MANAGEMENT'S DISCUSSION AND ANALYSIS
FOR THE YEAR ENDED NOVEMBER 30, 2023

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, 2023 ("Fiscal 2023"), compared to the year ended November 30, 2022 ("Fiscal 2022"), as well as 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 20, 2024, was approved by our Board of Directors on February 20, 2024 and should be read in conjunction with our audited annual consolidated financial statements and the notes thereto as at November 30, 2023 ("Audited Financial Statements").

Except as otherwise indicated, the financial information contained in this MD&A and in our Audited Financial Statements has been prepared in accordance 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.

Any references in this MD&A to the number of common shares (the "Common Shares") (including earnings per share), Marathon Warrants (as defined below), share options and the exercise price of the Marathon Warrants, share options and other equity-linked securities issued by the Corporation have been retrospectively adjusted and restated to reflect the effect of the Consolidation (as defined below), on a retrospective basis. See "Fiscal 2023 Highlights – Share Consolidation" below.

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 adult patients with lipodystrophy and the use of Trogarzo® (ibalizumab-uiyk) injection refers to ibalizumab for the treatment of multidrug resistant HIV-1 infected patients.

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;
- our revenue and Adjusted EBITDA (as defined below) guidance, which are based on our assumption that our revenues continue to grow in Fiscal 2024 and that we continue our close monitoring and management of expenses;
- our ability to generate a positive Adjusted EBITDA;
- 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 and our other peptide-drug conjugates;
- our capacity to enroll patients and complete our Phase 1 clinical trial studying sudocetaxel zendusortide;
- our ability to develop other peptide-drug conjugates generated through our SORT1+Technology™ platform;
- our ability to successfully address the questions raised by the United States Food and Drug Administration ("FDA") in its complete response letter ("CRL") regarding the F8 formulation of tesamorelin ("F8 Formulation") and to resubmit the F8 Formulation for approval to the FDA;
- the approval of the F8 Formulation by the FDA;
- our ability to successfully complete the human factors validation study ("HFS") and to resubmit a Changes Being Effected ("CBE") supplement with the FDA for

EGRIFTA SV® on or before September 15, 2024, or any other prescribed deadline we may be able to negotiate with the FDA;

- our capacity to meet the undertakings, covenants and obligations contained in the credit agreement (the "Marathon Credit Agreement") entered into in July 2022 with Marathon's affiliates (collectively "Marathon") 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 nonalcoholic steatohepatitis ("NASH") in the general population;

- our capacity to find a partner to pursue the development of sudocetaxel zendusortide once the Phase 1 clinical trial is completed;

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

- 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;

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- 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;

- we will be able to satisfactorily answer all of the questions asked by the FDA in the CRL related to the F8 Formulation and to resubmit our file to the FDA seeking the approval of the F8 Formulation;

- 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*® within the prescribed timelines;

- the FDA will approve the CBE supplement for *EGRIFTA SV*®*;*

- the FDA will approve the intramuscular ("IM") method of administration for the maintenance dose of Trogarzo®;

- we will not default under the terms and conditions of the Marathon Credit Agreement, including meeting the minimum liquidity and adjusted EBITDA target covenants therein;

- the interest rate on the amount borrowed from Marathon under the Marathon 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;

- we will be able to recruit patients for our Phase 1 clinical trial studying sudocetaxel zendusortide and will be able to see signs of efficacy without observing material adverse effects;

- we will find a partner to pursue the development of sudocetaxel zendusortide once the Phase 1 clinical trial has been completed;

- 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;

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- 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 Factors” (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-U.S. GAAP Measure

The information presented in this MD&A includes a measure that is not determined in accordance with 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, certain restructuring costs 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 from one period to another. The Corporation uses this non-IFRS measure to make financial, strategic and operating decisions. “Adjusted EBITDA” is not a standardized financial measure under the financial reporting framework used to prepare the financial statements of the Corporation to which the measure relates and might not be comparable to similar financial measures disclosed by other issuers. A quantitative reconciliation of Adjusted EBITDA is presented under the heading “Reconciliation of Adjusted EBITDA” in this MD&A.

The calculation of the “Adjusted EBITDA” in this MD&A is different from the calculation of the adjusted EBITDA (the “Marathon Adjusted EBITDA”) under the Marathon Credit Agreement for the purpose of complying with the covenants therein.

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 and is indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. We have been commercializing this product in the United States since May 1st, 2014.

Trogarzo® (ibalizumab-uiyk) injection was approved by the FDA in March 2018 and, in combination with other antiretroviral(s) ("ARV"), is indicated for the treatment of human immunodeficient virus type 1("HIV-1") infection in heavily treatment-experienced adults with multidrug resistant ("MDR") HIV-1 infection failing their current antiretroviral regimen. Trogarzo® was made commercially available in the United States in April 2018 and 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 ARV therapy that can lead to an undetectable viral load in combination with other ARVs.

Trogarzo® was also approved by the European Medicines Agency ("EMA") in September 2019 and is no longer under licence to us in Europe further to our decision to terminate and return to TaiMed Biologics Inc. ("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. Sudocetaxel zendusortide, a peptide-drug conjugate ("PDC") derived from our licensed platform SORT1+Technology™ that incorporates docetaxel, is designed to specifically target Sortilin ("SORT1") receptors expressed in cancer cells of various types of cancer. Sudocetaxel zendusortide is currently being studied in a Phase 1 clinical trial. We are also working on the development of other PDCs and the potential combination of anti-cancer agents with our existing PDCs and with any newly developed ones.

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.

We have also completed the submission of a supplemental Biologics Licence Application ("sBLA") for an IM method of administration for the maintenance dose of Trogarzo®.

OUR PIPELINE

Theratechnologies has established a promising pipeline of investigational medicines in areas of high unmet need, including innovative medicines in oncology and NASH. The Company's research & development activities also works on extending the lifecycle of its approved medicines, *EGRIFTA SV*® and Trogarzo® in HIV.

Lifecycle Management of Tesamorelin in Lipodystrophy

F8 Formulation

On September 25, 2023, the Corporation announced the filing of a sBLA with the FDA seeking the approval of the F8 Formulation. On January 23, 2024, the Company received a CRL from the FDA. The questions outlined in the CRL are largely related to chemistry, manufacturing and controls concerning the microbiology, assays, impurities and stability for both the lyophilized product and the final reconstituted drug product. In addition, the FDA requested further information to understand the potential impact of the proposed formulation on immunogenicity risk. The Company will address the FDA's questions and intends to pursue the approval of the F8 Formulation.

The F8 Formulation is eight times more concentrated than *EGRIFTA*® and two times more concentrated than the current F4 formulation sold under the trade name *EGRIFTA SV*®. The Company plans to withdraw *EGRIFTA SV*® from the market if and when the F8 Formulation is approved by the FDA. The F8 Formulation can be kept at room temperature, comes in a single vial and has a higher concentration resulting in a smaller volume of administration than *EGRIFTA SV*®. The F8 Formulation has the distinct advantage of requiring a single reconstitution per seven days of daily therapy.

Once approved, the F8 Formulation could be used in our proposed Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population.

Lifecycle Management of Trogarzo® in MDR HIV-1

New Methods of Administration of Ibalizumab

On October 3, 2022, the FDA approved a 30-second Intravenous ("IV") Push method of administration for the maintenance dose of Trogarzo® and on December 13, 2023, the FDA approved our sBLA for the IV Push administration of the loading dose of Trogarzo®.

On October 13, 2023, the Company announced results from a study evaluating the IM method of administration of Trogarzo®. The TMB-302 study, conducted in partnership with TaiMed, enrolled 21 subjects (7 HIV-positive and 14 HIV-negative) to assess the pharmacokinetics, efficacy, and safety of IM administration of Trogarzo® as compared to

IV infusion. Mean Trogarzo® trough concentrations were greater than 15 µg/mL, suggesting that IM injection was sufficient at maintaining the drug trough concentration above the therapeutic level of 0.3 µg/mL. The mean trough concentrations were comparable between IV infusion and IM injection in HIV-positive subjects. However, the primary endpoint measuring a 90% confidence interval of the ratio of IM injection to IV infusion (0.69, 1.08) did not meet the equivalence limits (0.8, 1.25). Viral suppression, a key secondary clinical endpoint, was maintained in all HIV-positive subjects throughout the IM phase and the overall study.

Each study subject received IM maintenance doses for eight weeks of treatment and a total of 152 IM injections were administered, which were well tolerated. One subject reported injection-site pruritus (itching) at a single time point, and no subjects reported injection-site pain when Trogarzo® was administered intramuscularly.

The Corporation has now completed the study of the use of an IM method of administration of Trogarzo® and, on January 2, 2024, we announced the filing of a sBLA with the FDA seeking the approval of the IM method of administration.

Sudocetaxel Zendusortide

Phase 1 Clinical Trial

In March 2021, we initiated a Phase 1 clinical trial evaluating sudocetaxel zendusortide 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 MTD and preliminary anti-tumor activity of sudocetaxel zendusortide 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”, initially consisted in recruiting a total of approximately 70 patients to study the safety and tolerability of sudocetaxel zendusortide 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/m^2 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 sudocetaxel zendusortide was decreased to 300 mg/m2 for the next dose level and was expanded to a total of six patients. No dose limiting toxicity (“DLT”) 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 300 mg/m^2 appeared to be a well-tolerated dose level. We further reported the observation of signs of efficacy in three heavily pretreated patients.

Following the determination of the MTD, we began enrolling patients in the basket trial. In December 2022, after consulting with our investigators, we decided to voluntarily pause the enrollment of patients and revisit the study design of our clinical trial studying sudocetaxel zendusortide in various types of cancer. 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.

Following the voluntary pause, the Company formed a scientific advisory committee to help determine the best developmental path forward for sudocetaxel zendusortide which led to the filing of an amended protocol with the FDA.

On June 2, 2023, we announced the FDA's agreement to our amended Phase 1 clinical trial protocol for sudocetaxel zendusortide following the submission of such amended protocol. The amended protocol is designed to improve the therapeutic window of sudocetaxel zendusortide and extend its duration of therapy. The amended protocol includes a change in the frequency of administration to weekly dosing and a narrowing of the patient population to focus on those with high-grade serous ovarian cancer, including high-grade peritoneal or fallopian tube cancer, or high-grade endometrioid cancer - a population in which preliminary efficacy has been observed thus far. Patient selection has also been refined to focus on those who are less heavily pretreated, with no more than one taxane failure and a maximum of eight prior cancer treatment regimens.

The amended study is a modified 6+6 design with two different dosing regimens that are within the efficacious range for sudocetaxel zendusortide: 1.75 mg/kg on days 1, 8, and 15 of a 28-day cycle (similar to 210 mg/m2 every 3 weeks) and 2.5 mg/kg on the same schedule (similar to 300 mg/m2 every 3 weeks). A minimum of six patients will be enrolled at the 1.75 mg/kg dose followed by an observational period of three months to assess DLT. If deemed safe (0 or 1 DLT), the trial will enroll an additional six patients at the 2.5 mg/kg dose. Following a second three-month observational period, four more patients will be enrolled at the higher dose, for a total of 16 patients in Part 3 of the trial. The amended protocol also includes an option for a basket expansion stage that would comprise patients with selected, difficult-to-treat tumor types in which sudocetaxel zendusortide has shown activity.

To date, all five of the U.S.-based clinical sites participating in the conduct of the Phase 1 clinical trial are activated to screen, enroll and dose advanced ovarian cancer patients. A sixth site based in Canada is also currently screening and enrolling patients as part of the trial. On October 12, 2023, we announced dosing of the first patient.

Consistent with the Company's objective of generating a positive Adjusted EBITDA on a quarterly basis, any new investments in sudocetaxel zendusortide will be stage-gated. Theratechnologies is currently reaching out to pharmaceutical companies to partner the development of sudocetaxel zendusortide once the Phase 1 clinical trial will have been completed.

For the fiscal year ended November 30, 2024 ("Fiscal 2024"), the Company has budgeted $4,800,000 to be allotted to the Phase 1 clinical trial and to other research and development activities related to its SORT1+Technology™ platform. Of this amount, $2,500,000 will be allocated to the Phase 1 clinical trial, $1,695,000 to laboratory work

and employee salaries, and the remainder ($605,000) will be allocated to pharmaceutical development and other external expenses.

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.

In July 2021, after completion of our discussions with both the FDA and the EMA, 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.

Currently, we are not planning on initiating this trial, unless we can find additional resources, including a partner. We continue to pursue potential NASH partners in the marketplace. We continue to maintain that the further development of tesamorelin allows the Corporation to keep 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.

Allocation of Expenses Related to Research and Development Activities

In its prospectus supplement dated January 13, 2021 (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 the net proceeds of the January 2021 Offering then estimated to be $42,500,000, an amount of $30,500,000 was earmarked for the conduct of a Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH and of $7,000,000 for the conduct of research and development activities in the field of oncology (including the sudocetaxel zendusortide Phase 1 clinical trial), with the remainder left for commercial and marketing activities and other uses.

As described above, 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 and, as part of its announcement in July 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 Phase 3 clinical trial evaluating tesamorelin for the

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treatment of NASH, the funds raised in the January 2021 Offering earmarked for such trial were added to the Company's available cash balance. The Corporation does not plan to initiate the development of tesamorelin for the treatment of NASH in the general population unless it finds additional resources, including through a partnership.

The following table shows the estimated use of proceeds from the January 2021 Offering compared with the actual use of proceeds as at November 30, 2023:

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	$10.1	$3.1
Commercial and marketing activities	$3.5	--	$(3.5)
Other	$1.5	$13.0	$11.5
Net Proceeds	$42.5	$25.9	$(16.6)

As at November 30, 2023, approximately $2,832,000 had been used in connection with the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH. The amount spent on this program to date allowed the Corporation to advance the negotiation of the trial design for the conduct of a Phase 2b/3 clinical trial. We are unable to assess the amounts required to finalize the Phase 2b/3 clinical trial with the FDA since we have voluntarily decided not to respond to the last questions received in February 2022 in order to address these with any potential partner we may find to optimize the design, if deemed relevant. The Corporation expects that the recruitment and dosing of the first 350 patients would cost approximately $50,000,000. Subject to the quality of the data obtained from the treatment of the first 350 patients, the Corporation estimates that an amount in excess of $100,000,000 will be necessary to complete the Phase 2b/3 and Phase 3 clinical trial. As previously sated, we will seek a partner before initiating any additional spending on the NASH program.

As at November 30, 2023, approximately $10,101,000 had been used in connection with research and development activities in oncology and the variance between the amount reserved and the amount used as at November 30, 2023, represents funds held in cash pending their planned allocation as costs are incurred. For Fiscal 2024, the Company has budgeted $4,800,000 to be allotted to the Phase 1 clinical trial evaluating sudocetaxel zendusortide and for other research and development activities related to its SORT1+Technology™ platform. Of this amount, $2,500,000 will be allocated to the Phase 1 clinical trial, $1,695,000 to laboratory work and employee salaries, and the remainder ($605,000) will be allocated to pharmaceutical development and other external expenses.

Finally, the Corporation has not implemented new initiatives in terms of commercial and marketing activities, such that the funds earmarked for such use were added to its working capital.

FISCAL 2023 HIGHLIGHTS

Amendments to Marathon Credit Agreement

In Fiscal 2023, we entered into various agreements with Marathon to amend some of the terms and conditions of the Marathon Credit Agreement.

On February 27, 2023, we entered into amendments to the Marathon Credit Agreement providing for, among other things: the removal of the condition related to the submission to the FDA of the Corporation's HFS results related to *EGRIFTA SV*® in order to be able to draw down on the $20,000,000 second tranche under the Marathon Credit Agreement. The amendment was entered into in consideration of the issuance of 5,000,000 common share purchase warrants (the "Marathon Warrants") to Marathon. Each Marathon Warrant then entitled the holder thereof to purchase one common share of the Corporation at a price of $5.80 per share (the "Exercise Price") until February 27, 2030. On June 21, 2023, the Corporation drew down on the second tranche of $20,000,000.

On May 15, 2023, we entered into an additional amendment to the Marathon Credit Agreement to lower the minimum net revenue target the Corporation was required to meet in its second quarter of Fiscal 2023 as part of its obligations.

On July 10, 2023, we entered into an additional amendment to the Marathon Credit Agreement to reduce the amount of liquidity the Corporation had to maintain from $20,000,000 to $14,000,000 from July 10, 2023, to July 21, 2023, and then to $16,000,000 until July 28, 2023.

On July 28, 2023, we entered into further amendments to the Marathon Credit Agreement providing for, among other things, (i) the delivery to Marathon until October 31, 2023, of weekly reports about the Corporation's liquidity position; and (ii) the amount of liquidity the Corporation had to maintain between various periods of time ranging from July 10, 2023, up and until October 31, 2023. Beginning on November 1, 2023, the prescribed level of liquidity was set at $20,000,000.

On September 21, 2023, we entered into an amended and restated fourth amendment to the Marathon Credit Agreement which reiterated the amendments agreed to on July 28, 2023, but contained a waiver from Marathon of any default or event or default that may have occurred as a result of the Corporation's failure to meet the minimum liquidity covenant between July 3, 2023, up to and including July 9, 2023.

On October 13, 2023, we entered into additional amendments to the Marathon Credit Agreement providing for, among other things: (i) revising the minimum liquidity requirements for all times following October 31, 2023 to be between $15,000,000 million and $20,000,000, based on the Marathon Adjusted EBITDA thresholds over the most recently ended four fiscal quarters; (ii) revising the minimum revenue requirements to be based on adjusted EBITDA-based targets instead of quarterly revenue-based targets, beginning with the quarter ending November 30, 2023; and (iii) deleting the prohibition against the Corporation having a going concern explanatory paragraph in the opinion of the independent registered public accounting firm of the Corporation that accompanies the Corporation's annual report.

In consideration of these amendments, the Corporation has agreed to (i) pay an amount equal to $600,000, or 100 basis points calculated on the funded debt as of that day ($60,000,000), over the term of the loan and added to the outstanding principal amount of

the funded debt as payment in kind; and (ii) reprice the Exercise Price of the Marathon Warrants to $2.30 from $5.80. Following the Consolidation completed on July 31, 2023, the exercise of four Marathon Warrants and the payment of $2.30 are required to purchase one Common Share of the Corporation, for up to a maximum issuance of 1,250,000 Common Shares.

Reimbursement of 5.75% Convertible Unsecured Senior Notes

On June 19, 2018, the Corporation issued by way of prospectus an aggregate principal amount of $57.5 million of 5.75% convertible unsecured senior notes maturing on June 30, 2023 (the "Convertible Notes"). In July 2022, the Corporation bought back and cancelled $30 million principal amount of Convertible Notes through private agreements with certain U.S. Convertible Note holders. On June 30, 2023, the Corporation reimbursed all of the outstanding principal amount of $27.5 million of Convertible Notes.

Reorganization of R&D Activities

As a result of the weakness in the Company's net revenues in the first half of Fiscal 2023, the Corporation initiated a reorganization in July 2023, mainly focused on its research and development activities, which is expected to result in annualized savings of at least $5,500,000 for the fiscal year ended November 30, 2024 and beyond. Most of these costs will be associated with headcount reduction and a decrease in the number and scope of research and development projects. As such, the Corporation recorded a charge of $719,000 in the third quarter of Fiscal 2023 to cover severance and other costs. On October 24, 2023, the Corporation announced further changes to its operations that would result in a tapering of research and development activities, which necessitated a reduction of approximately 25 positions. The Corporation expects to realize further recurring yearly savings of approximately $3,500,000 resulting from this reorganization and has recorded an additional restructuring charge of approximately $1,244,000 in the fourth quarter of Fiscal 2023.

Share Consolidation

On July 31, 2023, we announced that we had completed the consolidation of the issued and outstanding Common Shares of the Corporation's share capital on the basis of one (1) post-consolidation share for each four (4) pre-consolidation shares issued and outstanding (the "Consolidation"). The Company's Common Shares began trading on the TSX and the NASDAQ on a consolidated basis on July 31, 2023.

Public Offering and Concurrent Private Placement

On October 31, 2023, we announced the closing of a financing for gross proceeds of $25,000,000. The financing was done by way of prospectus (the "2023 Public Offering") resulting in the issuance of 12,500,000 Common Shares at $1.00 per Common Share (the "Offering Price") and by way of a private placement (the "Concurrent Private Placement") resulting in the issuance of 9,118,184 Common Shares at the Offering Price and of 3,381,816 fully-funded, non-voting subscription receipts exchangeable into Common Shares on a one-for-one basis (the "Exchangeable Subscription Receipts"). As part of the Concurrent Private Placement, the Company paid to the subscriber, Investissement

Québec, a commitment fee of 1.5%. In connection with the 2023 Public Offering, the Company also granted the underwriter a 30-day option to purchase up to 1,875,000 Common Shares at the Offering Price. This option was partially exercised resulting in gross proceeds of $160,000.

The component of the Concurrent Private Placement in the form of Exchangeable Subscription Receipts is designed to ensure that, following completion of the 2023 Public Offering and the Concurrent Private Placement, Investissement Québec does not have beneficial ownership or control over more than 19.9% of the issued and outstanding Common Shares and, therefore, is not a "control person" within applicable Canadian securities laws.

In its prospectus supplement dated October 25, 2023, filed as part of the 2023 Public Offering, the Corporation indicated that it intended to use the net proceeds of the 2023 Public Offering and the Concurrent Private Placement for general corporate purposes, which may include working capital, general and administrative expenses, commercialization expenses, repayment of outstanding debt under the Marathon Credit Agreement, and potential acquisitions or in-licensing of commercial products.

More specifically, in the short term, the Corporation intends to allocate the net proceeds of the 2023 Public Offering and of the Concurrent Private Placement as follows:

Funding of working capital	$19.1 million
General and administrative expenses	$2 million
Commercialization expenses	$2 million

A portion of the Corporation's working capital will be used to maintain the minimum amount of liquidities, ranging between $15 million and $20 million, that the Company is required to maintain at all times under the Marathon Credit Agreement based on the Marathon Adjusted EBITDA thresholds set forth in the Marathon Credit Agreement over the most recently ended four fiscal quarters (or any shorter period under the Marathon Credit Agreement).

The prepayment of the outstanding principal amount loaned to the Corporation under the Marathon Credit Agreement is subject to certain restrictions until the second anniversary of the date at which the various tranches are funded, and no such prepayment is expected to be made by the Corporation before then. Thereafter, any prepayment will be evaluated on prevailing circumstances, including the Corporation's financial position and opportunities available to the Corporation. Use of proceeds for the purpose of potential acquisitions or in-licensing of commercial products will depend on available opportunities as they may arise.

To date, the Corporation has not used any of the proceeds from the 2023 Public Offering and the Concurrent Private Placement.

Fiscal 2024 Corporate Objectives

Our business objectives for Fiscal 2024 are focused on: continue growing revenues and continue the management of expenses to deliver strong adjusted EBITDA; accelerate the growth and future profitability of the company by leveraging our commercial capabilities and acquiring immediately accretive products that are aligned to our expertise; derive value from our investment in oncology with our Phase 1 clinical trial and continue to seek out partners for sudocetaxel zendusortide and our entire oncology platform; and, continue to enhance and engage our talented team towards our new journey focused on commercialization.

2024 Revenue and Adjusted EBITDA Guidance

The Corporation is providing guidance for Fiscal 2024 for revenue to be in the range of $87,000,000 and $90,000,000, or growth of the commercial portfolio in the range of 6.3% and 10.0%, as compared to the 2023 fiscal year results. Adjusted EBITDA is expected to be in the range of $13,000,000 to $15,000,000 for Fiscal 2024.

Fourth-Quarter and Fiscal 2023 Revenue Highlights

(in 000s of US$)

	Three-month periods ended November 30,		**% change**	**Years ended November 30,**		**% change**
	2023	2022		**2023**	**2022**	
EGRIFTA SV® net sales	**16,958**	14,458	17.3%	**53,705**	50,454	6.4%
Trogarzo® net sales	**6,494**	6,963	(6.7%)	**28,059**	29,603	(5.2%)
Revenue	**$23,452**	$21,421	**9.5%**	**$81,764**	$80,057	2.1%

Fourth-Quarter Fiscal 2023 Financial Results

Revenue

Consolidated revenue for the three months ended November 30, 2023, amounted to $23,452,000 compared to $21,421,000 for the same period last year, representing an increase of 9.5%.

For the fourth quarter of Fiscal 2023, sales of *EGRIFTA SV*® reached $16,958,000 compared to $14,458,000 in the fourth quarter of the prior year, representing an increase of 17.3%. Strong sales of *EGRIFTA SV*® were mostly the result of increased unit sales, and somewhat offset by higher rebates to government payers than in Fiscal 2022.

In the fourth quarter of Fiscal 2023, Trogarzo® sales amounted to $6,494,000 compared to $6,963,000 for the same quarter of Fiscal 2022, representing a decrease of 6.7%. The

decrease was mainly due to lower unit sales in the quarter as compared to last year. Lower unit sales in the fourth quarter of Fiscal 2023, were also a result of higher inventory buildup in Fiscal 2022, a situation which has resolved itself in Fiscal 2023.

Cost of Sales

For the three-month period ended November 30, 2023, cost of sales was $5,066,000 compared to $5,909,000 in the comparable period of Fiscal 2022. Lower cost of sales for 2023 is explained by a provision in cost of goods sold for the fourth quarter of Fiscal 2022 which included a provision of $1,477,000 related to the write down of F8 Formulation for pre-commercial material which could expire prior to the launch of the F8 Formulation. This decrease was partially offset by an increase from higher sales of *EGRIFTA SV*® and various production-related costs.

R&D Expenses

R&D expenses in the three-month period ended November 30, 2023, amounted to $5,229,000 compared to $9,455,000 in the comparable period of Fiscal 2022. The decrease during the fourth quarter of Fiscal 2023 was largely due to lower spending across all areas, including the Phase 1 clinical trial for sudocetaxel zendusortide, the HFS for the F8 Formulation, as well as the development of the IM method of administration of Trogarzo®. These last two projects were mostly completed in the fourth quarter of Fiscal 2023. R&D expenses also included $876,000 in severance and other expenses related to the reorganization announced in July 2023.

Selling Expenses

Selling expenses in the three-month period ended November 30, 2023, amounted to $6,748,000 compared to $7,809,000 in the comparable period of Fiscal 2022.

The decrease in selling expenses is largely associated to the careful management of expenses to achieve our stated goal of achieving a positive Adjusted EBITDA towards the end of Fiscal 2023. Selling expenses also included $79,000 in severance and other expenses related to the reorganization announced in July 2023.

General and Administrative Expenses

General and administrative expenses in the fourth quarter of Fiscal 2023 amounted to $3,739,000, compared to $3,956,000 reported in the same period of Fiscal 2022. General and administrative expenses include $289,000 in severance and other expenses related to the reorganization announced in July 2023.

Net Finance Costs

Net finance costs for the three-month period ended November 30, 2023, were $5,352,000 compared to $2,078,000 in the same period last year. The increase in net finance costs is due to the higher balance outstanding under the Marathon Credit Agreement, which carries a higher interest than the Convertible Notes then outstanding in 2022. Net finance costs in the fourth quarter of Fiscal 2022 included interest on the Convertible Notes,

whereas this amount was nil in the fourth quarter of Fiscal 2023. The higher interest is also a function of higher interest rates in 2023 versus 2022. Other increases in the fourth quarter of Fiscal 2023 are related to the costs associated with the amendment to the Loan Facility ($890,000), the write-off of deferred financing costs ($954,000), and the change in fair value of the Marathon Warrants ($825,000).

Adjusted EBITDA

Adjusted EBITDA, a non-GAAP measure, was $4,965,000 for the fourth quarter of Fiscal 2023, compared to $(2,439,000) for the same period of Fiscal 2022. See “Non-IFRS and Non-US-GAAP Measure” above and see “Reconciliation of Adjusted EBITDA” below for a reconciliation to Net Loss for the relevant periods.

Net Loss

Taking into account the revenue and expense variations described above, we recorded a net loss of $2,755,000, or $0.08 per share, in the fourth quarter of Fiscal 2023 compared to a net loss of $7,929,000, or $0.09 per share, in the fourth quarter of Fiscal 2022.

Quarterly Financial Information

The following table is a summary of our unaudited consolidated operating results for the last 8 quarters of Fiscal 2023 and Fiscal 2022.

(in thousands of dollars, except per share amounts)

	2023				2022			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Revenue	**23,452**	20,855	17,549	19,908	21,421	20,811	19,268	18,557
Operating expenses								
Cost of sales								
Cost of goods sold	**5,066**	4,967	4,909	4,693	5,909	5,292	7,759	4,878
Amortization of other asset	**-**	-	-	-	-	-	1,220	1,221
R&D	**5,229**	5,396	10,389	9,356	9,455	8,425	11,056	8,003
Selling	**6,748**	6,728	6,479	6,814	7,809	8,404	15,371	7,807
General and administrative	**3,739**	3,710	3,716	4,452	3,956	4,209	4,823	4,368
Total operating expenses	**20,857**	20,801	25,493	25,315	27,129	26,330	40,229	26,277
Net finance costs	**(5,005)**	(674)	(1,943)	(4,940)	(2,078)	(1,879)	(1,644)	(1,285)
Income taxes	**(73)**	(126)	(126)	(96)	(143)	(151)	(122)	(27)
Net loss	**(2,755)**	(746)	(10,013)	(10,443)	(7,929)	(7,549)	(22,727)	(9,032)
Basic and diluted loss per share[(1)]	**(0.08)**	(0.03)	(0.40)	(0.44)	(0.36)	(0.32)	(0.96)	(0.36)

(1) Amounts from Q1-2022 to Q2-2023 have been restated to reflect the 1 for 4 share consolidation completed on July 31, 2023

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 Fiscal 2022 were associated with the development of our product pipeline and our decision to stop commercialization activities for Trogarzo® in the European territory. Lower R&D expenses in the second half of Fiscal 2023 are the result of lower overall activities due to the completion of lifecycle management programs for *EGRIFTA SV*® and Trogarzo®, and the absence of charges and provisions taken in the first and second quarters of Fiscal 2023 related to production and inventory.

The variability of Net finance costs is mostly due to the costs associated with the amendments to the Loan Facility, the write-off of deferred financing costs, and the change in fair value of the Marathon Warrants, which are remeasured to fair value on a quarterly basis.

Selected Annual Information
(in thousands of dollars, except per share amounts)

Years ended November 30	**2023**	2022	2021
Revenue	**81,764**	80,057	69,823
Cost of sales	**19,635**	26,279	23,260
Research and development expenses	**30,370**	36,939	28,274
Selling expenses	**26,769**	39,391	28,909
General and administrative expenses	**15,617**	17,356	14,616
Net loss	**(23,957)**	(47,237)	(31,725)
Loss per share: Basic and diluted	**(0.91)**	(1.98)	(1.37)
Cash, bonds and money market funds	**40,387**	33,070	40,354
Total assets	**77,769**	93,260	119,212
Loan Facility (including current portion)	**57,974**	37,894	--
Lease liabilities (including current portion)	**994**	1,922	2,518
Convertible unsecured senior notes	**-**	26,895	54,227

Fiscal Year 2023 Financial Results compared to Fiscal Year 2022 Financial Results

Revenue

Consolidated revenue for Fiscal 2023 was $81,764,000 compared to $80,057,000 for the same period last year, representing an increase of 2.1%.

For Fiscal 2023, sales of *EGRIFTA SV*® reached $53,705,000 compared to $50,454,000 for the same period last year representing growth of 6.4%. The increase in net sales of *EGRIFTA SV*® was mostly the result of a higher number of units sold compared to the previous year, as well as a higher net selling price. Overall growth of *EGRIFTA SV*® net sales was hampered in 2023 by draw downs in inventory at one of our large specialty pharmacies during the second quarter.

In Fiscal 2023, Trogarzo® net sales were $28,059,000 compared to $29,603,000 in the prior year, a decrease of 5.2%. Net sales of Trogarzo® were negatively affected in the second quarter of 2023 by two factors: (a) drawdowns in inventory at one of our large specialty pharmacies resulting from larger than necessary purchases in the latter part of calendar year 2022; and (b) further inventory drawdowns at another specialty pharmacy with which we renegotiated contract terms resulting in a lowering of their overall inventory levels. Net sales of Trogarzo® were also impacted by greater than anticipated rebates to government payers. The Trogarzo® net sales decrease is also attributable to a lesser degree to our decision to stop commercializing the product in Europe in Fiscal 2022, resulting in a $975,000 decrease in Fiscal 2023.

Cost of Sales

For Fiscal 2023, cost of sales was $19,635,000 compared to $26,279,000 in the comparable period of Fiscal 2022. Cost of sales included cost of goods sold that amounted to $19,635,000 in Fiscal 2023 compared to $23,838,000 in Fiscal 2022. The decrease in cost of goods sold was mainly due to a number of factors occurring in Fiscal 2022 that did not reoccur in Fiscal 2023, namely: (1) 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 in the amount of $1,788,000; and (2) a provision of $1,477,000 related to the write down of F8 Formulation for pre-commercial material which could expire prior to the launch of the F8 Formulation, if approved. Cost of goods sold for Fiscal 2023 also included other provisions totalling $220,000, related to the pending approval of the F8 Formulation (See Note 9 of the Audited Financial Statements).

In Fiscal 2022, cost of sales included an amortization charge of $2,441,000 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 Fiscal 2023.

R&D Expenses

R&D expenses were $30,370,000 for Fiscal 2023 compared to $36,939,000 for Fiscal 2022, a decrease of 17.8%, mostly due to lower spending on our various programs. R&D expenses in the first and second quarters of Fiscal 2023 were also negatively impacted by expenses of $3,730,000 related to sudocetaxel zendusortide material and expenses of $536,000 related to the production of bacteriostatic water for injection (“BWFI”). Excluding these expenses, R&D expenses are down significantly in Fiscal 2023 compared to last year, mostly as a result of lower spending on our oncology program. R&D expenses also included $1,384,000 in severance and other expenses related to the reorganization announced in July 2023.

Selling Expenses

Selling expenses for Fiscal 2023 were $26,769,000 compared to $39,391,000 for Fiscal 2022. The decrease in selling expenses is mainly related to higher expenses incurred in Fiscal 2022 related to the setting up of our internal field force in the United States as well as severance costs incurred following our decision in 2022 to exit the European market for the commercialization of Trogarzo®. The decrease is also due in large part to a charge of $6,356,000 related to the accelerated amortization, in the second quarter of Fiscal 2022, of the Trogarzo® commercialization rights for the European territory. Selling expenses in Fiscal 2023 included $220,000 in severance and other expenses related to the reorganization announced in July 2023.

The amortization of the intangible asset value for the *EGRIFTA SV*® and Trogarzo® commercialization rights is also included under selling expenses. As such, we recorded amortization expenses of $2,513,000 for Fiscal 2023, compared to $9,211,000 in Fiscal 2022 (which included the charge related to accelerated amortization of the Trogarzo® commercialization rights for the European territory).

General and Administrative Expenses

General and administrative expenses for Fiscal 2023 were $15,617,000 compared to $17,356,000 for the same period in Fiscal 2022. The decrease in general and administrative expenses is largely due to our decision to terminate the commercialization activities of Trogarzo® in Europe during the second quarter of Fiscal 2022. General and administrative expenses for Fiscal 2023 also included $359,000 in severance and other expenses related to the reorganization announced in July 2023.

Net Finance Costs

Net finance costs for Fiscal 2023 were $12,909,000 compared to $6,886,000 in Fiscal 2022. The increase in net finance costs in Fiscal 2023 versus Fiscal 2022 was mostly due to the higher interest expense on the Company's Loan Facility ($3,906,000), as well as expenses of $3,540,000 related to the amendments to the Marathon Credit Agreement. Other expenses in Fiscal 2023 include the write-off deferred financing costs ($954,000). These higher costs are offset by gain on the change of fair value of the Marathon Warrants and a lower foreign exchange loss.

Adjusted EBITDA

Adjusted EBITDA was $(2,907,000) for Fiscal 2023 compared to $(22,088,000) for Fiscal 2022. Adjusted EBITDA in the first and second quarters of Fiscal 2023 was negatively affected by expenses of $3,749,000 related to sudocetaxel zendusortide material and expenses of $536,000 related to the production of BWFI. No such expenses were recorded in the third and fourth quarters of Fiscal 2023. See "Non-IFRS and Non-US-GAAP Measure" above and see "Reconciliation of Adjusted EBITDA" below for a reconciliation to Net Loss for the relevant periods.

Net Loss

Taking into account the revenue and expense variations described above, we recorded a net loss of $23,957,000, or $0.91 per share, in Fiscal 2023 compared to $47,237,000, or $1.98 per share, in Fiscal 2022.

Fiscal Year 2022 Financial Results compared to Fiscal Year 2021 Financial Results

Revenue

Revenue for Fiscal 2022 was $80,057,000 compared to $69,823,000 in Fiscal 2021, representing an increase of 14.7%.

For Fiscal 2022, net sales of *EGRIFTA SV*® reached $50,454,000 compared to $43,009,000 for Fiscal 2021 representing growth of 17.3%. Strong net sales of *EGRIFTA SV*® were mostly the result of 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® net sales were $29,603,000 compared to $26,814,000 in Fiscal 2021, 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 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 in the amount of $1,788,000, and (3) a provision of $1,477,000 related to the write down of F8 Formulation for pre-commercial material which could expire prior to the launch of the F8 Formulation. Cost of goods sold for Fiscal 2022 also included 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 clinical trial, the IM method of administration clinical trial, spending on the development of the multi-dose pen injector for the F8 Formulation, and spending on the HFS for *EGRIFTA SV*®. Fiscal 2022 spending also included 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 decreased level of activity in Europe.

Selling Expenses

Selling expenses for Fiscal 2022 were $39,391,000 compared to $28,909,000 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 the second quarter of Fiscal 2022.

General and Administrative Expenses

General and administrative expenses for Fiscal 2022 were $17,356,000 compared to $14,616,000 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 Fiscal 2022 versus Fiscal 2021 was mostly due to higher interest expense on the Company's Loan Facility in the third quarter 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.

Adjusted EBITDA

Adjusted EBITDA was $(22,088,000) for Fiscal 2022 compared to $(14,586,000) for Fiscal 2021. Adjusted EBITDA in Fiscal 2022 was affected by higher overall spending, as detailed above. The increase in expenses was offset by higher net sales and gross margins. See "Non-IFRS and Non-US-GAAP Measure" above and see "Reconciliation of Adjusted EBITDA" below for a reconciliation to Net Loss for the relevant periods.

Net Loss

Taking into account the revenue and expense variations described above, we recorded a net loss of $47,237,000, or $1.98 per share, in Fiscal 2022 compared to $31,725,000, or $1.37 per share, in Fiscal 2021.

Financial Position, Liquidity and Capital Resources

Going Concern Uncertainty

As part of the preparation of the Audited 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, 2023. 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, 2023, the Company incurred a net loss of $23,957,000 (2022-$47,237,000; 2021-$31,725,000) and had negative cash flows from operating activities of $5,678,000 (2022- $14,692,000; 2021- $17,501,000). As at November 30, 2023, cash amounted to $34,097,000 and bonds and money market funds amounted to $6,290,000.

The Marathon Credit Agreement 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 Note 17 of the Audited Financial Statements). A liquidity breach provides the lender with the ability to demand immediate repayment of the Loan Facility and makes available to the lender the collateralized assets, which include substantially all cash, bonds and money market funds which are subject to control agreements. It may trigger an increase of 300 basis points of the interest rate on the outstanding loan balance. On July 3, 2023, the Company incurred a liquidity breach resulting in the lender having the ability to demand immediate repayment of the debt, which breach was waived on September 21, 2023. During Fiscal 2023, the Company entered into several amendments to the Marathon Credit Agreement to amend certain of the terms and conditions therein (see note 17 of the Audited Financial Statements).

The amendments to the Marathon Credit Agreement covenants resulted in: (i) revising the minimum liquidity requirements for all times following October 31, 2023 to be between $15,000,000 and $20,000,000, based on the Marathon Adjusted EBITDA thresholds over the most recently ended four fiscal quarters; (ii) revising the minimum revenue requirements to be based on Marathon Adjusted EBITDA targets instead of quarterly revenue-based targets, beginning with the quarter ending November 30, 2023; and (iii) deleting the prohibition against the Company having a going concern explanatory paragraph in the opinion of the independent registered public accounting firm of the Company that accompanies the Company's annual report. Notwithstanding the latest amendments, there is no assurance that the lender will agree to amend or to waive any future potential covenant breaches, if any. The Company does not meet the condition precedents to drawdown additional amounts under the Marathon Credit Agreement and does not currently have other committed sources of financing available to it.

The Company's ability to continue as a going concern for a period of at least, but not limited to, 12 months from November 30, 2023, involves significant judgement and is dependent on the adherence to the conditions of Marathon Credit Agreement or to obtain

the support of the lender (including possible waivers and amendments), increase its revenues and the management of its expenses (including the reorganization mainly focused on its R&D activities-see Note 16(a) of the Audited Financial Statements) in order to generate sufficient positive operating cash flows. Some elements of management's plans are outside of management's control and the outcome cannot be predicted at this time. Should management's plans not materialize, the Company may be in default under the Marathon Credit Agreement, be forced to reduce or delay expenditures and capital additions and seek additional alternative financing, or sell or liquidate its assets. 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.

The Audited 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. The Audited 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 the Audited 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, 2023, cash, bonds and money market funds amounted to $40,387,000 compared to $33,070,000 at November 30, 2022. 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 currently is required to maintain $20,000,000 in cash, bonds and money market funds to respect its minimum liquidity covenant (the "Liquidity Covenant"). The Liquidity Covenant can decrease to $17,500,000 and again to $15,000,000 should the Company achieve the predetermined Marathon Adjusted EBITDA thresholds (as set forth in the Marathon Credit Agreement).

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.

During Fiscal 2023, cash flows used in operating activities were $5,678,000, compared to $14,692,000 in Fiscal 2022.

In Fiscal 2023, changes in operating assets and liabilities had a positive impact on cash flow from operations of $8,133,000 (2022-positive impact of $13,017,000). These changes included positive impacts from a decrease in inventories ($10,327,000), lower prepaid expenses and deposits ($4,511,000) and higher provisions ($1,920,000). Decreased accounts payable ($7,508,000) had a negative impact on cash flow, as did higher trade and other receivables ($902,000). The decrease in inventories was mainly due to a planned reduction of Trogarzo® inventory levels.

During the fourth quarter of Fiscal 2023, cash flows used in operating activities were $5,606,000. Changes in operating assets and liabilities had a negative impact on cash flow from operations of $6,910,000. These changes included negative impacts from an increase in trade and other receivables ($4,339,000) and prepaid expenses and deposits ($1,366,000) as well as a decrease in accounts payable and accrued liabilities ($2,108,000).

During Fiscal 2023, the Company received net proceeds of $19,300,000 from the draw-down of the second tranche under the Marathon Credit Agreement. On June 30, 2023, we redeemed the remaining $27,452,000 of Convertible Notes. As at November 30, 2023, no Convertible Notes remained outstanding.

During the fourth quarter of Fiscal 2023, the Company realized net proceeds of $23,575,000 from the issuance of Common Shares, and Exchangeable Subscription Receipts from the 2023 Public Offering and Concurrent Private Placement. This amount includes the proceeds from the exercise of the over-allotment option, resulting in the issuance of 160,000 Common Shares.

The Company does not meet the conditions precedent to draw-down the third ($15,000,000) and fourth ($25,000,000) tranches of the Loan Facility. These will cease to be available to the Company after March 31, 2024.

As stated above, the amendments to the Marathon Credit Agreement covenants resulted in: (i) revising the minimum liquidity requirements for all times following October 31, 2023 to be between $15,000,000 and $20,000,000, based on Marathon Adjusted EBITDA thresholds over the most recently ended four fiscal quarters (or shorter period set forth in the Marathon Credit Agreement); and (ii) revising the minimum revenue requirements to be based on Marathon Adjusted EBITDA targets instead of quarterly revenue-based targets, beginning with the quarter ending November 30, 2023. While the Company's current cash, bonds and money market funds amounted to $40,387,000, we continue to monitor these balances in order to continuously meet the minimum liquidity requirements as set out in the Marathon Credit Agreement. We currently also meet the Marathon Adjusted EBITDA, and our current operating plan projects that we will continue to meet these targets for the foreseeable future. We plan to ensure continued compliance through close management of expenses and will adapt spending in the event of weakness in our revenues.

Commitments

Off Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Contractual obligations

The following table lists as of November 30, 2023, 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
Lease Liabilities	1,108,000	487,000	516,000	105,000	—
Term loan, including interest (1)	80,141,000	17,416,000	50,348,000	12,377,000	
Purchase Obligations (2)	15,489,000	10,989,000	2,250,000	2,250,000	—
Total	**$ 96,738,000**	**$ 28,892,000**	**$ 53,114,000**	**$ 14,732,000**	**$ —**

(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, 2023, the Corporation had outstanding purchase orders and minimum payments under these agreements amounting to $14,682,000 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 $807,000 in connection with its oncology platform.

License agreement

On February 4, 2020, the Company entered into an amended and restated licence agreement with the Massachusetts General Hospital ("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, the 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, the Company agreed to make certain milestone payments to the MGH related to the development of tesamorelin and to pay a low single-digit royalty on all sales of *EGRIFTA SV*® above a certain 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 Non-Alcoholic Fatty Liver Disease or NASH in the general population.

Financial Risk Management

This section provides disclosures relating to the nature and extent of the Company's exposure to risks arising from financial instruments, including credit risk, liquidity risk, currency risk and interest rate risk, and how the Company manages those risks.

Credit Risk

Credit risk refers to 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 (refer to Note 27 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 $12,798,000 (2022 – $10,659,000), 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, 2023 and 2022. Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consists 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 (2023 – $6,290,000; 2022 – $9,214,000). As at November 30, 2023, 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 refers to the risk that the Company will not be able to meet its financial obligations as they become due. As indicated in Note 24 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 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 regards to the expected timing of expenditures and prevailing interest rates.

Pursuant to the Marathon Credit Agreement, the Company is required to maintain cash, cash equivalents and eligible short-term investments overtime between $15,000,000 to $20,000,000 based on the last twelve months adjusted EBITDA-based targets, which restricts the management of the Company's liquidity. Refer to notes 1 and 17 of 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 euros.

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 following table presents the significant items in the original currencies exposed to currency risk as at November 30, 2023 and 2022.

(in thousands)

	2023		2022	
	CA$	**EURO**	**CA$**	**EURO**
Cash	358	123	1,547	236
Bonds and money market funds	8,543	-	12,387	-
Trade and other receivables	296	2	733	2,141
Tax credits and grants receivable	497	145	66	239
Accounts payables and accrued liabilities	(5,395)	(224)	(10,784)	(5,849)
Lease liabilities	(925)	(288)	(1,362)	(873)
Provisions	(326)	(3,192)	-	(3,486)
Total exposure	3,048	(3,434)	2,587	(7,592)

The following exchange rates are those applicable as at November 30, 2023 and 2022.

	2023		2022	
	Average rate	**Reporting date rate**	**Average rate**	**Reporting date rate**
CA$ – US$	0,7404	0,7363	0,7722	0,7439
Euro – US$	1,0792	1,0903	1,0600	1,0406

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 an impact on net earnings for CA$ and in the accumulated other comprehensive loss for euro as follows, assuming that all other variables remained constant.

(in thousands)

	2023		2022	
	CA$	**Euro**	**CA$**	**Euro**
Positive (negative) impact	152	(172)	129	(380)

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

Interest Rate Risk

Interest rate risk refers to 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 fair value through OCI, 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, 2023, 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 $42,000 (2022 – $79,000); 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 variable rates. 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, 2023 of $20,231,000 (2022 – $23,505,000), an assumed 0.5% increase in interest rates during such year would have increased future cash flows and net profit by approximately $101,000 (2022 – $118,000); an assumed decrease of 0.5% would have had an equal but opposite effect.

Based on the value of the Company's long-term loan as at November 30, 2023, an assumed 0.5% increase in SOFR rate during such year would have decreased future cash flows and net profit by approximately $300,000 and an assumed increase of 0.5% would have had an equal but opposite effect.

Determination of Fair Values

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.

Financial assets and financial liabilities measured at fair value

In establishing fair value, the Company uses a fair value hierarchy based on levels as defined below:

Level 1: Defined as observable inputs such as quoted prices in active markets.

Level 2: Defined as inputs other than quoted prices in active markets that are either directly or indirectly observable.

Level 3: Defined as inputs that are based on little or no observable market data, therefore requiring entities to develop their own assumptions.

Other financial assets and financial liabilities

The Company has determined that the carrying values of its short-term financial assets and financial liabilities, including cash, trade and other receivables, and accounts payable and accrued liabilities 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 (Level 2).

The Company has determined that the carrying value of its Loan Facility approximates its fair value because the terms were modified near the end of the 2023 fiscal 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 fair value of the DSUs is determined using the quoted price of the Common Shares of the Company and considered Level 2 in the fair value hierarchy.

The Marathon Warrants are recognized at fair value and considered Level 3 in the fair value hierarchy. A reasonably possible changes at the reporting date to one of the significant unobservable inputs, holding other inputs consistent, would have the following effects:

(in thousands)

	Net profit (loss)	
	Increase	**Decrease**
Expected volatility (10% movement (100 bps))	$ (100)	$ 125

Related party transactions

Refer to Note 28 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 (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 common 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 authorizations 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, the measurement of share-based arrangements, the Marathon Warrants and gain or loss on amendments to the Marathon Credit Agreement.

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

New Accounting Standard Adopted

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 applied to the Company's annual reporting periods beginning on December 1, 2022, to contracts existing at the date the amendments were first applied. The adoption of the standard did not have an impact on the financial statements.

Standards issued but not yet effective

A number of new standards are effective for annual periods beginning after December 1, 2023 and earlier application is permitted; however, the Company has not early adopted the new or amended standards in preparing the Audited 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 provide 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 will be 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 20, 2024, the number of issued and outstanding Common Shares amounted to 45,980,019. The following securities were also issued and outstanding: 5,000,000 Marathon Warrants, 2,053,231 share options and 3,381,816 Exchangeable Subscription Receipts.

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, 2023. 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, 2023, 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, concluded that a material weakness existed as described below, and due to this material weakness, the Company's internal control over financial reporting was 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 following control deficiency was considered to be a material weakness as of November 30, 2022:

- 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.

In Fiscal 2023, the Company's management team remediated the ineffective controls related to the above-described material weakness. The material weaknesses can now be considered fully remediated at November 30 2023 as management has concluded, through testing, that these controls are operating effectively.

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, 2023 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 as of November 30, 2023, our internal controls over financial reporting were appropriately designed and operating effectively.

Changes in Internal Control over Financial Reporting

Other than the remediation of the material weakness described above, there were no changes in our internal controls over financial reporting that occurred during the period from September 1st, 2023 to November 30, 2023, and the period from December 1, 2022 to November 2023 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Reconciliation of Adjusted EBITDA
(In thousands of U.S. dollars)

	Three-month periods ended November 30		Years ended November 30		
	2023	2022	**2023**	2022	2021
Net loss	**(2,755)**	(7,929)	**(23,957)**	(47,237)	(31,725)
Add :					
Depreciation and amortization[1]	**576**	940	**3,315**	12,471	8,748
Net Finance costs[2]	**5,352**	2,078	**12,909**	6,886	6,426
Income taxes	**73**	143	**421**	443	63
Share-based compensation	**418**	852	**2,215**	3,872	1,932
Inventory provision (reversal)[3]	**50**	1,477	**220**	1,477	(30)
Restructuring costs[4]	**1,244**	-	**1,963**	-	-
Adjusted EBITDA	**4,958**	(2,439)	**(2,914)**	(22,088)	(14,586)

[1] Includes depreciation of property and equipment, amortization of intangible, other assets and right-of-use assets.
[2] Includes all finance income and finance costs consisting of: Foreign exchange, interest income, accretion expense and amortization of deferred financing costs, interest expense, bank charges, gain or loss on financial instruments carried at fair value and loss on debt modification and gain on lease termination.
[3] Inventory provision pending marketing approval of the F8 Formulation.
[4] Restructuring costs include severance and other expenses associated with termination of employment related to the reorganization announced in July 2023 and completed in October 2023.

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RISKS FACTORS

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 ("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, 2023 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, 2023. The going concern note casts substantial doubt about the capacity of the Corporation to meet its monetary obligations.

The Corporation's Auditors Report to the shareholders and Board of Directors, as well as note 1 to the audited annual consolidated financial statements of the Corporation for the fiscal year ended November 30, 2023, 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 substantial doubt about the capacity of the Corporation to honor its obligations as they fall due during a period of at least 12 months from November 30, 2023.

A breach of a financial covenant under the Marathon Credit Agreement would entitle the lender to demand immediate repayment of the Corporation's debt. As at November 30, 2023, the Corporation's cash, bonds and money market funds amounted to $40.4 million whereas the principal of the loan to be reimbursed would amount to $60.6 million. Therefore, the Corporation could be unable to reimburse its debt unless it is able to find additional external financing by way of an equity offering. Absent such additional source of financing, the Corporation may have to resort to insolvency laws.

In the event there occurs an event of default under the Marathon Credit Agreement, 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. If Marathon was to declare all loaned amounts due and payable under the Marathon Credit Agreement, 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 in full the loaned amounts under the Marathon Credit Agreement. 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 Marathon Credit Agreement contains various covenants, undertakings and obligations, any breach of which could trigger an event of default under the Marathon Credit Agreement 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 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.

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 if liquidities readily available to the Corporation were below the amount of the debt to be repaid. As at November 30, 2023, the Corporation had approximatively $40.4 million in cash, bonds and money market funds while the principal of the debt amounted to $60.6 million. Alternative sources of financing could include 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.

In the past, the Corporation has breached certain terms and conditions of the Marathon Credit Agreement. While we have been successful in negotiating waivers of default and amendments to the Marathon Credit Agreement, there can be no assurance that, going forward, Marathon will agree to additional waivers or amendments to the Marathon Credit Agreement if the Corporation breaches any of the covenants, undertakings or obligations under such agreement. Furthermore, any additional waivers or amendments to the Marathon Credit Agreement could be costly to the Corporation. The failure to amend the Marathon Credit Agreement or to obtain a waiver from Marathon in the future in the event we are in default under the Marathon Credit Agreement 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.

We did not generate a profit from our operations in the fiscal year ended November 30, 2023., There can be no guarantee that we will ever achieve profitability.

We have a history of net losses, including a net loss of $24 million for the fiscal year ended November 30, 2023. In the future, our profitability will mainly depend on our capacity to successfully maintain the commercialization of *EGRIFTA SV*® and Trogarzo® in the United States through a low-cost and effective distribution network, compliance with applicable laws, the recruitment and retention of talented personnel, the deployment of effective marketing campaigns 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 long-term profitability will also depend on our ability and capacity to acquire or in-license additional commercialized drug products immediately accretive to our business, and 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 or that we will be successful in acquiring or in-licensing additional commercialized drug products. The acquisition or in-licensing of additional commercialized drug products will depend on our ability to identify such products, our capacity to enter into agreements on terms satisfactory to us and to obtain all approvals, if any are required. 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.

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 generate a level of positive cash flows from operating activities sufficient to pay the principal and interest on the loan provided by Marathon.

For the three months ended November 30, 2023, and for the fiscal year ended November 30, 2023, the Corporation had negative operating cash flows of $4.1 million and $5.7million, respectively. If the cash flow we generate and our 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, 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 Agreement and on our capacity to execute on our business plan.

The interest rate we have to pay Marathon under the Marathon Credit Agreement 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 Agreement 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 loss will increase and cash flows from operating activities, including cash available for servicing our indebtedness, will correspondingly decrease.

The Marathon Credit Agreement 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 Agreement 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 Agreement governing our outstanding $60.6 million loan imposes significant operating and financial restrictions on the Corporation. These restrictions limit our ability and the ability 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 Agreement imposes that we maintain a minimum level of liquidity of between $15 million and $20 million in cash, cash equivalent and eligible investments at all times based on the Marathon Adjusted EBITDA thresholds over the most recently ended four fiscal quarters. 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 Agreement also imposes a minimum Marathon Adjusted EBITDA covenant on a quarterly basis that began with the quarter ending November 30, 2023. The Marathon Credit Agreement 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 unless we are able to negotiate waivers or amendments to the Marathon Credit Agreement. 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 Agreement 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 Agreement 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 Agreement 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. In the event there occurs an event of default under the Marathon Credit Agreement 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, Bachem Americas Inc. (“Bachem”), and Jubilant HollisterStier, General Partnership (“Jubilant”), our distributor in the United States (Mckesson Specialty Care Distribution, LLC (“McKesson”), as well as other specialized third parties; and (f) remain compliant with applicable laws.

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 and could also result in a default to meet the Marathon Adjusted EBITDA covenant.

McKesson is our only client in the United States in connection with the sale of EGRIFTA SV® and Trogarzo® and we are currently negotiating the terms and conditions of a new agreement with McKesson. Any default or a dispute under our current agreement, or its termination, or the failure to enter into a new agreement, 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 McKesson that acts as our exclusive distributor in the United States. Our current agreement with McKesson is subject to automatic renewal in April of each year unless a party provides the other with a 120-day written notice of its intent not to renew the agreement or there is no agreement on the fees to be paid annually to McKesson if there is a material change in the industry that causes a financial hardship to McKesson to continue providing its services pursuant to the then agreed upon pricing. In the latter circumstances, McKesson could be entitled to terminate its agreement with us upon a 90-day prior written notice. Both parties also have termination rights in certain other circumstances such as a breach of the agreement. If our agreement with McKesson is terminated, or we are unable to agree on the terms of a new agreement and we are unable to find another distributor prior to its term, or if we are in default or engaged in a dispute with McKesson, our sales may be materially adversely impacted and our revenues could decrease substantially.

In addition, under the terms of our agreement with McKesson, we agreed to reimburse McKesson for chargebacks and other discounts that McKesson may offer to its clients. If McKesson's clients omit to timely claim from McKesson 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 McKesson for such discounts to which McKesson's 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 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 ("LSNE") for the manufacture of the F8 Formulation. 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. There are a limited number of third-party suppliers that are compliant with current good manufacturing practice, ("GMP"), and that also have the necessary expertise and capacity to manufacture our drug substance and drug product. 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 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. The delays associated with the validation of a third-party manufacturer could negatively affect our ability to commercialize our products in a timely manner and on budget. Given the long lead times to change manufacturers, existing manufacturers may utilize this as leverage in negotiations with us in a manner that is adverse to our business.

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 Apptec Biologics, Inc., ("WuXi") and Samsung Biologics Laboratories in South Korea ("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 McKesson 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 McKesson 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 service 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 New Drug Application (“ 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*® 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, epidemics including global health concerns, or insolvency; (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; (d) makes errors in manufacturing raw materials, components or products that could negatively affect the efficacy or safety of our products or cause delays in the shipment.

We may also be subject to distribution disruption and interrupted sales of *EGRIFTA SV*® and Trogarzo® in the United States if: (a) we are unable to negotiate the terms of a new agreement to include serialization services (b) McKesson becomes unavailable to us for any reason, including as a result of its failure to meet applicable laws; (c) McKesson experiences warehousing problems or other operational failure, such as unplanned facility shutdown or damage from any event, including fire, flood, earthquake, epidemics including global health concerns, business restructuring or insolvency; or (d) McKesson 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.

We no longer have a long-term supply agreement for the supply of sterile water for injection ("SWI") which is provided to patients with other ancillary devices contained in the administration box in connection with EGRIFTA SV®. As a result, we may run into supply issues because there exists no commitment to supply us with such product and we must order the SWI on a case-by-case basis. If we are unable to purchase SWI, we may have to change our offering to patients, and this could be perceived negatively and could adversely affect the sales, revenues, and operating results of the Corporation.

We no longer have a long-term supply agreement with a supplier of SWI. The Corporation provides SWI to patients in the medication box along with other ancillary devices including alcohol swabs, syringes and needles in connection with *EGRIFTA SV*®. As a result, we may run into supply issues because there exists no commitment to supply us with SWI and we must order the SWI on a case-by-case basis. If we are unable to purchase SWI, we may have to change our offering to patients, and this could be perceived negatively and could adversely affect the sales, revenues, and operating results of the Corporation.

We do not currently have plans to enter into a long-term supply agreement for SWI. The Corporation intends to pursue the approval of the F8 Formulation and plans to withdraw *EGRIFTA SV*® from the market if and when the F8 Formulation is approved by the FDA.

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 and to service the repayment of our debt under the Marathon Credit Agreement.

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 are currently few approved drug products competing directly with our approved products. However, with respect to Trogarzo®, we face competition from 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 costly, 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, a new formulation or a new method or route of administration will result in an approved drug, new formulation or new method or route of administration.

The development of new therapies is highly costly, 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 capital or access thereto, as well as 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 drug, a new formulation, a new method or route of administration or provide a new treatment, such as the conduct of our Phase 1 clinical trial using sudocetaxel zendusortide for the potential treatment of ovarian cancer, the development of our peptide-drug conjugates resulting from our SORT1+ Technology™ platform, and the potential development of tesamorelin for the treatment of NASH in the general population, will end up generating positive results leading to an approved drug, label expansion, new formulation, or a new method or route of administration by a regulatory authority. The failure to develop a new drug, a new formulation or a new method or route of administration could hamper the long-term growth of our business and have long-term adverse effects on our potential revenues and operating results.

The development of sudocetaxel zendusortide for the potential treatment of various types of sortilin-expressing cancers is still uncertain given that the Corporation's primary goal is to grow its Adjusted EBITDA and, to the extent it is successful in achieving such positive Adjusted EBITDA, the Corporation stated that upon completion of Part 3 of the Phase 1 clinical trial, the Corporation has decided that all future research in oncology would be made through partnership deals. There

can be no assurance that the development of sudocetaxel zendusortide will be completed, including the Phase 1 clinical trial, if the revenues generated from the sale of the Corporation's products and its operating expenses do not result in the achievement of a positive Adjusted EBITDA. Even if the Phase 1 clinical trial is completed, there can be no assurance that the further development of sudocetaxel zendusortide will be pursued if the Corporation is unable to find a partner or if the terms and conditions of any agreement with a partner are not satisfactory to the Corporation. As a result of any of the foregoing, the Corporation may have to cancel the development of sudocetaxel zendusortide, including its Phase 1 clinical trial, and the development of its SORT1+ Technology™ platform. Any such cancellation will materially adversely affect its pipeline of drug candidates, all of which would materially adversely affect its long-term growth and prospects. The cancellation of the research and development program in oncology could also have a material adverse effect on the price of our Common Share.

On January 4, 2023, we announced that the development of sudocetaxel zendusortide would be stage-gated and that all decisions related to its development would be carefully taken in the context of the Corporation's goal to generate a positive Adjusted EBITDA in 2023 and beyond. Over the course of the fiscal year 2023, we have reiterated this message and have implemented a reorganization in July and October 2023 mostly impacting research and development positions within the organization.

Despite the Corporation's goal of achieving a positive Adjusted EBITDA in 2023 and beyond, on June 2, 2023, the Corporation announced FDA's acceptance of the Corporation's amended protocol for the Phase 1 clinical trial using sudocetaxel zendusortide and the Corporation resumed the conduct of such Phase 1 clinical trial. The amended protocol was designed to improve the therapeutic window of sudocetaxel zendusortide and extend its duration of therapy. The frequency of administration was changed to weekly dosing and the patient population was narrowed to focus on those with high grade serous ovarian cancer, including high-grade peritoneal or fallopian tube cancer, or high-grade endometrioid cancer. Patient selection was also refined to focus on those who are less heavily pretreated, with no more than one taxane failure and a maximum of eight prior cancer treatment regimens. The Corporation has committed to delivering on Part 3 of the Phase 1 clinical trial in advanced ovarian cancers. However, this commitment remains subject to the Corporation becoming cash-flow positive and on growing its Adjusted EBITDA. The ability of the Corporation to generate a positive Adjusted EBITDA will depend on the Corporation's revenues generated from the sale of its products and on its operating expenses. There can be no assurance that the development of sudocetaxel zendusortide will be completed, including the Phase 1 clinical trial, if the revenues generated from the sale of the Corporation's products and its operating expenses do not result in the growth of its Adjusted EBITDA.

Additionally, to the extent the Phase 1 clinical trial using sudocetaxel zendusortide is not halted or cancelled prior to the finalization of the Phase 1 clinical trial, the Corporation has decided that, upon completion of the Phase 1 clinical trial, all future research in oncology, including the pursuit of the development of sudocetaxel zendusortide, will be made through partnership deals. 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 halt or cancel this program. The halt or the cancellation of the development of sudocetaxel zendusortide as well as any other research and development activities in oncology will materially adversely affect its pipeline of drug candidates, all of which would materially adversely affect the Corporation's long-term growth and prospects. The cancellation of the research and development program in oncology could also have a material adverse effect on the price of our Common Share.

Despite the resumption of the Phase 1 clinical trial, the conduct of clinical trials is risky and results may adversely vary from those that are expected. If any data collected from the Phase 1 clinical trial were to demonstrate safety or efficacy issues, the Corporation could halt or cancel the development of its SORT1+ Technology™ platform, including sudocetaxel zendusortide, all of which would materially adversely affect its long-term growth and prospects. Furthermore, 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 Corporation has filed a sBLA seeking the approval of the F8 Formulation. On January 24, 2024, the Corporation announced that the FDA had issued a CRL to the Corporation with questions largely related to chemistry, manufacturing and controls concerning the microbiology, assays, impurities and stability for both the lyophilized product and the final reconstituted drug product. The FDA also requested additional information to understand the potential impact of the proposed formulation on immunogenicity risk. Responding to the questions asked by the FDA in the CRL will result in additional expenses to be incurred by the Corporation. There can be no assurance that the Corporation will be able to satisfactorily respond to the questions raised by the FDA in its CRL, nor that the FDA will approve the F8 Formulation when a sBLA is resubmitted. If the F8 Formulation is not approved and commercialized, our revenues and operating results could be adversely affected and the introduction of a biosimilar version of EGRIFTA SV® in the United States market could be facilitated since EGRIFTA SV® is not patent protected. The entry of a biosimilar version of EGRIFTA SV® in the United States market could materially adversely affect the revenues and operating results of the Corporation.

The Corporation has conducted studies to assess the bioequivalence of the F8 Formulation against the original 1 mg/vial formulation of *EGRIFTA*®. In September 2023, the Corporation filed a sBLA with the FDA seeking the approval of the F8 Formulation for commercial use and, in January 2024, the Corporation received a CRL from the FDA.

The Corporation plans on addressing the questions raised by the FDA in its CRL. To adequately address these questions, the Corporation may have to incur additional expenses. Even if the Corporation addresses all of the questions raised by the FDA and resubmits a sBLA, the FDA could determine that the answers provided are not to its satisfaction and issue another CRL. If the FDA does not approve the F8 Formulation, the Corporation could 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 potential inventory

write-downs, all of which could adversely affect the Corporation's revenues, operating results and its potential profitability. Finally, the non-approval of the F8 Formulation would expose the Corporation to the entry of biosimilar versions of *EGRIFTA SV®* given that the patent protection for this product expired 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 entry of a biosimilar version of *EGRIFTA SV®* could materially adversely affect the revenues and operating results of the Corporation.

On March 26, 2021, the Corporation submitted to the FDA a CBE supplement to the Instructions For Use ("IFU") included in the EGRIFTA SV® product labeling. The FDA responded to our CBE supplement with a CRL on March 15, 2022, asking us to carry out a HFS to ensure that patients reconstitute the product in the proper manner. The Corporation subsequently filed two requests for an extension to file the HFS results. The FDA granted each request, and the Corporation has until September 15, 2024, to file the HFS results. If the Corporation is unable to complete and file the HFS results by that date, or if it is unable to obtain from the FDA an additional extension of time to file the HFS results, the Corporation will be in default under applicable laws. Even if the Corporation files the HFS results by the prescribed deadline set by the FDA, the FDA may not approve the HFS results and may issue an additional CRL. A default by the Corporation to comply with applicable laws could result in sanctions such as the imposition of fines or penalties, all of which could have a material adverse effect on the Corporation's operating results as well as its reputation. Moreover, the failure to submit the HFS results within the timelines prescribed by the FDA, or the issuance of a CRL based on the rejection by the FDA of the HFS results, could ultimately result in the FDA prohibiting the sale of EGRIFTA SV® in the United States due to the difficulty by patients to administer the right dose of EGRIFTA SV®. If we were unable to commercialize EGRIFTA SV® in the United States, absent the commercialization of the F8 Formulation, our revenues and operating results would be materially affected and would result in a default under the Marathon Credit Agreement.

Per the FDA request, the Corporation is required to complete a HFS for *EGRIFTA SV®* by September 15, 2024. To date, the Corporation has completed the first part of the study, the formative study. The validation study remains to be conducted and the results thereof remain to be filed and accepted by the FDA. If the F8 Formulation had been approved, the Corporation expected to withdraw the CBE and be relieved from the obligation to complete the HFS for *EGRIFTA SV®* given that the F8 Formulation would have replaced the current formulation of *EGRIFTA SV®* before the deadline to file the results of the HFS for *EGRIFTA SV®*. With the F8 Formulation having been subject to a CRL, if the Corporation is unable to complete and resubmit the results of the HFS of *EGRIFTA SV®* by September 15, 2024, or if the Corporation does not obtain from the FDA an additional extension of time to complete and file the results of such HFS before any prescribed deadline, the Corporation would be in violation of applicable laws which could result in sanctions such as the imposition of fines or penalties. If the results of the HFS are filed in due time but the FDA does not approve the HFS results, the FDA could issue an additional CRL. The failure to complete and submit the HFS results within prescribed timelines, or

the issuance of a CRL based on the rejection by the FDA of the HFS results, could ultimately result in the prohibition to sell *EGRIFTA SV*® in the United States due to the difficulty by patients to administer the right dose of *EGRIFTA SV*®. Any order issued by the FDA prohibiting the sale of *EGRIFTA SV*® in the United States would have a material adverse effect on the revenues and results of operations of the Corporation and, absent any material additional revenue-generating products commercialized by the Corporation, would result in a breach of the Marathon Credit Agreement. Any breach of the Marathon Credit Agreement under such circumstances would potentially lead to Marathon foreclosing on all of the assets of the Corporation or the Corporation resorting to insolvency laws.

The conduct of the second part of the study, the validation study, is expected to be costly, the result of which will be to adversely impact the operating expenses of the Corporation and its potential capacity to grow its Adjusted EBITDA as well as becoming profitable. In addition, there can be no assurance that the Corporation will be able to complete the HFS within any timelines prescribed by the FDA since the enrollment of patients in the first part of the HFS proved to be difficult and longer than expected. Furthermore, there can be no assurance that the FDA would grant any additional extension of time to the Corporation to complete and file the results of the HFS for *EGRIFTA SV*®. If the Corporation in unable to complete the HFS, the Corporation could be in violation of applicable laws and, in addition to the measures described above, the FDA could also impose additional requirements on the Corporation in order to continue its commercialization of *EGRIFTA SV*® in the United States (to the extent *EGRIFTA SV*® is not withdrawn from the market). These additional measures could result in additional expenses to the Corporation and could potentially adversely affect its operating results and its capacity to generate a positive Adjusted EBITDA.

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 European Medicines Agency ("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 decided to seek a potential partner to undertake this clinical trial. To date, we are still continuing to seek a partner and discussions are still ongoing.

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 CRO 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.

REGULATORY RISKS

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 *Federal Food, Drug and Cosmetic Act*, as amended, of the United States ("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.

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 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 research, development, manufacture and marketing of pharmaceutical products are governed by various governmental authorities throughout the world to ensure the efficacy and safety of such products. If we fail to comply with the applicable requirements at any time during the product development process,

approval process or commercialization process, we may be subject to administrative or judicial sanctions.

Governmental authorities in the United States, Canada, and other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products, such as *EGRIFTA SV*® and Trogarzo® and any other compound that we may develop. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. If we fail to comply with the applicable requirements at any time during the product development process, approval process or commercialization process, we may be subject to administrative or judicial sanctions. Sanctions could include, but are not limited to, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters or other enforcement letters, product recalls, import/export delays, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, and government reimbursement, restitution, disgorgement or civil or criminal penalties. Any sanctions could result in a material adverse effect on our reputation, business, financial condition and operating results.

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 expired in August 2023. Until we can commercialize tesamorelin using the F8 Formulation, the FDA-approved use of tesamorelin for the treatment of lipodystrophy is no longer 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 no longer patent protected in the United States. Tesamorelin, the active ingredient of *EGRIFTA SV*®, 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 would have an adverse effect on our operating results. Even if we 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® or any other drug product we may acquire or in-license 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 an entity owns or has rights to use patents pertaining to a subject matter in a country does not guarantee that it is not infringing one or more third-party patents in such country. Therefore, there can be no guarantee that any patent that we own of have rights to will not infringe or violate third-party patents and other third-party intellectual property rights in the country where such patent has been issued.

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.

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. Furthermore, if we fail to comply with securities laws and applicable pharmaceutical regulations in connection with the commercialization of our products, we may be exposed to claims for damages, fines, penalties, and other sanctions. Any claims for damages, and/or termination of our material contracts, the imposition of fines or penalties 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.

As a publicly traded pharmaceutical company we have to comply with securities laws and various laws related to the commercialization of drug products, any violation of which could result in claims for damages and/or the imposition of fines, penalties and other sanctions. If we are subject to claims for damages and/or the imposition of fines, penalties, or other sanctions this could have the effect of diverting management's attention from the operation

of the business, limit the financial resources available to the Corporation to execute its business plan and adversely affect the Corporation's reputation.

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, Ukraine, the Middle East, 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 and for new talents we may desire to recruit; (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 have a material adverse effect on our business, financial condition and operating results.

CYBERSECURITY AND DATA PRIVACY RISKS

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 have reviewed and are currently 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.

OTHER RISKS RELATED TO OUR BUSINESS

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, and to in-license or acquire approved products. Our business performance may prevent us from generating enough cash-flow to achieve our business plan 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 addition, the conditions precedent to have access to the third and fourth tranches under the Marathon Credit Agreement based on its current terms are not met, and therefore, unless an amendment to the Marathon Credit Agreement is entered into with Marathon, there is no ability to access these tranches. 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, incur additional debt, the terms and conditions of which may not be favorable to us. We currently have no arranged sources of financing available to us. 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. The loss of key account managers and medical science liaison personnel 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. In July 2023, we revised such revenue guidance to be in the range of $82 million to $87 million. In September 2023, such revenue guidance was tightened to be in the range of $82 million to $85 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, realizable value 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 authorizations 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 Agreement. For the fiscal year ended November 30, 2023, we have remediated such material weakness but there

can be no assurance that we will not identify other material weakness in our internal controls over financial reporting for the fiscal year ended November 30, 2024, and beyond. 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 Agreement. 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 Agreement. The Corporation's management team has implemented 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 succeeded in implementing remediation measures in the fiscal year ended November 30, 2023, there can be no assurance that we will not identify other material weakness in our internal controls over financial reporting for the fiscal year ended November 30, 2024, and beyond. If the Corporation 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 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 Toronto Stock Exchange ("TSX") and on the U.S. Nasdaq Capital market ("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, 2023, the Corporation's closing share price on Nasdaq has ranged from a low of $0.89 to a high of $16.28. 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 or 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 of our Common Shares could result in a decline in the price of our Common Shares. Being delisted from the Nasdaq stock market could also adversely affect analysts coverage of our business and prevent us from retaining U.S. investment bankers to raise capital in public offerings.

Under the Nasdaq minimum bid price requirement, the minimum bid price of our Common Shares may not remain below $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 $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.

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 $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, as performed on July 31, 2023, 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 Agreement; (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 the target price of 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 (“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.

We are governed by the corporate and securities laws of Canada, which in some cases have a different effect on shareholders than the corporate laws of Delaware, U.S. and U.S. securities laws.

We are governed by the *Business Corporations Act* (Québec) ("QBCA") and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a U.S. jurisdiction, and may, together with our charter documents, have the effect of delaying, deferring or discouraging another party from acquiring control of the Corporation by means of a tender offer, a proxy contest or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the QBCA and Delaware General Corporation Law ("DGCL") that may have the greatest such effect include, but are not limited to, the following: (i) for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions or amendments to the our articles) the QBCA generally requires a two-thirds majority vote by shareholders, whereas DGCL generally requires only a majority vote; and (ii) under the QBCA, holders of 10% or more of our shares that carry the right to vote at a meeting of shareholders can requisition a special meeting of shareholders, whereas such right does not exist under the DGCL.

The economic effects of a pandemic, epidemic or outbreak of an infectious disease could adversely affect our operations or the market price of our Common Shares.

Public health crises such as pandemics, epidemics or similar outbreaks, including coronavirus known as "COVID-19", could adversely impact our operations or the market price of our Common Shares. The extent to which a pandemic, epidemic or outbreak would affect our operations, or the market price of our Common Shares would depend on future developments, including the duration of any such pandemic, epidemic or outbreak and actions to contain or treat any such pandemic, epidemic or outbreak, among others.