \$ 18,851,244 | \$ 171,271 | \$ 58,614 |
| Net working capital (deficiency) | \$ 19,472,340 | \$ 1,021,928 | \$ (484,450) |
| Total assets | \$ 22,035,902 | \$ 2,290,457 | \$ 1,087,977 |
| Long-term liabilities | \$ Nil | \$ Nil | \$ Nil |

Comparison of Operations for the 2021 and 2020 Financial Years

Results of Operations

| | 2021 | 2020 | Change \$ | Change % |
|---|-------------|-----------|-------------|----------|
| Amortization | 17,882 | 20,439 | (2,557) | (13)% |
| Consulting | 724,272 | 102,880 | 621,392 | 604% |
| Directors' fees | 62,200 | - | 62,200 | - |
| General and administrative | 176,099 | 9,516 | 166,583 | 1751% |
| Investor relations | 518,615 | 241,177 | 277,438 | 115% |
| Listing fees | 236,801 | 52,138 | 184,663 | 354% |
| Professional fees | 272,943 | 162,580 | 110,363 | 68% |
| Research and development | 853,124 | 277,455 | 575,669 | 207% |
| Share-based payments | 499,158 | 293,443 | 205,715 | 70% |
| Travel | 2,339 | 8,460 | (6,121) | (72)% |
| Wages and benefits | 286,090 | 227,905 | 58,185 | 26% |
| Accretion | - | 846 | (846) | (100)% |
| Foreign exchange (gain) | (326,751) | (2,961) | (323,790) | 10935% |
| Gain on derivative warrant liability | (3,299,768) | - | (3,299,768) | - |
| Interest and other expenses | 5,598 | 12,666 | (7,068) | (56)% |
| Impairment of intangible assets | - | 64,562 | (64,562) | (100)% |
| Recovery of provision | - | (95,490) | 95,490 | (100)% |
| Transaction costs on derivative warrant liability | 1,623,680 | - | 1,623,680 | - |
| Forgiveness of debt | - | (91,014) | 91,014 | (100)% |
| Comprehensive Loss for the Year | 1,652,282 | 1,284,602 | 367,680 | 29% |
| Loss per Share | 0.17 | 0.19 | 0.53 | 289% |

Year ended December 31, 2021

The Company incurred a comprehensive loss of \$1,652,282 (\$0.17 per share) for the year ended December 31, 2021, compared to a loss of \$1,284,602 (\$0.19 per share) in the year ended December 31, 2020.

Variances within the loss items are as follows:

Consulting - \$724,272 (2020 - \$102,880) – Consulting expenses increased during the year ended December 31, 2021, as more consultants were engaged during 2021 due to an increase in Company activity with respect to corporate development.

Directors' fees - \$62,200 (2020 - \$nil) – Directors' fees expenses increased during the year ended December 31, 2021, as the Company began paying annual and meeting fees to its independent directors on July 1, 2021.

General and administrative - \$176,099 (2020 – \$9,516) General and administrative costs increased significantly mostly due to an increase in the director and officer insurance premium.

Investor relations - \$518,615 (2020 - \$241,177) – Investor relations increased during the year ended December 31, 2021 due to costs related to the increased number of shareholder communications as a result of the Company's listing on the TSXV and Nasdaq stock exchanges.

Listing fees - \$236,801 (2020 - \$52,138) – Listing fees increased during the year ended December 31, 2021 due to costs related to the Company's listings on the TSXV and Nasdaq stock exchanges.

Professional fees - \$272,943 (2020 - \$162,580) – Professional fees increased in the year ended December 31, 2021, as the result of an increase in legal and accounting fees related to the Company's increased activity with listing on the TSXV and Nasdaq stock exchanges.

Research and development - \$853,124 (2020 - \$277,455) – Research and development expenses increased in the year ended December 31, 2021, as detailed below.

The table below presents combined research and development costs for XRx-008, XRx-101, and XRx-225 as the Company's projects are presently run concurrently and in combination.

| | 2021 | 2020 | Change \$ | Change % |
|---|------------|------------|------------|----------|
| Manufacturing and related process expenses ¹ | 392,619 | 260,356 | 132,263 | 51% |
| Intellectual property expenses ² | 28,724 | 6,704 | 22,020 | 329% |
| Translational science expenses ³ | 210,605 | - | 210,605 | - |
| External consultants' expenses ⁴ | 201,090 | 10,395 | 190,695 | 1834% |
| Other related expenses ⁵ | 20,086 | - | 20,086 | - |
| Total Research and development | \$ 853,124 | \$ 277,455 | \$ 575,669 | 207% |

Notes:

- (1) Manufacturing and related process expenses include third party direct manufacturing costs, quality control testing and packaging costs. In 2021, the Company's manufacturing costs primarily related to oxypurinol manufacturing, feasibility study and chemical compound studies. The increase in manufacturing and related process expenses in 2021 as compared to 2020 is entirely attributable to increased activity geared towards the start of bridging study and registration trial in ADKPD planned for 2022. We expect our manufacturing expenses for 2022 to increase as compared to 2021 as we start the drug manufacturing for bridging study and registration trials in ADKPD as per future plan.
- (2) Intellectual property expenses include legal and filing fees associated with our patent portfolio. The increase in intellectual property expenses in 2021 as compared to 2020 related to increased legal fees as company expanded its patent portfolio. We expect intellectual property expenses in 2022 will increase as compared to 2021 as the Company expands its patent portfolio.
- (3) Translational science expenses include various research studies conducted to expand our intellectual knowledge base related to oxypurinol and our proprietary formulations of oxypurinol, pharmacokinetic testing, non-clinical bioavailability studies, pharmacology and toxicology testing and identification of potential licensing opportunities. The translational science expense in 2021 related to sponsored research work at the University of Denver, Colorado and Mount Sinai Hospital, New York. No such activity was undertaken in 2020. We expect translational science expense in 2022 will increase as compared to 2021 as the Company expands its patent portfolio.

- (4) External consultants' expense includes third party consultants engaged in the activities of research and development, including chemistry, manufacturing, drug product development, regulatory, non-clinical and clinical study execution. The increase in external consultants' expenses in 2021 as compared to 2020 was attributed to increased activity focused on the initiation of the Company's bridging study and thereafter a single registration trial associated with the XRx-008 program in individuals with ADKPD planned for 2022. We expect external consultants' expense in 2022 to increase as compared to 2021 as the Company conducts a bridging pharmacokinetic study associated with the XRx-008 drug product and thereafter initiation and conduct of a registration trial in ADKPD.
- (5) Other related expenses include various ancillary research and development costs. The expense in 2021 is entirely related to patent portfolio research and development expense. No such cost incurred in 2020. We expect other related expense in 2022 will remain same as compared to 2021.

Share-based payments - \$499,158 (2020 - \$293,443) – The share-based payment expense increased in the year ended December 31, 2021, as more options were granted than vested over the period.

Foreign exchange gain - \$326,751 (2020 - \$2,961) – Our foreign exchange gain was \$326,751 for the year ended December 31, 2021 as compared to loss of \$2,961 primarily due to an unrealized translation gain on the U.S. dollar denominated cash balance.

Transaction costs on derivative warrant liability and gain on derivative warrant liability – an expense of \$1,623,680 and a gain of \$3,299,768 respectively (2020 – \$nil and \$nil). The expense and gain relate to the warrants included in the units issued under the Private Placement and IPO. The transaction costs result from the valuation of finders' warrants and the gain on derivative liability resulting from the revaluation of the warrants issued as part of a unit. The Private Placement warrants were classified as a derivative financial liability as they contained a ratchet provision that provided for an adjustment in the exercise price of the warrants if shares or securities convertible to shares were sold at a price lower than the exercise price. The IPO warrants have an exercise price in US dollars and have a derivative financial liability as the exercise price is in a different currency than the functional currency of the entity. The warrants are initially recognized at fair value and subsequently measured at fair value with changes recognized through profit or loss. Gains and losses resulting from the revaluation of the derivative warrants are non-cash and do not impact our cash flows.

Comparison of cash flows for the year ended December 31, 2021

The Company realized a net cash inflow of \$18,679,973 for the year ended December 31, 2021, compared to \$112,657 for the year ended December 31, 2020. The variances in the cash flow for the year ended December 31, 2021, compared to December 31, 2020, were as follows:

Operating activities – Cash used in operating activities for the year ended December 31, 2021, was \$6,062,510 (2020 - \$728,401). The cash used in operating activities was primarily due to the net loss during the period offset by the non-cash items.

Investing activities – Cash used in investing activities for the year ended December 31, 2021, was \$39,809 (2020 - \$14,350). The cash used related to the acquisition of intangible assets during the period.

Financing activities – Cash provided by financing activities in the year ended December 31, 2021, was \$24,456,551 (2020 - \$855,408). The cash provided was mostly related to the public offering that occurred when the shares of the Company were listed on Nasdaq of 2,906,000 units, with each unit consisting of one common share, no par value, and one warrant to purchase one common share at a public offering price of US\$4.13 per Unit, for gross proceeds of \$14,851,850 (US\$12,001,780) as well as the private placement that took place in February 2021 raising gross proceeds of \$6,121,572 through the issuance of 2,085,687 units at a subscription price of \$2.935 per unit.

LIQUIDITY AND CAPITAL RESOURCES

As at December 31, 2021, the Company had a cash balance of \$18,851,244 and working capital of \$19,472,340 as compared to a cash balance of \$171,271 and working capital of \$1,021,928 as at December 31, 2020. During the year ended December 31, 2020, the Company closed a \$2,556,320 private placement and during the year ended December 31, 2021, the Company closed a public offering that occurred when the shares of the Company were listed on Nasdaq of 2,906,000 units, with each unit consisting of one common share, no par value, and one warrant to purchase one common share at a public offering price of US\$4.13 per Unit, for gross proceeds of \$14,851,850 (US\$12,001,780) as well as the private placement that took place in February 2021 raising gross proceeds of \$6,121,572 through the issuance of 2,085,687 units at a subscription price of \$2.935 per unit. The Company's primary source of funding is by way of raising capital through the issuance of equity to third party investors.

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

COMMITMENTS

The Company has long-term arrangements with commitments as at December 31, 2021 and 2020 as follows:

| | <u>December 31</u> <u>2021</u> | <u>December 31</u> <u>2020</u> |
|--------------------------------|-----------------------------------|-----------------------------------|
| | \$ | \$ |
| Management services – officers | 380,000 | 192,000 |

The President, CEO and a director of the Company has a long-term employment agreement with the Company. The agreement has a termination clause whereby he is entitled to the equivalent of 12 times his then current monthly salary which, as of December 31, 2021, equated to US\$300,000.

OFF BALANCE SHEET ARRANGEMENTS

The Company has no off-balance sheet arrangements.

TRANSACTIONS WITH RELATED PARTIES

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

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

- a) Wages and benefits were paid or accrued to Allen Davidoff, the Chief Executive Officer (“CEO”) and Amar Keshri, Chief Financial Officer (“CFO”) of the Company in the amount of \$278,840 (2020 - \$196,097 paid to the CEO).
- b) Professional fees were paid or accrued to 1282803 Ontario Inc., a company owned by Jim Fairbairn, former CFO of the Company, in the amount of \$58,500 (2020 - \$30,000).
- c) Professional fees were paid or accrued to Amar Keshri, CFO of the Company, in the amount of \$53,000 (2020 -\$nil).
- d) Research and development fees were paid or accrued to Haworth Biopharmaceutical, a company owned by Stephen Haworth, Chief Medical Officer (“CMO”) of the Company, in the amount of \$106,366 (2020 - \$nil).
- e) Consulting fees were accrued to directors of the Company in the amount of \$34,950 and directors’ fees (2020 - \$36,000) were accrued to the directors of the Company in the amount of \$62,200 (2020 - \$nil).
- f) As at December 31, 2021, \$nil (2020 - \$52,450) was payable to the former CFO of the Company for CFO services, and \$81,104 (2020 - \$20,340) was payable to directors of the Company, \$25,000 (2020 - \$518,084) was accrued to the CEO of the Company, for CEO services, and \$47,543 (2020 - \$nil) was accrued to the CMO of the Company, for consulting services. The balances are unsecured, non-interest bearing, and have no fixed terms of repayment.
- g) Management compensation transactions for the year ended December 31, 2021 and 2020 are summarized as follows:

| | Short-term employee benefits | Share-based payments | Total |
|-------------------------------------|---|---------------------------------|----------------|
| | <u>\$</u> | <u>\$</u> | <u>\$</u> |
| Year ended December 31, 2020 | | | |
| Directors and officers | 262,097 | 217,816 | 479,913 |
| Year ended December 31, 2021 | | | |
| Directors and officers | 593,856 | 331,809 | 925,665 |

FINANCIAL AND CAPITAL RISK MANAGEMENT

The Company's financial instruments consist of cash, accounts payable and accrued liabilities, and warrant liability. These financial instruments are classified as financial assets at FVTPL and financial liabilities at amortized cost. The fair values of these financial instruments approximate their carrying values at December 31, 2021, due to their short-term nature.

The following table presents the Company's financial instruments, measured at fair value on the consolidated statements of financial position as at December 31, 2021 and 2020 and categorized into levels of the fair value hierarchy:

| | Level | December 31, 2021 | | December 31, 2020 | |
|--|-------|-------------------|------------------------|-------------------|------------------------|
| | | Carrying Value | Estimated Fair Value * | Carrying Value | Estimated Fair Value * |
| | | \$ | \$ | \$ | \$ |
| FVTPL | | | | | |
| Cash | 1 | 18,851,244 | 18,851,244 | 171,271 | 171,271 |
| Other financial liabilities | | | | | |
| Accounts payable and accrued liabilities | 2 | 700,999 | 700,999 | 1,034,213 | 1,034,213 |
| FVTPL | | | | | |
| Derivative liability | 3 | 4,597,332 | 4,597,332 | - | - |

* The Company has determined that the carrying values of its short-term financial assets and financial liabilities, including cash and accounts payable and accrued liabilities approximate their fair value due to the short-term nature of the instruments. The fair value of the derivative warrant liability is revalued at the end of each period.

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

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

a) Credit risk

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

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

All of the Company's cash is held with major financial institutions in Canada and management believes the exposure to credit risk with such institutions is minimal. The Company considers the risk of material loss to be significantly mitigated due to the financial strength of the major financial institutions where cash is held. The Company's maximum exposure to credit risk as at December 31, 2021 and 2020 is the carrying value of its financial assets.

b) Liquidity risk

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

The Company's financial assets are comprised of its cash and funds held in trust, and the financial liabilities are comprised of its accounts payable and accrued liabilities and the liability component on convertible loans.

The contractual maturities of these financial liabilities as at December 31, 2021 and 2020 are summarized below:

| | Payments due by period as of December 31, 2021 | | | |
|--|--|--------------------|-----------------------------|-----------|
| | Total | Less than 3 months | Between 3 months and 1 year | 1-3 years |
| | \$ | \$ | \$ | \$ |
| Accounts payable and accrued liabilities | 700,999 | 700,999 | - | - |
| | 700,999 | 700,999 | - | - |
| | Payments due by period as of December 31, 2020 | | | |
| | Total | Less than 3 months | Between 3 months and 1 year | 1-3 years |
| | \$ | \$ | \$ | \$ |
| Accounts payable and accrued liabilities | 1,034,213 | 1,034,213 | - | - |
| | 1,034,213 | 1,034,213 | - | - |

c) Market risk

i) Interest Rate Risk

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

ii) Foreign Currency Risk

As at December 31, 2021, the Company is exposed to currency risk on the following financial assets and liabilities denominated in US Dollars ("USD") and British Pounds ("GBP"). The sensitivity of the Company's net earnings due to changes in the exchange rate between the USD and GBP against the Canadian dollar is included in the table below in Canadian dollar equivalents:

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

Capital Management

The Company defines capital that it manages as equity. The Company manages its capital structure in order to have funds available to support its research and development and sustain the future development of the business. When managing capital, the Company's objective is to ensure the entity continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders. Management adjusts the capital structure as necessary in order to support its activities.

The Company includes the following items in its managed capital as at the following periods:

Equity is comprised of:

| | <u>December 31</u> <u>2021</u> | <u>December 31</u> <u>2020</u> |
|---|-----------------------------------|-----------------------------------|
| | \$ | \$ |
| Share capital | 20,009,154 | 8,258,395 |
| Share-based payments, warrant reserve and other | 6,386,459 | 1,003,609 |
| Obligation to issue shares | 32,238 | 32,238 |
| Deficit | (9,690,280) | (8,037,998) |

Since inception, the Company's objective in managing capital is to ensure sufficient liquidity to finance its research and development activities, general and administrative expenses, expenses associated with intellectual property protection and its overall capital expenditures. The Company is not exposed to external requirements by regulatory agencies regarding its capital.

OUTSTANDING SHARE DATA

As at April 12, 2022, the Company had the following shares outstanding:

| | |
|--------------------------|------------------------------|
| - Class | Common Shares |
| - Authorized | Unlimited, without par value |
| - Issued and outstanding | 12,989,687 |

Options Outstanding:

The following table summarizes information on the 606,067 stock options outstanding as at April 12, 2022:

| <u>Exercise Price</u> | <u>Number Outstanding</u> | <u>Expiry Date</u> |
|-----------------------|---------------------------|--------------------|
| \$ 5.87 | 127,760 | March 19, 2023 |
| \$ 5.87 | 21,294 | November 5, 2023 |
| \$ 1.64 | 170,354 | June 23, 2025 |
| \$ 2.82 | 12,776 | August 27, 2025 |
| \$ 3.29 | 59,624 | January 11, 2026 |
| \$ 1.88 | 42,588 | May 12, 2026 |
| \$ 1.76 | 21,294 | June 16, 2026 |
| \$ 2.41 | 63,882 | July 14, 2026 |
| \$ 2.54 | 86,495 | December 21, 2026 |
| \$ 2.54 | 127,500 | January 12, 2027 |
| \$ 2.54 | 5,000 | February 18, 2027 |

Warrants Outstanding:

The following table summarizes information on the 5,329,796 outstanding warrants as at April 12, 2022:

| | Exercise Price | Number Outstanding | Expiry date |
|------|-----------------------|---------------------------|--------------------|
| \$ | 4.70 | 1,842,596 | February 9, 2026 |
| US\$ | 4.77 | 3,487,200 | October 15, 2026 |

RISKS RELATED TO THE BUSINESS

An investment in the Company is speculative and involves a high degree of risk. Accordingly, prospective investors should carefully consider the specific risk factors set out below, in addition to the other information contained in this MD&A, before making any decision to invest in the Company. The Directors consider the following risks and other factors to be the most significant for potential investors in the Company, but the risks listed do not necessarily comprise all those associated with an investment in the Company and are not set out in any particular order of priority. Additional risks and uncertainties not currently known to the Directors may also have an adverse effect on the Company's business. If any of the following risks actually occur, the Company's business, financial condition, capital resources, results or future operations could be materially adversely affected. In such a case, the price of the common shares could decline, and investors may lose all or part of their investment.

Speculative Nature of Investment Risk

An investment in the common shares of the Company carries a high degree of risk and should be considered as a speculative investment by purchasers. The Company has limited cash reserves, a limited operating history, has not paid dividends, and is unlikely to pay dividends in the immediate or near future. The Company is in the development stage. Operations are not yet sufficiently established such that the Company can mitigate the risks associated with planned activities.

Limited Operating History

The Company has no present prospect of generating revenue from the sale of products. The Company is therefore subject to many of the risks common to early-stage enterprises, including under-capitalization, cash shortages, limitations with respect to personnel, financial, and other resources and lack of revenues. There is no assurance that the Company will be successful in achieving a return on shareholders' investment and the likelihood of success must be considered in light of the early stage of operations.

Negative Cash Flow for the Foreseeable Future

The Company has a no history of earnings or cash flow from operations. The Company does not expect to generate material revenue or achieve self-sustaining operations for several years, if at all. To the extent that the Company has negative cash flow in future periods, the Company may need to allocate a portion of its cash reserves to fund such negative cash flow.

Reliance on Management

The success of the Company is dependent upon the ability, expertise, judgment, discretion and good faith of its management. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on the Company's business, operating results or financial condition.

Clinical trials for potential drug candidates will be expensive and time consuming, and their outcomes uncertain.

Before the Company can obtain regulatory approval for the commercial sale of any drug candidate or attract major pharmaceutical companies with which to collaborate, it will be required to complete extensive clinical trials to demonstrate safety and efficacy. Clinical trials are expensive and are difficult to design and implement. The clinical trial process is also time-consuming and can often be subject to unexpected delays.

The timing and completion of clinical trials may be subject to significant delays relating to various causes, including but not limited to: inability to manufacture or obtain sufficient quantities of materials for use in clinical trials; delays arising from collaborative partnerships; delays in obtaining regulatory approvals to commence a study, or government intervention to suspend or terminate a study; delays, suspensions or termination of clinical trials by the applicable institutional review board or independent ethics board responsible for overseeing the study to protect research subjects; delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites; slow rates of patient recruitment and enrollment; uncertain dosing issues; inability or unwillingness of medical investigators to follow clinical protocols; variability in the number and types of subjects available for each study and resulting difficulties in identifying and enrolling subjects who meet trial eligibility criteria; scheduling conflicts; difficulty in maintaining contact with subjects after treatment, resulting in incomplete data; unforeseen safety issues or side effects; lack of efficacy during clinical trials; reliance on clinical research organizations to efficiently and properly conduct clinical trials in accord with contracted arrangements and regulations, or other regulatory delays.

Risks Related to Food and Drug Administration (FDA) Approval

In the United States, the FDA regulates the approval of therapeutics and the FDA notification and approval process requires substantial time, effort and financial resources, and the Company cannot be certain that any approvals for its products will be granted on a timely basis, if at all.

Foreign jurisdictions have similar government regulatory bodies and requirements that the Company must meet prior to selling products in those jurisdictions.

The Company must be considered in light of the risks, expenses, shifts, changes and difficulties frequently encountered with companies whose businesses are regulated by various federal, state and local governments. The health care, wellness, workers' compensation and similar companies are subject to a variety of regulatory requirements and the regulatory environment is ever changing particularly with recent legislation, the full impact of which is not yet understood as regulations have not been issued. Failure to follow applicable regulatory requirements will have a materially negative impact on the business of the Company. Furthermore, future changes in legislation cannot be predicted and could irreparably harm the business of the Company.

Intellectual Property Rights

The Company could be adversely affected if it does not adequately protect its intellectual property rights. The Company regards its marks, rights, and trade secrets and other intellectual property rights as critical to its success. To protect its investments and the Company's rights in these various intellectual properties, it may rely on a combination of patents, trademark and copyright law, trade secret protection and confidentiality agreements and other contractual arrangements with its employees, clients, strategic partners, acquisition targets and others to protect proprietary rights. There can be no assurance that the steps taken by the Company to protect proprietary rights will be adequate or that third parties will not infringe or misappropriate the Company's copyrights, trademarks and similar proprietary rights, or that the Company will be able to detect unauthorized use and take appropriate steps to enforce rights. In addition, although the Company believes that its proprietary rights do not infringe on the intellectual property rights of others, there can be no assurance that other parties will not assert infringement claims against the Company. Such claims, even if not meritorious, could result in the expenditure of significant financial and managerial resources.

The Company will rely on trade secrets to protect technology where it does not believe patent protection is appropriate or obtainable. Trade secrets are difficult to protect. While commercially reasonable efforts to protect trade secrets will be used, strategic partners, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose information to competitors.

If the Company is not able to defend patents or trade secrets, then it will not be able to exclude competitors from developing or marketing competing products, and the Company may not generate enough revenue from product sales to justify the cost of development of products and to achieve or maintain profitability.

The results of preclinical studies or initial clinical trials are not necessarily predictive of future favorable results.

Preclinical tests and initial clinical trials are primarily designed to test safety and to understand the side effects of drug candidates and to explore efficacy at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Favorable results in early trials may not be repeated in later ones.

Difficulty to Forecast

The Company must rely largely on its own market research to forecast sales as detailed forecasts are not generally obtainable from other sources at this early stage of the industry. A failure in the demand for its products to materialize as a result of competition, technological change or other factors could have a material adverse effect on the business, results of operations and financial condition of the Company.

Litigation

The Company may become party to litigation from time to time in the ordinary course of business which could adversely affect its business. Should any litigation in which the Company becomes involved be determined against the Company such a decision could adversely affect the Company's ability to continue operating and the market price for the Company's common shares. Even if the Company is involved in litigation and wins, litigation can redirect significant Company resources.

Commercial success of the Company will depend in part on not infringing upon the patents and proprietary rights of other parties and enforcing its own patents and proprietary rights against others. The research and development programs will be in highly competitive fields in which numerous third parties have issued patents and pending patent applications with claims closely related to the subject matter of the Company's programs. The Company is not currently aware of any litigation or other proceedings or claims by third parties that its technologies or methods infringe on their intellectual property.

While it is the practice of the Company to undertake pre-filing searches and analyses of developing technologies, it cannot guarantee that it has identified every patent or patent application that may be relevant to the research, development, or commercialization of its products. Moreover, it cannot assure that third parties will not assert valid, erroneous, or frivolous patent infringement claims.

Uninsurable Risks

The business of the Company may not be insurable or the insurance may not be purchased due to high cost. Should such liabilities arise, they could reduce or eliminate any future profitability and result in increasing costs and a decline in the value of the Company.

The market price of the Company's common shares may be subject to wide price fluctuations.

The market price of the Company's common shares may be subject to wide fluctuations in response to many factors, including variations in the operating results of the Company and its subsidiaries, divergence in financial results from analysts' expectations, changes in earnings estimates by stock market analysts, changes in the business prospects for the Company and its subsidiaries, general economic conditions, legislative changes, and other events and factors outside of the Company's control. In addition, stock markets have from time-to-time experienced extreme price and volume fluctuations, which, as well as general economic and political conditions, could adversely affect the market price for the Company's common shares.

Dividends

The Company has no earnings or dividend record and does not anticipate paying any dividends on the common shares in the foreseeable future.

Dilution

The financial risk of the Company's future activities will be borne to a significant degree by purchasers of the common shares. If the Company issues common shares from its treasury for financing purposes, control of the Company may change and purchasers may suffer additional dilution.

Rapid Technological Change

The business of the Company is subject to rapid technological changes. Failure to keep up with such changes may adversely affect the business of the Company. The Company is subject to the risks of companies operating in the medical and healthcare business. The market in which the Company competes is characterized by rapidly changing technology, evolving industry standards, frequent new service and product announcements, introductions and enhancements and changing customer demands. As a result, an investment in the stocks of the Company is highly speculative and is only suitable for investors who recognize the high risks involved and can afford a total loss of investment.

Risks Associated with Acquisitions

If appropriate opportunities present themselves, the Company may acquire businesses, technologies, services or products that the Company believes are strategic. The Company currently has no understandings, commitments or agreements with respect to any other material acquisition and no other material acquisition is currently being pursued. There can be no assurance that the Company will be able to identify, negotiate or finance future acquisitions successfully, or to integrate such acquisitions with its current business. The process of integrating an acquired business, technology, service or product into the Company may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of the Company's business. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to goodwill and other intangible assets, which could materially adversely affect the Company's business, results of operations and financial condition. Any such future acquisitions of other businesses, technologies, services or products might require the Company to obtain additional equity or debt financing, which might not be available on terms favorable to the Company, or at all, and such financing, if available, might be dilutive.

Economic Environment

The Company's operations could be affected by the economic context should the unemployment level, interest rates or inflation reach levels that influence consumer trends and consequently, impact the Company's future sales and profitability.

Global Economy Risk

The ongoing economic problems and downturn of global capital markets has generally made the raising of capital by equity or debt financing more difficult. Access to financing has been negatively impacted by the ongoing global economic risks. As such, the Company is subject to liquidity risks in meeting its development and future operating cost requirements in instances where cash positions are unable to be maintained or appropriate financing is unavailable. These factors may impact the Company's ability to raise equity or obtain loans and other credit facilities in the future and on terms favorable to the Company. If uncertain market conditions persist, the Company's ability to raise capital could be jeopardized, which could have an adverse impact on the Company's operations and the trading price of the Company's Shares on the stock exchange.

Going-Concern Risk

The Company's future operations are dependent upon the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that the Company will be successful in completing an equity or debt financing or in achieving profitability.

Financial Risk Exposures

The Company may have financial risk exposure to varying degrees relating to the currency of each of the countries where it operates and has financial risk exposure towards digital currencies. The level of the financial risk exposure related to a currency and exchange rate fluctuations will depend on the Company's ability to hedge such risk or use another protection mechanism.

Attracting and keeping senior management and key scientific personnel

The success of the Company depends on the continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel and to develop and maintain important relationships with leading academic institutions, companies, and thought leaders. Allen Davidoff, the Company's Chief Executive Officer and Director, exercises significant control over the day-to-day affairs of the Company. The Company depends on Dr. Davidoff to engage with third parties and contractors to operate the business.

SEGMENT REPORTING

We view our operations and manage our business in one segment, which is the development and commercialization of bio-pharmaceuticals, initially focused on the treatment of progressive kidney disease.

TREND INFORMATION

Other than as disclosed elsewhere we are not aware of any trends, uncertainties, demands, commitments, or events that are reasonably likely to have a material effect on our net revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause reported financial information not necessarily to be indicative of future operating results or financial condition.

MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL STATEMENTS

The Company's management is responsible for presentation and preparation of the financial statements and the MD&A. The MD&A have been prepared in accordance with the requirements of securities regulators, including National Instrument 51-102 of the Canadian Securities Administrators.

The financial statements and information in the MD&A necessarily include amounts based on informed judgments and estimates of the expected effects of current events and transactions with appropriate consideration to materiality. In addition, in preparing the financial information, we must interpret the requirements described above, make determinations as to the relevancy of information included, and make estimates and assumptions that affect reported information. The MD&A also includes information regarding the impact of current transactions and events, sources of liquidity and capital resources, operating trends, risks and uncertainties. Actual results in the future may differ materially from our present assessment of this information because future events and circumstances may not occur as anticipated.
