MANAGEMENT'S DISCUSSION AND ANALYSIS
FOR THE YEAR ENDED NOVEMBER 30, 2022

The following Management's Discussion and Analysis("MD&A"), provides Management's point of view on the financial position and results of operations of Theratechnologies Inc., on a consolidated basis, for the year ended November 30, 2022 ("Fiscal 2022"), compared to the year ended November 30, 2021 ("Fiscal 2021"). Unless otherwise indicated or unless the context requires otherwise, all references in this MD&A to "Theratechnologies", the "Company", the "Corporation", "we", "our", "us" or similar terms refer to Theratechnologies Inc. and its subsidiaries on a consolidated basis. This MD&A is dated February 27, 2023, was approved by our Board of Directors on February 27, 2023 and should be read in conjunction with our audited annual consolidated financial statements and the notes thereto as at November 30, 2022 ("Audited Financial Statements").

Except as otherwise indicated, the financial information contained in this MD&A and in our Audited Financial Statements has been prepared with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB).

The Company's functional and presentation currency is the United States dollar (USD). All monetary amounts set forth in this MD&A and the Audited Financial Statements are expressed in USD, unless otherwise noted.

In this MD&A, the use of *EGRIFTA*® and *EGRIFTA SV*® (tesamorelin for injection) refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and the use of Trogarzo® (ibalizumab-uiyk) injection refers to ibalizumab for the treatment of multidrug resistant HIV-1 infected patients. The use of tesamorelin refers to the use of our tesamorelin compound for the potential treatment of nonalcoholic steatohepatitis (NASH) in the general population and in people living with HIV.

Forward-Looking Information

This MD&A contains forward-looking statements and forward-looking information within the meaning of applicable securities laws that are based on our management's belief and assumptions and on information currently available to our management, collectively, "forward-looking statements". In some cases, you can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "expect", "plan", "anticipate", "believe", "estimate", "project", "predict", "intend", "potential", "continue" and similar expressions intended to identify forward-looking statements. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the commercialization of *EGRIFTA SV*® and Trogarzo®, despite new market entrants;

- our ability and capacity to grow the sales of *EGRIFTA SV*® and Trogarzo® successfully in the United States;

- our capacity to meet supply and demand for our products;

- the market acceptance of *EGRIFTA SV*® and Trogarzo® in the United States;

- the continuation of our collaborations and other significant agreements with our existing commercial partners and third-party suppliers and our ability to establish and maintain additional collaboration agreements;

- our success in continuing to seek and in maintaining reimbursement for *EGRIFTA SV*® and Trogarzo® by third-party payors in the United States;

- the pricing and reimbursement conditions of other competing drugs or therapies that are or may become available;

- our ability to protect and maintain our intellectual property rights in tesamorelin;

- the filing of a supplemental biologic application ("sBLA") for an intramuscular method of administration of Trogarzo®;

- the approval of an intramuscular method of administration of Trogarzo® by the United States Food and Drug Administration ("FDA");

- the filing of a sBLA with the FDA for a new formulation of tesamorelin ("F8 Formulation");

- the approval of the F8 Formulation by the FDA;

- our ability to successfully complete the human factors validation study ("HFS") and to resubmit a CBE supplement with the FDA for *EGRIFA SV*® in the 2023 fiscal year;

- our capacity to meet the undertakings, covenants and obligations contained in the credit agreement entered into with Marathon's affiliates and not be in default thereof;

- our capacity to find a partner to conduct a Phase 2b/3 clinical trial using tesamorelin for the treatment of NASH in the general population;

- the filing of an amendment to our protocol to resume the conduct of our Phase 1 clinical trial using TH1902 in various types of cancer;

- our capacity to find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed;

- our capacity to pursue the development of other PDCs in the field of oncology;

- our capacity to acquire, in-license, or copromote new products;

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- our expectations regarding our financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes;

- our estimates regarding our capital requirements; and

- our ability to meet the timelines set forth herein.

Such statements reflect our current views with respect to future events and are subject to certain risks, uncertainties and assumptions which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed in or implied by the forward-looking statements. Certain assumptions made in preparing the forward-looking statements include that:

- sales of *EGRIFTA SV*® and Trogarzo® in the United States will increase over time;

- our expenses will remain under control;

- our commercial practices in the United States will not be found to be in violation of applicable laws;

- the long-term use of *EGRIFTA SV*® and Trogarzo® will not change their respective current safety profile;

- no recall or market withdrawal of *EGRIFTA SV*® and Trogarzo® will occur;

- no laws, regulation, order, decree or judgment will be passed or issued by a governmental body negatively affecting the marketing, promotion or sale of *EGRIFTA SV*® and Trogarzo® in the United States;

- continuous supply of *EGRIFTA SV*® and Trogarzo® will be available to meet market demand on a timely basis;

- our relations with third-party suppliers of *EGRIFTA SV*® and Trogarzo® will be conflict-free;

- the level of product returns and the value of chargebacks and rebates will not exceed our estimates in relation thereto;

- no biosimilar version of tesamorelin will be approved by the FDA;

- our intellectual property will prevent companies from commercializing biosimilar versions of tesamorelin in the United States;

- we will file a sBLA for the F8 Formulation in the 2023 fiscal year;

- the FDA will approve the F8 Formulation;

- no vaccine or cure will be found for the prevention or eradication of HIV;

- the HFS will be successfully completed and we will resubmit a CBE supplement with the FDA for *EGRIFTA SV*® by the end of the 2023 fiscal year;

- the FDA will approve the CBE supplement;

- we will not default under the terms and conditions of the credit agreement entered into with Marathon's affiliates, including meeting the minimum liquidity and revenue target covenants therein;

- we will meet all of the conditions set forth under the credit agreement entered into with Marathon's affiliates to draw down the $20 million second tranche;

- the interest rate on the amount borrowed from Marathon's affiliates under the credit agreement will not materially vary upwards;

- the Corporation will continue as a going concern;

- we will find a partner to conduct a Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population;

- the FDA will approve the amendments to our protocol allowing us to resume the conduct of our Phase 1 clinical trial using TH1902 in various types of cancer;

- our Phase 1 clinical trial studying TH1902 in various types of cancer will demonstrate positive efficacy and safety results;

- we will find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed;

- our research and development activities will yield positive results;

- the data obtained from our market research on the potential market for *EGRIFTA SV*® and on the potential market for Trogarzo® in the United States are accurate;

- the timelines set forth herein will not be materially adversely impacted by unforeseen events that could arise subsequent to the date of this MD&A;

- our business plan will not be substantially modified; and

- no international event, such as a pandemic or worldwide war, will occur and adversely affect global trade.

Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these risks and uncertainties, the forward-looking statements and circumstances discussed in this MD&A may not occur, and you should not place undue reliance on these forward-looking statements. We discuss many of our risks in greater detail under Risks and Uncertainties (below) but additional risks and uncertainties, including those that we do not know about or that we currently believe are immaterial, may also adversely affect the forward-looking

statements, our business, financial condition and prospects. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this MD&A. We undertake no obligation and do not intend to update or revise these forward-looking statements, unless required by law. We qualify all of the information presented in this MD&A, and particularly our forward-looking statements, with these cautionary statements.

NON-IFRS AND NON-US GAAP MEASURE

The information presented in this MD&A includes a measure that is not determined in accordance with International Financial Reporting Standards ("IFRS") or U.S. generally accepted accounting principles ("U.S. GAAP"), being the term "Adjusted EBITDA". "Adjusted EBITDA" is used by the Corporation as an indicator of financial performance and is obtained by adding to net profit or loss, finance income and costs, depreciation and amortization, income taxes, share-based compensation from stock options, and certain write-downs (or related reversals) of inventories. "Adjusted EBITDA" excludes the effects of items that primarily reflect the impact of long-term investment and financing decisions rather than the results of day-to-day operations. The Corporation believes that this measure can be a useful indicator of its operational performance and financial condition from one period to another. The Corporation uses this non-IFRS measure to make financial, strategic and operating decisions.

BUSINESS OVERVIEW

We are a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs.

Our business strategy is to grow revenues and to achieve a positive Adjusted EBITDA from the sale of our existing and potential future assets in North America and to develop a portfolio of complementary products, compatible with our expertise in drug development and our commercialization know-how.

We currently have two approved products: *EGRIFTA SV*® and Trogarzo® in the United States.

EGRIFTA SV® (tesamorelin for injection) is a new formulation of *EGRIFTA*® which was originally approved by the FDA in November 2010 and was launched in the United States in January 2011. *EGRIFTA SV*® was approved by the FDA in November 2018, was launched in 2019 and has now replaced *EGRIFTA*® in such country. *EGRIFTA SV*® can be kept at room temperature, comes in a single vial and has a higher concentration resulting in a smaller volume of administration. *EGRIFTA SV*® is currently the only approved therapy in the United States for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and our organization has been commercializing this product in this country since May1st, 2014.

Trogarzo® (ibalizumab-uiyk) injection was approved by the FDA in March 2018 and was made commercially available in the United States in April 2018. Trogarzo® was the first HIV treatment approved with a new mechanism of action in more than 10 years. The treatment is administered every two weeks. It is a long-acting antiretroviral ("ARV") therapy that can lead to an undetectable viral load in combination with other ARVs.

Trogarzo® was also approved by the EMA in September 2019 and is no longer under licence to us in Europe further to our decision to terminate and return to TaiMed our commercialization rights to this product in April 2022. The EMA has since withdrawn the marketing approval of Trogarzo® in Europe.

In addition to the sale of our products, we are conducting research and development activities. We have a pipeline of investigational medicines in the areas of NASH and oncology. Tesamorelin, the active ingredient in *EGRIFTA SV*®, is designed to increase endogenous growth hormone secretion and is the foundation for its potential use for the treatment of NASH in the general population. Tesamorelin has a well-established safety profile, with more than 10 years of product history in HIV lipodystrophy. TH1902, a PDC derived from our licensed platform SORT1+ Technology™ that attaches to docetaxel, is designed to specifically target Sortilin ("SORT1") receptors expressed in cancer cells of various types of cancer. TH1902 was studied in a Phase 1 clinical trial until we decided to voluntarily pause the recruitment of patients in December 2022. We are also working on the development of other PDCs.

Our plan to initiate a Phase 2b/3 clinical trial to study tesamorelin for the treatment of NASH in the general population has been postponed until we can find a partner.

To date, we have completed the in-house bioequivalence study of the F8 Formulation and have begun assessing the development of a device, such as a pen (the "Pen"), intended to be used eventually with the F8 Formulation. As a result of issues in sourcing bacteriostatic water for injection in the past fiscal year, we have delayed the filing of a sBLA with the FDA seeking the approval of the F8 Formulation until later in fiscal 2023.

We have also completed the enrollment of patients for the development of an intramuscular method of administration of Trogarzo® and plan on filing a sBLA with the FDA seeking its approval in the current fiscal year.

2022 Year in Review

- *2023 Fiscal Year Guidance and Key Objectives.* On January 4, 2023, we announced, among other things, revenue guidance between $90 million and $95 million for the fiscal year 2023, our key objectives for the fiscal year 2023 consisting of achieving positive Adjusted EBITDA and the creation of an advisory scientific committee whose mandate is to optimize the protocol amendments for the development of TH1902.

- Volu*ntary Pause of Phase 1 Clinical Trial Studying TH1902.* On December 1, 2022, we announced our decision to voluntarily pause the enrollment of patients in our Phase 1 clinical trial studying TH1902 and to revisit the study design of this clinical trial.

- *FDA Approval of 30-Second Intravenous Push Method of Administration of Trogarzo®.* On October 3, 2022, we announced that the FDA approved the 30-Second Intravenous Push Method of Administration of Trogarzo®.

- *Closing of Funding of $40 million Under Credit Agreement.* On July 27, 2022, we announced that we received $40 million under the terms of a credit agreement with affiliated funds of Marathon Asset Management.

- *Conclusion of Non-Dilutive Term Loan of Up to $100 million.* On July 13, 2022, we announced that we had entered into a binding commitment with affiliated funds of Marathon Asset Management providing for a non-dilutive term loan of up to $100 million (the "Marathon Credit Facility"). On February [27], 2023, we entered into a first amendment to the Marathon Credit Facility (the "First Amendment to the Marathon Credit Facility"). The First Amendment to the Marathon Credit Facility and the Marathon Credit Facility are collectively referred to as the "Marathon Credit Facility". See "Item 9 – Material Contracts – Marathon Credit Facility" below for a description of the Marathon Credit Facility.

- *Strategic Hire Supporting Investor Relations.* On May 31, 2022, we announced the hiring of a new Head of Investor Relations.

- *Initiation of Basket Trial in Phase 1 Clinical Trial Studying TH1902.* On May 10, 2022, we announced the initiation of the recruitment of patients in the basket

portion of the first-in-human study of TH1902. The dose of TH1902 was then established at 300 mg/m^2.

- *Return of European Commercialization Rights of Trogarzo® to TaiMed.* On April 27, 2022, we announced that we notified TaiMed of our decision to return the European commercialization rights to Trogarzo® to TaiMed within the next 180 days pursuant to the terms of the TaiMed Agreement.

- *Launch of an Internal Sales Force.* On February 15, 2022, we announced the launch of our own field force through the hiring of key account managers joining from our long-term contract sales organization. We also announced the hiring of medical science liaison and community liaison personnel as part of the internalization of commercial and medical dedicated personnel.

OUR 2023 BUSINESS OBJECTIVES

Our business objectives in 2023 is focused on: increasing sales of *EGRIFTA SV®* and Trogarzo® in the United States and on managing our expenses to achieve a positive Adjusted EBITDA by year-end; continuing pursuing potential product acquisition, in-licensing transactions, copromotion, or other similar opportunities to grow our revenues; filing sBLAs in the United States for both the intramuscular method of administration of Trogarzo® and the F8 Formulation; resubmitting a CBE supplement with the FDA in relation to the HFS for *EGRIFTA SV®*; filing an amended protocol with the FDA to resume our Phase 1 clinical trial studying TH1902 in various types of cancer; seeking potential partners for our Phase 2b/3 in NASH using tesamorelin and, once our Phase 1 clinical trial has resumed, for TH1902; and, managing our financial position to ensure we can successfully execute on our 2023 business objectives.

Program Updates in Review

EGRIFTA SV®

In HIV-associated lipodystrophy, we are on track to complete the Human Factors Study (HFS) for *EGRIFTA SV®* in the first half of 2023, and we are diligently completing the work associated to the supplemental biologic license application (sBLA) filing for the F8 formulation of Tesamorelin with the United States Food and Drug Administration (“FDA”).

We are also confident in successfully addressing the shortage of bacteriostatic water for injection (“BWFI”) by placing the sourcing of this drug component under our own control via the services of a third-party manufacturer, thereby securing a secondary source of supply for this important component to the F8 formulation. The further development of Tesamorelin allows Theratechnologies to maintain its positioning as one of the few options for drug developers to immediately partner with a company in order to launch a Phase 2b/3 NASH clinical trial.

Trogarzo® Lifecycle Management

During 2022, we made progress towards improving Trogarzo®'s method of administration and now have FDA approval for Trogarzo®'s 30-Second Intravenous ("IV") Push administration, simplifying the method of administration for heavily treatment-experienced populations. We are also working closely with our partner, TaiMed Biologics, in completing the development of an intra-muscular method of administration for Trogarzo®, and subsequent filing of a new supplemental sBLA with the FDA. These projects will serve to ensure lifecycle management of Trogarzo® for years to come.

TH1902 Development Pathway

Subsequent to the end of the quarter and FY2022, the Company announced on December 1, 2022 that it had decided to pause the enrollment of patients in its Phase 1 clinical trial of TH1902, the Company's lead investigational peptide drug conjugate (PDC) for the treatment of sortilin-expressing cancers.

Theratechnologies voluntarily made the decision to pause enrollment and revisit the study design after consulting with its investigators. Efficacy results observed thus far were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. As previously reported, these adverse events consist mainly of neuropathy and eye toxicity.

Following the voluntary pause, the Company formed a Scientific Advisory Committee (SAC) to help determine the best developmental path forward for TH1902. In addition to the study's principal investigator, the SAC includes several medical oncologists from across the U.S., who are leading experts in the end-to-end lifecycle of oncology drug development:

- Erika Hamilton, MD, director of Breast Cancer and Gynecologic Cancer Research for Sarah Cannon Research Institute at Tennessee Oncology;
- Daniel Petrylak, MD, professor of medicine in Medical Oncology and Urology and chief, Genitourinary Oncology at Yale School of Medicine; and
- Anthony Tolcher, MD, medical oncologist at Texas Oncology-San Antonio Medical Center.

The Company will continue to seek advice and input from Mace Rothenberg, MD, who is currently a scientific advisor to Theratechnologies.

Since announcing our decision to pause enrollment in the basket trial, we have had discussions with the FDA, and the agency has indicated that it agreed with our voluntary pause. Further to our discussions with the FDA, we received a letter indicating that our Phase 1 clinical trial was placed on a partial clinical hold subject to our responses to a list of questions.

Theratechnologies is currently analyzing data and preparing responses to questions received from the FDA. This work is well underway and will be considered by the SAC as part of their meeting, which is scheduled for the latter half of March when the analyses are expected to be ready. Once expert advice is

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considered, the Company intends to promptly amend the protocol and re-submit to the FDA.

The FDA had earlier indicated that their review of the protocol amendment would be completed within thirty days of submission.

Consistent with the Company's 2023 objective of generating positive Adjusted EBITDA by fiscal year end, any new investments in TH1902 will be stage gated. Once the Phase 1 clinical trial has resumed, Theratechnologies will also evaluate potential partnerships for TH1902.

NASH

Our NASH program is still on pause pending availability of BWFI for the F8 formulation and finding a partner with resources and capabilities. We continue to have discussions with potential NASH partners and are encouraged to see renewed NASH interest with recent industry announcements.

RESEARCH AND DEVELOPMENT ACTIVITIES

Below is a description of our research and development activities using our proprietary and licensed drugs and peptides.

Tesamorelin

EGRIFTA SV® Human Factors Study

Following complaints received by patients relating to the reconstitution of *EGRIFTA SV®* after its launch in 2019, we have submitted in March 2021 to the FDA a Changes Being Effected ("CBE") supplement to the Instructions For Use ("IFU") included in the *EGRIFTA SV®* product labeling and, per the timelines set forth in the regulation, we implemented these changes, which included an amended IFU. We also provided patients with detailed training through our call center, *THERA Patient Support®*, related to the changes and the number of complaints has since been significantly reduced. The FDA responded to our CBE supplement with a complete response letter asking us to carry out a HFS to ensure that patients reconstitute the product in the proper manner. We had one year to complete and resubmit the supplemental application including the HFS to the FDA and the FDA has recently granted until September 15, 2023, a six-month extension period, to submit the response to the FDA complete response letter. The first part of the HFS, the formative study, has now been completed and the Company filed its proposed HFS protocol with the FDA for its review prior to initiate the summative study. The Company has yet to receive a response from the FDA on its proposed protocol.

F8 Formulation

We have completed the in-house bioequivalence study of the F8 Formulation. The F8 Formulation is eight times more concentrated than the F1 formulation and twice as concentrated as the current *EGRIFTA SV®* formulation. The F8 Formulation has a number

of advantages for patients over the F1 formulation: (1) it is intended to be presented in a multidose vial that will be reconstituted once per week; (2) it is expected to be stable at room temperature, even once reconstituted; and (3) the volume of administration will be smaller, approximately 0.2 ml. To date, all process validation batches have been manufactured.

The F8 Formulation requires the use of bacteriostatic water for injection ("BWFI") since the reconstituted product will be used for seven daily injections. In the spring of 2022, we were informed by the sole global supplier of BWFI that its manufacturing plant had been the subject of an FDA inspection that resulted in this supplier having to make modifications to its facilities before being able to resume manufacturing and shipment of its BWFI. As a result, our plan to file a sBLA by the end of the first quarter of 2022 had to be delayed until this supplier could resume the manufacture of BWFI and the shipment thereof or until we could find an alternate supplier to source BWFI. We have entered into a development agreement with a third party supplier for the manufacture of our own supply of BWFI and, to date, the engineering and validation batches of BWFI have been manufactured. We have initiated discussions with this third party supplier with the aim of entering into a long term supply agreement for BWFI. In addition, with the requirement of the FDA to conduct a HFS for *EGRIFTA SV*®, we have proactively decided to conduct one for the F8 Formulation as well prior to submitting a sBLA seeking the approval of the F8 Formulation. This study is expected to be completed after the *EGRIFTA SV*® HFS. We now plan on filing an sBLA with the FDA seeking the approval of the F8 Formulation in the fourth quarter of 2023 for the treatment of lipodystrophy in people living with HIV.

The F8 Formulation is also intended to be used in our Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population. See "Tesamorelin for NASH in the General Population" below.

Multi-Dose Pen Injector
In the fiscal year 2021, we began developing the Pen intended to be used in conjunction with the F8 Formulation. To date, its development is not completed and we are still assessing the feasibility. As a result, no timeline has been set for the development of the Pen.

Tesamorelin for NASH in the General Population
On September 10, 2020, we announced our intent to study tesamorelin for the potential treatment of NASH in the general population using the F8 Formulation. In November 2020, we filed an Investigational New Drug Application ("IND") with the FDA for a Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH and we received a "Study May Proceed" letter for such Phase 3 clinical trial from the FDA in December 2020. The letter contained a recommendation that the Corporation requests a meeting to discuss the questions and comments contained in such letter to address certain aspects of the proposed trial design to ensure alignment with the agency's expectations with NASH trials. The Corporation followed up on the FDA's recommendation and requested a meeting with the agency. On July 15, 2021, we announced that we had completed discussions with the FDA following an end of Phase 2 meeting and with the EMA following a scientific advice meeting regarding the Phase 3 clinical trial in NASH.

The finalized Phase 3 trial design is planned for a multicenter, randomized, double-blind, placebo-controlled two-part study designed to evaluate the safety and efficacy of tesamorelin in liver-biopsy confirmed patients with NAS score of at least 4 and stage 2 or 3 fibrosis. Part 1 of the study will include a total of approximately 1,100 patients (1:1, tesamorelin:placebo), including approximately 75 to 100 people living with HIV. A second liver biopsy will be performed after the first approximately 1,100 participants have completed 18 months of treatment. This should form the basis for filing an sBLA with the FDA. The clinical trial will also include a futility analysis that would be conducted after the first approximately 400 patients have completed 18 months of treatment and have received a second liver biopsy. The futility analysis will provide a perfunctory review indicating if an early treatment effect with tesamorelin has been observed and will determine if the study should proceed as planned. Following a potential sBLA approval, Part 2 of the trial will continue to enroll an additional approximately 1,800 patients (3:1, tesamorelin:placebo) to continue to measure clinical outcomes over a period of five years. A total of approximately 2,900 patients are expected to be enrolled.

In July 2021, we announced that the final Phase 3 clinical trial design would result in higher costs than what we had expected and, as a result, we were assessing our options to best execute this program, including seeking a potential partner. To date, we are still continuing to seek a partner and discussions are still ongoing.

In order to de-risk the Phase 3 trial, in February 2022, the Corporation submitted an amended protocol to the FDA resulting in the FDA providing us with a list of questions and comments on this amended protocol. We have voluntarily decided not to respond to those questions and comments in order to address these with any potential partner we may find to optimize the design, if deemed relevant. The amended protocol includes a Phase 2b/3 seamless study design where the first 350 or so patients' data will be analyzed by a data monitoring committee to assess the efficacy of tesamorelin on a smaller subset of patients. The amended protocol would allow us to generate hard endpoint data on NAS score and fibrosis. A decision would then be made whether to continue the study until the full number of patients (1,094) have completed 18 months of treatment. These amendments would not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH, but it would inform the continuation of enrollment while providing an indication of benefit to patients.

NAFLD includes nonalcoholic fatty liver ("NAFL"), NASH and NASH cirrhosis. NAFLD is the leading cause of liver diseases in the Western world (Central Europe and United States). As the global epidemic of obesity fuels NAFLD prevalence, NASH has become one of the most common liver disorders. In the absence of approved therapies, NASH remains widely untreated, and has become a critical public health concern with high unmet medical needs.

Without therapeutic intervention, NASH can cause the development of fibrosis, which is the accumulation of non-functional scar tissue, as the body tries to heal itself.
Because this build-up leads to tissue remodeling, development of fibrosis leads to progressive loss of liver function which may ultimately progress to life-threatening conditions such as cirrhosis, liver cancer and ultimately liver failure, a stage where patients have no other choice than undergoing a liver transplantation.

In addition to its deleterious effects on the liver, NASH multiplies the risk of a patient developing cardiovascular problems (myocardial infarction, stroke and peripheral vascular accident).

This contributes to higher mortality rates in NASH patients, and cardiovascular disease is the leading cause of death in NASH patients.

The U.S. market is expected to represent a significant and growing opportunity in the general population suffering from NASH. The Corporation estimates that the number of NASH cases in this country is projected to increase by 63% from 16.5 million patients in 2015 to 27 million patients in 2030. Out of these numbers, it is projected that the number of patients with fibrosis scores of 2 and 3 was around 5.4 million in 2015 and will be around 10.6 million in 2030.

Ibalizumab

Intramuscular Method of Administration of Trogarzo®
The Corporation has now completed the enrollment of all patients for this study and the study is completed. We are presently completing the analysis of the data related thereto. The study consisted of assessing the safety and pharmacokinetic levels of Trogarzo® when administered intramuscularly using a syringe. We expect to file a sBLA with the FDA seeking the approval of the intramuscular method of administration in the course of the 2023 fiscal year.

TH1902

Phase 1 Clinical Trial
In December 2020, we filed an IND application with the FDA for the initiation of a Phase 1 first-in-human clinical trial evaluating TH1902 for the treatment of various cancers. The FDA granted “fast track” designation to TH1902 as a single agent for the treatment of all sortilin-positive recurrent advanced solid tumors that are refractory to standard therapy.

“Fast Track” designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose of “Fast Track” designation is to bring important new drugs to patients earlier. A drug that receives “Fast Track” designation is eligible for some or all of the following: (i) more frequent meetings with FDA to discuss the drug’s development plan and ensure collection of appropriate data needed to support drug approval; (ii) more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers; (iii) eligibility for “Accelerated Approval” and “Priority Review”, if relevant criteria are met; and (iv) “Rolling Review”, which means that a sponsor can submit completed sections of its new drug application for review by FDA, rather than waiting until every section of the new drug application is completed before the entire application can be reviewed.

In March 2021, we initiated our Phase 1 clinical trial evaluating TH1902 for the treatment of cancers where the sortilin receptor is expressed. The Phase 1 clinical trial design included a Part A dose escalation study to evaluate the safety, pharmacokinetics, maximum tolerated dose (the “MTD”) and preliminary anti-tumor activity of TH1902

administered once every three weeks in patients with advanced solid tumors refractory to available anti-cancer therapies. Part B of the Phase 1 clinical trial, also known as the "basket trial" consisted in recruiting a total of approximately 70 patients to study the safety and tolerability of TH1902 in the following various solid tumor types, including HR+ breast cancer, triple negative breast cancer, ovarian cancer, endometrial cancer, melanoma, thyroid cancer, small cell lung cancer, and prostate cancer.

As per the study protocol, the MTD is established once a significant adverse event is observed in two or more patients.

Part A of the Phase 1 clinical trial was completed in the summer of 2022. We then reported that a total of 18 heavily pre-treated patients, who received an average of eight prior cancer treatments, were enrolled in the dose escalation portion of the study. Following the safety observations at 420 mg/m2 including grade 3 neuropathy, grade 4 neutropenia, grade 3 ocular changes (visual acuity, keratitis and ocular surface dryness) and grade 2 skin toxicities (rash, pruritis and inflammation), the dose of TH1902 was decreased to 300 mg/m2 for the next dose level and was expanded to a total of six patients. No dose limiting toxicities ("DLTs") were observed during the first cycle, therefore, the dose of 300 mg/m2 was selected for continuation of the basket trial.

In addition, we reported that the levels of free docetaxel were low, at only 11% of those observed at docetaxel treatment dosage of 75 mg/m2. 300 mg/m2 appeared to be a well-tolerated dose level.

We further reported the observation of signs of efficacy in three heavily pretreated patients and the recorded results included:

- confirmed partial response in one prostate cancer patient with 53% overall reduction in target lesions after three cycles of TH1902 at 300 mg/m2, although the prostate specific antigen ("PSA") continued to progress;
- stabilized disease in a prostate cancer patient with measurable reduction in target lesion sizes (single digit percentages), including one PSA response (the patient was treated with mixed cycles of TH1902 from 420 mg/m2 to 300 mg/m2); and
- stabilized disease in an endometrial cancer patient with measurable reduction in target lesion sizes (single digit percentages) after receiving a total of 11 cycles (the patient's dose was escalated from 60 mg/m2 to 360 mg/m2).

Following the determination of the MTD, we began enrolling patients in the basket trial and, in December 2022, we decided to voluntarily pause the enrollment of patients and revisit the study design of our clinical trial studying TH1902 in various types of cancer. The decision was made after consulting with our investigators. The efficacy results observed were not convincing enough to pursue the enrollment of patients and did not outweigh the adverse events seen in some patients.

The Corporation is currently studying the data from its Phase 1 clinical trial and has formed a scientific advisory committee ("SAC") comprised of the study's principal investigator, and several medical oncologists from across the United States who are leading experts in the end-to-end lifecycle of oncology drug development to help determine the best

developmental path forward for TH1902. The meeting of the SAC is scheduled to take place in the latter half of March 2023.

Further to our decision to voluntarily pause the enrollment of patients, we have had discussions with the FDA. Following such discussions, we received a letter from the FDA indicating that our Phase 1 clinical trial was placed on a partial clinical hold subject to our responses to a list of questions. We intend to respond to the FDA's questions along with the filing of the amended protocol. Questions raised by the FDA were already being addressed by our team as part of our analysis of the data accumulated so far in the Phase 1 clinical trial and we are confident that we will be able to address all of the FDA's questions. The FDA indicated that their review of the protocol amendment would be completed within thirty days of submission.

Consistent with our 2023 objectives of achieving a positive Adjusted EBITDA, any new investment in the development of TH1902 will be stage-gated. Once the Phase 1 clinical trial has resumed, we plan on evaluating potential partnerships for TH1902.

SORT1+ Technology™ Platform

Description
SORT1+ Technology™ is the name we gave our platform that provides for the development of new proprietary peptides for cancer drug development targeting SORT1 receptors. SORT1 is a receptor that plays a significant role in protein internalization, sorting and trafficking. It is highly expressed in cancer cells compared to healthy tissue making it an attractive target for cancer drug development. Expression has been demonstrated in, but not limited to, ovarian, triple-negative breast, endometrial, skin, small cell and non-small cell lung, colorectal and pancreatic cancers. Expression of SORT1 is associated with aggressive disease, poor prognosis and decreased survival. Preliminary assessments have demonstrated that the SORT1 receptor is expressed in 40% to 90% of cases of endometrial, ovarian, colorectal, triple-negative breast and pancreatic cancers.

The Corporation's innovative PDCs generated through the SORT1+ Technology™ demonstrate distinct pharmacodynamic and pharmacokinetic properties that differentiate them from traditional chemotherapy. In contrast to traditional chemotherapy, our proprietary PDCs are designed to enable selective delivery of certain anti-cancer drugs within the tumor microenvironment, and more importantly, directly inside SORT1 cancer cells. Commercially available anticancer drugs, like docetaxel, doxorubicin, SN38 or tyrosine kinase inhibitors are conjugated to our peptide to specifically target SORT1 receptors. This could potentially improve the efficacy and safety of those agents.

In preclinical data, the Corporation's lead investigational PDC, TH1902, derived from our SORT1+ Technology™, has shown to improve anti-tumor activity and reduce neutropenia and systemic toxicity compared to traditional chemotherapy. Additionally, in preclinical models, TH1902 has shown to bypass the multidrug resistance protein 1 (MDR1; also known as P-glycoprotein) and inhibit the formation of vasculogenic mimicry - two key resistance mechanisms to chemotherapy treatment. TH1902 combines our proprietary peptide and the cytotoxic drug, docetaxel.

We are no longer conducting research and development work on TH1904, one of our other investigational PDCs. However, we continue the conduct of research and development activities on other PDCs, primarily to advance a PDC using SN38.
Since announcing our decision to voluntarily pause the enrollment of patients in our Phase 1 clinical trial studying TH1902 in various types of cancer, partnership discussions in Greater China regarding the development and commercialization of TH1902 have been paused as well.

Acquisition of SORT1+ Technology™ Platform
We acquired the SORT1+ Technology™ platform following the acquisition of all of the issued and outstanding shares of Katana BioPharma Inc. ("Katana") on February 25, 2019 (the "Katana Agreement"). Katana had the exclusive worldwide rights, through a royalty-bearing licence agreement entered into with Transfert Plus, LP ("Transfert Plus"), to a technology platform using peptides as a vehicle to specifically deliver cytotoxic agents to sortilin receptors, which are overexpressed on cancer cells (the "Transfert Plus License Agreement"). Katana has since been wound up into Theratechnologies and we became a party to the Transfer Plus License Agreement.

In consideration of the acquisition of all of the issued and outstanding shares of Katana, the Corporation agreed to pay a purchase price aggregating CAD 6.9 million in various tranches. To date, there remains a balance of CAD 2,880,000 payable through the issuance of common shares upon our decision to pursue the development of TH1902, or any other PDCs studied in a Phase 1 clinical trial, that warrant the pursuit of its development beyond the completion of such Phase 1 clinical trial.

NOTABLE TRANSACTIONS 2022

$100 million Credit Agreement with Marathon Asset Management

On July 13, the Company announced it received a binding commitment letter with respect to a non-dilutive term loan with Marathon Asset Management for up to $100,000 (the "Loan Facility"). Highlights of the agreement are as follows:

- Senior secured term loan of up to $100,000 across four tranches;
- $40,000 is expected to be funded before July 29, 2022 ("Tranche 1 Loan");
- $20,000 to be made available by no later than June 30, 2023, if the Company has filed with the FDA its sBLA for the EGRIFTA SV® human factor study and has had net revenues of at least $75,000 for the 12-month period immediately preceding the funding of the tranche ("Tranche 2 Loan");
- $15,000 to be made available by no later than March 2024 if the Company has obtained approval from the FDA for its F8 formulation of tesamorelin and has had net revenues of at least $90,000 for the 12-month period immediately preceding the funding of the tranche ("Tranche 3 Loan");
- Up to an additional $25,000 to be made available no later than December 31, 2024, if the Company has had at least $110,000 in net revenues for the 12-month

period immediately preceding the funding of the tranche and at least $20,000 in EBITDA (as defined in the Credit Agreement) (“Tranche 4 Loan”);

• The facility will have an initial term of five years (six years if Tranche 3 is drawn), provide for an interest-only period of 24 months (36 months if Tranche 3 is drawn), and bear interest at the Secured Overnight Financing Rate (SOFR) plus 9.5%;

• The proceeds from the Tranche 1 Loan shall be used to purchase $30,000 principal amount of issued and outstanding convertible unsecured senior notes and the proceeds of the Tranche 2 Loan shall be used to reimburse the remaining issued and outstanding Convertible Notes at maturity; and,

• The proceeds of both the Tranche 3 Loan and Tranche 4 Loan can be used for general corporate purposes.

The Company also announced the signing of purchase agreements with a number of convertible noteholders aggregating $30,000 principal amount of Convertible Notes. The purchase price of these Convertible Notes will be made promptly after the funding of the Tranche 1 Loan.

On July 27, 2022, the Company announced that it received funding of $40 million under the terms of this Credit Agreement. A portion of the net proceeds from this amount was used to buy back and cancel $30 million principal amount of convertible notes due June 30, 2023, through private agreements with certain 7 Theratechnologies Inc. 2015 Peel Street, 11th Floor Montreal, Québec H3A 1T8 noteholders, while the remainder was allocated to working capital. All amounts drawn under the Credit Agreement bear interest at SOFR plus 9.5%.

JANUARY 2021 OFFERING

Use of Proceeds

In its prospectus supplement dated January 13, 2021 relating to the January 2021 offering, the Company indicated that it intended to use the net proceeds from such offering primarily to fund research and development activities, commercialization initiatives, general and administrative expenses, working capital needs and other general corporate purposes. More specifically, out of net proceeds of the offering then estimated to be $42,500,000, an amount of $30,500,000 was earmarked for the NASH Phase 3 clinical trial and $7,000,000 for oncology research and development (including the TH1902 Phase 1 clinical trial), with the remainder left for commercial and marketing activities and other uses.

In the months following the January 2021 offering, the Company was able to complete its discussions with the FDA and the EMA regarding the design and protocol for the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH. As part of its announcement on July 15, 2021 regarding the finalization of the trial design, the Company also announced that the changes made to the design pursuant to the discussions held with the FDA and the EMA would result in higher costs than previously estimated, and that the Company was evaluating its options to best execute its late-stage development program for tesamorelin, including seeking a potential partner. As a result of the delay in the

initiation of the NASH Phase 3 clinical trial, the funds raised in the January 2021 offering earmarked for such trial have been added to the Company's available cash balance. The Company's ability to execute its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH will be dependent on its ability to secure additional financial resources.

The following table shows the estimated use of proceeds, compared with the actual use of proceeds as at November 30, 2022:

In millions	**Estimated Use of Proceeds**	**Actual Use of Proceeds**	**Variance**
Nash Phase 3 clinical trial	$30.5	$2.8	$(27.7)
Oncology R&D	7.0	8.1	1.1
Commercial and marketing activities	3.5	--	(3.5)
Other	1.5	2.0	0.5
Net Proceeds	$42.5	$12.9	$(29.6)

As at November 30, 2022, approximately $2,828,000 had been used in connection with the NASH Phase 3 clinical trial.

As at November 30, 2022, approximately $8,114,000 had been used in connection with oncology research and development activities and the variance between the amount reserved and the amount used as at November 30, 2022 represents funds held in cash pending their planned allocation as costs are incurred.

Finally, the Company has not implemented new initiatives in terms of commercial and marketing activities, such that the funds earmarked for such use have been added to the Company's working capital.

Fourth-Quarter and Fiscal 2022 Revenue Highlights

(in 000s of US$)

	Three-month periods ended November 30,		**% change**	**Years ended November 30,**		**% change**
	2022	2021		**2022**	**2021**	
EGRIFTA®, *EGRIFTA SV*® net sales	**14,458**	**12,753**	13.4%	**50,454**	**43,009**	17.3%
Trogarzo® net sales	**6,963**	**6,001**	16.0%	**29,603**	**26,814**	10.4%
Revenue	**$21,421**	**$18,754**	**14.2%**	**$80,057**	**$69,823**	14.7%

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Fourth-Quarter Fiscal 2022 Financial Results

Revenue

Consolidated revenue for the three months ended November 30, 2022 amounted to $21,421,000 compared to $18,754,000 for the same period last year, representing an increase of 14.2%.

For the fourth quarter of Fiscal 2022, sales of *EGRIFTA SV*® reached $14,458,000 compared to $12,753,000 in the fourth quarter of the prior year, representing an increase of 13.4%. Strong sales of *EGRIFTA SV*® were mostly the result increased unit sales and a higher net selling price.

In the fourth quarter of Fiscal 2022, Trogarzo® sales amounted to $6,963,000 compared to $6,001,000 for the same quarter of 2021, representing an increase of 16.0%. During the fourth quarter of Fiscal 2021, Trogarzo® net sales were impacted by a provision related to greater than anticipated clawbacks on units sold in France prior to finalization of reimbursement terms, pursuant to temporary use authorizations ("ATU" and "AAP"). Trogarzo sales in the fourth quarter of 2022 were up marginally in the United States and were affected by lower inventory levels at our distributor at the close of the quarter and slightly higher rebates to government payers.

Cost of Sales

For the three-month period ended November 30, 2022, cost of sales was $5,909,000 compared to $6,411,000 in the comparable period of Fiscal 2021. Cost of goods sold increased to $5,909,000 compared to $5,191,000 for the same period last year. Cost of goods sold for the fourth quarter of 2022 includes a provision of $1,477,000 related to the write down of F8 formulation of tesamorelin for pre-commercial material which could expire prior to the launch of the F8, if approved.

In the fourth quarter of 2021, cost of sales included an amortization charge of $1,220,000 in connection with the settlement of the future royalty obligation which has been accounted as "Other asset" on the consolidated statement of the financial position. The Other asset was fully amortized during the first half of Fiscal 2022, and thus this charge was Nil in the fourth quarter of Fiscal 2022.

R&D Expenses

R&D expenses in the three-month period ended November 30, 2022 amounted to $9,455,000 compared to $8,678,000 in the comparable period of Fiscal 2021. The increase during the fourth quarter of Fiscal 2022 was largely due to the development of our oncology platform, including the Phase 1 trial for TH1902, the Human Factor Study for *EGRIFTA SV*®, as well as the development of the Intramuscular method of administration of Trogarzo®.

Selling Expenses

Selling expenses in the three-month period ended November 30, 2022 amounted to $7,809,000 compared to $8,193,000 in the comparable period of Fiscal 2021.

The decrease in selling expenses is largely associated to the decision to exit the European market in 2022, and is offset by higher spending in the United States.

General and Administrative Expenses
General and administrative expenses in the fourth quarter of Fiscal 2022 amounted to $3,956,000, compared to $3,537,000 reported in the same period of Fiscal 2021. The increased is due to an overall increase in activity to reflect the growth of our business in North America related to the on boarding of our field force during 2022.

Net Finance Costs
Net finance costs for the three-month period ended November 30, 2022 were $2,078,000 compared to $1,817,000 in the same period last year. The increase in net finance cost is due to the higher interest on the company's outstanding long-term debt due to the new Loan Facility in Q3 of fiscal 2022. The increase was offset by higher interest income and a lower net foreign currency loss.

Net loss
Taking into account the revenue and expense variations described above, we recorded a net loss of $7,929,000, or $0.09 per share, in the fourth quarter of Fiscal 2022 compared to a net loss of $9,901,000, or $0.10 per share, in the fourth quarter of Fiscal 2021.

Quarterly Financial Information

The following table is a summary of our unaudited consolidated operating results for the last 8 quarters of Fiscal 2022 and Fiscal 2021.

(in thousands of dollars, except per share amounts)

	2022				2021			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Revenue	**21,421**	20,811	19,268	18,557	18,754	17,852	17,787	15,430
Operating expenses								
Cost of sales								
Cost of goods sold	**5,909**	5,292	7,759	4,878	5,191	4,283	4,714	4,190
Amortization of other asset	**-**	-	1,220	1,221	1,220	1,221	1,220	1,221
R&D	**9,455**	8,425	11,056	8,003	8,678	8,296	6,417	4,883
Selling	**7,809**	8,404	15,371	7,807	8,193	7,657	6,901	6,158
General and administrative	**3,956**	4,209	4,823	4,368	3,537	3,633	3,884	3,562
Total operating expenses	**27,129**	26,330	40,229	26,277	26,819	25,090	23,136	20,014

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Net finance costs	**(2,078)**	(1,879)	(1,644)	(1,285)	(1,817)	(2,254)	(1,023)	(1,332)
Income taxes	**(143)**	(151)	(122)	(27)	(19)	(18)	(20)	(6)
Net loss	**(7,929)**	(7,549)	(22,727)	(9,032)	(9,901)	(9,510)	(6,392)	(5,922)
Basic and diluted loss per share	**(0.09)**	(0.08)	(0.24)	(0.09)	(0.10)	(0.10)	(0.07)	(0.07)

Factors Affecting the Variability of Financial Results

There are quarter-over-quarter variations in net sales revenue, principally due to changes in distributor inventory levels with some additional impact from time to time related to average net selling price, which is affected by changes in the mix of private payors versus government drug reimbursement plans.

Higher expenses in 2022 were associated with the development of our product pipeline and our decision to stop commercialisation activities for Trogarzo in the European territory.

Fiscal Year 2022 Financial Results

Revenue

Consolidated revenue for Fiscal 2022 was $80,057,000 compared to $69,823,000 for the same period last year, representing an increase of 14.7%.

For Fiscal 2022, sales of *EGRIFTA SV*® reached $50,454,000 compared to $43,009,000 for the same period last year representing growth of 17.3%. Strong sales of *EGRIFTA SV*® were mostly the result a higher number of units sold compared to the previous year, as well as higher net selling price. In addition, COVID-19 had a lesser impact on new prescriptions in Fiscal 2022 compared to Fiscal 2021.

In Fiscal 2022, Trogarzo® sales were $29,603,000 compared to $26,814,000 last year, an increase of 10.4%. Higher sales were a result of higher unit sales and a higher net selling price in the United States but were offset by slightly lower revenue in Europe. During Fiscal 2021, Trogarzo® net sales in Europe were impacted by a provision taken in the fourth quarter related to greater than anticipated clawbacks on units sold in France prior to finalization of reimbursement terms, pursuant to temporary use authorizations (“ATU” and “AAP”).

Cost of Sales

For Fiscal 2022, cost of sales was $26,279,000 compared to $23,260,000 in the comparable period of Fiscal 2021. Cost of sales included cost of goods sold that amounted to $23,838,000 in Fiscal 2022 compared to $18,378,000 in Fiscal 2021. The increase in cost of goods sold was mainly due to (1) higher product sales, (2), to a charge arising from the non-production of scheduled batches of *EGRIFTA SV*® that were cancelled due to the planned transition to the F8 formulation of tesamorelin in the amount of $1,788,000, and (3) a provision of $1,477,000 related to the write down of F8 formulation of tesamorelin for

pre-commercial material which could expire prior to the launch of the F8, if approved. Cost of goods sold for 2022 also includes other write downs totalling $660,000 (See Note 9 of the Audited Financial Statements).

In Fiscal 2021, cost of sales included an amortization charge of $4,882,000 in connection with the settlement of the future royalty obligation which has been accounted as “Other asset” on the consolidated statement of the financial position. The Other asset was fully amortized during the first half of Fiscal 2022, and thus this charge was lower in Fiscal 2022, in the amount of $2,441,000.

R&D Expenses

R&D expenses were $36,939,000 for Fiscal 2022 compared to $28,274,000 for Fiscal 2021. The increase in R&D expenses was largely due to the development of our oncology platform, including the Phase 1 study, the Intramuscular method of administration clinical trial clinical trial, spending on the development of the multi-dose pen injector for the F8 formulation, spending on the Human factors study for *EGRIFTA SV®*. Fiscal 2022 spending also includes costs associated to the VAMOS and Promise studies in the United States, as well as increased salaries related to the higher level of activity. These costs were offset by lower spending on the preparation of the NASH clinical trial and a decrease level of activity in Europe.

Selling Expenses

Selling expenses for Fiscal 2022 were $39,391,000 compared to $28,909,000 for the same period in Fiscal 2021. The increase is mainly due to the addition of personnel and an increase in promotional activities related to our commercial products in the United States and was offset by lower levels of activity in Europe. The increase is also related to the accelerated amortization of the Trogarzo® commercialization rights for the European territory in the amount of $6,356,000 following our decision to cease commercialization activities in that territory in Q2 2022.

General and Administrative Expenses

General and administrative expenses for Fiscal 2022 were $17,356,000 compared to $14,616,000 for the same period in Fiscal 2021. The increase in general and administrative expenses was mainly associated with an overall increase in business activities following the on boarding of our field force in the United States, as well as higher share-based compensation expense.

Net Finance Costs

Net finance costs for Fiscal 2022 were $6,886,000 compared to $6,426,000 in Fiscal 2021. The increase in net finance costs in 2022 versus the comparable period in 2021 was mostly due to higher interest expense on the Company’s Loan Facility in Q3 of Fiscal 2022 and convertible notes and were offset by higher interest income and a gain on the repurchase of convertible notes in July 2022.

Net loss

Taking into account the revenue and expense variations described above, we recorded a net loss of $47,237,000, or $0.50 per share, in Fiscal 2022 compared to $31,725,000, or $0.34 per share, in Fiscal 2021.

Selected Annual Information

(in thousands of dollars, except per share amounts)

Years ended November 30	**2022**	2021	2020
Revenue	**80,057**	69,823	66,053
Selling expenses	**39,391**	28,909	26,859
Research and development expenses	**36,939**	28,274	18,019
General and administrative expenses	**17,356**	14,616	12,230
Net loss	**(47,237)**	(31,725)	(22,667)
Loss per share: Basic and diluted	**(0.50)**	(0.34)	(0.29)
Cash, bonds and money market funds	**33,070**	40,354	20,768
Total assets	**93,260**	119,212	100,142
Term loan and other obligations	**37,894**	--	4,666
Lease liabilities (including current portion)	**1,922**	2,518	2,980
Convertible unsecured senior notes	**26,895**	54,227	52,403

Financial Position, Liquidity and Capital Resources

Going Concern Uncertainty

As part of the preparation of the financial statements, management is responsible for identifying any event or situation that may cast doubt on the Company's ability to continue as a going concern. Substantial doubt regarding the Company's ability to continue as a

going concern exists if events or conditions, considered collectively, indicate that the Company may be unable to honor its obligations as they fall due during a period of at least, but not limited to, 12 months from November 30, 2022. If the Company concludes that events or conditions cast substantial doubt on its ability to continue as a going concern, it must assess whether the plans developed to mitigate these events or conditions will remove any possible substantial doubt.

For the year ended November 30, 2022, the Company incurred a net loss of $47,237,000 (2021 – $31,725,000) and had negative operating cash flows of $14,692,000 (2021 - $17,501,000). The Company's total current liabilities exceeded total current assets at November 30, 2022. The Company's outstanding $27,500,000 convertible unsecured senior notes mature in June 2023 (refer to Note 19 to the Audited Financial Statements) requiring the Company to use its cash balance and draw the Tranche 2 Loan (as defined in Note 18 to the Audited Financial Statements) of its term loan facility available (the "Loan Facility") to repay the principal and the interest thereon. The Loan Facility is available in four tranches and contains various covenants, including minimum liquidity covenants whereby the Company needs to maintain significant cash, cash equivalent and eligible short-term investments balances in specified accounts, which restricts the management of the Company's liquidity (refer to notes 18 and 24 to the Audited Financial Statements). There are also operational milestones and required revenue targets in order for the Company to comply with the conditions of the Loan Facility or to be able to borrow money forming part of the various tranches.

The Company's ability to continue as a going concern for period of at least, but not limited to, 12 months from November 30, 2022 involves significant judgement and is dependent on its ability to increase revenues and manage expenses to generate sufficient positive cash flows from operations and/or find alternative source of funding to respect all the various covenants of its Loan Facility, including obtaining the approval from the FDA for its F8 formulation of tesamorelin on or before March 31, 2024, and/or to obtain the continued support of its lender. On February 27, 2023, the lender removed the condition related to the submission to the FDA of the results from the human factors validation study by no later than June 30, 2023, in order to access the Tranche 2 Loan under the Loan Facility (refer to Note 30 to the Audited Financial Statements). Management believes its plans will comply with all of the other various covenants of the Loan Facility to draw the Tranche 2 Loan, repay all the convertible unsecured senior notes due June 30, 2023 and to comply with the covenants for the foreseeable future. However, there can be no assurance that management's plans will be realized since some elements of these plans are outside of management's control and cannot be predicted at this time. Should management's plans not materialize, the Company may be forced to reduce or delay expenditures and capital additions, seek additional financing through the issuance of equity or obtain from the lender waivers of these covenants, if available. Raising additional equity capital is subject to market conditions. As a result, there is material uncertainty related to events or conditions that cast substantial doubt about the Company's ability to continue as a going concern.

Furthermore, the Loan Facility includes a covenant prohibiting having a going concern explanatory paragraph in the annual report of the independent registered public accounting firm but the lender has agreed to amend the Loan Facility to exclude the fiscal year ended November 30, 2022. There is no assurance that the lender will agree to amend

or to waive potential future covenant breaches, if any. As the amendment occurred subsequent to the Company's fiscal year end, the term loan has been classified as a current liability pursuant to IFRS requirements.

These consolidated financial statements have been prepared assuming the Company will continue as a going concern, which assumes the Company will continue its operations in the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the normal course of business. These consolidated financial statements do not include any adjustments to the carrying values and classification of assets and liabilities and reported expenses that might result from the outcome of this uncertainty and that may be necessary if the going concern basis was not appropriate for these consolidated financial statements. If the Company was unable to continue as a going concern, material impairment of the carrying values of the Company's assets, including intangible assets, could be required.

Analysis of cash flows

As at November 30, 2022, cash, bonds and money market funds amounted to $33,070,000 compared to $40,354,000 at November 30, 2021. Available cash is invested in highly liquid fixed income instruments including governmental, municipal and paragovernmental organizations, high-grade corporate bonds and money market funds.

The Company voluntarily changed its accounting policy in Fiscal 2022 to classify interest paid and received as part of operating activities, which were previously classified as cash flow from financing activities and interest received as cash flows from investing activities. The Fiscal 2021 amounts presented herein have been recasted to reflect the change in policy.

For Fiscal 2022, cash flow used in operating activities was $14,692,000 compared to $17,501,000 in Fiscal 2021. Changes in operating assets and liabilities for Fiscal 2022 had a positive impact on cash flow of $13,017,000. These changes included a decrease of $8,991,000 in inventories, a decrease in prepaid expenses and deposits of $3,058,000, and an increase in provisions of $3,627,000 and these were offset by an increase in trade and other receivables of $1,669,000, and a decrease in accounts payable and accrued liabilities of $1,131,000. The decrease in inventories is mainly due to a planned reduction of Trogarzo inventory levels.

During Fiscal 2022, the Company realized net proceeds from the issuance of a long-term loan of $37,715,000. We also received net proceeds for the issuance of common stock to an institutional investor in the amount of $2,871,000 under its ATM program. Significant uses of cash for financing activities included the purchase of convertible notes for $28,819,000 (including costs related to the purchase), and $1,527,000 in deferred financing costs related to the establishment of the Loan Facility.

On January 19, 2021, the Company completed a public offering for the sale and issuance of 16,727,900 units of the Company for a gross cash consideration of $46,002,000 including the full exercise of the over-allotment option. Share issue costs of $3,394,000 resulted in net proceeds of $42,608,000.

Each unit is comprised of one common share of the Company and one-half of one common share purchase warrant of the Company (each whole warrant, a "Warrant"). Each Warrant entitles the holder to purchase one common share of the Company at an exercise price of $3.18 until January 19, 2024.

During Fiscal 2022, cash used in investing activities included $985,000 for the acquisition of research equipment.

Commitments

Off Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Subsequent events

On February 27, 2023, the Company issued to affiliates of Marathon Asset Management (collectively, "Marathon"), prorata to their participation under the Loan Facility, an aggregate of 5,000,000 common share purchase warrants (the "Marathon Warrants"). Each Marathon Warrant entitles the holder thereof to subscribe for one common share of the Company at a price of $1.45 for a period of seven years. The Marathon Warrants will not be traded on any stock exchange. They are transferable only to affiliates of Marathon or to other potential lenders under the terms of the Loan Facility and their affiliates.

The Marathon Warrants were issued as consideration for various amendments made to the Loan Facility, including:

- An amendment to remove the second tranche condition requiring the Company to have filed with the FDA the results of its HFS Study before June 30, 2023; and
- An amendment to allow for the inclusion of a going concern explanatory paragraph in the annual report of the independent registered public accounting firm for the fiscal year ended November 30, 2022.

Contractual obligations

The following table lists as of November 30, 2022 information with respect to the Company's contractual obligations.

Contractual Obligations	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Convertible unsecured senior notes, including interest	29,081,000	29,081,000	—	—	—
Lease Liabilities	2,196,000	595,000	1,145,000	405,000	51,000
Term loan, including interest (1)	57,667,000	5,649,000	28,421,000	23,597,000	
Purchase Obligations (2)	3,822,000	3,822,000	—	—	—

Total	**$ 92,766,000**	**$ 39,147,000**	**$ 29,566,000**	**$ 24,002,000**	**$ 51,000**

(1) Based on SOFR forward rates. The maturities above reflect the fact that the Loan Facility has been amended in the subsequent event period and as such, the contractual maturities are used.
(2) The Corporation has long-term procurement agreements with third party suppliers in connection with the commercialization of *EGRIFTA SV*® and Trogarzo®. As at November 30, 2022, the Corporation had outstanding purchase orders and minimum payments under these agreements amounting to $1,644,000 for the manufacture of Trogarzo®, *EGRIFTA SV*® and for various services. The Corporation also had research commitments and outstanding clinical material purchase orders amounting to $1,310,000 in connection with its oncology platform and $868,000 in connection with a new formulation of tesamorelin and a multi-dose pen injector developed for this new formulation.

License agreement

On February 4, 2020, the Company entered into an amended and restated license agreement with MGH as amended on April 15, 2020, in order to benefit from its assistance and knowledge for the development of tesamorelin for the potential treatment of NASH in the general population. Under the terms of the amended agreement, MGH, through Dr Steven Grinspoon, will provide services related to the study design, selection of optimal patient population, dosing, study duration and other safety matters and participate, if need be, in regulatory meetings with the FDA or the EMA. In consideration, we agreed to make certain milestone payments to MGH related to the development of tesamorelin and to pay a low single-digit royalty on all sales of *EGRIFTA*® and *EGRIFTA SV*® above a certain threshold amount. The payment of the royalty will begin upon approval by the FDA or the EMA (the first to occur) of an expanded label of tesamorelin for the treatment of any fatty liver disease, including NASH in the general population.

Milestones

Reference should be made to Note 13 (Intangible Assets) to the Audited Financial Statements for a description of potential commercial milestones payable by the Company.

Financial Risk Management

This section provides disclosure relating to the nature and extent of our exposure to risks arising from financial instruments, including credit risk, liquidity risk, currency risk and interest rate risk, and how we manage those risks.

Credit Risk

Credit risk is the risk of a loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations. The Company regularly monitors credit risk exposure and takes steps to mitigate the likelihood of this exposure resulting in losses.

The Company's exposure to credit risk currently relates to accounts receivable with one major customer (see Note 28 to the Audited Financial Statements), other receivable and derivative financial assets which it manages by dealing only with highly rated Canadian financial institutions. Included in the consolidated statements of financial position are trade receivables of $10,659,000 (2021 – $9,261,000), all of which were aged under 60 days,

or received after year-end. There was no amount recorded as bad debt expense for the years ended November 30, 2022 and 2021. Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds and money market funds. The Company invests its available cash in highly liquid fixed income instruments from governmental, paragovernmental, municipal and high-grade corporate bodies and money market funds (2022 – $9,214,000; 2021 – $19,955,000). As at November 30, 2022, the Company believes it was not exposed to any significant credit risk. The Company's maximum credit exposure corresponded to the carrying amount of these financial assets.

Liquidity Risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they become due. As indicated in Note 25 to the Audited Financial Statements, the Company manages this risk through the management of its capital structure. It also manages liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors and/or the Audit Committee reviews and approves the Company's operating and capital budgets, as well as any material transactions out of the ordinary course of business.

The Company has adopted an investment policy in respect of the safety and preservation of its capital designed to ensure that the Company's liquidity needs are met. The instruments are selected with regard to the expected timing of expenditures and prevailing interest rates.

The Company is required to maintain cash, cash equivalents and eligible short-term investments for an aggregate value of at least $20 million currently (which amount can increase in certain circumstances) relating to the Loan Facility, which restricts the management of the Company's liquidity. Refer to notes 1 and 18 to the Audited Financial Statements.

Currency Risk

The Company is exposed to financial risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. Currency risk is limited to the portion of the Company's business transactions denominated in currencies other than US$, primarily cash, sale of goods and expenses incurred in CA$ and Euro.

Exchange rate fluctuations for foreign currency transactions can cause cash flows, as well as amounts recorded in the consolidated statements of net loss, to vary from period to period and not necessarily correspond to those forecasted in operating budgets and projections. Additional earnings variability arises from the translation of monetary assets and liabilities denominated in currencies other than the US$ at the rates of exchange at each consolidated statement of financial position date, the impact of which is reported as foreign exchange gain or loss in the consolidated statements of net loss. The Company does not believe a sudden change in foreign exchange rates would impair or enhance its ability to pay its CA$ or Euro denominated obligations.

The following table presents the significant items in the original currencies exposed to currency risk as at November 30, 2022 and 2021.

(in thousands)

	2022		2021	
	CA$	**EURO**	**CA$**	**EURO**
Cash	1,547	236	589	61
Bonds and money market funds	12,387	-	16,298	-
Trade and other receivables	733	2,141	331	1,553
Tax credits and grants receivable	66	239	385	123
Accounts payables and accrued liabilities	(10,784)	(5,849)	(6,819)	(7,256)
Lease liabilities	(1,362)	(873)	(1,755)	(1,010)
Provisions	-	(3,486)	-	(1,970)
Total exposure	2,587	(7,592)	9,029	(8,499)

The following exchange rates are those applicable as at November 30, 2022 and 2021.

	2022		2021	
	Average rate	**Reporting date rate**	**Average rate**	**Reporting date rate**
CA$ – US$	0,7722	0,7439	0,7979	0,7822
Euro – US$	1,0600	1,0406	1,1906	1,1338

Based on the Company's foreign currency exposures noted above, varying the above foreign exchange rates to reflect a 5% strengthening of the CA$ or the Euro would have a positive impact on net earnings as follows, assuming that all other variables remained constant.

(in thousands)

	2022		2021	
	CA$	**EURO**	**CA$**	**EURO**

Positive (negative) impact	129	(380)	451	(425)

An assumed 5% weakening of the CA$ or the EURO would have had an equal but opposite effect on the above currencies in the amounts shown above, assuming that all other variables remain constant.

Interest Rate Risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

Short-term bonds held by the Company are invested at fixed interest rates and/or mature in the short term. Long-term bonds are also instruments that bear interest at fixed rates. The risk that the Company will realize a loss as a result of a decline in the fair value of its bonds is limited because these investments, although they are classified as available for sale, are generally held until close to maturity. The unrealized gains or losses on bonds are recorded in accumulated other comprehensive income (loss).

Based on the value of the Company's short- and long-term bonds as at November 30, 2022, an assumed 0.5% decrease in market interest rates would have increased the fair value of these bonds and the accumulated other comprehensive income (loss) by approximately $79,000 (2021 – $141,000); an assumed increase in market interest rates of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

Cash and money market funds bear interest at a variable rate. Trade and other receivables, accounts payable and accrued liabilities and provisions bear no interest.

Based on the average value of variable interest-bearing cash and money market funds during the year ended November 30, 2022 of $23,505,000 (2021 – $41,491,000), an assumed 0.5% increase in interest rates during such year would have increased future cash flows and net profit by approximately $118,000 (2021 – $207,000); an assumed decrease of 0.5% would have had an equal but opposite effect.

As the Company's convertible unsecured senior notes bear interest at a fixed rate of 5.75%, the Company does not face cash flow interest rate risk, but is subject to market price interest rate risk.

Based on the value of the Company's long-term loan as at November 30, 2022, an assumed 0.5% increase in SOFR rate during such year would have decreased future cash flows and net profit by approximately $70,000; and assumed an increase of 0.5% would have had an equal but opposite effect.

Fair Values of Financial Instruments

Certain of the Company's accounting policies and disclosures require the determination of fair value, for both financial and non-financial assets and liabilities. Fair values have been determined for measurement and/or disclosure purposes based on the following methods. When applicable, further information about the assumptions made in determining fair values is disclosed in the notes specific to that asset or liability.

The Company has determined that the carrying values of its short-term financial assets and financial liabilities, including cash, trade and other receivables, accounts payable and accrued liabilities and approximate their fair value because of their relatively short period to maturity.

Bonds and money market funds and derivative financial assets and financial liabilities are stated at fair value, determined by inputs that are primarily based on broker quotes at the reporting date.

The fair value of the convertible unsecured senior notes, including the equity portion, as at November 30, 2022 was approximately $24,200,000 ($52,756,000 at November 30, 2021) based on market quotes.

The Company has determined that the carrying value of its term loan approximates its fair value because it was issued near the 2022 year-end.

Share-based payment transactions
The fair value of the employee stock options is measured based on the Black-Scholes valuation model. Measurement inputs include share price on measurement date, exercise price of the instrument, expected volatility (based on weighted average historical volatility adjusted for changes expected due to publicly available information), weighted average expected life of the instruments (based on historical experience and general option holder behaviour), expected dividends, and the risk-free interest rate (based on government bonds). Service and non-market performance conditions attached to the transactions, if any, are not taken into account in determining fair value.

The DSU liability is recognized at fair value and considered Level 2 in the fair value hierarchy for financial instruments. The fair value is determined using the quoted price of the common shares of the Company.

Related party transactions
Refer to Note 29 of the Audited Financial Statements.

Critical Accounting Estimates

Use of estimates and judgments
The preparation of the Company's consolidated financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting year.

Judgments in applying accounting policies
Information about critical judgments in applying accounting policies and assumptions that have the most significant effect on the amounts recognized in the consolidated financial statements is noted below.

Milestones payments
The purchase consideration for the oncology platform (see Note 13 to the Audited Financial Statements) includes additional milestone payments based on the attainment of commercial milestones that will be settled through the issuance of the Company's shares, which represent a transaction in the scope of IFRS 2. Accordingly, the fair value of the oncology platform at the date of acquisition incorporates management's judgement as to the probability of attaining the share-based milestones as well as the expected timing of the attainment of the milestones.

Management uses judgement in determining whether milestone payments are performance-related development milestones which are capitalized as an intangible asset or are milestones related to the activity or usage of an asset which are expensed.

Key sources of estimation uncertainty
Key sources of estimation uncertainty that have a significant risk of resulting in a material adjustment to the carrying amount of assets and liabilities within the next financial year are as follows:

Sales allowances
Management uses judgment in estimating provisions for sale allowances such as cash discounts, returns, rebates and chargebacks, including potential clawbacks in certain jurisdictions when pricing terms are based on temporary use authorisations and thus subject to future negotiation. The product revenue recognized quarter over quarter is net of these estimated allowances. Such estimates require the need to make estimates about matters that are inherently uncertain. These estimates take into consideration historical experience, current contractual and statutory requirements, specific known market events and trends such as competitive pricing and new product introductions, estimated inventory levels, and the shelf life of products. If actual future results vary, these estimates need to be adjusted, with an effect on sales and earnings in the period of the adjustment. (see Notes 2 (Revenue recognition) and 3 to the Audited Financial Statements for additional information).

Recoverability of inventories
The Company regularly reviews inventory to determine whether the inventory cost exceeds its net realizable value. The determination of the net realizable value requires management to make estimates and use judgement in considering shelf life of a product, the effects of technological changes and new product introductions.

Other
Other areas of judgment and uncertainty are related to the estimation of accruals for clinical trial expenses, the recoverability of intangible assets, the measurement of derivative financial assets, and the measurement of share-based arrangements.

The Company is subject to risks and uncertainties that may cause actual results to differ from estimated amounts, such as changes in the healthcare environment, competition, litigation, legislation and regulations. Management regularly evaluates estimates and assumptions using historical experience and expectations about the future. Management adjusts estimates and assumptions when facts and circumstances indicate the need for change. Revisions to accounting estimates are recognized in the year in which the estimates are revised and in any future years affected.

Recent Changes in Accounting Standards

Standards issued but not yet effective

A number of new standards are effective for annual periods beginning after December 1, 2022 and earlier application is permitted; however, the Company has not early adopted the new or amended standards in preparing these consolidated financial statements.

Onerous contracts – Cost of Fulfilling a Contract (Amendments to IAS 37)

The amendments specify which costs an entity includes in determining the cost of fulfilling a contract for the purpose of assessing whether the contract is onerous. The amendments apply for the Company's annual reporting periods beginning on December 1, 2022 to contracts existing at the date when the amendments are first applied. At the date of initial application, the cumulative effect of applying the amendments is recognised as an opening balance adjustment to retained earnings or other components of equity, as appropriate. The comparatives are not restated. The Company is currently evaluating the impact of the amendments on its financial statements.

Classification of Liabilities as Current or Non-current (Amendments to IAS 1)

For the purposes of non-current classification, the amendments removed the requirement for a right to defer settlement or roll over of a liability for at least twelve months to be unconditional. Instead, such a right must exist at the end of the reporting period and have substance.

The amendments reconfirmed that only covenants with which a company must comply on or before the reporting date affect the classification of a liability as current or non-current. Covenants with which a company must comply after the reporting date do not affect a liability's classification at that date.

The amendments also clarify how a company classifies a liability that includes a counterparty conversion option. The amendments state that: settlement of a liability includes transferring a company's own equity instruments to the counterparty; and when classifying liabilities as current or non-current a company can ignore only those conversion options that are recognized as equity.

The amendments are effective for the Company's annual reporting period beginning on December 1, 2025. The Company is currently evaluating the impact of the amendments on its financial statements.

Outstanding Securities Data

As at February 27, 2023, the number of common shares issued and outstanding was 96,806,299, we also had 8,130,550 Warrants and 5,000,000 Marathon Warrants issued and outstanding, while outstanding options granted under our stock option plan amounted to 5,137,137. We also had $27,500,000 aggregate principal amount of Notes due June 30, 2023 issued and outstanding as a result of the public offering of those notes closed on June 19, 2018. These notes are convertible into common shares at the option of the holder at a conversion price of $14.85, representing a conversion rate of approximately 67.3401 common share per $1,000 principal amount of notes. The conversion of all of the outstanding notes would result in the issuance of 1,851,852 common shares.

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the annual filings, interim filings or other reports filed under securities legislation is recorded, processed, summarized and reported within the time periods specified in the securities legislation and include controls and procedures designed to ensure that information required to be disclosed is accumulated and communicated to management, including our President and Chief Executive Officer, and our Senior Vice President and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, have evaluated, or caused the evaluation of, under their direct supervision, the design and operating effectiveness of the Company's disclosure controls and procedures, as defined under National Instrument 52-109 – Certification of Disclosure and Rule 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934 within the U.S. in Issuer's Annual and Interim Filings as at November 30, 2022. Based upon that evaluation, our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, have concluded that, as of November 30, 2022, our disclosure controls and procedures were designed and operating effectively.

Management's Report on Internal Control over Financial Reporting

Our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as defined under National Instrument 52-109 – Certification of Disclosure in Issuer's Annual and Interim Filings and Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934 within the U.S. Our internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS, as issued by the IASB. Internal controls over financial reporting include those policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets, (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with

IFRS, as issued by the IASB, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements on a timely basis. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to consolidated financial statements preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, assessed the design and operating effectiveness of our internal controls over financial reporting as of November 30, 2022 based on the criteria established in the "*Internal Control - Integrated Framework*" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Management's assessment included an evaluation of the design of our internal controls over financial reporting and testing of the operating effectiveness of our internal control over financial reporting. Based on that assessment, our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, concluded that a material weakness exists as described below, and due to this material weakness, the Company's internal control over financial reporting is not effective as of November 30, 2022.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented on a timely basis.

In connection with the Company's evaluation of internal controls over financial reporting, the follow control deficiency was considered to be a material weakness;

- The process level controls were ineffective relating to the documentation of the analysis and relating to the monitoring of certain conditions and covenants included in a financing arrangement. This control failure caused ineffective controls over the assessment of going concern uncertainty, including the underlying financial data and assumptions supporting the forecasted financial information utilized to prepare projected cash flows and liquidity requirements to comply with some of the covenants in such financing arrangement.

Notwithstanding this material weakness, management has concluded that the Company's Audited Financial Statement as at and for the year ended November 30, 2022 present fairly, in all material respects, the Company's financial position, financial performance, changes in equity and cash flows in accordance with IFRS as issued by the IASB. The material weakness did not have an impact on the Company's financial reporting and as a result, there were no material adjustments to the Company's audited annual financial

statements for the year ended November 30, 2022 and there were no changes to previously released financial results. However, because the material weakness creates a reasonable possibility that a material misstatement to our financial statements would not be prevented or detected on a timely basis, we concluded that as of November 30, 2022 the internal control over financial reporting was not effective.

Management has initiated and continues to implement remediation measures designed to ensure that control deficiencies contributing to the material weakness are remediated, such that these controls are designed, implemented and operating efficiently. The remediation actions include;

- Documentation enhancement of the analysis and the monitoring of certain conditions and covenants of the Company's financing agreements;
- Review with the CEO and CFO, among others, of the analysis and monitoring, on a monthly and quarterly basis, of all relevant conditions and covenants included in the Company's financing arrangements; and,
- Relevant documentation and review of financial data and assumptions used in financial forecasts to ensure the Company meets and expects to continue to meet all conditions and covenants included in the financing arrangements; and,
- Quarterly reporting on the remediation measures to the Audit Committee of the Board of Directors.

While remediation measures related to the Company's financing arrangement are expected to be completed in the 2023 fiscal year, the Company cannot be certain when the remediation will be completed. The material weakness will not be considered fully remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control over Financial Reporting

Other than the material weakness described above, there were no changes in our internal controls over financial reporting that occurred during the period from September 1st, 2022 to November 30, 2022 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

RISK AND UNCERTAINTIES

Before you invest in our securities, you should understand the high degree of risk involved and consider carefully the risks and uncertainties described below. The following risks may adversely impact our business, financial condition, operating results and prospects. Additional risks and uncertainties, including those that we do not know about or that we currently believe are immaterial, may also develop as our operations evolve and, therefore, may adversely affect our business, financial condition, operating results or prospects. As a result, the trading price of our securities, including our common shares, could decline and you could lose all or part of your investment.

RISKS RELATED TO THE CORPORATION'S CASH POSITION

The Corporation's report of independent registered public accounting firm (the "Auditors Report") to shareholders and the Board of Directors of the Corporation,

as well as note 1 to the audited consolidated financial statements of the Corporation for the fiscal year ended November 30, 2022 contains a going concern note about the Corporation's ability to continue as a going concern and its capacity to honor its obligations as they fall due during a period of at least, but not limited to, 12 months from November 30, 2022. The going concern note casts substantial doubt about the capacity of the Corporation to meet its monetary obligations. The inclusion of a going concern note in the Corporation's Auditors Report triggers an event of default under the Marathon Credit Facility. However, in connection with the issuance of the Auditors Report for the fiscal year ended November 30, 2022, subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to exclude the inclusion of a going concern note in the Auditors Report of the Corporation, the effect of which has been to waive any default under the Marathon Credit Facility. There can be no assurance that additional amendments or waivers of such event of default will be obtained from Marathon in future years if the yearly Auditors Report of the Corporation contains a going concern note. In the event there occurs an event of default under the Marathon Credit facility, the interest rate payable on the loaned amount increases by 300 basis points and Marathon has the right to declare all amounts outstanding under the loan immediately due and payable and not fund any additional tranches under the Marathon Credit Facility. If Marathon was to declare all loaned amounts due and payable under the Marathon Credit Facility, the Corporation would not currently be able to repay such amount unless it secures additional financings. Therefore, the Corporation would have to issue additional equity or secure access to alternative funding enabling it to repay wholly the loaned amounts under the Marathon Credit Facility. The issuance of additional equity would dilute current shareholders and such dilution could be substantial depending on the amount of money the Corporation would have to raise and the price at which such equity offering would be made. In the event the Corporation is unable to implement measures allowing it to secure the repayment of its debt, the Corporation could also have to sell or liquidate its assets or resort to insolvency laws. A recourse to any of these alternatives would have a material adverse effect on the Corporation and its shareholders.

The Corporation's Auditors Report to the shareholders and Board of Directors, as well as note 1 to the audited consolidated financial statements of the Corporation for the fiscal year ended November 30, 2022 contains a going concern note about the Corporation's ability to continue as a going concern and the capacity of the Corporation to realize its assets and discharge its liabilities and commitments in the normal course of business. The going concern note casts doubt about the capacity of the Corporation to meet its monetary obligations. For the year ended November 30, 2022, the Company incurred a net loss of $47.2 million and had negative operating cash flows of $14.7 million. The Corporation's total current liabilities exceeded total current assets at November 30, 2022. The Corporation's outstanding $27.5 million convertible unsecured senior notes mature on June 30, 2023 (the "Notes") requiring the Corporation to use its cash balance to repay the principal of the Notes.

The Marathon Credit Facility contains various covenants, including a prohibition on the inclusion of a going concern note in the Corporation's Auditors Report. The inclusion of a going concern note in the Corporation's Auditors' Report related to the Corporation's

audited consolidated financial statements would trigger an event of default under the Marathon Credit Facility resulting in the interest rate payable on any outstanding loaned amount to be increased by 300 basis points and would allow Marathon to declare such principal amount and interest thereon immediately due and payable. Marathon would also no longer have the obligation to fund any additional tranches under the Marathon Credit Facility and would have the option to foreclose on all of the assets of the Corporation pursuant to the liens registered against all of the assets of the Corporation.

Subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to exclude the inclusion of a going concern note in the Auditors Report of the Corporation for the fiscal year ended November 30, 2022, the effect of which has been to waive any default under the Marathon Credit Facility. There can be no assurance that Marathon will agree to amend the Marathon Credit Facility or grant a waiver in future years if the Corporation's future Auditors Report include a going concern note. The failure to amend the Marathon Credit Facility or to obtain a waiver from Marathon in future years in the event additional going concern notes are included in the Corporation's Auditors Reports could have a material adverse effect on the Corporation and its business prospects in the event Marathon declares all principal amounts and interest thereon immediately due and payable and the Corporation is unable to repay the loaned amounts.

An event of default under the Marathon Credit Agreement resulting in Marathon declaring all principal amount and interest thereon immediately due and payable would require the Corporation to seek and find alternative sources of financing. Such alternative sources of financing could be the issuance of equity, subject to then prevailing market conditions. The issuance of equity security would dilute shareholders and such dilution could be substantial depending on the price at which the equity offering would be made and the amount to be raised. If the Corporation was unable to secure additional financing to repay any of its outstanding loaned amount, the Corporation could have to sell or liquidate its assets or resort to insolvency laws. A recourse to any of these alternatives would have a material adverse effect on the Corporation and its shareholders.

We did not generate a profit from our operations in the fiscal year ended November 30, 2022. In addition, despite announcing our goal to achieve a positive Adjusted EBITDA by the end of the 2023 fiscal year, there can be no guarantee that we will achieve these milestones, nor that we will achieve profitability.

We have a history of net losses, including a net loss of $47.2 million for the fiscal year ended November 30, 2022. In the future, our profitability will mainly depend on our capacity to maintain the commercialization of *EGRIFTA SV*® and Trogarzo® successfully in the United States through a low-cost and effective distribution network, the recruitment and retention of talented personnel, the deployment of an effective marketing campaign and through continued reimbursement coverage for *EGRIFTA SV*® and Trogarzo® under U.S. Medicare and Medicaid programs and under private-health insurers programs in the United States. Our profitability will also depend on our ability and capacity to control our operating expenses.

There is no guarantee that we will continue succeeding in growing sales of *EGRIFTA SV*® and Trogarzo® in the United States. If revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, financial condition and

operating results could be materially adversely affected and we may never obtain or sustain profitability.

We may not be able to generate sufficient cash from our operating activities to service our debt obligations.

Our ability to repay the $27.5 million outstanding Notes due on June 30, 2023 requires that we access the $20 million second tranche of the loan under the Marathon Credit Facility or obtain alternative equity financing in the near term and also depends on our future financial and operating performance to avoid, among other things, being in default under the Marathon Credit Facility. Future financial and operating performance remain subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We may be unable to achieve a level of positive cash flows from operating activities sufficient to pay the principal and interest on the loan provided by Marathon or our Notes. Furthermore, if our share price remains below the conversion price of the Notes, the Notes are unlikely to be converted and we will have to pay all accrued interest thereon and their principal on their maturity date (June 30, 2023) and, therefore, we need to ensure we have adequate cash resources available by June 30, 2023, to repay the Notes and to continue our operations.

To mitigate the aforementioned risk, subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to remove as a condition to accessing the $20 million second tranche of the loan, being the filing to the FDA of the results of the HFS the Corporation is currently conducting. Notwithstanding the removal of this condition, access to the $20 million second tranche remains subject to compliance by June 30, 2023 with a twelve-month revenue target of $75 million and other covenants. As a result, there remain risks under the Marathon Credit Facility that the Corporation will not be able to access the second tranche for the repayment of the Notes on June 30, 2023 since a default under the Marathon Credit Facility, unless waived by Marathon, prevents the Corporation from borrowing additional money.

For the year ended November 30, 2022, the Corporation had negative operating cash flows of $14.7 million. In addition, the Corporation had a working capital deficiency (total current liabilities exceed total current assets) at November 30, 2022 of $40.9 million due in part to the amount borrowed under the Marathon Credit Facility being classified as a current liability as a result of the amendment to the Marathon Credit Facility having been entered into after the fiscal year end of the Corporation. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay expenditures and capital additions, seek additional capital or restructure or refinance our debt. These measures may not be successful and may not permit us to meet our scheduled debt service obligations. In the absence of such cash flows and resources or in the absence of accessing the $20 million second tranche, we could face substantial liquidity problems and we could have to resort to insolvency laws to seek protection from our creditors.

Interest rate fluctuations may have a material adverse effect on our capacity to reimburse the loaned amounts under the Marathon Credit Facility and on our capacity to execute on our business plan.

The interest rate we have to pay Marathon under the Marathon Credit Facility is based on the Secured Overnight Financing Rate ("SOFR"), plus 9.5%.

SOFR is a broad measure of the cost of borrowing cash overnight collateralized by U.S. Treasury securities. SOFR has a limited history, and the future performance of SOFR cannot be predicted based on its limited historical performance. The level of SOFR may bear little or no relation to historical actual or indicative data. Prior observed patterns, if any, in the behavior of market variables and their relation to SOFR, such as correlations, may change in the future. While some pre-publication historical data have been released by the Federal Reserve Bank of New York, such analysis inherently involves assumptions, estimates and approximations, and hypothetical or historical performance data are not indicative of, and have no bearing on, the potential performance of SOFR. The future performance of SOFR is therefore impossible to predict, and no future performance of SOFR may be inferred from any of the historical actual or indicative data. Changes in the levels of SOFR will affect the interest rate we have to pay to Marathon under the Marathon Credit Facility during the term of the loan and may adversely affect the amount of cash we will have to allocate to the repayment of the loan.

Interest rates are highly sensitive to many factors, including governmental monetary policies, domestic and international economic and political conditions, and other factors beyond our control. If SOFR increases as a result of events over which we have no control, this could have a material adverse effect on our financial condition and results of operations. If SOFR increases, our debt service obligations would increase even if the amount borrowed remained the same, and our net income and cash flows, including cash available for servicing our indebtedness, will correspondingly decrease.

The Marathon Credit Facility includes significant operating and financial restrictions on the Corporation, any of which could prevent us from capitalizing on business opportunities. In addition, our failure to comply with such restrictions could trigger an event of default which would increase by 300 basis points the interest payable on any loaned amounts under the Marathon Credit Facility and would allow Marathon to declare the outstanding loaned amounts immediately due and payable in addition to providing Marathon with the right to foreclose on all of the assets of the Corporation pursuant to the liens registered against all of the assets of the Corporation. If we are unable to cure an event of default or obtain a waiver from Marathon in relation to such event of default, and if we do not have the financial capacity to repay any amount loaned becoming due and payable, we may have to cease our operations and to resort to insolvency laws.

The Marathon Credit Facility governing our outstanding $40 million loan and potential additional tranches which may be drawn thereunder impose significant operating and financial restrictions on the Corporation. These restrictions limit our ability and the ability of certain of our subsidiaries to, among other things: (i) incur or guarantee additional debt or issue disqualified stock or preferred stock; (ii) pay dividends and make other distributions on, or redeem or repurchase, capital stock; (iii) make certain investments; (iv) incur additional liens; (v) enter into transactions related to the acquisition, disposition, in-licensing or out-licensing of assets; and (vi) merge or consolidate.

In addition, the Marathon Credit Facility imposes that we maintain a minimum of $20 million in cash and cash equivalent at all times. This minimum liquidity amount goes up

to $30 million if we do not obtain the approval of the F8 Formulation by March 31, 2024. The minimum liquidity covenant restricts the management of the Corporation's liquidity and could increase the likelihood that the Corporation may not be able to meet its obligations as they become due. The Marathon Credit facility also imposes revenue targets on a quarterly basis. The Marathon Credit Facility further imposes reporting requirements on our business activities on a quarterly basis. These reporting requirements extend beyond those that we have to comply with under securities regulations and add a layer of complexity to our reporting obligations. The minimum liquidity covenant restricts the management of the Corporation's liquidity and increases the likelihood that the Corporation may not be able to meet its obligations as they become due. As a result of the restrictions and obligations described above, we will be limited as to how we conduct our business and we may be unable to enter into transactions that may be accretive to our business to compete effectively or to take advantage of new business opportunities. Debt financing opportunities will also be limited in the event that we are unable to raise capital through the issuance of equity. There can be no assurances that we will be able to maintain compliance with these requirements and covenants in the future and, if we fail to do so, that we will be able to obtain waivers from Marathon and/or amend the covenants contained in the Marathon Credit Facility to remove those obligations.

Our failure to comply with the covenants described above as well as other terms of our indebtedness will result in an event of default under the Marathon Credit Facility which, if not cured or waived, will result in an increase of 300 basis point on the interest payable on the outstanding loaned amount. An event of default under the Marathon Credit Facility would also allow Marathon to declare all loaned amounts immediately due and payable and entitle Marathon to execute on its first ranking security interest on all of our assets and foreclose on our assets. If we were to default under the Marathon Credit Facility and Marathon were to declare all amounts outstanding under the loan immediately due and payable, this would also trigger a default under the terms of the Notes. In the event there occurs an event of default under the Marathon Credit Facility and we are unable to cure such event of default or obtain a waiver from Marathon in relation thereto, and if we do not have the financial capacity to repay any amount loaned becoming due and payable, we may have to cease our operations and to resort to insolvency laws. Any of those circumstances will have a material adverse effect on shareholders as they will lose the entire value of their investment in the capital of the Corporation.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS

Our commercial success and revenue growth depend on the commercialization of EGRIFTA SV® and Trogarzo® in the United States; unsatisfactory future sales levels of EGRIFTA SV® and Trogarzo® in the United States will have a material adverse effect on us.

Our ability to generate revenue and sustain growth is currently concentrated solely on the commercialization of EGRIFTA SV® and Trogarzo® in the United States. Our success in generating sales revenue from *EGRIFTA SV®* and Trogarzo® in the United States will depend on our capacity: (a) to pursue the deployment of a commercialization strategy that will be accepted by patients, healthcare professionals and third-party payors; (b) to maintain reimbursement coverage for *EGRIFTA SV®* and Trogarzo® by third-party payors; (c) to maintain the registration of *EGRIFTA SV®* and Trogarzo® on U.S. governmental forms as drugs available for purchase in the United States; (d) to ensure that adequate

supplies of *EGRIFTA SV*® and Trogarzo® are available; (e) to maintain conflict-free relationships with our principal third-party suppliers of services, namely our manufacturers (TaiMed and Jubilant HollisterStier, General Partnership ("Jubilant")), our distributor in the United States (RxC Acquisition Company, LLC ("RxCrossroads")), as well as other specialized third parties; and (f) to defend our intellectual property rights regarding tesamorelin against third parties.

Our success in commercializing our products in the United States will also depend on our capacity to retain qualified, motivated and talented sales representatives and other key individuals instrumental in the commercialization of our products and the capacity of our third-party suppliers to comply with all laws and regulations applicable to the conduct of their respective businesses.

There can be no assurance that sales of our products to customers in the United States will increase in the future or that we will generate sales at a profitable level. If sales of our products decrease, our revenue would be adversely affected which, in turn, could materially adversely affect our business, financial condition and operating results.

Because we expect to be dependent on revenues solely from *EGRIFTA SV*® and Trogarzo® for the foreseeable future, any negative developments relating to these products, such as safety or efficacy issues, manufacturing issues, the introduction or greater acceptance of competing products, or adverse regulatory or legislative developments, or our inability to successfully manage any of the abovementioned factors, will have a material adverse effect on our business and our future business prospects.

RxCrossroads is our only client in the United States in connection with the sale of EGRIFTA SV® and Trogarzo® and a default or a dispute under our agreement, or its termination or non-renewal at term, would materially adversely affect our revenues, business and operating results.

More than 95% of our revenues are derived from the sale of our products to RxCrossroads that acts as our exclusive distributor in the United States. If our agreement with RxCrossroads is terminated, or is not renewed at term and we are unable to find another distributor prior to its term, or if we are in default or engaged in a dispute with RxCrossroads, our sales may be materially adversely impacted and our revenues could decrease substantially.

In addition, under the terms of our agreement with RxCrossroads, we agreed to reimburse RxCrossroads for chargebacks and other discounts that RxCrossroads may offer to its clients. If RxCrossroads' clients omit to timely claim from RxCrossroads any discount they are entitled to, or if they make a mistake in assessing the types of discounts they are entitled to claim and they claim those discounts later in a year, we will have to refund RxCrossroads for such discounts to which RxCrossroads' clients are entitled to and this may materially adversely affect our level of revenues and operating results for the year.

We rely on third parties for the manufacture, distribution and commercialization of our products and such reliance may adversely affect our revenues, business and future business prospects if the third parties are unable or unwilling to fulfill their obligations.

We have a single third-party service provider for some of our core business activities pertaining to the commercialization of our products, namely their manufacturing and distribution. Any material issues such third-party service providers may encounter that relate to the provision of services to us would have a material adverse effect on our revenues, business and future business prospects since these third-party service providers may not be easily or rapidly replaced.

We do not own or operate manufacturing facilities for the production of *EGRIFTA SV*® and tesamorelin, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on Bachem Americas, Inc. ("Bachem") and Jubilant to manufacture and supply all of our required raw materials, drug substance and drug product for sales of *EGRIFTA SV*®. We will also rely on a single third-party supplier, Lyophilization Services of New England, Inc.("LSNE") for the manufacture of the F8 Formulation. Our agreement with Bachem has expired and we are currently renegotiating the terms and conditions of a new manufacturing agreement. Although we are in discussions with Bachem, our inventory of drug product is high and potential alternative suppliers and manufacturers have been identified, but we have not entered into any agreements with Bachem yet. Also, we have not qualified alternative manufacturers to date and no assurance can be given that such manufacturers will be qualified in the future or receive necessary regulatory approvals. The replacement of a third-party manufacturer is time-consuming and costly due to the required validation of their capabilities. The validation process includes an assessment of the capacity of such third-party manufacturer to produce the quantities that we may request from time to time, the manufacturing process and its compliance with current good manufacturing practice, or GMP, regulations. In addition, the third-party manufacturer would have to familiarize itself with our technology. Validation of an additional third-party manufacturer takes at least twenty-four (24) months and could take as long as thirty-six (36) months or more. If we fail to renegotiate the terms and conditions of the Bachem Agreement, we may no longer be able to rapidly manufacture tesamorelin for *EGRIFTA SV*®, for the F8 Formulation and for our potential Phase 2b/3 clinical trial in NASH. Despite our current level of inventory of tesamorelin, we could incur a shortage of tesamorelin by the time new manufacturers are qualified.

TaiMed is our sole supplier of Trogarzo®. TaiMed does not currently own or operate any manufacturing facilities for the production of Trogarzo® and must rely on its suppliers, WuXi and Samsung. We are not in a contractual relationship with WuXi and Samsung for Trogarzo® and, therefore, we may not be able to interact with any of them in the event they encounter issues which could adversely affect the supply of Trogarzo®. In such circumstances, we will need to rely on TaiMed to address any of those issues. We have no control over the time and efforts that TaiMed will devote in finding solutions to supply issues if such were to occur, or any say on the solution itself. Any delay in addressing manufacturing issues or any solution to address a manufacturing problem that is not to our liking could have a material adverse effect on the supply and sale of Trogarzo® and, accordingly, materially adversely affect our revenues.

We do not have state licensure in the United States to distribute *EGRIFTA SV*®, Trogarzo® or any other product we may acquire or in-license and we have not made any application to obtain the licenses required in order to distribute a drug product in the United States. Our supply chain model is based upon that fact and the distribution of *EGRIFTA SV*® and Trogarzo® in the United States is done through RxCrossroads which currently holds all

state licensure required to distribute a drug product in every American state. Although potential alternative third-party service providers have been identified to replace RxCrossroads in the event that it becomes unable to distribute *EGRIFTA SV*® and Trogarzo®, we have not entered into any agreements with them and no assurance can be given that such providers would enter into any agreement with us on terms satisfactory to us.

Syneos Health, Inc. ("Syneos") continues to provide us with support for the commercialization of *EGRIFTA SV*® and Trogarzo® in the United States through the provision of personnel as part of the managed market and reimbursement teams. Although we are aware that there exist other third-party services providers that could provide the same services as Syneos, we have not entered into any agreements with them nor conducted any audit on them. If we need to find another third-party service provider for some or all of the services provided by Syneos, it will be time-consuming and will be disruptive to our business. In addition, there can be no assurance that we will be able to find such third-party service provider if we are unable to agree on the terms and conditions of an agreement with them.

Finally, we may retain contract research organizations ("CROs") to support us with the conduct of clinical trials from time to time. These CROs will be tasked with the recruitment of patients, negotiations of clinical study agreements with various clinics and the monitoring of those clinics in connection with our clinical trials. If these CROs default on their covenants or are found, for instance, to be in violation of applicable laws, our clinical trials could be delayed, and any timelines set forth in our public communications could be wrong. In addition, if these CROs are found to be in violation of applicable laws, any data generated in the course of our clinical trials could be questioned by regulatory agencies and this could lead to a rejection of any data submitted to those regulatory agencies at the time of submitting a sBLA or NDA seeking the approval of our products.

Our reliance on single third-party service providers for some of our core business activities exposes us to a number of risks. For instance, we may be subject to delays in, or suspension of, the manufacturing of *EGRIFTA SV*®, the F8 Formulation and Trogarzo® if a third-party manufacturer: (a) becomes unavailable to us, or to TaiMed, for any reason, including as a result of the failure to comply with GMP regulations; (b) experiences manufacturing problems or other operational failures, such as labour disputes, equipment failures or unplanned facility shutdowns required to comply with GMP, or damage from any event, including fire, flood, earthquake, business restructuring, labour disputes or insolvency; or (c) fails to perform its contractual obligations under our agreement, such as failing to deliver the quantities requested on a timely basis or not meeting product specifications.

We may also be subject to distribution disruption and interrupted sales of *EGRIFTA SV*® and Trogarzo® in the United States if: (a) RxCrossroads becomes unavailable to us for any reason, including as a result of its failure to meet applicable laws; (b) RxCrossroads experiences warehousing problems or other operational failure, such as unplanned facility shutdown or damage from any event, including fire, flood, earthquake, business restructuring or insolvency; or (c) RxCrossroads fails to perform its contractual obligations under our agreement.

We may be subject to a decrease in sales of our products in the United States or we may face reimbursement challenges if Syneos (a) becomes unavailable to us for any reason, including as a result of its incapacity to motivate and retain the employees working on the commercialization of *EGRIFTA SV*® and/or Trogarzo®; (b) experiences compliance issues with the FDA; or (c) fails to perform its contractual obligations under our agreement.

Significant safety problems may arise with respect to EGRIFTA SV® and Trogarzo® which could result in restrictions in EGRIFTA SV®'s or Trogarzo®'s label, product recall or withdrawal of any of our products from the market, any of which could materially adversely impact our business and our future business prospects.

New safety issues may arise as *EGRIFTA SV*® and Trogarzo® are used over longer periods of time by a wider group of patients, some of whom may be taking numerous other medicines, or may suffer from additional underlying health problems. Such safety issues could include an increase in the severity or frequency of known problems or the discovery of previously unknown problems and may result in a variety of adverse regulatory actions. Under U.S. laws, the FDA has broad authority over drug manufacturers to compel any number of actions if safety problems arise, including, but not limited to: (i) requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandating labeling changes to a product based on new safety information; or (iii) requiring manufacturers to implement a risk evaluation mitigation strategy where necessary to assure safe use of the drug. Similar laws and regulations exist in countries outside of the United States.

Previously unknown safety problems could also result in product recalls, or withdrawal of the products from the territory(ies) where they are approved for commercialization. If new safety issues are discovered, sales of *EGRIFTA SV*® and/or Trogarzo® may decrease and result in a material adverse effect on our business, financial condition and operating results.

Our levels of revenues are highly dependent on obtaining and maintaining patient reimbursement for EGRIFTA SV® and Trogarzo®.

Market acceptance and sales of *EGRIFTA SV*® and Trogarzo® substantially depend on the availability of reimbursement from third-party payors such as governmental authorities, including U.S. Medicare and Medicaid, managed care providers, and private insurance plans and may be affected by healthcare reform measures in the United States. Third-party payors decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors are attempting to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors have been challenging the prices charged for products. Third-party payors may decrease the level of reimbursement of a product or cease such reimbursement and the occurrence of any of these events could materially adversely affect the sales of *EGRIFTA SV*® and Trogarzo®.

Sales of *EGRIFTA SV*® and Trogarzo® to patients benefitting from U.S. Government funded reimbursement programs represent a significant part of our sales. Denial of coverage for any of those products under any of the current programs would materially adversely affect our revenues.

Even though EGRIFTA SV® and Trogarzo® are approved for sale in the United States, revenue that we generate from their sales may be limited.

Sales of *EGRIFTA SV*® and Trogarzo® will continue to depend upon the acceptance of such products by the medical community, including physicians, patients and third-party payors. The degree of market acceptance of these products will depend on a number of factors, including: (a) demonstrated product safety, including the prevalence and severity of side effects, and effectiveness as a treatment that addresses a significant unmet medical need; (b) storage requirements, dosing regimen and ease of administration; (c) the availability of competitive alternatives; (d) our ability to obtain and maintain sufficient third-party coverage for reimbursement from government health care programs, including U.S. Medicare and Medicaid, private health insurers and other third-party payors; (e) the willingness and ability of patients to pay out-of-pocket for medications; (f) the product price; and (g) the effectiveness of sales and marketing efforts.

If our products are not accepted by the marketplace, the revenue generated therefrom will be limited and our capacity to grow our revenue and become profitable will be hampered. Our failure to grow our revenue and to become profitable will adversely impact the value of the Corporation, including the market price of our shares. If we fail to achieve adequate sales, we may not generate sufficient revenue in order to become profitable.

We face competition and the development of new products by other companies could materially adversely affect our business and operating results.

The biopharmaceutical and pharmaceutical industries are highly competitive and we must compete with pharmaceutical companies, biotechnology companies, academic and research institutions as well as governmental agencies for the development and commercialization of products, most of which have substantially greater financial, technical and personnel resources than us. We believe there is currently few approved drug products competing directly with our approved products. However, with respect to Trogarzo®, we face competition from the approval of Fostemsavir and Lenacapavir in the United States. In addition, we are aware of other agents, including dolutegravir and darunavir, that are either indicated or commonly used in combination in regimens to treat heavily-treatment experienced patients with MDR HIV-1. With respect to *EGRIFTA SV*®, we face competition from companies selling human growth hormone, testosterone, insulin sensitizing agents, GLP-1 receptor agonists and sermorelin as those products may be prescribed by physicians. In addition, other approaches to reduce visceral adipose tissue in the abdominal area include coping mechanisms such as lifestyle modification (diet and exercise), switching ARTs or liposuction.

The development of a vaccine against HIV or of any cure against HIV would have a material adverse effect on our business, operating results and financial conditions.

Although there exists no known vaccine and cure for HIV, we are aware that there are research and development activities carried out in order to eradicate this disease. We are also aware that a very low number of patients were cured from HIV. If a vaccine or a cure was found to prevent or cure HIV, sales of our products would be materially adversely impacted and our revenue growth would be hampered. The discovery of any vaccine or cure against HIV would have a material adverse effect on our business, operating results and financial condition.

RISKS RELATED TO RESEARCH AND DEVELOPMENT ACTIVITIES

The conduct of research and development activities is risky and results obtained therefrom may not be those anticipated. Therefore, there can be no assurance that any research and development plan on a product candidate or medical device will result in an approved drug or medical device.

The development of new therapies is highly risky and the results obtained therefrom may not yield any of the anticipated benefits. The development of a product candidate into a new drug requires the conduct of many tests on animals and humans, all of which must comply with stringent regulation and require substantial investments. There can be no assurance that any research and development program designed to develop a new formulation, a new drug, a new method or route of administration or provide a new treatment, such as the development of the F8 Formulation and the Pen, the development of tesamorelin for the potential treatment of NASH in the general population and the development of our peptide-drug conjugates resulting from our SORT1+ Technology™ platform, will end up generating positive results leading up to an approved formulation, label expansion, new medical device or a new product by a regulatory authority. The failure to develop a new formulation, a new method of treatment, a new method or route of administration or a drug product could hamper the future growth of our business and have long-term adverse effects on our potential revenues and operating results.

The development of TH1902 for the potential treatment of various types of sortilin-expressing cancers is still uncertain given that, after consultation with investigators, we have voluntarily paused the enrollment of patients in the Phase 1 clinical trial since efficacy results observed were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. The FDA has since placed the Phase 1 clinical trial of TH1902 on partial clinical hold and asked a series of questions to the Corporation requiring satisfactory responses thereto prior to resuming the Phase 1 clinical trial. If the Corporation is unable to answer the questions raised by the FDA to the FDA's satisfaction and if the Corporation is unable to resume its Phase 1 clinical trial with TH1902, the Corporation will have to discontinue its Phase 1 clinical trial. Any halt in the Corporation's Phase 1 clinical trial could materially adversely affect the development of its SORT1+ Technology™ platform and reduce its pipeline of drug candidates, all of which would materially adversely affect its long-term growth and prospects.

The enrollment of patients in the Corporation's Phase 1 clinical trial evaluating TH1902 was voluntarily paused by the Corporation after consulting with its investigators. The efficacy results observed were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. The FDA has since placed the clinical trial on partial clinical hold and has issued a series of questions to the Corporation that will need to be answered to the satisfaction of the FDA prior to resuming the Phase 1 clinical trial. The Corporation has also formed a SAC to help determine the best developmental path forward for TH1902. The decision made by the Corporation illustrates that, to date, we have not been able to replicate results obtained from our preclinical *in vivo* work and that the conduct of clinical trials is risky as results may adversely vary from those that are expected.

If the Corporation is unable to resume its Phase 1 clinical trial with TH1902 because (i) it is unable to adequately answer to all of the questions raised by the FDA, (ii) the SAC is unable to agree on the best developmental path forward for TH1902, or (iii) the FDA does not accept the terms of an amended protocol, the development program of TH1902 will need to be halted. Any halt in the Corporation's Phase 1 clinical trial would materially adversely affect the development of its SORT1+ Technology™ platform and reduce its pipeline of drug candidates, all of which would materially adversely affect its long-term growth and prospects. Even if the Corporation is allowed to resume its Phase 1 clinical trial with TH1902, the Corporation may have difficulty enrolling new patients in the resumed trial. The difficulty in enrolling patients would cause additional delays in advancing the development of TH1902. In addition, there can be no guarantee that the results obtained from the resumed Phase 1 clinical trial would yield positive results. In the event that the resumed clinical trial did not yield positive results, the value associated to the SORT1+ Technology™ platform asset would be depreciated, thereby adversely impacting the market value of the Corporation, including the price of its Common Shares.

The conduct of research and development activities is very costly and capital intensive. We have already indicated that the development of tesamorelin for the treatment of NASH in the general population was on pause until we find a partner and that the development of TH1902 would be stage-gated in order to meet our goal of achieving a positive Adjusted EBITDA in the 2023 fiscal year. We have also indicated that we would assess a partnership for the development of TH1902 once the Phase 1 clinical trial has resumed. If we are unable to find a partner for the development of tesamorelin for the treatment of NASH or for the pursuit of the development of TH1902 once the Phase 1 clinical trial has resumed, we may have to cease the development of those assets, any of which could have a material adverse effect on our long-term potential revenue growth and business prospects.

The development of pharmaceutical products is very costly and capital intensive.

As a result of our assessment of the costs associated with our proposed Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population, we have decided to seek a partner prior to launching such trial. The contemplated development of tesamorelin for the treatment of NASH will require the enrollment of over 2,000 patients and the study will be conducted over many years. Therefore, we expect the development of tesamorelin for the treatment of NASH in the general population to cost multiple millions of dollars.

Consistent with our objective of achieving a positive Adjusted EBITDA by the end of the current fiscal year and beyond, we also announced that the development of TH1902 would be stage-gated and that further to resuming the Phase 1 clinical trial, we would assess partnering the development of TH1902.

There can be no assurance that we will be able to find a partner for either the development of tesamorelin for the potential treatment of NASH or for the further development of TH1902. Finding a partner for those development programs will depend on a variety of factors, including the preclinical and clinical data that we have generated for those drug candidates, the current advancement of the programs and the risk related thereto, the regulatory path to seek approval of those drug candidates, the market environment related to NASH and oncology, competition from other products and general market conditions.

In addition, even we were to find a partner for any of those programs, there can be no assurance that the terms and conditions contained in any partnership agreement would be suitable to us. The failure to find a partner for the development of tesamorelin for the potential treatment of NASH and the further development of TH1902 could lead to a halt in the development of those programs.

A complete halt in the conduct of those programs could adversely impact our long-term growth and business prospect since the Corporation would have a reduced pipeline of product candidates.

The Corporation has not filed a sBLA seeking the approval of the F8 Formulation and, consequently, the FDA has not approved the F8 Formulation as being bioequivalent to the Corporation's original formulation of EGRIFTA®. If the FDA does not approve the F8 Formulation, the Corporation may have to conduct additional clinical studies to prove the bioequivalence of the F8 Formulation against the original formulation, resulting in additional spending and delays in the use of the F8 Formulation.

The Corporation has conducted studies to assess the bioequivalence of the F8 Formulation against the original 1 mg/vial formulation of *EGRIFTA®*. These studies were conducted based on the current FDA regulation to show the bioequivalence of formulations. The Corporation has not yet filed a sBLA with the FDA seeking the approval of the F8 Formulation for commercial use although this is planned for 2023.

If the FDA does not approve the F8 Formulation as being bioequivalent to the original formulation, the Corporation would have to conduct additional testing using the F8 Formulation which would delay the time by which the Corporation could commercialize the F8 Formulation and which would require the Corporation to incur additional expenses and inventory write-downs, all of which could adversely affect the Corporation's financial condition or results of operations. Furthermore, the non-approval of the F8 Formulation would prevent the Corporation from pursuing the assessment of the development of the Pen, or any other device to be used with the F8 Formulation. Finally, the non-approval of the F8 Formulation would expose the Corporation to the entry of biosimilar versions of tesamorelin for the treatment of lipodystrophy given that the patent protection for this product will expire in August 2023. Since the F8 Formulation is patent protected until 2033 in the United States, the commercialization of tesamorelin for the treatment of lipodystrophy using the F8 Formulation could protect the entry of biosimilar versions until the expiry of this patent in 2033.

The Corporation has decided to seek a partner to conduct a Phase 2b/3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population. Although the Corporation has begun the search for a potential partner and preliminary discussions are ongoing, there can be no assurance that a partner will be found or that a partnership agreement will be entered into on terms satisfactory to the Corporation. If a partner is not found, the Corporation may have to cancel this program unless it has access to substantial financial resources to pursue such development program and there can be no guarantee that the Corporation will secure such substantial resources in an amount sufficient to initiate or complete the Phase 2b/3 clinical trial. Moreover, the FDA has issued comments and asked questions on the revised protocol filed by the Corporation in February 2022 and the

Corporation has voluntarily decided not to reply to those comments and questions until it can find a partner. In addition, the Corporation's decision to design its Phase 2b/3 clinical trial to meet the FDA's primary endpoints may prevent the Corporation from seeking approval of tesamorelin for the treatment of NASH in the general population from the EMA since the primary endpoint for this agency is different from that of the FDA. If the Corporation is unable to find a partner to develop tesamorelin for the treatment of NASH in the general population or to secure substantial financial resources to do it on its own, the Corporation may cancel this program and the development of tesamorelin for the treatment of NASH may never occur. Even if the Corporation finds a partner, the conduct of the Phase 2b/3 clinical trial may be delayed or never begun if the Corporation is unable to properly address the comments and questions raised by the FDA based on the Corporation's amended protocol. Finally, if the Corporation is unable to meet the endpoints of its Phase 2b/3 clinical trial, it will not receive approval for tesamorelin for the treatment of NASH in the general population. Even if the Corporation meets the endpoints of the clinical trial, the FDA could issue a conditional approval letter such that if the Corporation is unable to meet the conditions contained in such letter, the Corporation could lose such approval. If the conduct of the clinical trial is cancelled, or if the Corporation does not receive approval for tesamorelin for the treatment of NASH in the general population, its potential long-term revenues, growth and prospects will be materially adversely affected.

In July 2021, we announced that the final Phase 3 clinical trial design would result in higher costs than what we had expected and, as a result, we were assessing our options to best execute this program, including seeking a potential partner. There are currently ongoing preliminary discussions with potential partners.

In February 2022, in order to de-risk the Phase 3 trial, the Corporation submitted an amended protocol to the FDA resulting in the FDA providing us with a list of questions and comments on this amended protocol. We have voluntarily decided not to respond to those questions and comments in order to address them with any potential partner we may find to optimize the design, if deemed relevant. The amended protocol includes a Phase 2b/3 seamless study design where the first 350 or so patients' data will be analyzed by a data monitoring committee to assess the efficacy of tesamorelin on a smaller subset of patients. The amended protocol would allow us to generate hard endpoint data on NAS score and fibrosis. A decision would then be made whether to continue the study until the full number of patients (1,094) have completed 18 months of treatment. These amendments would not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH, but it would inform the continuation of enrollment while providing an indication of benefit to patients.

There can be no guarantee that tesamorelin will be studied for the treatment of NASH in the general population if the Corporation is unable to find a partner to conduct the development program on its own. Even if the Corporation finds a partner, the terms and conditions pursuant to which such partner may be interested in assisting the Corporation may not be satisfactory to the Corporation or may be unfavorable. Under such circumstances, the Corporation may decide to forego the development of tesamorelin for the treatment of NASH in the general population or turn to alternative sources of financing. If the Corporation is unable to, or does not proceed with, the development of tesamorelin

for the treatment of NASH in the general population, it could have a material adverse effect on its potential long-term revenues, growth and business prospects.

Even if the Corporation finds a partner to initiate a Phase 2b/3 clinical trial, there can be no guarantee that the FDA will be satisfied with the responses to the questions and comments asked in connection with the amendments to the protocol filed in February 2022 and allow the initiation of such trial. Even if the FDA or any other regulatory agency approves the study of tesamorelin for the treatment of NASH in the general population, there can be no guarantee that the results will meet the endpoints of the study and that tesamorelin will be approved for such treatment. Even if the Corporation meets the FDA's primary endpoints and approval is received from the FDA, such approval may be conditioned on conducting additional studies which, if not conducted or if the results therefrom are not positive on certain clinical outcomes, could result in the FDA withdrawing its approval for the use of tesamorelin for the treatment of NASH in the general population.

The Corporation has decided to design its Phase 2b/3 clinical trial based on the FDA guidelines requiring it to demonstrate "NASH resolution and no worsening of fibrosis" as primary endpoints. This trial design does not follow the current EMA guidelines which require a sponsor to demonstrate both (i) NASH resolution and no worsening of fibrosis and (ii) improvement of fibrosis by one stage without worsening of NASH as primary endpoints. Therefore, even if the Corporation meets the primary endpoints for FDA purposes, the EMA may not approve tesamorelin for the treatment of NASH in this territory since the trial was not designed to demonstrate both endpoints.

If the Corporation is unable to obtain approval of tesamorelin for the treatment of NASH in the United States, this would have material adverse effects on its revenues, financial results and long-term growth and prospects. In addition, even if the FDA approves tesamorelin for the treatment of NASH, the lack of an approval in Europe will limit the Corporation's ability to maximize its revenue growth potential, therefore potentially hampering its long-term growth and prospects.

The conduct of clinical trials is subject to a variety of risks, many of which can be beyond the control of the Corporation forcing it to delay the initiation or conduct of clinical trials or forego same.

The beginning or completion of clinical trials may be delayed or prevented for several reasons, including, among others: (a) negative results from the Corporation's clinical trial resulting in a failure to meet the endpoints of its clinical trial; (b) delays in reaching or failing to reach agreement on acceptable terms with clinical study sites, the terms of which can be subject to considerable negotiation and may vary significantly among different study sites; (c) any breach of the terms of any contract research organization agreement by us or by our third-party suppliers that have responsibility to assist us with the conduct of our clinical trials; (d) inadequate quantity or quality of the active pharmaceutical ingredient or other materials necessary to conduct clinical trials; (e) challenges in recruiting and enrolling patients to participate in clinical trials, such as the proximity of patients to study sites, eligibility criteria to be included in a clinical trial, the nature of a clinical trial and the competition from other clinical study programs for the treatment of similar diseases as those the Corporation may seek to treat; (f) severe or unexpected adverse drug effects experienced by patients; (g) regulatory agencies requiring a sponsor to conduct additional clinical studies prior to approving a new drug application, a sBLA, or

the equivalent thereof in other jurisdictions after review of Phase 3 clinical trial results; (h) regulatory agencies may disagree with a sponsor 's interpretation of data resulting from its Phase 3 clinical trials, or may change the requirements for approval even after they have approved the sponsor's Phase 3 clinical trial design; and (i) difficulties in retaining patients who have enrolled in a sponsor's Phase 3 clinical trial but who may be prone to withdraw due to rigours of the clinical trial, lack of efficacy, side effects, personal issues or loss of interest.

In addition, clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. A sponsor may decide to suspend or terminate its clinical trial, or regulatory agencies could order a sponsor to do so for several reasons, including, among others, failure to conduct the clinical trial in accordance with the regulatory requirements of a sponsor's study protocol and inspections of the clinical study operations or study sites by regulatory agencies that would reveal deficiencies or violations requiring a sponsor to undertake corrective actions (to the extent any are available).

If the Corporation incurs any delay in the conduct of a clinical trial or decides to suspend or terminate such trial, this could materially adversely affect the business prospects of the Corporation and its potential long-term revenues derived from the potential sale of its drug candidates. Any delay or suspension of a clinical trial may also adversely impact the duration of the protection afforded by the issuance of patents covering the drug candidate subject to such clinical trial and lead to earlier entries of competitors in the market.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

Our patent protection related to the use of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy is scheduled to expire in August 2023. Until we can commercialize tesamorelin using the F8 Formulation, the FDA-approved use of tesamorelin for the treatment of lipodystrophy will no longer be patent protected and we may face direct competition from biosimilar versions of EGRIFTA SV®. If we face competition from biosimilar products, our revenues are likely to be reduced thus adversely affecting our revenue growth and results of operations.

The use of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy is patent protected in the United States until August 2023. Tesamorelin, the composition of matter, is no longer patent protected and the formulation of *EGRIFTA SV®* is not patent protected. If, and when approved, the Corporation will rely on the use of the F8 Formulation to benefit from patent protection until 2033 in the United States in connection with the sale of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.

Although we are not aware that a company has filed any biosimilar version of tesamorelin with the FDA, nothing prevents a company from filing with the FDA a biosimilar version of tesamorelin using the same formulation as that of *EGRIFTA SV®* and to seek the same indication as that of *EGRIFTA SV®*.

If such a filing was made and the FDA were to approve a biosimilar version of *EGRIFTA SV®*, we would expect the price of that biosimilar to be lower than that of *EGRIFTA SV®* and we could have to lower our price in order to be able to compete with such biosimilar.

A lower price of *EGRIFTA SV*® would reduce our revenue and could have an adverse effect on our goal of achieving a positive Adjusted EBITDA by the end of the 2023 fiscal year. Even if were to introduce the F8 Formulation, such biosimilar version could still be a direct competitor to us, albeit with an older formulation of tesamorelin.

Our failure to protect our intellectual property may have a material adverse effect on our ability to develop and commercialize our products.

We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our intellectual property rights are covered and protected by valid and enforceable patents, trademarks and copyrights or are effectively maintained as trade secrets. We try to protect our intellectual property position by, among other things, filing patent applications and trademark applications related to our proprietary technologies, inventions, improvements and tradenames that are important to the development of our business.

Because the patent and trademark position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope, validity, and enforceability of patents and trademarks cannot be predicted with certainty. Patents and trademarks, if issued, may be challenged, invalidated or circumvented. For example, if our patents are invalidated or found to be unenforceable, we would lose the ability to exclude others from making, using or selling the inventions claimed. Moreover, an issued patent does not guarantee us the right to use the patented technology or commercialize a product using that technology. Third parties may have blocking patents that could be used to prevent us from developing our compounds, selling our products or commercializing our patented technology. Thus, patents that we own may not allow us to exploit the rights conferred by our intellectual property protection.

Our pending patent applications may not be issued or granted as patents. Even if issued, they may not be issued with claims of sufficient breadth to protect our product candidates and technologies or may not provide us with a competitive advantage against competitors with similar products or technologies. Furthermore, others may independently develop products or technologies similar to those that we have developed or may reverse engineer or discover our trade secrets through proper means. In addition, the laws of many countries do not protect intellectual property rights to the same extent as the laws of Canada, the United States and the European Patent Convention, and those countries may also lack adequate rules and procedures for defending intellectual property rights effectively.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties who have access to such confidential information, such as our current and prospective suppliers, distributors, manufacturers, commercial partners, employees and consultants. Any of these parties may breach the agreements and disclose confidential information to our competitors. It is possible that a competitor will make use of such information, and that our competitive position could be disadvantaged.

Enforcing a claim that a third party infringes on, has illegally obtained or is using an intellectual property right, including a trade secret or know-how, is expensive and time-

consuming and the outcome is unpredictable. In addition, enforcing such a claim could divert management's attention from our business. If any intellectual property right were to be infringed, disclosed to, or independently developed by, a competitor, our competitive position could be harmed. Any adverse outcome of such litigation or settlement of such a dispute could subject us to significant liabilities, could put one or more of our pending patent applications at risk of being invalidated or interpreted narrowly, could put one or more of our patents at risk of not issuing, or could facilitate the entry of generic products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, confidential information may be disclosed, inadvertently or as ordered by the court, in the form of documents or testimony in connection with discovery requests, depositions or trial testimony. This disclosure would provide our competitors with access to our proprietary information and may harm our competitive position.

Our commercial success depends, in part, on our ability not to infringe on third party patents and other intellectual property rights.

Our capacity to commercialize *EGRIFTA SV*® and Trogarzo® will depend, in part, upon our ability to avoid infringing third party patents and other third-party intellectual property rights. The biopharmaceutical and pharmaceutical industries have produced a multitude of patents and it is not always easy for participants, including us, to determine which patents cover various types of products, processes of manufacture or methods of use. The scope and breadth of patents is subject to interpretation by the courts and such interpretation may vary depending on the jurisdiction where the claim is filed and the court where such claim is litigated. For instance, the fact that we own patents for the treatment of HIV-related lipodystrophy in the United States and in other jurisdictions does not guarantee that we are not infringing one or more third-party patents in such country or in other jurisdictions and there can be no guarantee that we will not infringe or violate third-party patents and other third-party intellectual property rights in the United States or other jurisdictions.

Patent analysis for non-infringement is based in part on a review of publicly available databases. Although we review from time to time certain databases to conduct patent searches, we do not have access to all databases. It is also possible that we will not have reviewed some of the information contained in the databases or we found it to be irrelevant at the time we conducted the searches. In addition, because patents take years to issue, there may be currently pending applications that have not yet been published or that we are unaware of, which may issue later as patents. As a result, there can be no guarantee that we will not violate third-party patents.

Because of the difficulty in analyzing and interpreting patents, there can be no guarantee that a third party will not assert that we infringe such third-party's patents or any of its other intellectual property rights. Under such circumstances, there is no guarantee that we would not become involved in litigation. Litigation with any third party, even if the allegations are without merit, is expensive, time-consuming and would divert management's attention from the daily execution of our business plan. Litigation implies that a portion of our financial assets would be used to sustain the costs of litigation instead of being allocated to further the development of our business.

If we are involved in patent infringement litigation, we would need to prevail in demonstrating that our products do not infringe the asserted patent claims of the relevant patent, that the patent claims are invalid or that the patent is unenforceable. If we are found to infringe a third-party patent or other intellectual property right, we could be required to enter into royalty or licensing agreements on terms and conditions that may not be favorable to us, and/or pay damages, including up to treble damages in the United States (for example, if found liable of willful infringement) and/or cease the development and commercialization of our product candidates. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property and to compete with us.

There may be issued patents that we are unaware of that our products may infringe, or patents that we believe we do not infringe but ultimately could be found to infringe. If we were to challenge the validity of a competitor's issued United States patent in a United States court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. We cannot guarantee that a court would find in our favour on questions of infringement and validity. Any finding that we infringe or violate a third-party patent or other intellectual property right could materially adversely affect our business, financial condition and operating results.

REGULATORY RISKS

We may be subject to enforcement action if we engage in the off-label promotion of EGRIFTA SV® or Trogarzo®.

Our promotional materials and training methods must comply with the *Federal Food, Drug and Cosmetic Act*, as amended, of the United States ("FFDCA"), as well as with other applicable laws and regulations, including restraints and prohibitions on the promotion of off-label, or unapproved, use. Physicians may prescribe our products for off-label use without regard to these prohibitions, as the FFDCA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training of company employees or agents constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, issue corrective action, or subject us to regulatory or enforcement actions, including but not limited to the issuance of an untitled letter or warning letter, and a judicial action seeking injunction, product seizure and civil or criminal penalties. It is also possible that other federal, state or non-U.S. enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Our reputation would also be damaged. Although our policy is to refrain from written or oral statements that could be considered off-label promotion of our products, the FDA could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

We are not allowed to conduct promotional activities related to *EGRIFTA SV®* and Trogarzo® in Canada and in Europe since none of those products have been approved in

this territory. Promotional activities may begin once a drug is approved by the heath authority of a country.

The pharmaceutical industry is highly regulated and pharmaceutical companies are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-kickback Statute and the federal False Claims Act.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include: (a) the federal healthcare program's anti-kickback law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs; (b) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; (c) the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; (d) the FFDCA and similar laws regulating advertisement and labeling; and (e) U.S. States' law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In the United States, the federal anti-kickback law has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce or reward prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most American states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws. Further, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty under the federal anti-kickback law without actual knowledge of the statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the U.S. government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition and operating results.

To enforce compliance with the federal laws, the U.S. Department of Justice ("DOJ"), scrutinizes interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time and resource consuming and can divert management's attention from the business. Additionally, if a healthcare provider settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips or items and gifts of value to prescribers, "sham" consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

In addition, there has been a recent trend of increased federal and state regulation on payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to certain healthcare professionals. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

If our activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our activities with regard to the commercialization of our products in the United States, which could harm the commercial sales of our products and materially affect our business, financial condition and results of operations. We cannot guarantee that we will be able to mitigate all operational risks. In addition, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on *EGRIFTA SV®,* Trogarzo® or their respective manufacturing processes, withdrawal of *EGRIFTA SV®* or Trogarzo® from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material adverse effect on our product sales, business and results of operations.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. U.S. federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial

condition. Any state or federal regulatory review of us or the third parties with whom we contract, regardless of the outcome, would be costly and time-consuming.

LITIGATION RISKS

If we fail to comply with our contractual obligations, undertakings and covenants under our agreements with our commercial partners and third-party service providers, we may be exposed to claims for damages and/or termination of these agreements, all of which could materially adversely affect the commercialization of EGRIFTA SV® and Trogarzo®, our capacity to generate revenues and management's attention to the development of our business.

We rely on third-party service providers for distribution and manufacturing activities related to *EGRIFTA SV*® and Trogarzo® in the United States. Under our agreements with our third-party service providers, we have assumed certain obligations, undertakings and covenants which, if breached by us and not remedied within the agreed upon periods, could expose us to claims for damages and/or termination of these agreements. If we are unable to meet our obligations under any of our agreements with such third-party service providers which results in termination of such agreements, this will materially adversely affect our business, financial condition and operating results since we rely on single third-party service providers, each of whom performing key services for the success of our business plan. Additionally, if such third-party service providers do not meet their obligations under agreements and we decide to litigate any breach or dispute any amount owed under our agreements, this might materially adversely affect our relationship with such third-party services providers which, in turn, could adversely affect our capacity and ability to deliver on our business plan.

If product liability lawsuits are brought against us, they could result in costly and time-consuming litigation and significant liabilities.

Despite all reasonable efforts to ensure the safety of our products we may be commercializing, it is possible that we or our commercial partners will sell products which are defective, to which patients react in an unexpected manner, or which are alleged to have side effects. The development, manufacture and sale of such products may expose us to potential liability, and the pharmaceutical industry has been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and operating results. A product liability claim could also tarnish our reputation, whether or not such claims are with or without merit.

If a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim and, if the claim is successful, damage awards may be substantial and/or may not be covered, in whole or in part, by our insurance. We may not have sufficient capital resources to pay the damages resulting from a judgment, in which case our creditors could levy against our assets. We may also be obligated to indemnify our commercial partners and third-party service providers as well as make payments to other parties with respect to product liability damages and claims. Defending any product liability claims, or indemnifying others against those claims, could require us to expend

significant financial and managerial resources and would have a material adverse effect on our reputation and our financial condition.

GEO-POLITICAL RISKS

A variety of risks associated with our international business relationships could materially adversely affect our business.

International business relationships in the United States, Europe, China, Taiwan and elsewhere subject us to additional risks, including: (a) disruptions of important government services; (b) differing regulatory requirements for drug approvals in foreign countries; (c) potentially reduced protection for intellectual property rights, including unexpected changes in the rules governing patents and their enforcement; (d) potential third-party patent rights in foreign countries; (e) the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market, with low or lower prices, rather than buying them locally; (f) unexpected changes in tariffs, trade barriers and regulatory requirements; (g) economic weakness, including inflation, or political instability, particularly in foreign economies and markets; (h) compliance with tax, employment, immigration and labor laws for employees traveling abroad; (i) foreign taxes; (j) foreign exchange contracts and foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; (k) workforce uncertainty in countries where labor unrest is more common than in the United States and Canada; (l) production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and (m) business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or epidemic such as the one related to the coronavirus.

These and other risks of international business relationships may materially adversely affect our business, financial condition and operating results.

OTHER RISKS RELATED TO OUR BUSINESS

We rely extensively on the information technology systems of third-party service providers to store data, such as personal identifiable information, regarding our commercial activities for EGRIFTA SV® and Trogarzo®. Security breaches and other disruptions to those information technology systems could cause a violation of privacy laws, exposing us to liability which could cause our business and reputation to suffer.

In the ordinary course of business, we rely upon information technology and networks, most of which are managed by third parties, to process, transmit and store electronic information to manage and support our business decisions and strategy. We have no control and access over the information technology systems of third-party service providers where most of this information is stored and we are unable to assess whether appropriate measures have been implemented to prevent or limit a security breach of their information technology systems.

We also use our information technology systems to collect and store proprietary data, such as those related to our intellectual property, customers, employees and suppliers.

In connection with our presence in Canada and Europe, we must comply with privacy laws and regulations of Québec and Europe. Both of those laws and regulations introduced data protection requirements relating to the consent of individuals to whom the personnel data relates, the information provided to the individuals, the security we must retain, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. These laws have increased the responsibility of all parties collecting personal data. We are currently reviewing and complementing our in-house policies and related procedures to ensure compliance with those laws. In the United States, there exists no federal laws regarding the protection of personal information and all such laws are State-regulated. With the addition of a sales and medical team in-house, we are in the process of assessing compliance with the privacy laws in each of the States where the bulk of our activities is conducted. However, there can be no guarantee that the Corporation will not be found to violate some of those laws as a result of the combination of our business activities in various jurisdictions and the complexity of those laws and their interpretations.

The secure and uninterrupted operation of third-party information technology systems and of ours is material to our business operations and strategy. More and more businesses are subject to information technology system intrusion for which cyber-terrorists often use ransomware to demand payment of a ransom to allow those businesses to regain access to its data. Despite the measures that we have implemented against unwanted intrusion by third parties, there can be no guarantee that our systems could resist to a cyber-attack. Unauthorized access to data files held in our information technology systems or those of third parties could result in inappropriate use, change or disclosure of sensitive and/or personal data of our customers, employees, suppliers and patients. Any such access, disclosure or other loss of information could subject us to litigation, regulatory fines, penalties or reputational damages, any of which could have a material adverse effect on our competitive position, reputation, business, financial condition and operating results.

We may require additional funding and may not be able to raise the capital necessary to fund all or part of our capital requirements.

We may need financing in order to fund all or part of our capital requirements to sustain our growth, to develop our marketing and commercial capabilities, to in-license or acquire approved products, to meet our compliance obligations with various rules and regulations to which we are subject, and to conduct research and development activities related to our products. However, our business performance may prevent us from generating enough cash-flow to meet our obligations and the market conditions may also prevent us from having access to the public market in the future at the times or in the amounts necessary. Therefore, there can be no guarantee that we will be able to continue to raise additional capital by way of public or private offerings in the future. In such a case, we would have to use other means of financing, such as entering into private financing or, with the consent of Marathon, credit agreements, the terms and conditions of which may not be favorable to us. In addition, the issuance and sale of substantial amounts of equity, or other securities, or the perception that such issuances and sales may occur could adversely affect the market price of our Common Shares.

We depend on our current personnel to pursue our business plan and the loss of our key employees and the inability to attract and hire highly qualified individuals to replace the loss of our current key employees could have a material adverse effect on our business and growth potential.

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our key employees and on our ability to be able to attract, retain and motivate qualified commercial, medical, regulatory and scientific personnel. We have entered into employment agreements with our executive officers and provided them, as well as to other key employees, with long-term incentives as a retention mechanism, but such agreements and incentives do not guarantee that our executive officers and other key employees will remain employed by us for any significant period of time, or at all. In addition, we have a limited workforce to pursue our business plan and the loss of any of our key employees could materially adversely affect our business. We have recently hired a team comprised of key account managers and medical science liaison personnel and the loss of any of those individuals and our inability to attract and retain them could have a material adverse effect on our commercial and medical activities related to *EGRIFTA SV*® and Trogarzo®, and, accordingly, on our business, financial condition and operating results. In addition, it could adversely affect the market price of our Common Shares.

There is intense competition for qualified personnel in the areas of our activities, and we and our third-party service providers may not be able to continue to attract and retain the qualified personnel necessary for the growth of our business. Our failure and the failure of our third-party service providers to attract and retain such personnel could impose significant limits on our business operations and hinder our ability to successfully and efficiently realize our business plan.

We may not achieve our publicly announced financial, milestones or our commercial objectives on time.

In January 2023, we announced revenue guidance for the fiscal year ended November 30, 2023, in the range of $90 million to $95 million. From time to time, we publicly announce the timing of certain events to occur or the attainment of certain commercial objectives. These statements are forward-looking and are based on the best estimate of management at the time, relating to the achievement of such guidance or to the occurrence of such events. However, the actual timing of such events or our ability to achieve these objectives may differ from what has been publicly disclosed. Events such as beginning of commercialization of a product, levels of sales, revenues and other financial metrics may vary from what is publicly disclosed. These variations may occur as a result of a series of events, including problems with a supplier or a commercial partner, change in the procurement policy of a commercial partner or any other event having the effect of delaying the publicly announced timeline or reducing the publicly announced commercial objective. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of certain events having the effect of postponing such events or any variation in the occurrence of certain events having the effect of altering publicly announced commercial objectives could have a material adverse effect on our business, financial condition and operating results. In addition, it could adversely affect the market price of our Common Shares.

In connection with the reporting of our financial results, we are required to make estimates and assumptions, which involve uncertainties and any significant differences between our estimates and actual results could have an adverse impact on our reported financial position, operating results and cash flows.

The preparation of our consolidated financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, our management evaluates our critical and other significant estimates and assumptions, including among others, those associated with revenue and sales allowances and chargebacks, recoverability of inventories, estimation of accruals for clinical trial expenses, measurement and recoverability of intangible assets, the measurement of derivative financial assets, and the measurement of share-based arrangements. Any significant differences between our actual results and our estimates and assumptions could negatively impact our reported financial position, operating results and cash flows.

If actual future payments for allowances for discounts, returns, rebates and chargebacks exceed the estimates the Corporation made at the time of the sale of its products, its financial position, results of operations, and cash flows may be negatively impacted.

Pursuant to the Corporation's accounts and revenue recognition policies, the product revenue recognized quarter over quarter by the Corporation is net of estimated allowances for discounts, returns, rebates and chargebacks, including potential clawbacks in certain jurisdictions when pricing terms are based on temporary use authorisations and thus subject to future negotiations. Such estimates require subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Based on industry practice, pharmaceutical companies, including the Corporation, have liberal return policies, sometimes making it difficult to estimate the timing and amount of expected revenues.

A chargeback is the difference between the price the wholesaler pays the Corporation (wholesale acquisition cost) and the price that the wholesaler's customer pays for the Corporation's product (contracted customer). The Corporation's products were subject to certain programs with federal government qualified entities whereby pricing on products is discounted to such entities and results in a chargeback claim to the Corporation, or for the Corporation to bill certain qualifying Public Health Service end-users at government-mandated pricing. To the extent that the Corporation's sales to discount purchasers, such as federal government qualified entities, increases, chargeback claims will also increase. There may be significant lag time between the Corporation's original sale to the wholesaler and the Corporation's receipt of the corresponding government chargeback claims from the Corporation's wholesalers.

The Corporation's products are subject to state government-managed Medicaid programs, whereby rebates for purchases are issued to participating state governments. These rebates arise when the patient treated with the Corporation's products is covered under Medicaid. The Corporation's calculations require the Corporation to estimate end-user and patient mix to determine which of its sales will likely be subject to these rebates. There is a significant time lag in the Corporation receiving

these rebate notices (generally several months after its sale is made). The Corporation's estimates are based on its historical claims from participating state governments, as supplemented by management's judgment.

Although the Corporation believes that it has sufficient allowances, actual results may differ significantly from its estimated allowances for discounts, returns, rebates and chargebacks. Changes in estimates and assumptions based upon actual results may have a material impact on its financial condition, results of operations and cash flows. Such changes to estimates will be made to the financial statements in the period in which the estimate is changed. In addition, the Corporation's financial position, results of operations and cash flows may be negatively impacted if actual future payments for allowances, discounts, returns, rebates and chargebacks exceed the estimates the Corporation made at the time of the sale of its products.

We have identified a material weakness in our internal controls over financial reporting for the fiscal year ended November 30, 2022 in connection with the documentation of the analysis and relating to the monitoring of certain conditions and covenants included in the Marathon Credit Facility. A material weakness may hamper our ability to meet our reporting obligations and could result in a material misstatement in the Corporation's financial statements. As a result, the trading price of our Common Shares could be negatively affected.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that we are unable to comply with our reporting obligations and/or that the financial information we report contains material errors. Any of those events could materially adversely affect the trading price of our Common Shares. A failure to comply with our reporting requirements could also subject us to sanctions and/or investigations by securities regulatory authorities.

We have identified a material weakness in our internal controls over financial reporting for the fiscal year ended November 30, 2022, in connection with the documentation of the analysis and relating to the monitoring of certain conditions and covenants included in the Marathon Credit Facility. This control failure caused ineffective controls over the assessment of going concern uncertainty, including the underlying financial data and assumptions supporting the forecasted financial information utilized to prepare projected cash flows and liquidity requirements to comply with some of the covenants in the Marathon Credit Facility. The Corporation's management team has initiated and continues to implement remediation measures designed to ensure that control deficiencies contributing to the material weakness are remediated, such that these controls are designed, implemented and operating efficiently. While the Corporation expects these remediation measures to be completed in the fiscal year 2023, it cannot be certain when the remediation will be completed. If the Corporation fails to fully remediate this material weakness or fails to maintain effective internal controls in the future, it could result in a material misstatement of the Corporation's financial statements, which could cause investors to lose confidence in the Corporation's financial statements and cause the trading price of its Common Shares to decline.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under Canadian securities laws to report annually on our internal control over financial reporting. We are not currently required, and do not, obtain an audit of our internal controls over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met.

RISKS RELATED TO OUR COMMON SHARES

Our share price has been volatile, and an investment in our Common Shares could suffer a decline in value.

The Corporation's Common Shares are listed on the TSX and on the Nasdaq. The market price of the Common Shares on the Nasdaq and the TSX has fluctuated significantly in the past and the Corporation expects the market prices to continue to fluctuate in the future, and such prices may decline. For example, since the Corporation's listing of its Common Shares on Nasdaq to December 31, 2022, the Corporation's closing share price on Nasdaq has ranged from a low of $0.8262 to a high of $11.23. Consequently, you may not be able to sell your Common Shares at prices equal to or greater than the price paid by you. In addition, the market price of the Common Shares may be influenced by many factors, some of which are or may be beyond the Corporation's control, including: actual or anticipated variations in the Corporation's operating results and/or research and development activities; announcements by the Corporation or the Corporation's competitors of significant contracts or acquisitions; additions and departures of key personnel; announcement or expectation of additional financing efforts; impairment of assets; changes in accounting principles; changes in the general market and economic conditions; future sales of the Common Shares; the failure of financial analysts to initiate or maintain coverage of the Common Shares, changes in financial estimates by financial analysts, or any failure by the Corporation to meet or exceed any of these estimates, or changes in the recommendations of any financial analysts that elect to follow the Common Shares or the shares of the Corporation's competitors; and investor perceptions of the Corporation and the industry in which the Corporation operates.

In addition, stock markets, in general, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors may materially harm the market price of the Common Shares, regardless of the Corporation's operating performance. Dual listing of the Common Shares on the Nasdaq and the TSX may increase share price volatility on both exchanges because trading is in the two markets, which may result in less liquidity on both exchanges. In addition, different liquidity levels, volumes of trading, currencies and market conditions on the two exchanges may result in different prevailing trading prices. In the past, following periods of volatility in the market price of certain companies' securities, securities class action litigation has sometimes been instituted against these companies. This litigation, if instituted against the Corporation, could adversely affect the financial condition or results of operations of the Corporation.

The liquidity of our Common Shares is uneven and oftentimes scarce and shareholders desiring to purchase or sell Common Shares could be unable to, if the liquidity in our Common Shares is low.

The volume of Common Shares traded on the TSX and the Nasdaq has been uneven over time and is often low. Therefore, any investor who desires to purchase or sell Common Shares of the Corporation over the TSX or the Nasdaq may be unable to rapidly execute its order and, if the liquidity is low, the price at which such investor may purchase or sell Common Shares may be adversely affected by the lack of trading volume.

Our Common Shares may be delisted from the Nasdaq stock market if the minimum bid price of our Common Shares remains below US$1.00 per share for 30 consecutive trading days. The delisting of our Common Shares could reduce the liquidity in our Common Shares and could trigger a sell-off from U.S. shareholders. Any reduction in the liquidity of our Common Shares or a sell-off our Common Shares would result in a decline in the price of our Common Shares. Being delisted from the Nasdaq stock exchange could also adversely affect analysts coverage of our Common Shares and prevent us from retaining U.S. investment bankers to raise equity in public offerings.

Under Nasdaq minimum bid price requirement, the minimum bid price of our Common Shares may not remain below US$1.00 per share for 30 consecutive trading days. If such event occurs, the Corporation will receive a deficiency notice providing the Corporation with a 180-calendar day cure period from the date of the notice during which the minimum bid price of the Common Shares will have to be US$1.00 or more per share for ten consecutive business days in order to avoid delisting. If, at the expiry of the 180-calendar day cure period, the Corporation has not regained compliance with the minimum bid price requirement, the Corporation could be afforded an additional 180-calendar day cure period, provided that it meets certain conditions, one of which could be to undertake a reverse-split of its Common Shares to regain compliance with Nasdaq rules.

If the Common Shares of the Corporation are delisted from the Nasdaq stock market, the liquidity in our Common Shares could decrease and investors may have difficulties in buying or selling our Common Shares. In addition, a delisting of our Common Shares on the Nasdaq stock market could trigger a sell-off from current U.S-based shareholders whose internal policies could prevent them from holding securities of companies that are not traded on a U.S. stock market. Any sell-off by these shareholders could result in a material decline in the price of our Common Shares.

Finally, if the minimum bid price of the Common Shares were to be below US$1.00 per share for 30-consecutive trading days, there can be no assurance that the cure period provided by Nasdaq rules to regain compliance with the minimum bid price requirement would result in the Corporation regaining compliance with such rules in order to avoid a delisting of the Common Shares. Even if the Corporation was to proceed with a reverse-split of its Common Shares, there can be no assurance that the long term bid price of the Common Shares *post* reverse-split would meet the minimum bid price requirement of the Nasdaq stock market.

Our revenues and expenses may fluctuate significantly and any failure to meet financial expectations and/or our own financial guidance, if any, may disappoint

securities analysts or investors and result in a decline in the price of our Common Shares.

Our revenues and expenses have fluctuated in the past and are likely to do so in the future. These fluctuations could cause our share price to decline. Some of the factors that could cause revenues and expenses to fluctuate include the following: (a) the level of sales of *EGRIFTA SV*® in the United States; (b) the level of sales of Trogarzo® in the United States; (c) supply issues with *EGRIFTA SV*® or Trogarzo®; (d) default under the terms of the Marathon Credit Facility or our Notes; (e) the inability to adequately manage our liquidity; (f) the outcome of any litigation; (g) payment of fines or penalties for violations of laws; (h) foreign currency and/or interest rate fluctuations; (i) the timing of achievement and the receipt of milestone or royalty payments from future third parties; and (j) failure to enter into new or the expiration or termination of current agreements with third parties.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, or if we need to reduce our financial guidance, if any, the price of our Common Shares could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, the price of our Common Shares and trading volume may decline.

The trading market for our Common Shares will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our Common Shares, the lack of research coverage may adversely affect the market price of our Common Shares. Furthermore, if one or more of the analysts who do cover us downgrade our Common Shares or if those analysts issue other unfavorable commentary about us or our business, the price of our Common Shares would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our Common Shares could decrease, which in turn could cause our share price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

We do not intend to pay dividends on our Common Shares and, consequently, the ability of investors to achieve a return on their investment will depend on appreciation in the price of our Common Shares.

We have never declared or paid any cash dividend on our Common Shares and we do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. Therefore, the success of an investment in our Common Shares will depend upon any future appreciation in their value. There is no guarantee that our Common Shares will appreciate in value or even maintain the price at which our shareholders have purchased their shares.

Our shareholder rights plan and certain Canadian laws could delay or deter a change of control.

Our shareholder rights plan entitles a rights holder, other than a person or group holding 20% or more of our Common Shares, to subscribe for our Common Shares at a discount of 50% to the market price at that time, subject to certain exceptions.

The *Investment Canada Act* (Canada) subjects an acquisition of control of a company by a non-Canadian to government review if the value of the assets as calculated pursuant to the legislation exceeds a threshold amount. A reviewable acquisition may not proceed unless the relevant minister is satisfied that the investment is likely to be a net benefit to Canada.

Any of the foregoing could prevent or delay a change of control and may deprive or limit strategic opportunities for our shareholders to sell their shares.

The Corporation's report of independent registered public accounting firm (the "Auditors Report") to shareholders and the Board of Directors of the Corporation, as well as note 1 to the audited consolidated financial statements of the Corporation for the fiscal year ended November 30, 2022 contains a going concern note about the Corporation's ability to continue as a going concern and its capacity to honor its obligations as they fall due during a period of at least, but not limited to, 12 months from November 30, 2022. The going concern note casts substantial doubt about the capacity of the Corporation to meet its monetary obligations. The inclusion of a going concern note in the Corporation's Auditors Report triggers an event of default under the Marathon Credit Facility. However, in connection with the issuance of the Auditors Report for the fiscal year ended November 30, 2022, subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to exclude the inclusion of a going concern note in the Auditors Report of the Corporation, the effect of which has been to waive any default under the Marathon Credit Facility. There can be no assurance that additional amendments or waivers of such event of default will be obtained from Marathon in future years if the yearly Auditors Report of the Corporation contains a going concern note. In the event there occurs an event of default under the Marathon Credit facility, the interest rate payable on the loaned amount increases by 300 basis points and Marathon has the right to declare all amounts outstanding under the loan immediately due and payable and not fund any additional tranches under the Marathon Credit Facility. If Marathon was to declare all loaned amounts due and payable under the Marathon Credit Facility, the Corporation would not currently be able to repay such amount unless it secures additional financings. Therefore, the Corporation would have to issue additional equity or secure access to alternative funding enabling it to repay wholly the loaned amounts under the Marathon Credit Facility. The issuance of additional equity would dilute current shareholders and such dilution could be substantial depending on the amount of money the Corporation would have to raise and the price at which such equity offering would be made. In the event the Corporation is unable to implement measures allowing it to secure the repayment of its debt, the Corporation could also have to sell or liquidate its assets or resort to insolvency laws. A recourse to any of these alternatives would have a material adverse effect on the Corporation and its shareholders.

The Corporation's Auditors Report to the shareholders and Board of Directors, as well as note 1 to the audited consolidated financial statements of the Corporation for the fiscal

year ended November 30, 2022 contains a going concern note about the Corporation's ability to continue as a going concern and the capacity of the Corporation to realize its assets and discharge its liabilities and commitments in the normal course of business. The going concern note casts doubt about the capacity of the Corporation to meet its monetary obligations. For the year ended November 30, 2022, the Company incurred a net loss of $47.2 million and had negative operating cash flows of $14.7 million. The Corporation's total current liabilities exceeded total current assets at November 30, 2022. The Corporation's outstanding $27.5 million convertible unsecured senior notes mature on June 30, 2023 (the "Notes") requiring the Corporation to use its cash balance to repay the principal of the Notes.

The Marathon Credit Facility contains various covenants, including a prohibition on the inclusion of a going concern note in the Corporation's Auditors Report. The inclusion of a going concern note in the Corporation's Auditors' Report related to the Corporation's audited consolidated financial statements would trigger an event of default under the Marathon Credit Facility resulting in the interest rate payable on any outstanding loaned amount to be increased by 300 basis points and would allow Marathon to declare such principal amount and interest thereon immediately due and payable. Marathon would also no longer have the obligation to fund any additional tranches under the Marathon Credit Facility and would have the option to foreclose on all of the assets of the Corporation pursuant to the liens registered against all of the assets of the Corporation.

Subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to exclude the inclusion of a going concern note in the Auditors Report of the Corporation for the fiscal year ended November 30, 2022, the effect of which has been to waive any default under the Marathon Credit Facility. There can be no assurance that Marathon will agree to amend the Marathon Credit Facility or grant a waiver in future years if the Corporation's future Auditors Report include a going concern note. The failure to amend the Marathon Credit Facility or to obtain a waiver from Marathon in future years in the event additional going concern notes are included in the Corporation's Auditors Reports could have a material adverse effect on the Corporation and its business prospects in the event Marathon declares all principal amounts and interest thereon immediately due and payable and the Corporation is unable to repay the loaned amounts.

An event of default under the Marathon Credit Agreement resulting in Marathon declaring all principal amount and interest thereon immediately due and payable would require the Corporation to seek and find alternative sources of financing. Such alternative sources of financing could be the issuance of equity, subject to then prevailing market conditions. The issuance of equity security would dilute shareholders and such dilution could be substantial depending on the price at which the equity offering would be made and the amount to be raised. If the Corporation was unable to secure additional financing to repay any of its outstanding loaned amount, the Corporation could have to sell or liquidate its assets or resort to insolvency laws. A recourse to any of these alternatives would have a material adverse effect on the Corporation and its shareholders.

We did not generate a profit from our operations in the fiscal year ended November 30, 2022. In addition, despite announcing our goal to achieve a positive Adjusted EBITDA by the end of the 2023 fiscal year, there can be no guarantee that we will achieve these milestones, nor that we will achieve profitability.

We have a history of net losses, including a net loss of $47.2 million for the fiscal year ended November 30, 2022. In the future, our profitability will mainly depend on our capacity to maintain the commercialization of *EGRIFTA SV*® and Trogarzo® successfully in the United States through a low-cost and effective distribution network, the recruitment and retention of talented personnel, the deployment of an effective marketing campaign and through continued reimbursement coverage for *EGRIFTA SV*® and Trogarzo® under U.S. Medicare and Medicaid programs and under private-health insurers programs in the United States. Our profitability will also depend on our ability and capacity to control our operating expenses.

There is no guarantee that we will continue succeeding in growing sales of *EGRIFTA SV*® and Trogarzo® in the United States. If revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, financial condition and operating results could be materially adversely affected and we may never obtain or sustain profitability.

We may not be able to generate sufficient cash from our operating activities to service our debt obligations.

Our ability to repay the $27.5 million outstanding Notes due on June 30, 2023 requires that we access the $20 million second tranche of the loan under the Marathon Credit Facility or obtain alternative equity financing in the near term and also depends on our future financial and operating performance to avoid, among other things, being in default under the Marathon Credit Facility. Future financial and operating performance remain subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We may be unable to achieve a level of positive cash flows from operating activities sufficient to pay the principal and interest on the loan provided by Marathon or our Notes. Furthermore, if our share price remains below the conversion price of the Notes, the Notes are unlikely to be converted and we will have to pay all accrued interest thereon and their principal on their maturity date (June 30, 2023) and, therefore, we need to ensure we have adequate cash resources available by June 30, 2023, to repay the Notes and to continue our operations.

To mitigate the aforementioned risk, subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to remove as a condition to accessing the $20 million second tranche of the loan, being the filing to the FDA of the results of the HFS the Corporation is currently conducting. Notwithstanding the removal of this condition, access to the $20 million second tranche remains subject to compliance by June 30, 2023 with a twelve-month revenue target of $75 million and other covenants. As a result, there remain risks under the Marathon Credit Facility that the Corporation will not be able to access the second tranche for the repayment of the Notes on June 30, 2023 since a default under the Marathon Credit Facility, unless waived by Marathon, prevents the Corporation from borrowing additional money.

For the year ended November 30, 2022, the Corporation had negative operating cash flows of $14.7 million. In addition, the Corporation had a working capital deficiency (total current liabilities exceed total current assets) at November 30, 2022 of $40.9 million due in part to the amount borrowed under the Marathon Credit Facility being classified as a current liability as a result of the amendment to the Marathon Credit Facility having been entered into after the fiscal year end of the Corporation. If our cash flows and capital

resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay expenditures and capital additions, seek additional capital or restructure or refinance our debt. These measures may not be successful and may not permit us to meet our scheduled debt service obligations. In the absence of such cash flows and resources or in the absence of accessing the $20 million second tranche, we could face substantial liquidity problems and we could have to resort to insolvency laws to seek protection from our creditors.

Interest rate fluctuations may have a material adverse effect on our capacity to reimburse the loaned amounts under the Marathon Credit Facility and on our capacity to execute on our business plan.

The interest rate we have to pay Marathon under the Marathon Credit Facility is based on the Secured Overnight Financing Rate ("SOFR"), plus 9.5%.

SOFR is a broad measure of the cost of borrowing cash overnight collateralized by U.S. Treasury securities. SOFR has a limited history, and the future performance of SOFR cannot be predicted based on its limited historical performance. The level of SOFR may bear little or no relation to historical actual or indicative data. Prior observed patterns, if any, in the behavior of market variables and their relation to SOFR, such as correlations, may change in the future. While some pre-publication historical data have been released by the Federal Reserve Bank of New York, such analysis inherently involves assumptions, estimates and approximations, and hypothetical or historical performance data are not indicative of, and have no bearing on, the potential performance of SOFR. The future performance of SOFR is therefore impossible to predict, and no future performance of SOFR may be inferred from any of the historical actual or indicative data. Changes in the levels of SOFR will affect the interest rate we have to pay to Marathon under the Marathon Credit Facility during the term of the loan and may adversely affect the amount of cash we will have to allocate to the repayment of the loan.

Interest rates are highly sensitive to many factors, including governmental monetary policies, domestic and international economic and political conditions, and other factors beyond our control. If SOFR increases as a result of events over which we have no control, this could have a material adverse effect on our financial condition and results of operations. If SOFR increases, our debt service obligations would increase even if the amount borrowed remained the same, and our net income and cash flows, including cash available for servicing our indebtedness, will correspondingly decrease.

The Marathon Credit Facility includes significant operating and financial restrictions on the Corporation, any of which could prevent us from capitalizing on business opportunities. In addition, our failure to comply with such restrictions could trigger an event of default which would increase by 300 basis points the interest payable on any loaned amounts under the Marathon Credit Facility and would allow Marathon to declare the outstanding loaned amounts immediately due and payable in addition to providing Marathon with the right to foreclose on all of the assets of the Corporation pursuant to the liens registered against all of the assets of the Corporation. If we are unable to cure an event of default or obtain a waiver from Marathon in relation to such event of default, and if we do not have the financial capacity to repay any amount loaned becoming due and payable, we may have to cease our operations and to resort to insolvency laws.

The Marathon Credit Facility governing our outstanding $40 million loan and potential additional tranches which may be drawn thereunder impose significant operating and financial restrictions on the Corporation. These restrictions limit our ability and the ability of certain of our subsidiaries to, among other things: (i) incur or guarantee additional debt or issue disqualified stock or preferred stock; (ii) pay dividends and make other distributions on, or redeem or repurchase, capital stock; (iii) make certain investments; (iv) incur additional liens; (v) enter into transactions related to the acquisition, disposition, in-licensing or out-licensing of assets; and (vi) merge or consolidate.

In addition, the Marathon Credit Facility imposes that we maintain a minimum of $20 million in cash and cash equivalent at all times. This minimum liquidity amount goes up to $30 million if we do not obtain the approval of the F8 Formulation by March 31, 2024. The minimum liquidity covenant restricts the management of the Corporation's liquidity and could increase the likelihood that the Corporation may not be able to meet its obligations as they become due. The Marathon Credit facility also imposes revenue targets on a quarterly basis. The Marathon Credit Facility further imposes reporting requirements on our business activities on a quarterly basis. These reporting requirements extend beyond those that we have to comply with under securities regulations and add a layer of complexity to our reporting obligations. The minimum liquidity covenant restricts the management of the Corporation's liquidity and increases the likelihood that the Corporation may not be able to meet its obligations as they become due. As a result of the restrictions and obligations described above, we will be limited as to how we conduct our business and we may be unable to enter into transactions that may be accretive to our business to compete effectively or to take advantage of new business opportunities. Debt financing opportunities will also be limited in the event that we are unable to raise capital through the issuance of equity. There can be no assurances that we will be able to maintain compliance with these requirements and covenants in the future and, if we fail to do so, that we will be able to obtain waivers from Marathon and/or amend the covenants contained in the Marathon Credit Facility to remove those obligations.

Our failure to comply with the covenants described above as well as other terms of our indebtedness will result in an event of default under the Marathon Credit Facility which, if not cured or waived, will result in an increase of 300 basis point on the interest payable on the outstanding loaned amount. An event of default under the Marathon Credit Facility would also allow Marathon to declare all loaned amounts immediately due and payable and entitle Marathon to execute on its first ranking security interest on all of our assets and foreclose on our assets. If we were to default under the Marathon Credit Facility and Marathon were to declare all amounts outstanding under the loan immediately due and payable, this would also trigger a default under the terms of the Notes. In the event there occurs an event of default under the Marathon Credit Facility and we are unable to cure such event of default or obtain a waiver from Marathon in relation thereto, and if we do not have the financial capacity to repay any amount loaned becoming due and payable, we may have to cease our operations and to resort to insolvency laws. Any of those circumstances will have a material adverse effect on shareholders as they will lose the entire value of their investment in the capital of the Corporation.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS

Our commercial success and revenue growth depend on the commercialization of EGRIFTA SV® and Trogarzo® in the United States; unsatisfactory future sales

levels of EGRIFTA SV® and Trogarzo® in the United States will have a material adverse effect on us.

Our ability to generate revenue and sustain growth is currently concentrated solely on the commercialization of EGRIFTA SV® and Trogarzo® in the United States. Our success in generating sales revenue from *EGRIFTA SV*® and Trogarzo® in the United States will depend on our capacity: (a) to pursue the deployment of a commercialization strategy that will be accepted by patients, healthcare professionals and third-party payors; (b) to maintain reimbursement coverage for *EGRIFTA SV*® and Trogarzo® by third-party payors; (c) to maintain the registration of *EGRIFTA SV*® and Trogarzo® on U.S. governmental forms as drugs available for purchase in the United States; (d) to ensure that adequate supplies of *EGRIFTA SV*® and Trogarzo® are available; (e) to maintain conflict-free relationships with our principal third-party suppliers of services, namely our manufacturers (TaiMed and Jubilant HollisterStier, General Partnership ("Jubilant")), our distributor in the United States (RxC Acquisition Company, LLC ("RxCrossroads")), as well as other specialized third parties; and (f) to defend our intellectual property rights regarding tesamorelin against third parties.

Our success in commercializing our products in the United States will also depend on our capacity to retain qualified, motivated and talented sales representatives and other key individuals instrumental in the commercialization of our products and the capacity of our third-party suppliers to comply with all laws and regulations applicable to the conduct of their respective businesses.

There can be no assurance that sales of our products to customers in the United States will increase in the future or that we will generate sales at a profitable level. If sales of our products decrease, our revenue would be adversely affected which, in turn, could materially adversely affect our business, financial condition and operating results.

Because we expect to be dependent on revenues solely from *EGRIFTA SV*® and Trogarzo® for the foreseeable future, any negative developments relating to these products, such as safety or efficacy issues, manufacturing issues, the introduction or greater acceptance of competing products, or adverse regulatory or legislative developments, or our inability to successfully manage any of the abovementioned factors, will have a material adverse effect on our business and our future business prospects.

RxCrossroads is our only client in the United States in connection with the sale of EGRIFTA SV® and Trogarzo® and a default or a dispute under our agreement, or its termination or non-renewal at term, would materially adversely affect our revenues, business and operating results.

More than 95% of our revenues are derived from the sale of our products to RxCrossroads that acts as our exclusive distributor in the United States. If our agreement with RxCrossroads is terminated, or is not renewed at term and we are unable to find another distributor prior to its term, or if we are in default or engaged in a dispute with RxCrossroads, our sales may be materially adversely impacted and our revenues could decrease substantially.

In addition, under the terms of our agreement with RxCrossroads, we agreed to reimburse RxCrossroads for chargebacks and other discounts that RxCrossroads may offer to its

clients. If RxCrossroads' clients omit to timely claim from RxCrossroads any discount they are entitled to, or if they make a mistake in assessing the types of discounts they are entitled to claim and they claim those discounts later in a year, we will have to refund RxCrossroads for such discounts to which RxCrossroads' clients are entitled to and this may materially adversely affect our level of revenues and operating results for the year.

We rely on third parties for the manufacture, distribution and commercialization of our products and such reliance may adversely affect our revenues, business and future business prospects if the third parties are unable or unwilling to fulfill their obligations.

We have a single third-party service provider for some of our core business activities pertaining to the commercialization of our products, namely their manufacturing and distribution. Any material issues such third-party service providers may encounter that relate to the provision of services to us would have a material adverse effect on our revenues, business and future business prospects since these third-party service providers may not be easily or rapidly replaced.

We do not own or operate manufacturing facilities for the production of *EGRIFTA SV®* and tesamorelin, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on Bachem Americas, Inc. ("Bachem") and Jubilant to manufacture and supply all of our required raw materials, drug substance and drug product for sales of *EGRIFTA SV®*. We will also rely on a single third-party supplier, Lyophilization Services of New England, Inc.("LSNE") for the manufacture of the F8 Formulation. Our agreement with Bachem has expired and we are currently renegotiating the terms and conditions of a new manufacturing agreement. Although we are in discussions with Bachem, our inventory of drug product is high and potential alternative suppliers and manufacturers have been identified, but we have not entered into any agreements with Bachem yet. Also, we have not qualified alternative manufacturers to date and no assurance can be given that such manufacturers will be qualified in the future or receive necessary regulatory approvals. The replacement of a third-party manufacturer is time-consuming and costly due to the required validation of their capabilities. The validation process includes an assessment of the capacity of such third-party manufacturer to produce the quantities that we may request from time to time, the manufacturing process and its compliance with current good manufacturing practice, or GMP, regulations. In addition, the third-party manufacturer would have to familiarize itself with our technology. Validation of an additional third-party manufacturer takes at least twenty-four (24) months and could take as long as thirty-six (36) months or more. If we fail to renegotiate the terms and conditions of the Bachem Agreement, we may no longer be able to rapidly manufacture tesamorelin for *EGRIFTA SV®*, for the F8 Formulation and for our potential Phase 2b/3 clinical trial in NASH. Despite our current level of inventory of tesamorelin, we could incur a shortage of tesamorelin by the time new manufacturers are qualified.

TaiMed is our sole supplier of Trogarzo®. TaiMed does not currently own or operate any manufacturing facilities for the production of Trogarzo® and must rely on its suppliers, WuXi and Samsung. We are not in a contractual relationship with WuXi and Samsung for Trogarzo® and, therefore, we may not be able to interact with any of them in the event they encounter issues which could adversely affect the supply of Trogarzo®. In such circumstances, we will need to rely on TaiMed to address any of those issues. We have

no control over the time and efforts that TaiMed will devote in finding solutions to supply issues if such were to occur, or any say on the solution itself. Any delay in addressing manufacturing issues or any solution to address a manufacturing problem that is not to our liking could have a material adverse effect on the supply and sale of Trogarzo® and, accordingly, materially adversely affect our revenues.

We do not have state licensure in the United States to distribute *EGRIFTA SV*®, Trogarzo® or any other product we may acquire or in-license and we have not made any application to obtain the licenses required in order to distribute a drug product in the United States. Our supply chain model is based upon that fact and the distribution of *EGRIFTA SV*® and Trogarzo® in the United States is done through RxCrossroads which currently holds all state licensure required to distribute a drug product in every American state. Although potential alternative third-party service providers have been identified to replace RxCrossroads in the event that it becomes unable to distribute *EGRIFTA SV*® and Trogarzo®, we have not entered into any agreements with them and no assurance can be given that such providers would enter into any agreement with us on terms satisfactory to us.

Syneos Health, Inc. ("Syneos") continues to provide us with support for the commercialization of *EGRIFTA SV*® and Trogarzo® in the United States through the provision of personnel as part of the managed market and reimbursement teams. Although we are aware that there exist other third-party services providers that could provide the same services as Syneos, we have not entered into any agreements with them nor conducted any audit on them. If we need to find another third-party service provider for some or all of the services provided by Syneos, it will be time-consuming and will be disruptive to our business. In addition, there can be no assurance that we will be able to find such third-party service provider if we are unable to agree on the terms and conditions of an agreement with them.

Finally, we may retain contract research organizations ("CROs") to support us with the conduct of clinical trials from time to time. These CROs will be tasked with the recruitment of patients, negotiations of clinical study agreements with various clinics and the monitoring of those clinics in connection with our clinical trials. If these CROs default on their covenants or are found, for instance, to be in violation of applicable laws, our clinical trials could be delayed, and any timelines set forth in our public communications could be wrong. In addition, if these CROs are found to be in violation of applicable laws, any data generated in the course of our clinical trials could be questioned by regulatory agencies and this could lead to a rejection of any data submitted to those regulatory agencies at the time of submitting a sBLA or NDA seeking the approval of our products.

Our reliance on single third-party service providers for some of our core business activities exposes us to a number of risks. For instance, we may be subject to delays in, or suspension of, the manufacturing of *EGRIFTA SV*®, the F8 Formulation and Trogarzo® if a third-party manufacturer: (a) becomes unavailable to us, or to TaiMed, for any reason, including as a result of the failure to comply with GMP regulations; (b) experiences manufacturing problems or other operational failures, such as labour disputes, equipment failures or unplanned facility shutdowns required to comply with GMP, or damage from any event, including fire, flood, earthquake, business restructuring, labour disputes or insolvency; or (c) fails to perform its contractual obligations under our agreement, such as

failing to deliver the quantities requested on a timely basis or not meeting product specifications.

We may also be subject to distribution disruption and interrupted sales of *EGRIFTA SV*® and Trogarzo® in the United States if: (a) RxCrossroads becomes unavailable to us for any reason, including as a result of its failure to meet applicable laws; (b) RxCrossroads experiences warehousing problems or other operational failure, such as unplanned facility shutdown or damage from any event, including fire, flood, earthquake, business restructuring or insolvency; or (c) RxCrossroads fails to perform its contractual obligations under our agreement.

We may be subject to a decrease in sales of our products in the United States or we may face reimbursement challenges if Syneos (a) becomes unavailable to us for any reason, including as a result of its incapacity to motivate and retain the employees working on the commercialization of *EGRIFTA SV*® and/or Trogarzo®; (b) experiences compliance issues with the FDA; or (c) fails to perform its contractual obligations under our agreement.

Significant safety problems may arise with respect to EGRIFTA SV® and Trogarzo® which could result in restrictions in EGRIFTA SV®'s or Trogarzo®'s label, product recall or withdrawal of any of our products from the market, any of which could materially adversely impact our business and our future business prospects.

New safety issues may arise as *EGRIFTA SV*® and Trogarzo® are used over longer periods of time by a wider group of patients, some of whom may be taking numerous other medicines, or may suffer from additional underlying health problems. Such safety issues could include an increase in the severity or frequency of known problems or the discovery of previously unknown problems and may result in a variety of adverse regulatory actions. Under U.S. laws, the FDA has broad authority over drug manufacturers to compel any number of actions if safety problems arise, including, but not limited to: (i) requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandating labeling changes to a product based on new safety information; or (iii) requiring manufacturers to implement a risk evaluation mitigation strategy where necessary to assure safe use of the drug. Similar laws and regulations exist in countries outside of the United States.

Previously unknown safety problems could also result in product recalls, or withdrawal of the products from the territory(ies) where they are approved for commercialization. If new safety issues are discovered, sales of *EGRIFTA SV*® and/or Trogarzo® may decrease and result in a material adverse effect on our business, financial condition and operating results.

Our levels of revenues are highly dependent on obtaining and maintaining patient reimbursement for EGRIFTA SV® and Trogarzo®.

Market acceptance and sales of *EGRIFTA SV*® and Trogarzo® substantially depend on the availability of reimbursement from third-party payors such as governmental authorities, including U.S. Medicare and Medicaid, managed care providers, and private insurance plans and may be affected by healthcare reform measures in the United States. Third-party payors decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment.

Government authorities and these third-party payors are attempting to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors have been challenging the prices charged for products. Third-party payors may decrease the level of reimbursement of a product or cease such reimbursement and the occurrence of any of these events could materially adversely affect the sales of *EGRIFTA SV*® and Trogarzo®.

Sales of *EGRIFTA SV*® and Trogarzo® to patients benefitting from U.S. Government funded reimbursement programs represent a significant part of our sales. Denial of coverage for any of those products under any of the current programs would materially adversely affect our revenues.

Even though EGRIFTA SV® and Trogarzo® are approved for sale in the United States, revenue that we generate from their sales may be limited.

Sales of *EGRIFTA SV*® and Trogarzo® will continue to depend upon the acceptance of such products by the medical community, including physicians, patients and third-party payors. The degree of market acceptance of these products will depend on a number of factors, including: (a) demonstrated product safety, including the prevalence and severity of side effects, and effectiveness as a treatment that addresses a significant unmet medical need; (b) storage requirements, dosing regimen and ease of administration; (c) the availability of competitive alternatives; (d) our ability to obtain and maintain sufficient third-party coverage for reimbursement from government health care programs, including U.S. Medicare and Medicaid, private health insurers and other third-party payors; (e) the willingness and ability of patients to pay out-of-pocket for medications; (f) the product price; and (g) the effectiveness of sales and marketing efforts.

If our products are not accepted by the marketplace, the revenue generated therefrom will be limited and our capacity to grow our revenue and become profitable will be hampered. Our failure to grow our revenue and to become profitable will adversely impact the value of the Corporation, including the market price of our shares. If we fail to achieve adequate sales, we may not generate sufficient revenue in order to become profitable.

We face competition and the development of new products by other companies could materially adversely affect our business and operating results.

The biopharmaceutical and pharmaceutical industries are highly competitive and we must compete with pharmaceutical companies, biotechnology companies, academic and research institutions as well as governmental agencies for the development and commercialization of products, most of which have substantially greater financial, technical and personnel resources than us. We believe there is currently few approved drug products competing directly with our approved products. However, with respect to Trogarzo®, we face competition from the approval of Fostemsavir and Lenacapavir in the United States. In addition, we are aware of other agents, including dolutegravir and darunavir, that are either indicated or commonly used in combination in regimens to treat heavily-treatment experienced patients with MDR HIV-1. With respect to *EGRIFTA SV*®, we face competition from companies selling human growth hormone, testosterone, insulin sensitizing agents, GLP-1 receptor agonists and sermorelin as those products may be prescribed by physicians. In addition, other approaches to reduce visceral adipose tissue

in the abdominal area include coping mechanisms such as lifestyle modification (diet and exercise), switching ARTs or liposuction.

The development of a vaccine against HIV or of any cure against HIV would have a material adverse effect on our business, operating results and financial conditions.

Although there exists no known vaccine and cure for HIV, we are aware that there are research and development activities carried out in order to eradicate this disease. We are also aware that a very low number of patients were cured from HIV. If a vaccine or a cure was found to prevent or cure HIV, sales of our products would be materially adversely impacted and our revenue growth would be hampered. The discovery of any vaccine or cure against HIV would have a material adverse effect on our business, operating results and financial condition.

RISKS RELATED TO RESEARCH AND DEVELOPMENT ACTIVITIES

The conduct of research and development activities is risky and results obtained therefrom may not be those anticipated. Therefore, there can be no assurance that any research and development plan on a product candidate or medical device will result in an approved drug or medical device.

The development of new therapies is highly risky and the results obtained therefrom may not yield any of the anticipated benefits. The development of a product candidate into a new drug requires the conduct of many tests on animals and humans, all of which must comply with stringent regulation and require substantial investments. There can be no assurance that any research and development program designed to develop a new formulation, a new drug, a new method or route of administration or provide a new treatment, such as the development of the F8 Formulation and the Pen, the development of tesamorelin for the potential treatment of NASH in the general population and the development of our peptide-drug conjugates resulting from our SORT1+ Technology™ platform, will end up generating positive results leading up to an approved formulation, label expansion, new medical device or a new product by a regulatory authority. The failure to develop a new formulation, a new method of treatment, a new method or route of administration or a drug product could hamper the future growth of our business and have long-term adverse effects on our potential revenues and operating results.

The development of TH1902 for the potential treatment of various types of sortilin-expressing cancers is still uncertain given that, after consultation with investigators, we have voluntarily paused the enrollment of patients in the Phase 1 clinical trial since efficacy results observed were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. The FDA has since placed the Phase 1 clinical trial of TH1902 on partial clinical hold and asked a series of questions to the Corporation requiring satisfactory responses thereto prior to resuming the Phase 1 clinical trial. If the Corporation is unable to answer the questions raised by the FDA to the FDA's satisfaction and if the Corporation is unable to resume its Phase 1 clinical trial with TH1902, the Corporation will have to discontinue its Phase 1 clinical trial. Any halt in the Corporation's Phase 1 clinical trial could materially adversely affect the development of its SORT1+ Technology™ platform and reduce its pipeline of drug

candidates, all of which would materially adversely affect its long-term growth and prospects.

The enrollment of patients in the Corporation's Phase 1 clinical trial evaluating TH1902 was voluntarily paused by the Corporation after consulting with its investigators. The efficacy results observed were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. The FDA has since placed the clinical trial on partial clinical hold and has issued a series of questions to the Corporation that will need to be answered to the satisfaction of the FDA prior to resuming the Phase 1 clinical trial. The Corporation has also formed a SAC to help determine the best developmental path forward for TH1902. The decision made by the Corporation illustrates that, to date, we have not been able to replicate results obtained from our preclinical *in vivo* work and that the conduct of clinical trials is risky as results may adversely vary from those that are expected.

If the Corporation is unable to resume its Phase 1 clinical trial with TH1902 because (i) it is unable to adequately answer to all of the questions raised by the FDA, (ii) the SAC is unable to agree on the best developmental path forward for TH1902, or (iii) the FDA does not accept the terms of an amended protocol, the development program of TH1902 will need to be halted. Any halt in the Corporation's Phase 1 clinical trial would materially adversely affect the development of its SORT1+ Technology™ platform and reduce its pipeline of drug candidates, all of which would materially adversely affect its long-term growth and prospects. Even if the Corporation is allowed to resume its Phase 1 clinical trial with TH1902, the Corporation may have difficulty enrolling new patients in the resumed trial. The difficulty in enrolling patients would cause additional delays in advancing the development of TH1902. In addition, there can be no guarantee that the results obtained from the resumed Phase 1 clinical trial would yield positive results. In the event that the resumed clinical trial did not yield positive results, the value associated to the SORT1+ Technology™ platform asset would be depreciated, thereby adversely impacting the market value of the Corporation, including the price of its Common Shares.

The conduct of research and development activities is very costly and capital intensive. We have already indicated that the development of tesamorelin for the treatment of NASH in the general population was on pause until we find a partner and that the development of TH1902 would be stage-gated in order to meet our goal of achieving a positive Adjusted EBITDA in the 2023 fiscal year. We have also indicated that we would assess a partnership for the development of TH1902 once the Phase 1 clinical trial has resumed. If we are unable to find a partner for the development of tesamorelin for the treatment of NASH or for the pursuit of the development of TH1902 once the Phase 1 clinical trial has resumed, we may have to cease the development of those assets, any of which could have a material adverse effect on our long-term potential revenue growth and business prospects.

The development of pharmaceutical products is very costly and capital intensive.

As a result of our assessment of the costs associated with our proposed Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population, we have decided to seek a partner prior to launching such trial. The contemplated development of tesamorelin for the treatment of NASH will require the enrollment of over 2,000 patients and the study will be conducted over many years. Therefore, we expect the

development of tesamorelin for the treatment of NASH in the general population to cost multiple millions of dollars.

Consistent with our objective of achieving a positive Adjusted EBITDA by the end of the current fiscal year and beyond, we also announced that the development of TH1902 would be stage-gated and that further to resuming the Phase 1 clinical trial, we would assess partnering the development of TH1902.

There can be no assurance that we will be able to find a partner for either the development of tesamorelin for the potential treatment of NASH or for the further development of TH1902. Finding a partner for those development programs will depend on a variety of factors, including the preclinical and clinical data that we have generated for those drug candidates, the current advancement of the programs and the risk related thereto, the regulatory path to seek approval of those drug candidates, the market environment related to NASH and oncology, competition from other products and general market conditions. In addition, even we were to find a partner for any of those programs, there can be no assurance that the terms and conditions contained in any partnership agreement would be suitable to us. The failure to find a partner for the development of tesamorelin for the potential treatment of NASH and the further development of TH1902 could lead to a halt in the development of those programs.

A complete halt in the conduct of those programs could adversely impact our long-term growth and business prospect since the Corporation would have a reduced pipeline of product candidates.

The Corporation has not filed a sBLA seeking the approval of the F8 Formulation and, consequently, the FDA has not approved the F8 Formulation as being bioequivalent to the Corporation's original formulation of EGRIFTA®. If the FDA does not approve the F8 Formulation, the Corporation may have to conduct additional clinical studies to prove the bioequivalence of the F8 Formulation against the original formulation, resulting in additional spending and delays in the use of the F8 Formulation.

The Corporation has conducted studies to assess the bioequivalence of the F8 Formulation against the original 1 mg/vial formulation of *EGRIFTA®*. These studies were conducted based on the current FDA regulation to show the bioequivalence of formulations. The Corporation has not yet filed a sBLA with the FDA seeking the approval of the F8 Formulation for commercial use although this is planned for 2023.

If the FDA does not approve the F8 Formulation as being bioequivalent to the original formulation, the Corporation would have to conduct additional testing using the F8 Formulation which would delay the time by which the Corporation could commercialize the F8 Formulation and which would require the Corporation to incur additional expenses and inventory write-downs, all of which could adversely affect the Corporation's financial condition or results of operations. Furthermore, the non-approval of the F8 Formulation would prevent the Corporation from pursuing the assessment of the development of the Pen, or any other device to be used with the F8 Formulation. Finally, the non-approval of the F8 Formulation would expose the Corporation to the entry of biosimilar versions of tesamorelin for the treatment of lipodystrophy given that the patent protection for this product will expire in August 2023. Since the F8 Formulation is patent protected until 2033

in the United States, the commercialization of tesamorelin for the treatment of lipodystrophy using the F8 Formulation could protect the entry of biosimilar versions until the expiry of this patent in 2033.

The Corporation has decided to seek a partner to conduct a Phase 2b/3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population. Although the Corporation has begun the search for a potential partner and preliminary discussions are ongoing, there can be no assurance that a partner will be found or that a partnership agreement will be entered into on terms satisfactory to the Corporation. If a partner is not found, the Corporation may have to cancel this program unless it has access to substantial financial resources to pursue such development program and there can be no guarantee that the Corporation will secure such substantial resources in an amount sufficient to initiate or complete the Phase 2b/3 clinical trial. Moreover, the FDA has issued comments and asked questions on the revised protocol filed by the Corporation in February 2022 and the Corporation has voluntarily decided not to reply to those comments and questions until it can find a partner. In addition, the Corporation's decision to design its Phase 2b/3 clinical trial to meet the FDA's primary endpoints may prevent the Corporation from seeking approval of tesamorelin for the treatment of NASH in the general population from the EMA since the primary endpoint for this agency is different from that of the FDA. If the Corporation is unable to find a partner to develop tesamorelin for the treatment of NASH in the general population or to secure substantial financial resources to do it on its own, the Corporation may cancel this program and the development of tesamorelin for the treatment of NASH may never occur. Even if the Corporation finds a partner, the conduct of the Phase 2b/3 clinical trial may be delayed or never begun if the Corporation is unable to properly address the comments and questions raised by the FDA based on the Corporation's amended protocol. Finally, if the Corporation is unable to meet the endpoints of its Phase 2b/3 clinical trial, it will not receive approval for tesamorelin for the treatment of NASH in the general population. Even if the Corporation meets the endpoints of the clinical trial, the FDA could issue a conditional approval letter such that if the Corporation is unable to meet the conditions contained in such letter, the Corporation could lose such approval. If the conduct of the clinical trial is cancelled, or if the Corporation does not receive approval for tesamorelin for the treatment of NASH in the general population, its potential long-term revenues, growth and prospects will be materially adversely affected.

In July 2021, we announced that the final Phase 3 clinical trial design would result in higher costs than what we had expected and, as a result, we were assessing our options to best execute this program, including seeking a potential partner. There are currently ongoing preliminary discussions with potential partners.

In February 2022, in order to de-risk the Phase 3 trial, the Corporation submitted an amended protocol to the FDA resulting in the FDA providing us with a list of questions and comments on this amended protocol. We have voluntarily decided not to respond to those questions and comments in order to address them with any potential partner we may find to optimize the design, if deemed relevant. The amended protocol includes a Phase 2b/3 seamless study design where the first 350 or so patients' data will be analyzed by a data monitoring committee to assess the efficacy of tesamorelin on a smaller subset of patients. The amended protocol would allow us to generate hard endpoint data on NAS score and

fibrosis. A decision would then be made whether to continue the study until the full number of patients (1,094) have completed 18 months of treatment. These amendments would not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH, but it would inform the continuation of enrollment while providing an indication of benefit to patients.

There can be no guarantee that tesamorelin will be studied for the treatment of NASH in the general population if the Corporation is unable to find a partner to conduct the development program on its own. Even if the Corporation finds a partner, the terms and conditions pursuant to which such partner may be interested in assisting the Corporation may not be satisfactory to the Corporation or may be unfavorable. Under such circumstances, the Corporation may decide to forego the development of tesamorelin for the treatment of NASH in the general population or turn to alternative sources of financing. If the Corporation is unable to, or does not proceed with, the development of tesamorelin for the treatment of NASH in the general population, it could have a material adverse effect on its potential long-term revenues, growth and business prospects.

Even if the Corporation finds a partner to initiate a Phase 2b/3 clinical trial, there can be no guarantee that the FDA will be satisfied with the responses to the questions and comments asked in connection with the amendments to the protocol filed in February 2022 and allow the initiation of such trial. Even if the FDA or any other regulatory agency approves the study of tesamorelin for the treatment of NASH in the general population, there can be no guarantee that the results will meet the endpoints of the study and that tesamorelin will be approved for such treatment. Even if the Corporation meets the FDA's primary endpoints and approval is received from the FDA, such approval may be conditioned on conducting additional studies which, if not conducted or if the results therefrom are not positive on certain clinical outcomes, could result in the FDA withdrawing its approval for the use of tesamorelin for the treatment of NASH in the general population.

The Corporation has decided to design its Phase 2b/3 clinical trial based on the FDA guidelines requiring it to demonstrate "NASH resolution and no worsening of fibrosis" as primary endpoints. This trial design does not follow the current EMA guidelines which require a sponsor to demonstrate both (i) NASH resolution and no worsening of fibrosis and (ii) improvement of fibrosis by one stage without worsening of NASH as primary endpoints. Therefore, even if the Corporation meets the primary endpoints for FDA purposes, the EMA may not approve tesamorelin for the treatment of NASH in this territory since the trial was not designed to demonstrate both endpoints.

If the Corporation is unable to obtain approval of tesamorelin for the treatment of NASH in the United States, this would have material adverse effects on its revenues, financial results and long-term growth and prospects. In addition, even if the FDA approves tesamorelin for the treatment of NASH, the lack of an approval in Europe will limit the Corporation's ability to maximize its revenue growth potential, therefore potentially hampering its long-term growth and prospects.

The conduct of clinical trials is subject to a variety of risks, many of which can be beyond the control of the Corporation forcing it to delay the initiation or conduct of clinical trials or forego same.

The beginning or completion of clinical trials may be delayed or prevented for several reasons, including, among others: (a) negative results from the Corporation's clinical trial resulting in a failure to meet the endpoints of its clinical trial; (b) delays in reaching or failing to reach agreement on acceptable terms with clinical study sites, the terms of which can be subject to considerable negotiation and may vary significantly among different study sites; (c) any breach of the terms of any contract research organization agreement by us or by our third-party suppliers that have responsibility to assist us with the conduct of our clinical trials; (d) inadequate quantity or quality of the active pharmaceutical ingredient or other materials necessary to conduct clinical trials; (e) challenges in recruiting and enrolling patients to participate in clinical trials, such as the proximity of patients to study sites, eligibility criteria to be included in a clinical trial, the nature of a clinical trial and the competition from other clinical study programs for the treatment of similar diseases as those the Corporation may seek to treat; (f) severe or unexpected adverse drug effects experienced by patients; (g) regulatory agencies requiring a sponsor to conduct additional clinical studies prior to approving a new drug application, a sBLA, or the equivalent thereof in other jurisdictions after review of Phase 3 clinical trial results; (h) regulatory agencies may disagree with a sponsor 's interpretation of data resulting from its Phase 3 clinical trials, or may change the requirements for approval even after they have approved the sponsor's Phase 3 clinical trial design; and (i) difficulties in retaining patients who have enrolled in a sponsor's Phase 3 clinical trial but who may be prone to withdraw due to rigours of the clinical trial, lack of efficacy, side effects, personal issues or loss of interest.

In addition, clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. A sponsor may decide to suspend or terminate its clinical trial, or regulatory agencies could order a sponsor to do so for several reasons, including, among others, failure to conduct the clinical trial in accordance with the regulatory requirements of a sponsor's study protocol and inspections of the clinical study operations or study sites by regulatory agencies that would reveal deficiencies or violations requiring a sponsor to undertake corrective actions (to the extent any are available).

If the Corporation incurs any delay in the conduct of a clinical trial or decides to suspend or terminate such trial, this could materially adversely affect the business prospects of the Corporation and its potential long-term revenues derived from the potential sale of its drug candidates. Any delay or suspension of a clinical trial may also adversely impact the duration of the protection afforded by the issuance of patents covering the drug candidate subject to such clinical trial and lead to earlier entries of competitors in the market.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

Our patent protection related to the use of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy is scheduled to expire in August 2023. Until we can commercialize tesamorelin using the F8 Formulation, the FDA-approved use of tesamorelin for the treatment of lipodystrophy will no longer be patent protected and we may face direct competition from biosimilar versions of EGRIFTA SV®. If we face competition from biosimilar products, our revenues are likely to be reduced thus adversely affecting our revenue growth and results of operations.

The use of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy is patent protected in the United States until August 2023. Tesamorelin, the composition of matter, is no longer patent protected and the formulation of *EGRIFTA SV*® is not patent protected. If, and when approved, the Corporation will rely on the use of the F8 Formulation to benefit from patent protection until 2033 in the United States in connection with the sale of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.

Although we are not aware that a company has filed any biosimilar version of tesamorelin with the FDA, nothing prevents a company from filing with the FDA a biosimilar version of tesamorelin using the same formulation as that of *EGRIFTA SV*® and to seek the same indication as that of *EGRIFTA SV*®.

If such a filing was made and the FDA were to approve a biosimilar version of *EGRIFTA SV*®, we would expect the price of that biosimilar to be lower than that of *EGRIFTA SV*® and we could have to lower our price in order to be able to compete with such biosimilar. A lower price of *EGRIFTA SV*® would reduce our revenue and could have an adverse effect on our goal of achieving a positive Adjusted EBITDA by the end of the 2023 fiscal year. Even if were to introduce the F8 Formulation, such biosimilar version could still be a direct competitor to us, albeit with an older formulation of tesamorelin.

Our failure to protect our intellectual property may have a material adverse effect on our ability to develop and commercialize our products.

We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our intellectual property rights are covered and protected by valid and enforceable patents, trademarks and copyrights or are effectively maintained as trade secrets. We try to protect our intellectual property position by, among other things, filing patent applications and trademark applications related to our proprietary technologies, inventions, improvements and tradenames that are important to the development of our business.

Because the patent and trademark position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope, validity, and enforceability of patents and trademarks cannot be predicted with certainty. Patents and trademarks, if issued, may be challenged, invalidated or circumvented. For example, if our patents are invalidated or found to be unenforceable, we would lose the ability to exclude others from making, using or selling the inventions claimed. Moreover, an issued patent does not guarantee us the right to use the patented technology or commercialize a product using that technology. Third parties may have blocking patents that could be used to prevent us from developing our compounds, selling our products or commercializing our patented technology. Thus, patents that we own may not allow us to exploit the rights conferred by our intellectual property protection.

Our pending patent applications may not be issued or granted as patents. Even if issued, they may not be issued with claims of sufficient breadth to protect our product candidates and technologies or may not provide us with a competitive advantage against competitors with similar products or technologies. Furthermore, others may independently develop products or technologies similar to those that we have developed or may reverse engineer or discover our trade secrets through proper means. In addition, the laws of many

countries do not protect intellectual property rights to the same extent as the laws of Canada, the United States and the European Patent Convention, and those countries may also lack adequate rules and procedures for defending intellectual property rights effectively.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties who have access to such confidential information, such as our current and prospective suppliers, distributors, manufacturers, commercial partners, employees and consultants. Any of these parties may breach the agreements and disclose confidential information to our competitors. It is possible that a competitor will make use of such information, and that our competitive position could be disadvantaged.

Enforcing a claim that a third party infringes on, has illegally obtained or is using an intellectual property right, including a trade secret or know-how, is expensive and time-consuming and the outcome is unpredictable. In addition, enforcing such a claim could divert management's attention from our business. If any intellectual property right were to be infringed, disclosed to, or independently developed by, a competitor, our competitive position could be harmed. Any adverse outcome of such litigation or settlement of such a dispute could subject us to significant liabilities, could put one or more of our pending patent applications at risk of being invalidated or interpreted narrowly, could put one or more of our patents at risk of not issuing, or could facilitate the entry of generic products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, confidential information may be disclosed, inadvertently or as ordered by the court, in the form of documents or testimony in connection with discovery requests, depositions or trial testimony. This disclosure would provide our competitors with access to our proprietary information and may harm our competitive position.

Our commercial success depends, in part, on our ability not to infringe on third party patents and other intellectual property rights.

Our capacity to commercialize *EGRIFTA SV*® and Trogarzo® will depend, in part, upon our ability to avoid infringing third party patents and other third-party intellectual property rights. The biopharmaceutical and pharmaceutical industries have produced a multitude of patents and it is not always easy for participants, including us, to determine which patents cover various types of products, processes of manufacture or methods of use. The scope and breadth of patents is subject to interpretation by the courts and such interpretation may vary depending on the jurisdiction where the claim is filed and the court where such claim is litigated. For instance, the fact that we own patents for the treatment of HIV-related lipodystrophy in the United States and in other jurisdictions does not guarantee that we are not infringing one or more third-party patents in such country or in other jurisdictions and there can be no guarantee that we will not infringe or violate third-party patents and other third-party intellectual property rights in the United States or other jurisdictions.

Patent analysis for non-infringement is based in part on a review of publicly available databases. Although we review from time to time certain databases to conduct patent searches, we do not have access to all databases. It is also possible that we will not have reviewed some of the information contained in the databases or we found it to be irrelevant at the time we conducted the searches. In addition, because patents take years to issue, there may be currently pending applications that have not yet been published or that we are unaware of, which may issue later as patents. As a result, there can be no guarantee that we will not violate third-party patents.

Because of the difficulty in analyzing and interpreting patents, there can be no guarantee that a third party will not assert that we infringe such third-party's patents or any of its other intellectual property rights. Under such circumstances, there is no guarantee that we would not become involved in litigation. Litigation with any third party, even if the allegations are without merit, is expensive, time-consuming and would divert management's attention from the daily execution of our business plan. Litigation implies that a portion of our financial assets would be used to sustain the costs of litigation instead of being allocated to further the development of our business.

If we are involved in patent infringement litigation, we would need to prevail in demonstrating that our products do not infringe the asserted patent claims of the relevant patent, that the patent claims are invalid or that the patent is unenforceable. If we are found to infringe a third-party patent or other intellectual property right, we could be required to enter into royalty or licensing agreements on terms and conditions that may not be favorable to us, and/or pay damages, including up to treble damages in the United States (for example, if found liable of willful infringement) and/or cease the development and commercialization of our product candidates. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property and to compete with us.

There may be issued patents that we are unaware of that our products may infringe, or patents that we believe we do not infringe but ultimately could be found to infringe. If we were to challenge the validity of a competitor's issued United States patent in a United States court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. We cannot guarantee that a court would find in our favour on questions of infringement and validity. Any finding that we infringe or violate a third-party patent or other intellectual property right could materially adversely affect our business, financial condition and operating results.

REGULATORY RISKS

We may be subject to enforcement action if we engage in the off-label promotion of EGRIFTA SV® or Trogarzo®.

Our promotional materials and training methods must comply with the *Federal Food, Drug and Cosmetic Act*, as amended, of the United States ("FFDCA"), as well as with other applicable laws and regulations, including restraints and prohibitions on the promotion of off-label, or unapproved, use. Physicians may prescribe our products for off-label use without regard to these prohibitions, as the FFDCA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA

determines that our promotional materials or training of company employees or agents constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, issue corrective action, or subject us to regulatory or enforcement actions, including but not limited to the issuance of an untitled letter or warning letter, and a judicial action seeking injunction, product seizure and civil or criminal penalties. It is also possible that other federal, state or non-U.S. enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Our reputation would also be damaged. Although our policy is to refrain from written or oral statements that could be considered off-label promotion of our products, the FDA could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

We are not allowed to conduct promotional activities related to *EGRIFTA SV*® and Trogarzo® in Canada and in Europe since none of those products have been approved in this territory. Promotional activities may begin once a drug is approved by the heath authority of a country.

The pharmaceutical industry is highly regulated and pharmaceutical companies are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-kickback Statute and the federal False Claims Act.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include: (a) the federal healthcare program's anti-kickback law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs; (b) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; (c) the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; (d) the FFDCA and similar laws regulating advertisement and labeling; and (e) U.S. States' law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In the United States, the federal anti-kickback law has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce or reward prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe

harbor. Most American states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws. Further, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty under the federal anti-kickback law without actual knowledge of the statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the U.S. government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition and operating results.

To enforce compliance with the federal laws, the U.S. Department of Justice ("DOJ"), scrutinizes interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time and resource consuming and can divert management's attention from the business. Additionally, if a healthcare provider settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips or items and gifts of value to prescribers, "sham" consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

In addition, there has been a recent trend of increased federal and state regulation on payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to certain healthcare professionals. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

If our activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our activities with regard to the commercialization of our products in the United States, which could harm the commercial sales of our products and materially affect our business, financial condition and results of operations. We cannot guarantee that we will be able to mitigate all

operational risks. In addition, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on *EGRIFTA SV®,* Trogarzo® or their respective manufacturing processes, withdrawal of *EGRIFTA SV®* or Trogarzo® from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material adverse effect on our product sales, business and results of operations.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. U.S. federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of us or the third parties with whom we contract, regardless of the outcome, would be costly and time-consuming.

LITIGATION RISKS

If we fail to comply with our contractual obligations, undertakings and covenants under our agreements with our commercial partners and third-party service providers, we may be exposed to claims for damages and/or termination of these agreements, all of which could materially adversely affect the commercialization of EGRIFTA SV® and Trogarzo®, our capacity to generate revenues and management's attention to the development of our business.

We rely on third-party service providers for distribution and manufacturing activities related to *EGRIFTA SV®* and Trogarzo® in the United States. Under our agreements with our third-party service providers, we have assumed certain obligations, undertakings and covenants which, if breached by us and not remedied within the agreed upon periods, could expose us to claims for damages and/or termination of these agreements. If we are unable to meet our obligations under any of our agreements with such third-party service providers which results in termination of such agreements, this will materially adversely affect our business, financial condition and operating results since we rely on single third-party service providers, each of whom performing key services for the success of our business plan. Additionally, if such third-party service providers do not meet their obligations under agreements and we decide to litigate any breach or dispute any amount owed under our agreements, this might materially adversely affect our relationship with such third-party services providers which, in turn, could adversely affect our capacity and ability to deliver on our business plan.

If product liability lawsuits are brought against us, they could result in costly and time-consuming litigation and significant liabilities.

Despite all reasonable efforts to ensure the safety of our products we may be commercializing, it is possible that we or our commercial partners will sell products which are defective, to which patients react in an unexpected manner, or which are alleged to

have side effects. The development, manufacture and sale of such products may expose us to potential liability, and the pharmaceutical industry has been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and operating results. A product liability claim could also tarnish our reputation, whether or not such claims are with or without merit.

If a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim and, if the claim is successful, damage awards may be substantial and/or may not be covered, in whole or in part, by our insurance. We may not have sufficient capital resources to pay the damages resulting from a judgment, in which case our creditors could levy against our assets. We may also be obligated to indemnify our commercial partners and third-party service providers as well as make payments to other parties with respect to product liability damages and claims. Defending any product liability claims, or indemnifying others against those claims, could require us to expend significant financial and managerial resources and would have a material adverse effect on our reputation and our financial condition.

GEO-POLITICAL RISKS

A variety of risks associated with our international business relationships could materially adversely affect our business.

International business relationships in the United States, Europe, China, Taiwan and elsewhere subject us to additional risks, including: (a) disruptions of important government services; (b) differing regulatory requirements for drug approvals in foreign countries; (c) potentially reduced protection for intellectual property rights, including unexpected changes in the rules governing patents and their enforcement; (d) potential third-party patent rights in foreign countries; (e) the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market, with low or lower prices, rather than buying them locally; (f) unexpected changes in tariffs, trade barriers and regulatory requirements; (g) economic weakness, including inflation, or political instability, particularly in foreign economies and markets; (h) compliance with tax, employment, immigration and labor laws for employees traveling abroad; (i) foreign taxes; (j) foreign exchange contracts and foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; (k) workforce uncertainty in countries where labor unrest is more common than in the United States and Canada; (l) production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and (m) business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or epidemic such as the one related to the coronavirus.

These and other risks of international business relationships may materially adversely affect our business, financial condition and operating results.

OTHER RISKS RELATED TO OUR BUSINESS

We rely extensively on the information technology systems of third-party service providers to store data, such as personal identifiable information, regarding our commercial activities for EGRIFTA SV® and Trogarzo®. Security breaches and other disruptions to those information technology systems could cause a violation of privacy laws, exposing us to liability which could cause our business and reputation to suffer.

In the ordinary course of business, we rely upon information technology and networks, most of which are managed by third parties, to process, transmit and store electronic information to manage and support our business decisions and strategy. We have no control and access over the information technology systems of third-party service providers where most of this information is stored and we are unable to assess whether appropriate measures have been implemented to prevent or limit a security breach of their information technology systems.

We also use our information technology systems to collect and store proprietary data, such as those related to our intellectual property, customers, employees and suppliers.

In connection with our presence in Canada and Europe, we must comply with privacy laws and regulations of Québec and Europe. Both of those laws and regulations introduced data protection requirements relating to the consent of individuals to whom the personnel data relates, the information provided to the individuals, the security we must retain, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. These laws have increased the responsibility of all parties collecting personal data. We are currently reviewing and complementing our in-house policies and related procedures to ensure compliance with those laws. In the United States, there exists no federal laws regarding the protection of personal information and all such laws are State-regulated. With the addition of a sales and medical team in-house, we are in the process of assessing compliance with the privacy laws in each of the States where the bulk of our activities is conducted. However, there can be no guarantee that the Corporation will not be found to violate some of those laws as a result of the combination of our business activities in various jurisdictions and the complexity of those laws and their interpretations.

The secure and uninterrupted operation of third-party information technology systems and of ours is material to our business operations and strategy. More and more businesses are subject to information technology system intrusion for which cyber-terrorists often use ransomware to demand payment of a ransom to allow those businesses to regain access to its data. Despite the measures that we have implemented against unwanted intrusion by third parties, there can be no guarantee that our systems could resist to a cyber-attack. Unauthorized access to data files held in our information technology systems or those of third parties could result in inappropriate use, change or disclosure of sensitive and/or personal data of our customers, employees, suppliers and patients. Any such access, disclosure or other loss of information could subject us to litigation, regulatory fines, penalties or reputational damages, any of which could have a material adverse effect on our competitive position, reputation, business, financial condition and operating results.

We may require additional funding and may not be able to raise the capital necessary to fund all or part of our capital requirements.

We may need financing in order to fund all or part of our capital requirements to sustain our growth, to develop our marketing and commercial capabilities, to in-license or acquire approved products, to meet our compliance obligations with various rules and regulations to which we are subject, and to conduct research and development activities related to our products. However, our business performance may prevent us from generating enough cash-flow to meet our obligations and the market conditions may also prevent us from having access to the public market in the future at the times or in the amounts necessary. Therefore, there can be no guarantee that we will be able to continue to raise additional capital by way of public or private offerings in the future. In such a case, we would have to use other means of financing, such as entering into private financing or, with the consent of Marathon, credit agreements, the terms and conditions of which may not be favorable to us. In addition, the issuance and sale of substantial amounts of equity, or other securities, or the perception that such issuances and sales may occur could adversely affect the market price of our Common Shares.

We depend on our current personnel to pursue our business plan and the loss of our key employees and the inability to attract and hire highly qualified individuals to replace the loss of our current key employees could have a material adverse effect on our business and growth potential.

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our key employees and on our ability to be able to attract, retain and motivate qualified commercial, medical, regulatory and scientific personnel. We have entered into employment agreements with our executive officers and provided them, as well as to other key employees, with long-term incentives as a retention mechanism, but such agreements and incentives do not guarantee that our executive officers and other key employees will remain employed by us for any significant period of time, or at all. In addition, we have a limited workforce to pursue our business plan and the loss of any of our key employees could materially adversely affect our business. We have recently hired a team comprised of key account managers and medical science liaison personnel and the loss of any of those individuals and our inability to attract and retain them could have a material adverse effect on our commercial and medical activities related to *EGRIFTA SV*® and Trogarzo®, and, accordingly, on our business, financial condition and operating results. In addition, it could adversely affect the market price of our Common Shares.

There is intense competition for qualified personnel in the areas of our activities, and we and our third-party service providers may not be able to continue to attract and retain the qualified personnel necessary for the growth of our business. Our failure and the failure of our third-party service providers to attract and retain such personnel could impose significant limits on our business operations and hinder our ability to successfully and efficiently realize our business plan.

We may not achieve our publicly announced financial, milestones or our commercial objectives on time.

In January 2023, we announced revenue guidance for the fiscal year ended November 30, 2023, in the range of $90 million to $95 million. From time to time, we publicly announce the timing of certain events to occur or the attainment of certain commercial objectives. These statements are forward-looking and are based on the best estimate of

management at the time, relating to the achievement of such guidance or to the occurrence of such events. However, the actual timing of such events or our ability to achieve these objectives may differ from what has been publicly disclosed. Events such as beginning of commercialization of a product, levels of sales, revenues and other financial metrics may vary from what is publicly disclosed. These variations may occur as a result of a series of events, including problems with a supplier or a commercial partner, change in the procurement policy of a commercial partner or any other event having the effect of delaying the publicly announced timeline or reducing the publicly announced commercial objective. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of certain events having the effect of postponing such events or any variation in the occurrence of certain events having the effect of altering publicly announced commercial objectives could have a material adverse effect on our business, financial condition and operating results. In addition, it could adversely affect the market price of our Common Shares.

In connection with the reporting of our financial results, we are required to make estimates and assumptions, which involve uncertainties and any significant differences between our estimates and actual results could have an adverse impact on our reported financial position, operating results and cash flows.

The preparation of our consolidated financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, our management evaluates our critical and other significant estimates and assumptions, including among others, those associated with revenue and sales allowances and chargebacks, recoverability of inventories, estimation of accruals for clinical trial expenses, measurement and recoverability of intangible assets, the measurement of derivative financial assets, and the measurement of share-based arrangements. Any significant differences between our actual results and our estimates and assumptions could negatively impact our reported financial position, operating results and cash flows.

If actual future payments for allowances for discounts, returns, rebates and chargebacks exceed the estimates the Corporation made at the time of the sale of its products, its financial position, results of operations, and cash flows may be negatively impacted.

Pursuant to the Corporation's accounts and revenue recognition policies, the product revenue recognized quarter over quarter by the Corporation is net of estimated allowances for discounts, returns, rebates and chargebacks, including potential clawbacks in certain jurisdictions when pricing terms are based on temporary use authorisations and thus subject to future negotiations. Such estimates require subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Based on industry practice, pharmaceutical companies, including the Corporation, have liberal return policies, sometimes making it difficult to estimate the timing and amount of expected revenues.

A chargeback is the difference between the price the wholesaler pays the Corporation (wholesale acquisition cost) and the price that the wholesaler's customer pays for the

Corporation's product (contracted customer). The Corporation's products were subject to certain programs with federal government qualified entities whereby pricing on products is discounted to such entities and results in a chargeback claim to the Corporation, or for the Corporation to bill certain qualifying Public Health Service end-users at government-mandated pricing. To the extent that the Corporation's sales to discount purchasers, such as federal government qualified entities, increases, chargeback claims will also increase. There may be significant lag time between the Corporation's original sale to the wholesaler and the Corporation's receipt of the corresponding government chargeback claims from the Corporation's wholesalers.

The Corporation's products are subject to state government-managed Medicaid programs, whereby rebates for purchases are issued to participating state governments. These rebates arise when the patient treated with the Corporation's products is covered under Medicaid. The Corporation's calculations require the Corporation to estimate end-user and patient mix to determine which of its sales will likely be subject to these rebates. There is a significant time lag in the Corporation receiving these rebate notices (generally several months after its sale is made). The Corporation's estimates are based on its historical claims from participating state governments, as supplemented by management's judgment.

Although the Corporation believes that it has sufficient allowances, actual results may differ significantly from its estimated allowances for discounts, returns, rebates and chargebacks. Changes in estimates and assumptions based upon actual results may have a material impact on its financial condition, results of operations and cash flows. Such changes to estimates will be made to the financial statements in the period in which the estimate is changed. In addition, the Corporation's financial position, results of operations and cash flows may be negatively impacted if actual future payments for allowances, discounts, returns, rebates and chargebacks exceed the estimates the Corporation made at the time of the sale of its products.

We have identified a material weakness in our internal controls over financial reporting for the fiscal year ended November 30, 2022 in connection with the documentation of the analysis and relating to the monitoring of certain conditions and covenants included in the Marathon Credit Facility. A material weakness may hamper our ability to meet our reporting obligations and could result in a material misstatement in the Corporation's financial statements. As a result, the trading price of our Common Shares could be negatively affected.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that we are unable to comply with our reporting obligations and/or that the financial information we report contains material errors. Any of those events could materially adversely affect the trading price of our Common Shares. A failure to comply with our reporting requirements could also subject us to sanctions and/or investigations by securities regulatory authorities.

We have identified a material weakness in our internal controls over financial reporting for the fiscal year ended November 30, 2022, in connection with the documentation of the

analysis and relating to the monitoring of certain conditions and covenants included in the Marathon Credit Facility. This control failure caused ineffective controls over the assessment of going concern uncertainty, including the underlying financial data and assumptions supporting the forecasted financial information utilized to prepare projected cash flows and liquidity requirements to comply with some of the covenants in the Marathon Credit Facility. The Corporation's management team has initiated and continues to implement remediation measures designed to ensure that control deficiencies contributing to the material weakness are remediated, such that these controls are designed, implemented and operating efficiently. While the Corporation expects these remediation measures to be completed in the fiscal year 2023, it cannot be certain when the remediation will be completed. If the Corporation fails to fully remediate this material weakness or fails to maintain effective internal controls in the future, it could result in a material misstatement of the Corporation's financial statements, which could cause investors to lose confidence in the Corporation's financial statements and cause the trading price of its Common Shares to decline.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under Canadian securities laws to report annually on our internal control over financial reporting. We are not currently required, and do not, obtain an audit of our internal controls over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met.

RISKS RELATED TO OUR COMMON SHARES

Our share price has been volatile, and an investment in our Common Shares could suffer a decline in value.

The Corporation's Common Shares are listed on the TSX and on the Nasdaq. The market price of the Common Shares on the Nasdaq and the TSX has fluctuated significantly in the past and the Corporation expects the market prices to continue to fluctuate in the future, and such prices may decline. For example, since the Corporation's listing of its Common Shares on Nasdaq to December 31, 2022, the Corporation's closing share price on Nasdaq has ranged from a low of $0.8262 to a high of $11.23. Consequently, you may not be able to sell your Common Shares at prices equal to or greater than the price paid by you. In addition, the market price of the Common Shares may be influenced by many factors, some of which are or may be beyond the Corporation's control, including: actual or anticipated variations in the Corporation's operating results and/or research and development activities; announcements by the Corporation or the Corporation's competitors of significant contracts or acquisitions; additions and departures of key personnel; announcement or expectation of additional financing efforts; impairment of assets; changes in accounting principles; changes in the general market and economic conditions; future sales of the Common Shares; the failure of financial analysts to initiate or maintain coverage of the Common Shares, changes in financial estimates by financial analysts, or any failure by the Corporation to meet or exceed any of these estimates, or changes in the recommendations of any financial analysts that elect to follow the Common Shares or the shares of the Corporation's competitors; and investor perceptions of the Corporation and the industry in which the Corporation operates.

In addition, stock markets, in general, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors may materially harm the market price of the Common Shares, regardless of the Corporation's operating performance. Dual listing of the Common Shares on the Nasdaq and the TSX may increase share price volatility on both exchanges because trading is in the two markets, which may result in less liquidity on both exchanges. In addition, different liquidity levels, volumes of trading, currencies and market conditions on the two exchanges may result in different prevailing trading prices. In the past, following periods of volatility in the market price of certain companies' securities, securities class action litigation has sometimes been instituted against these companies. This litigation, if instituted against the Corporation, could adversely affect the financial condition or results of operations of the Corporation.

The liquidity of our Common Shares is uneven and oftentimes scarce and shareholders desiring to purchase or sell Common Shares could be unable to, if the liquidity in our Common Shares is low.

The volume of Common Shares traded on the TSX and the Nasdaq has been uneven over time and is often low. Therefore, any investor who desires to purchase or sell Common Shares of the Corporation over the TSX or the Nasdaq may be unable to rapidly execute its order and, if the liquidity is low, the price at which such investor may purchase or sell Common Shares may be adversely affected by the lack of trading volume.

Our Common Shares may be delisted from the Nasdaq stock market if the minimum bid price of our Common Shares remains below US$1.00 per share for 30 consecutive trading days. The delisting of our Common Shares could reduce the liquidity in our Common Shares and could trigger a sell-off from U.S. shareholders. Any reduction in the liquidity of our Common Shares or a sell-off our Common Shares would result in a decline in the price of our Common Shares. Being delisted from the Nasdaq stock exchange could also adversely affect analysts coverage of our Common Shares and prevent us from retaining U.S. investment bankers to raise equity in public offerings.

Under Nasdaq minimum bid price requirement, the minimum bid price of our Common Shares may not remain below US$1.00 per share for 30 consecutive trading days. If such event occurs, the Corporation will receive a deficiency notice providing the Corporation with a 180-calendar day cure period from the date of the notice during which the minimum bid price of the Common Shares will have to be US$1.00 or more per share for ten consecutive business days in order to avoid delisting. If, at the expiry of the 180-calendar day cure period, the Corporation has not regained compliance with the minimum bid price requirement, the Corporation could be afforded an additional 180-calendar day cure period, provided that it meets certain conditions, one of which could be to undertake a reverse-split of its Common Shares to regain compliance with Nasdaq rules.

If the Common Shares of the Corporation are delisted from the Nasdaq stock market, the liquidity in our Common Shares could decrease and investors may have difficulties in buying or selling our Common Shares. In addition, a delisting of our Common Shares on the Nasdaq stock market could trigger a sell-off from current U.S-based shareholders whose internal policies could prevent them from holding securities of companies that are

not traded on a U.S. stock market. Any sell-off by these shareholders could result in a material decline in the price of our Common Shares.

Finally, if the minimum bid price of the Common Shares were to be below US$1.00 per share for 30-consecutive trading days, there can be no assurance that the cure period provided by Nasdaq rules to regain compliance with the minimum bid price requirement would result in the Corporation regaining compliance with such rules in order to avoid a delisting of the Common Shares. Even if the Corporation was to proceed with a reverse-split of its Common Shares, there can be no assurance that the long term bid price of the Common Shares *post* reverse-split would meet the minimum bid price requirement of the Nasdaq stock market.

Our revenues and expenses may fluctuate significantly and any failure to meet financial expectations and/or our own financial guidance, if any, may disappoint securities analysts or investors and result in a decline in the price of our Common Shares.

Our revenues and expenses have fluctuated in the past and are likely to do so in the future. These fluctuations could cause our share price to decline. Some of the factors that could cause revenues and expenses to fluctuate include the following: (a) the level of sales of *EGRIFTA SV*® in the United States; (b) the level of sales of Trogarzo® in the United States; (c) supply issues with *EGRIFTA SV*® or Trogarzo®; (d) default under the terms of the Marathon Credit Facility or our Notes; (e) the inability to adequately manage our liquidity; (f) the outcome of any litigation; (g) payment of fines or penalties for violations of laws; (h) foreign currency and/or interest rate fluctuations; (i) the timing of achievement and the receipt of milestone or royalty payments from future third parties; and (j) failure to enter into new or the expiration or termination of current agreements with third parties.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, or if we need to reduce our financial guidance, if any, the price of our Common Shares could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, the price of our Common Shares and trading volume may decline.

The trading market for our Common Shares will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our Common Shares, the lack of research coverage may adversely affect the market price of our Common Shares. Furthermore, if one or more of the analysts who do cover us downgrade our Common Shares or if those analysts issue other unfavorable commentary about us or our business, the price of our Common Shares would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our Common Shares could decrease, which in turn could cause our share price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

We do not intend to pay dividends on our Common Shares and, consequently, the ability of investors to achieve a return on their investment will depend on appreciation in the price of our Common Shares.

We have never declared or paid any cash dividend on our Common Shares and we do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. Therefore, the success of an investment in our Common Shares will depend upon any future appreciation in their value. There is no guarantee that our Common Shares will appreciate in value or even maintain the price at which our shareholders have purchased their shares.

Our shareholder rights plan and certain Canadian laws could delay or deter a change of control.

Our shareholder rights plan entitles a rights holder, other than a person or group holding 20% or more of our Common Shares, to subscribe for our Common Shares at a discount of 50% to the market price at that time, subject to certain exceptions.

The *Investment Canada Act* (Canada) subjects an acquisition of control of a company by a non-Canadian to government review if the value of the assets as calculated pursuant to the legislation exceeds a threshold amount. A reviewable acquisition may not proceed unless the relevant minister is satisfied that the investment is likely to be a net benefit to Canada.

Any of the foregoing could prevent or delay a change of control and may deprive or limit strategic opportunities for our shareholders to sell their shares.