MANAGEMENT'S DISCUSSION AND ANALYSIS
FOR THE YEAR ENDED NOVEMBER 30, 2021

The following Management's Discussion and Analysis, or 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, 2021, or Fiscal 2021, compared to the year ended November 30, 2020, or Fiscal 2020. 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 23, 2022, was approved by our Board of Directors on February 23, 2022 and should be read in conjunction with our audited annual consolidated financial statements and the notes thereto as at November 30, 2021, or Audited Financial Statements.

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

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

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

Forward-Looking Information

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

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

- our capacity to meet supply and demand for our products;
- the market acceptance of *EGRIFTA SV*® and Trogarzo® in the United States;
- the continuation of our collaborations and other significant agreements with our existing commercial partners and third-party suppliers and our ability to establish and maintain additional collaboration agreements;
- our success in continuing to seek and in maintaining reimbursement for *EGRIFTA SV*® and Trogarzo® by third-party payors in the United States;
- the pricing and reimbursement conditions of other competing drugs or therapies that are or may become available;
- our ability to protect and maintain our intellectual property rights in tesamorelin;
- our success in obtaining commercially attractive pricing and reimbursement for Trogarzo® in countries of the European Union and the United Kingdom;
- our ability and capacity to launch and successfully commercialize Trogarzo® in various countries of the European Union and the United Kingdom;
- the approval of the intravenous push, or IV Push, mode of administration of Trogarzo® by the United States Food and Drug Administration, or FDA;
- the approval of a new formulation of tesamorelin, or F8 Formulation by the FDA;
- our capacity to develop a multi-dose pen injector, or Pen, for use with the F8 Formulation;
- the approval of our amended protocol by the FDA regarding our planned Phase 3 trial in NASH using tesamorelin;
- our capacity to finance or finding a partner to conduct a Phase 3 clinical trial using tesamorelin for the treatment of NASH in the general population;
- our capacity to pursue the conduct of our Phase 1 clinical trial using our TH1902 PDC in various types of cancers;
- our capacity to enter into a partnership agreement with a third party regarding our TH1902 PDC for Greater China;
- our capacity to pursue the development of our other PDCs in the field of oncology;
- our capacity to acquire or in-license new products and/or compounds;
- 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:

- the current pandemic and the measures implemented to control it will have limited material adverse effect on our operations, including our commercial regular practice associated with the sale of our products;
- the vaccines recently developed to thwart the coronavirus will be safe and effective at combatting the coronavirus in its current form and in any variant form thereof;
- sales of *EGRIFTA SV*® and Trogarzo® in the United States will increase over time;

Theratechnologies Inc.
2015 Peel Street, 11th Floor
Montreal, Québec H3A 1T8

- our commercial practices in the United States and the countries of the European Union where we commercialize our products 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 countries where such products are commercialized;
- continuous supply of *EGRIFTA SV*® and Trogarzo® will be available;
- our relations with third-party suppliers of *EGRIFTA SV*® and Trogarzo® will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply *EGRIFTA SV*® and Trogarzo® to meet market demand on a timely basis;
- no biosimilar version of tesamorelin will be approved by the FDA;
- our intellectual property will prevent companies from commercializing biosimilar versions of tesamorelin in the United States;
- Trogarzo® will be added to the list of reimbursed drugs by countries of the European Union and the United Kingdom;
- the integration of U.S. employees into our U.S. subsidiary will not be disruptive to our business and will strengthen our commercial capabilities in the United States;
- the FDA will approve the F8 Formulation;
- no vaccine or cure will be found for the prevention or eradication of HIV;
- we will succeed in developing the Pen or any other device for use with the F8 Formulation and the FDA will approve the use of such device for the F8 Formulation;
- we will have the financial means or will find a partner to conduct a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- the FDA will approve the amendments to our current Phase 3 trial protocol evaluating the use tesamorelin for the potential treatment of NASH in the general population;
- we will succeed in recruiting patients and in conducting our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- we will succeed in recruiting and in conducting our Phase 1 clinical trial studying TH1902 in various types of cancers;
- our Phase 1 clinical trial studying TH1902 in various types of cancer will demonstrate strong efficacy results;
- we will succeed in entering into a partnership agreement with a third party for TH1902 in Greater China;
- our research and development activities will yield positive results;
- the data obtained from our market research on the potential market for the treatment of NASH in the general population and on the potential market for Trogarzo® in the United States and in the European Union are accurate;
- our European infrastructure is adequate to successfully launch and commercialize Trogarzo® in key European countries;
- 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; and
- our business plan will not be substantially modified.

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 "Risk 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.

BUSINESS OVERVIEW

Theratechnologies is a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs. We have a promising pipeline of investigational medicines in oncology and NASH and two approved medicines (*EGRIFTA SV*® and Trogarzo®) for people living with HIV. The Company has a sales and marketing infrastructure to commercialize its products in the U.S. and Europe. We continue to assess the market for potential product acquisitions or in-licensing transactions that would be complementary to our business and further drive future sustainable growth and value creation.

OUR MEDICINES

The Company has two approved medicines for people living with HIV, namely Trogarzo® in the United States, European Union, and United Kingdom, and *EGRIFTA SV*® in the United States. *EGRIFTA*® is commercially available in Canada. Sales of *EGRIFTA*® in Canada are not material to our business.

EGRIFTA SV® is a new formulation of *EGRIFTA*® that was approved by the FDA for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and launched in the United States in November 2019. Unlike *EGRIFTA*®, *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.

Trogarzo® was the first HIV treatment approved with a new mechanism of action in more than 10 years. It is the first in a new class of antiretrovirals, or ARV, and is a long-acting ARV therapy that can lead to an undetectable viral load in heavily treatment-experienced adult HIV-infected patients when used in combination with other ARVs. The treatment is infused once every two weeks.

Trogarzo® was approved by the FDA in March 2018 for the treatment of human immunodeficiency virus type 1, or HIV-1, infection in heavily treatment-experienced adults with multidrug resistant, or MDR, HIV-1 infection failing their current antiretroviral regimen. Trogarzo® was also approved by the European Medicines Agency, or EMA, in September 2019 for the treatment of adults infected with MDR HIV-1 for whom it is otherwise not possible to construct a suppressive antiviral regimen. Trogarzo® is currently commercially available in Germany and in Italy, and the Company expects to launch Trogarzo® in key

additional European countries later in 2022. A number of patients are also being treated with Trogarzo® in some European countries through early access programs. Trogarzo® will be launched on a country-by-country basis across Europe as it gains public reimbursement in each such country. In addition, Trogarzo® was approved in Israel in January 2022 and is now commercially available.

In March 2016, we obtained the rights to commercialize Trogarzo® in the United States and Canada pursuant to a distribution and licensing agreement with TaiMed Biologics, Inc., or TaiMed. In March 2017, the agreement was amended to include the commercial rights to Trogarzo® in the European Union and in other countries such as Israel, Norway, Russia and Switzerland, or TaiMed Agreement.

The Company's commercial product strategy for the 2022 fiscal year is to generate revenue growth through increased sales of our medicines in the United States while working on securing an appropriate price and widespread reimbursement for Trogarzo® in additional European countries and launch Trogarzo® in those key European countries.

IMPACT OF THE COVID-19 PANDEMIC

In Fiscal 2021, face-to-face interactions in clinics, hospitals, AIDS services organizations and other offices were reduced and patient treatment initiations were delayed due to restrictions implemented to stop the spread of COVID-19. In Fiscal 2021, we continued to offer virtual interactions to provide education and support for people in need of our medications, people living with HIV, case managers, healthcare providers and their staff, on how to manage HIV during the COVID-19 pandemic. While these efforts have helped support our goal to increase U.S. sales of Trogarzo® and *EGRIFTA SV*® new rounds of closures related to the Omicron variant of the virus have slowed some of these initiatives. In the European Union, sales of Trogarzo® and the review of regulatory dossiers were adversely impacted by COVID-19 due to strict lockdown measures imposed in many European countries.

To date, our on-going Phase 1 clinical trial of TH1902 for the treatment of various cancers and preparations for our Phase 3 clinical trial of tesamorelin for the treatment of NASH have not been materially adversely impacted by the COVID-19 pandemic.

OUR PIPELINE

Theratechnologies has established a promising pipeline of investigational medicines in areas of high unmet need, including NASH, oncology and HIV.

Tesamorelin

During fiscal year 2020, the Company completed evaluation and development of the F8 Formulation which, based on internal studies, is bioequivalent to the original commercialized formulation of tesamorelin, or F1 formulation. The F8 formulation has a number of advantages over the current formulation of *EGRIFTA SV*®. Specifically, it is two times more concentrated resulting in a smaller volume of administration and is intended to be presented in a multi-dose vial that can be reconstituted once per week. Similar to the current formulation of *EGRIFTA SV*®, the F8 Formulation is stable at room temperature, even once reconstituted. We intend to file a sBLA with the FDA to seek approval of the bioequivalence of the F8 Formulation in the first half of calendar 2022 for the treatment of lipodystrophy in people living with HIV.

The F8 Formulation is patent protected in the United States until 2033 and until 2034 in major European countries. Furthermore, the United States Patent and Trademark Office issued two U.S. patents to Massachusetts General Hospital, or MGH, relating to the treatment of hepatic disease using growth hormone related hormone, or GHRH, or analogues thereof which are scheduled to expire in 2040. We have an exclusive worldwide license with MGH for these patents.

The Company is currently working on the development of the Pen to be used in conjunction with the F8 Formulation. To date, its development is not completed, and we are still working on the Pen. As a result, no timeline has been set for the filing of an sBLA with the FDA in relation to the Pen.

In September 2020, we announced our intent to develop tesamorelin for the treatment of NASH in the general population. This decision was largely based on positive scientific evidence in addition to discussions with scientific advisors and the FDA and European regulatory agencies regarding drug development for the treatment of NASH.

In conjunction with The Liver Meeting® 2020 of the American Association for the Study of Liver Diseases, or AASLD, in November 2020, Lindsay T. Fourman, M.D., of the Metabolism Unit, Department of Medicine, Massachusetts General Hospital presented results from a new proteomics sub-analysis that demonstrated that serum levels of three proteins associated with the development of NASH and fibrosis, Vascular Endothelial Growth Factor A (VEGFA), Transforming Growth Factor Beta 1 (TGFβ1) and Colony Stimulating Factor 1 (CSF1), were significantly reduced in tesamorelin patients compared to a placebo group. These results help to understand how tesamorelin may induce key metabolic pathways that could have a direct effect on liver inflammation, fat and fibrosis and support the Company's plan to develop tesamorelin for the treatment of NASH.

In November 2020, we filed an Investigational New Drug Application, or 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 request a meeting to discuss the questions and comments contained in such letter to address certain aspects of the proposed trial design to ensure alignment with the agency's expectations with NASH trials. The Corporation followed up on the FDA's recommendation and requested a meeting with the agency. On July 15, 2021, we announced that we had completed discussions with the FDA following an end of Phase 2 meeting and with the EMA following a scientific advice meeting regarding the Phase 3 clinical trial in NASH.

The finalized Phase 3 trial design is planned for a multicenter, randomized, double-blind, placebo-controlled two-part study designed to evaluate the safety and efficacy of tesamorelin in liver-biopsy confirmed patients with NAS score of at least 4 and stage 2 or 3 fibrosis. Part 1 of the study will include a total of approximately 1,100 patients (1:1, tesamorelin:placebo), including approximately 75 to 100 people living with HIV. A second liver biopsy will be performed after the first approximately 1,100 participants have completed 18 months of treatment. This should form the basis for filing an sBLA with the FDA. The clinical trial will also include a futility analysis that would be conducted after the first approximately 400 patients have completed 18 months of treatment and have

received a second liver biopsy. The futility analysis will provide a perfunctory review indicating if an early treatment effect with tesamorelin has been observed and will determine if the study should proceed as planned. Following a potential sBLA approval, Part 2 of the trial will continue to enroll an additional approximately 1,800 patients (3:1, tesamorelin:placebo) to continue to measure clinical outcomes over a period of five years. A total of approximately 2,900 patients are expected to be enrolled.

On July 15, 2021, we also 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. An external U.S.-based biopharma advisory firm was retained for that purpose. To date, we are still continuing to seek a partner and to assess additional options, such as certain forms of financing.

In order to further de-risk the Phase 3 trial, the Company intends to submit an amended protocol to the FDA. The new protocol will include 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. A decision will then be made whether to continue the study until full number of patients (1,094) have completed 18 months of treatment. This does not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH.

Theratechnologies intends to use the F8 Formulation for the Phase 3 clinical trial in NASH. The Phase 3 trial in NASH will compare the F8 Formulation to a placebo.

The Company has retained the services of a contract research organization, or CRO, with experience in implementing large and late-stage clinical trials to assist with the execution of its Phase 3 clinical trial in NASH.

The Company is also conducting a study titled Visceral Adiposity Measurement and Observation Study, or VAMOS, to reflect our commitment to improve the health outcomes of people living with HIV. VAMOS is an epidemiologic cross-sectional study to answer the unknown associations between visceral fat and cardiovascular disease risk, liver fat, liver fibrosis, pericardial fat, and muscle fat in today's HIV patient. These associations will be measured across a diversity of weights, BMIs, genders, and races so that the impact of visceral fat can be understood with external validity to the results. Additionally, the performance of anthropometric measurements like waist circumference (WC) and hip circumference (HC) will be assessed in a modern HIV population. The aims of this study are two-fold: (1) To determine the utility of WC's ability to predict cardiovascular risk scores, liver fat, liver fibrosis, and abnormal glucose homeostasis across the full VAMOS population and subgroups (2) Identify common clinical data points in today's standard of care that can be used to assess a patient's risk of having excess visceral fat. The VAMOS results is expected to direct clinicians on why and which patients in their practice should be screened for excess visceral fat and treatment.

SORT1+ Technology™

The Company is currently developing a platform of new proprietary peptides for cancer drug development targeting the sortilin, or SORT1, receptor. SORT1 is expressed in ovarian, triple-negative breast, skin, lung, colorectal and pancreatic cancers, among

others. SORT1 plays a significant role in protein internalization, sorting and trafficking, and therefore, is an attractive target for anticancer drug development. Our innovative peptide-drug conjugates, or PDCs, generated through our SORT1+ Technology™ embody distinct pharmacodynamic and pharmacokinetic properties that differentiate them from traditional chemotherapy. In contrast to traditional chemotherapy, our proprietary PDCs are designed to enable selective delivery of certain anticancer drugs within the tumor microenvironment, and more importantly, directly inside sortilin positive cancer cells.

Our SORT1+ Technology™ was acquired in February 2019 as part of the acquisition of Katana Biopharma, Inc., or Katana. Through the acquisition, Theratechnologies obtained the worldwide rights to this platform based on an exclusive royalty-bearing license entered into between Katana and Transfer Plus L.P.

Preclinical *in vivo* data demonstrated that our SORT1+ Technology™ improved anti-tumor activity and reduced neutropenia and systemic toxicity. It also was shown in preclinical models to bypass the multidrug resistance protein 1, or MDR1; also known as P-glycoprotein, one of the mechanisms of chemotherapy drug resistance. In addition, our SORT1+ Technology™ demonstrated activity in preclinical models against the formation of vasculogenic mimicry, or VM, a mechanism also associated with cancer resistance. *In vivo* preclinical toxicity data have also demonstrated that TH1902, our lead PDC (docetaxel conjugate), could be administered at three times the maximum tolerated dose, or MTD, of docetaxel alone. The Company expects to present additional scientific data supporting these findings at scientific meetings to be held in 2022.

In February 2021, we received fast track designation from the FDA for TH1902 as a single agent for the treatment of patients with sortilin positive recurrent advanced solid tumors that are refractory to standard therapy.

In March 2021, a Phase 1 clinical trial was initiated evaluating TH1902 for the treatment of cancers where the sortilin receptor is expressed. The Phase 1 clinical trial design includes a Part A dose escalation study to evaluate the safety, pharmacokinetics, maximum tolerated dose, or MTD, and preliminary anti-tumor activity of TH1902 administered once every three weeks in patients with advanced solid tumors refractory to available anti-cancer therapies.

The Corporation's Phase 1 study evaluating its novel investigational proprietary PDC TH1902 for the treatment of sortilin positive cancers is progressing as planned. The Company is in the final stages of a Phase 1/Part A dose escalation study evaluating its lead investigational peptide-drug conjugate (PDC) TH1902 for the treatment of sortilin-positive cancers. As previously mentioned, we are currently evaluating patients in order to establish the safety of TH1902 as well as establish the maximum tolerated dose (MTD). As per study protocol, the MTD is established once a significant adverse event is observed in two or more patients. . In total, 4 patients in the trial have been administered significant doses of TH1902 at 420 mg/m^2 doses of TH1902, equivalent to nearly two times the indicated therapeutic dose of docetaxel. To date, Theratechnologies has observed a dose limiting toxicity (DLT) (grade 4 neutropenia lasting more than 7 days) in one patient, as well as other adverse events after more than one cycle at 420 mg/m^2. As a result, we have decided to pursue the study at a lower dose of 300 mg/m^2 (or approximately 1.5 times the usual dose of docetaxel). We currently are enrolling patients at the 300 mg/m^2 dose to

confirm the absence of DLTs following the first cycle. Once MTD has been established, the study protocol allows for immediate initiation of enrollment of a larger open label basket trial. The basket trial will further assess the safety and tolerability of TH1902. The preliminary anti-tumor activity of TH1902 will be evaluated for all patients as per the response evaluation criteria in solid tumors. Based on additional research we have conducted on the Sortilin receptor, we have submitted an amendment to the Phase 1 protocol to the FDA to include the following solid tumor types: Hormone Receptor-Positive (HR+) Breast Cancer, Triple Negative Breast Cancer, Ovarian Cancer, Endometrial Cancer, Melanoma (10 patients per tumor type). In addition, one arm will be added to include Thyroid, Small Cell Lung, Prostate and potential other high Sortilin expressing cancers (15 patients in total). The original trial design consisted of 40 patients across a selection of solid tumors, including colorectal and pancreatic cancers. The plan is now to enroll a total of approximately 70 patients in the basket trial to evaluate the potential anti-tumor activity of TH1902.

We are exploring the possibility of out-licensing development and commercialization rights for TH1902 in Greater China. We are pleased to report that there has been solid interest on the part of Chinese companies, and that discussions are ongoing with a number of different pharmaceutical and biotech companies.

Ibalizumab for HIV

An sBLA was filed with the FDA in the fourth quarter of 2021 for the Company's Intravenous (IV) Push method of administration of Trogarzo® for the treatment of human immunodeficiency virus type 1, or HIV-1. The FDA has accepted our filing and has provided a target action date of October 3, 2022 in accordance with the Prescription Drug User Fee Act (PDUFA).

Theratechnologies and TaiMed are also evaluating an intramuscular (IM) method of administration for Trogarzo® within the TMB-302 study. Patient screening for the IM study is in progress and we expect completion in the second half of 2022.

In connection with the September 2019 approval of Trogarzo® in Europe, the EMA has requested a post-authorization efficacy study, or Registry, to be conducted to evaluate the long-term efficacy and durability of Trogarzo® in combination with other antiretrovirals. The Company has initiated enrolment in this post-authorization study evaluating the real-world long-term efficacy and durability of Trogarzo® in combination with other antiretrovirals in Europe. The study, named Prospective and Retrospective, Observational Multicenter Ibalizumab Study of Efficacy (PROMISE). We are also conducting a similar trial in the United States, (PROMISE-US). PROMISE-US is a Prospective and Retrospective Observational study of Multidrug-resistant patient outcomes with and without Ibalizumab in a real-world SEtting. We intend to use the PROMISE-US data as part of the PROMISE trial.

The Company is also required to conduct a pediatric investigation plan, or PIP, to evaluate Trogarzo® in children aged 6 to <18 years old. The PIP will be comprised of two studies with the first study expected to begin in the latter part of 2022.

JANUARY 2021 OFFERING

Use of Proceeds

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

In the months following the January 2021 offering, the Company was able to complete its discussions with the FDA and the EMA regarding the design and protocol for the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH. As part of its announcement on July 15, 2021 regarding the finalization of the trial design, the Company also announced that the changes made to the design pursuant to the discussions held with the FDA and the EMA would result in higher costs than previously estimated, and that the Company was evaluating its options to best execute its late-stage development program for tesamorelin, including seeking a potential partner. As a result of the delay in the initiation of the NASH Phase 3 clinical trial, the funds raised in the January 2021 offering earmarked for such trial have been added to the Company's available cash balance. The Company's ability to execute its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH will be dependent on its ability to secure additional financial resources.

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

In millions	**Estimated Use of Proceeds**	**Actual Use of Proceeds**	**Variance**
Nash Phase 3 clinical trial	$30.5	$2.4	$(28.1)
Oncology R&D	7.0	$ 2.9	(4.1)
Commercial and marketing activities	3.5	--	(3.5)
Other	1.5	--	(1.5)
Net Proceeds	$42.5	$5.3	$(37.2)

As at November 30, 2021, approximately $2,418,000 had been used in connection with the NASH Phase 3 clinical trial.

As at November 30, 2021, approximately $2,886,000 had been used in connection with oncology research and development activities and the variance between the amount reserved and the amount used as at November 30, 2021 represents funds held in cash pending their planned allocation as costs are incurred.

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

2022 BUSINESS STRATEGY AND OBJECTIVES

Our 2022 Business Strategies and Objectives are as follows:

- Continue to grow sales of *EGRIFTA SV*® in North America and Trogarzo® in the United States and in the European Countries where it has obtained reimbursement;

- Seek commercially attractive pricing and reimbursement of Trogarzo® in additional countries of the European Union, including France, Spain and the United Kingdom and launch Trogarzo® therein;

- Launch the F8 Formulation of tesamorelin and the IV Push mode of administration of ibalizumab in the U.S.;

- Initiate Part B of our Phase 1 clinical trial studying TH1902 in various types of cancer;

- Begin a Phase 3 clinical trial using tesamorelin for the potential treatment of NASH in the general population after having secured additional financing or having found a partner;

- Pursue potential product acquisitions and in-licensing transactions or other similar opportunities complementary to our business;,

- Seek potential partners for our licensed SORT1+ Technology™ platform in countries where we do not intend to develop and conduct clinical trials;

- We plan on retaining and attracting a pool of diverse talents at all levels to participate and contribute to the successful execution of our business strategy and objectives; and

- Manage our financial position to ensure we can successfully execute on our 2022 business strategy and objectives.

Fourth-Quarter and Fiscal 2021 Revenue Highlights

(in thousands of dollars)

	Three-month periods ended November 30,		% change	Years ended November 30,		% change
	2021	2020		**2021**	**2020**	
EGRIFTA®, *EGRIFTA SV*® net sales	**12,753**	**10,751**	18.6%	**43,009**	**35,399**	21.5%
Trogarzo® net sales	**6,001**	**8,372**	-28.3%	**26,814**	**30,654**	-12.5%
Revenue	**$18,754**	**$19,123**	**-1.9%**	**$69,823**	**$66,053**	5.7%

Fourth-Quarter Fiscal 2021 Financial Results

Revenue

Consolidated revenue for the three months ended November 30, 2021 amounted to $18,754,000 compared to $19,123,000 for the same period last year, representing a decrease of 1.9%.

For the fourth quarter of Fiscal 2021, sales of *EGRIFTA SV*® reached $12,753,000 compared to $10,751,000 in the fourth quarter of the prior year, representing an increase of 18.6%. Strong sales of *EGRIFTA SV*® were mostly the result a higher selling price and lower government rebates and chargebacks.

In the fourth quarter of Fiscal 2021, Trogarzo® sales amounted to $6,001,000 compared to $8,372,000 for the same quarter of 2020, representing a decrease of 28.3%. During the fourth quarter of Fiscal 2021, Trogarzo® net sales were impacted by a provision related to greater than anticipated clawbacks on units sold in France prior to finalization of reimbursement terms, pursuant to temporary use authorizations (“ATU” and “AAP”). Negotiations are still ongoing with the Economic Committee for Health Products (“CEPS”) to finalize pricing and reimbursement terms in France. Sales were also affected by lower unit sales as a result of lower patient access to hospitals and clinics because of COVID-19 and the impact of a new competitor.

Cost of Sales

For the three-month period ended November 30, 2021, cost of sales was $6,411,000 compared to $6,650,000 in the comparable period of Fiscal 2020. Cost of goods sold were stable at $5,191,000 compared to $5,190,000 for the same period last year.

Cost of sales included an amortization of $1,220,000 in the fourth quarter of 2021 and 2020 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.

R&D Expenses

R&D expenses in the three-month period ended November 30, 2021 amounted to $8,678,000 compared to $6,795,000 in the comparable period of Fiscal 2020. The

increase during the fourth quarter of Fiscal 2020 was largely due to the development of our oncology platform, including the Phase 1 trial for TH1902, the F8 Formulation and multi-dose pen injector, and spending related to the development of tesamorelin for the treatment of NASH in the general population as well as regulatory expenses and increased medical education initiatives in Europe in preparation for the Trogarzo® launch.

Out of the foregoing R&D expenses, expenses relating specifically to the Company's program evaluating TH1902 for the treatment of sortilin-positive cancers (currently in Phase 1) reached approximately $782,000 in the three-month period ended November 30, 2021, and those relating to its program evaluating tesamorelin for the treatment of NASH (currently at Phase 3 preparation stage) totaled $460,000 for the same period. As explained previously, the Phase 1 study involving TH1902 is progressing as planned, while the initiation of the Phase 3 clinical trial for tesamorelin has been delayed pending assessment of our options to best execute this program, including seeking additional resources or potential partnership.

Selling Expenses
Selling expenses in the three-month period ended November 30, 2021 amounted to $8,193,000 compared to $6,532,000 in the comparable period of Fiscal 2020.

The increase in selling expenses is largely associated with the addition of senior personnel in North America to build a stronger sales organization, as well as increased activities in Europe ahead of the launch of Trogarzo in key markets.

General and Administrative Expenses
General and administrative expenses in the fourth quarter of Fiscal 2021 amounted to $3,537,000, compared to $3,255,000 reported in the same period of Fiscal 2020. The increased is due to an overall increase in activity to reflect the growth of our business.

Net Finance Costs
Net finance costs for the three-month period ended November 30, 2021 were $1,817,000 compared to $1,424,000 in the same period last year.

Adjusted EBITDA[1]
Adjusted EBITDA for the fourth quarter of Fiscal 2021 was $(5,501,000) compared to $(1,417,000) in same period of Fiscal 2020.

The increase in Adjusted EBITDA loss from Q4 2020 to Q4 2021 was mainly due to higher selling expenses and increased spending on research and development activities in the fourth quarter of 2021.

Net loss
Taking into account the revenue and expense variations described above, we recorded a net loss of $9,901,000, or $0.10 per share, in the fourth quarter of Fiscal 2021 compared to a net loss of $5,549,000, or $0.07 per share, in the fourth quarter of Fiscal 2020.

[1] Adjusted EBITDA is a Non-GAAP Financial Measure. See the "Non-IFRS Financial Measures" section of the MD&A for a description of the composition and reconciliation of this measure.

Quarterly Financial Information

The following table is a summary of our unaudited consolidated operating results for the last 8 quarters of Fiscal 2021 and Fiscal 2020.

(in thousands of dollars, except per share amounts)

	2021				2020			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Revenue	**18,754**	17,852	17,787	15,430	19,123	14,049	17,162	15,719
Operating expenses								
Cost of sales								
Cost of goods sold	**5,191**	4,283	4,714	4,190	5,190	4,611	5,769	5,400
Other production-related costs	**-**	-	-	-	240	280	391	140
Amortization of other asset	**1,220**	1,221	1,220	1,221	1,220	1,220	1,220	1,221
R&D	**8,678**	8,296	6,417	4,883	6,795	4,183	3,622	3,419
Selling	**8,193**	7,657	6,901	6,158	6,532	7,025	6,941	6,361
General and administrative	**3,537**	3,633	3,884	3,562	3,255	2,699	3,706	2,570
Total operating expenses	**26,819**	25,090	23,136	20,014	23,232	20,018	21,649	19,111
Net finance costs	**(1,817)**	(2,254)	(1,023)	(1,332)	(1,424)	(799)	(1,319)	(1,152)
Income taxes	**(19)**	(18)	(20)	(6)	(16)	-	-	-
Net loss	**(9,901)**	(9,510)	(6,392)	(5,922)	(5,549)	(6,768)	(5,806)	(4,544)
Basic and diluted loss per share	**(0.10)**	(0.10)	(0.07)	(0.07)	(0.07)	(0.09)	(0.08)	(0.06)

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 research and development expenses in 2021 were associated with the development of our product pipeline.

Fiscal Year 2021 Financial Results

Revenue
Consolidated revenue for Fiscal 2021 was $69,823,000 compared to $66,053,000 for the same period last year, representing an increase of 5.7%.

For Fiscal 2021, sales of *EGRIFTA SV*® reached $43,009,000 compared to $35,399,000 for the same period last year (which also included sales of *EGRIFTA*®) representing growth of 21.5%. Strong sales of *EGRIFTA SV*® were mostly the result a higher number of units sold compared to the previous year, as well as higher selling price and lower government rebates and chargebacks. In addition, COVID-19 had a lesser impact on new prescriptions in Fiscal 2021 compared to Fiscal 2020.

In Fiscal 2021, Trogarzo® sales were $26,814,000 compared to $30,654,000 last year. During Fiscal 2021, Trogarzo® net sales 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”). Negotiations are still ongoing with the Economic Committee for Health Products (“CEPS”) to finalize pricing and reimbursement terms in France. Sales were also affected by lower unit sales as a result of lower patient access to hospitals and clinics because of COVID-19 and the impact of a new competitor.

Cost of Sales
For Fiscal 2021, cost of sales was $23,260,000 compared to $26,902,000 in the comparable period of Fiscal 2020. Cost of sales included cost of goods sold that amounted to $18,378,000 in Fiscal 2021 compared to $20,970,000 in Fiscal 2020. The decrease in cost of goods sold was mainly due to a higher proportion of *EGRIFTA SV*® sales, which carry lower cost of goods sold, and a lower transfer price for Trogarzo® since the fourth quarter of Fiscal 2020 given the achievement of a predetermined amount of net sales of the product on the U.S. market. In addition, cost of sales in Fiscal 2020 included other production-related costs of $1,051,000 compared to nil in 2021.

R&D Expenses
R&D expenses were $28,274,000 for Fiscal 2021 compared to $18,019,000 for Fiscal 2020. The increase in R&D expenses was largely due to the development of our oncology platform, including the Phase 1 study, spending on the development of the F8 formulation and multi-dose pen injector, costs associated to the preparation Phase 3 trial of tesamorelin for the treatment of NASH in the general population as well as regulatory expenses and increased medical education initiatives in Europe in preparation for the Trogarzo® launch.

Out of the foregoing R&D expenses, expenses relating specifically to the Company’s program evaluating TH1902 for the treatment of sortilin-positive cancers (currently in

Phase 1) reached approximately $2,686,000 in Fiscal 2021, and those relating to its program evaluating tesamorelin for the treatment of NASH (currently in the Phase 3 preparation stage) totaled $2,983,000 for the same period. As explained previously, the Phase 1 study involving TH1902 is progressing as planned, while the initiation of the Phase 3 clinical trial for tesamorelin has been delayed pending assessment of our options to best execute this program, including seeking additional resources or potential partnership.

Selling Expenses
Selling expenses for Fiscal 2021 were $28,909,000 compared to $26,859,000 for the same period in Fiscal 2020. The increase is mainly due to the addition of senior personnel and an increase in promotional activities related to our commercial products in the United States, as well as additional spending in Europe, in anticipation of the launch of Trogarzo® in key markets.

General and Administrative Expenses
General and administrative expenses for Fiscal 2021 were $14,616,000 compared to $12,230,000 for the same period in Fiscal 2020. The increase in general and administrative expenses was mainly associated with an overall increase in business activities, senior hires to support our corporate initiatives in North America and increased overall activity in Europe.

Net Finance Costs
Net finance costs for the Fiscal 2021 were $6,426,000 compared to $4,694,000 in Fiscal 2020. The increase in net finance costs in 2021 versus the comparable period in 2020 was mostly due to foreign currency variations. We recorded a net foreign currency loss of $320,000 in Fiscal 2021, versus a net foreign currency gain of $418,000 in 2020. We also recorded higher accretion expense in Fiscal 2021 ($2,358,000) than in Fiscal 2020 ($2,056,000).

Adjusted EBITDA[2]
Adjusted EBITDA for Fiscal 2021 was $(14,586,000) compared to $(7,093,000) in Fiscal 2020, reflecting increased R&D expenses and higher selling, general and administrative expenses, as well as investments towards building our infrastructure in Europe. These higher expenses were partially offset by higher revenues and gross margins mostly due to increasing *EGRIFTA SV* sales.

Net loss
Taking into account the revenue and expense variations described above, we recorded a net loss of $31,725,000, or $0.34 per share, in Fiscal 2021 compared to $22,667,000, or $0.29 per share, in Fiscal 2020.

[2] Adjusted EBITDA is a Non-GAAP Financial Measure. See the "Non-IFRS Financial Measures" section of the MD&A for a description of the composition and reconciliation of this measure.

Selected Annual Information

(in thousands of dollars, except per share amounts)

Years ended November 30	**2021**	2020	2019
Revenue	**69,823**	66,053	63,216
Selling expenses	**28,909**	26,859	26,482
Research and development expenses	**28,274**	18,019	10,841
General and administrative expenses	**14,616**	12,230	8,330
Adjusted EBITDA [3]	**(14,586)**	(7,093)	323
Net loss	**(31,725)**	(22,667)	(12,496)
Loss per share: Basic and diluted	**(0.34)**	(0.29)	(0.16)
Cash, bonds and money market funds	**40,354**	20,768	41,244
Total assets	**119,212**	100,142	117,555
Long-term obligations (including current portion)	**--**	4,666	7,987
Lease liabilities	**2,518**	2,980	--
Convertible unsecured senior notes	**54,227**	52,403	50,741

[3] Adjusted EBITDA is a Non-GAAP Financial Measure. See the "Non-IFRS Financial Measures" section of the MD&A for a description of the composition and reconciliation of this measure.

Liquidity and Capital Resources

Our objective in managing capital is to ensure a sufficient liquidity position to finance our business activities. We depend primarily on revenue generated by sales of *EGRIFTA SV*® and Trogarzo® in the United States and Europe, and, from time to time, on public offerings of securities in North America. Currently, our general policy on dividends is to retain cash to keep funds available to finance our growth.

As at November 30, 2021, cash, bonds and money market funds amounted to $40,354,000 compared to $20,768,000 at November 30, 2020. Available cash is invested in highly liquid fixed income instruments including governmental, municipal and paragovernmental organizations, high-grade corporate bonds and money market funds.

For Fiscal 2021, cash flow used in operating activities was $14,477,000 compared to $13,554,000 in Fiscal 2020. Changes in operating assets and liabilities for Fiscal 2021 had a positive impact on cash flow of $242,000. These changes included an increase of $4,187,000 in inventories, an increase in prepaid expenses and deposits of $5,569,000, and were offset by a decrease in trade and other receivables of $1,852,000, by an increase in accounts payable and accrued liabilities of $5,549,000, and by an increase in provisions of $2,226,000. These changes are mostly related to an increase in our commercial activities.

During Fiscal 2021, the Company realized net proceeds from the issue of common shares and warrants of $42,608,000 and recorded net proceeds from the exercise of warrants of $742,000 and stock options of $545,000. Significant uses of cash included the payment of a $5,000,000 milestone related to the launch of Trogarzo in Europe, as well as $3,306,000 in interest on the convertible unsecured senior notes.

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

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

Our current cash, bond and money market funds will be sufficient to fund the Company’s operations for at least the next twelve months from the balance sheet date. The Company has also announced that it will evaluate its options in funding late-stage development programs, which may include seeking a potential partner or additional financing. The Company is also evaluating its options with respect to the convertible debentures which become due in June 2023. During the year, the Company entered into an ATM program (see note 21(c) to the Audited Financial Statements) under which it may sell, from time to time, up to $50 million of its common shares.

Commitments

Off Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Subsequent events

On December 1, 2021, the Company granted 2,099,651 stock options at an exercise price of CA $4.21 and 269,170 stock options at an exercise price of $3.30.

On November 23, 2021, the Company filed a short form base shelf prospectus with the Securities and Exchange Commission and Canadian securities regulatory authorities with the intent of filing a prospectus supplement to renew the prospectus supplement of July 23, 2021 relating to the $50,000 ATM facility. Such prospectus supplement was filed on December 16, 2021 and the ATM was renewed (see Note 21 (c) to the Audited Financial Statements).

Contractual obligations

The following table lists as of November 30, 2021 information with respect to the Company's contractual obligations.

Contractual Obligations	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 years
Convertible unsecured senior notes, including interest	64,113,000	3,306,000	60,807,000	—	—
Lease Liabilities	2,973,000	624,000	1,275,000	1,074,000	—
Purchase Obligations [(1)]	8,575,000	8,575,000	—	—	—
					—
Total	$ 75,661,000	$ 12,505,000	$ 62,082,000	$ 1,074,000	$

(1) 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, 2021, the Corporation had outstanding purchase orders and minimum payments under these agreements amounting to $6,598,000 for the manufacture of Trogarzo®, *EGRIFTA SV*® and for various services. The Corporation also had research commitments and outstanding clinical material purchase orders amounting to $1,253,000 in connection with its oncology platform and $724,000 in connection with the F8 Formulation and the Pen developed for the F8 Formulation.

Long-term obligations are contingent upon occurrence of certain stated events in commercialization rights and license agreements.

Credit facility

The Company has a CA$1,500,000 credit facility for its ongoing operations, bearing interests at the bank's Canadian prime rate, plus 1.0%, and a US$1,000,000 revolving credit facility bearing interest at the Bank's U.S. prime rate plus 1.0%. Under the terms of the credit facility, the bank has a first rank movable hypothec on all of the assets of the Company.

As at November 30, 2021 and 2020, the Company did not have any borrowings outstanding under this credit facility.

License agreement

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

Post-Approval Commitments

In connection with the approval of Trogarzo® in Europe, we are required to conduct a PIP and a Registry. The PIP is comprised of two studies: the first one consists in evaluating the pharmacokinetics, pharmacodynamics, safety and tolerability of Trogarzo® in children from 6 to less than 18 years of age with HIV-1 infection in order to provide pharmacokinetics and pharmacodynamics data to support the extrapolation of efficacy from adults; and the second study is a modelling and simulation study to evaluate the use of Trogarzo® in the treatment of HIV-1 infection resistant to at least 1 agent in 3 different classes in children from 6 to less than 18 years of age. The Registry consists primarily in evaluating the long-term efficacy and durability of Trogarzo® in combination with other antiretrovirals by comparing the virologic, immunologic and clinical outcomes of patients receiving Trogarzo® treatment *versus* matched patients not receiving Trogarzo®. The study comprising the Registry should be conducted over a five-year period. The cost of the Registry, estimated to be approximately 4,000,000 Euros, will be borne as to 52% by TaiMed and as to 48% by us.

Milestones

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

Financial Risk Management

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

Credit Risk

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

The Company's exposure to credit risk currently relates to accounts receivable with one major customer (see Note 28 to the Audited Financial Statements), other receivable and derivative financial assets which it manages by dealing only with highly rated Canadian financial institutions. Included in the consolidated statements of financial position are trade receivables of $9,261,000 (2020 – $10,947,000), all of which were aged under 60 days. There was no amount recorded as bad debt expense for the years ended November 30, 2021 and 2020. Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds and money market funds. The Company invests its available cash in highly liquid fixed income instruments from governmental, paragovernmental, municipal and high-grade corporate bodies and money market funds (2021 – $19,955,000; 2020 – $8,031,000). As at November 30, 2021, the Company believes it was not exposed to any significant credit risk. The Company's maximum credit exposure corresponded to the carrying amount of these financial assets.

Liquidity Risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they become due. As indicated in Note 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 and/or the Audit Committee reviews and approves the Company's operating and capital budgets, as well as any material transactions out of the ordinary course of business.

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

Currency Risk

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

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

The following table presents the significant items in the original currencies exposed to currency risk as at November 30, 2021 and 2020.

(in thousands)

	2021		2020	
	CA$	**EURO**	**CA$**	**EURO**
Cash	589	61	871	36
Bonds and money market funds	16,298	-	821	-
Trade and other receivables	331	1,553	522	1,052
Tax credits and grants receivable	385	123	942	25
Accounts payables and accrued liabilities	(6,819)	(7,256)	(4,937)	(4,496)
Lease liabilities	(1,755)	(1,010)	(2,109)	(1,138)
Provisions	-	(1,970)	-	-
Total exposure	9,029	(8,499)	(3,890)	(4,521)

The following exchange rates are those applicable as at November 30, 2021 and 2020 to:

	2021		2020	
	Average rate	**Reporting date rate**	**Average rate**	**Reporting date rate**
CA$ – US$	0.7979	0.7822	0.7445	0.7695
Euro – US$	1.1906	1.1338	1.1325	1.1928

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

(in thousands)

	2021		2020	
	CA$	**EURO**	**CA$**	**EURO**
Positive impact	451	(425)	(195)	(226)

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

Interest Rate Risk

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

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

Based on the value of the Company's short and long term bonds as at November 30, 2021, 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 $141,000 (2020: nil); an assumed increase in market interest rates of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

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

Based on the average value of variable interest-bearing cash and money market funds during the year ended November 30, 2021 of $41,491,000 (2020: $28,124,000), an assumed 0.5% increase in interest rates during such year would have increased future cash flows and net profit by approximately $207,000 (2020: $141,000); an assumed decrease of 0.5% would have had an equal but opposite effect.

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

Fair Values of Financial Instruments

Certain of the Company's accounting policies and disclosures require the determination of fair value, for both financial and non-financial assets and liabilities. Fair values have

been determined for measurement and/or disclosure purposes based on the following methods. When applicable, further information about the assumptions made in determining fair values is disclosed in the notes specific to that asset or liability.

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

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

The fair value of the convertible unsecured senior notes, including the equity portion, as at November 30, 2021 was approximately $52,756,000 ($43,125,000 at November 30, 2020) based on market quotes.

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

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

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

Critical Accounting Estimates

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

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

Milestone payments related to Trogarzo®
The commercialization rights related to Trogarzo® are subject to additional cash-based milestone payments based on the attainment of commercial milestones, including development, launch and sales milestones. Milestone payments will be accrued and recorded in the cost of intangible assets when it is probable that they will be achieved. The determination of probability of paying the milestones is subject to judgment. In order to demonstrate that the commercial milestone payment is probable, the following are taken into consideration: product approval; product launch; and approved development plan. In addition, there should be a sufficient history of sales to have reasonable expectation that the commercial milestone payments related to the sales milestone will be reached.

Contingent consideration related to oncology platform
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 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.

Convertible senior unsecured notes
The determination of the fair value of the liability component of a convertible instrument was at time of issuance based on the estimated interest rate that the Company could obtain for a similar debt instrument without a conversion option.

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 further negotiation. The product revenue we recognize quarter over quarter is net of these estimated allowances. Such estimates require the need to make estimates about matters that are inherently uncertain. The Company's estimates are based on our historical claims as supplemented by management's judgment (see Notes 2 (Revenue recognition) and 3 for additional information).

Other
Other areas of judgment and uncertainty are related to the estimation of accruals for clinical trial expenses, the recoverability of inventories from the effects of technological change or new product introductions, the measurement and recoverability of intangible assets, the measurement of derivative financial assets, and the measurement of share-based arrangements.

Reported amounts and note disclosures reflect the overall economic conditions that are most likely to occur and the anticipated measures management intends to take. Actual results could differ from those estimates.

The above estimates and assumptions are reviewed regularly. Revisions to accounting estimates are recognized in the year in which the estimates are revised and in any future years affected.

Recent Changes in Accounting Standards

Standards issued but not yet effective
A number of new standards are effective for annual periods beginning after December 1, 2021 and earlier application is permitted; however, the Company has not early adopted the new or amended standards in preparing these consolidated financial statements.

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

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

Outstanding Securities Data
As at February 23, 2022, the number of common shares issued and outstanding was 95,121,639 while outstanding options granted under our stock option plan were 5,126,564. We also had $57,500,000 aggregate principal amount of Notes due June 30, 2023 issued and outstanding as a result of the public offering of those notes closed on June 19, 2018. These notes are convertible into common shares at the option of the holder at a conversion price of $14.85, representing a conversion rate of approximately 67.3401 common share per $1,000 principal amount of notes. The conversion of all of the outstanding notes would result in the issuance of 3,872,055 common shares.

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Disclosure Controls and Procedures

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

Our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, have evaluated, or caused the evaluation of, under their direct supervision, the design and operating effectiveness of the Company's disclosure controls and procedures, as defined under National Instrument 52-109 – Certification of Disclosure in Issuer's Annual and Interim Filings as at November 30, 2021. 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, 2021, our disclosure controls and procedures were designed and operating effectively.

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. Our internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS, as issued by the IASB. Internal controls over financial reporting include those policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets, (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS, as issued by the IASB, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

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

Our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, assessed the design and operating effectiveness of our internal controls over financial reporting as of November 30, 2021 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, 2021, our internal controls over financial reporting were appropriately designed and operating effectively.

Changes in Internal Control over Financial Reporting

There was no change in our internal controls over financial reporting that occurred during the period from September 1st, 2021 to November 30, 2021 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Non-IFRS Financial Measures

Reconciliation of net profit or loss to adjusted earnings before interest, taxes, depreciation and amortization (Adjusted EBITDA)

Adjusted EBITDA is a non-IFRS financial measure. A reconciliation of the Adjusted EBITDA to net profit (loss) is presented in the table below. We use adjusted financial measures to assess our operating performance. Securities regulations require that companies caution readers that earnings and other measures adjusted to a basis other than IFRS do not have standardized meanings and are unlikely to be comparable to similar measures used by other companies. Accordingly, they should not be considered in isolation. We use Adjusted EBITDA to measure operating performance from one period to the next without the variation caused by certain adjustments that could potentially distort the analysis of trends in our business, and because we believe it provides meaningful information on our operating results.

We obtain our Adjusted EBITDA measurement by adding to net profit or loss, finance income and costs, depreciation and amortization, and income taxes. We also exclude the effects of certain non-monetary transactions recorded, such as share-based compensation for the stock option plan, lease inducements prior to the adoption of IFRS-16, and write-downs (or related reversals) of inventories, for our Adjusted EBITDA calculation. We believe it is useful to exclude these items as they are either non-cash expenses, items that cannot be influenced by management in the short term, or items that do not impact core operating performance. Excluding these items does not imply they are necessarily nonrecurring. Stock-option based compensation costs are a component of employee remuneration and can vary significantly with changes in the market price of the Company's shares. In addition, other items that do not impact core operating performance of the Company may vary significantly from one period to another. As such, Adjusted EBITDA provides improved continuity with respect to the comparison of our operating results over a period of time. Management believes this non-GAAP financial measure, in addition to conventional measures prepared in accordance with IFRS, enable investors to

evaluate the Company's operating results, underlying performance and future prospects in a manner similar to management.

Our method for calculating Adjusted EBITDA may differ from that used by other companies and, accordingly, our definition of this non-GAAP financial measure may not be comparable to similar measures presented by other issuers. Although Adjusted EBITDA is frequently used by securities analysts, lenders and others in their evaluation of companies, it has limitations as an analytical tool. Investors are cautioned that non-GAAP financial measures should not be construed as an alternative to net income determined in accordance with IFRS as indicators of our performance or to cash flows from operating activities as measures of liquidity and cash flows.

Adjusted EBITDA

(in thousands of dollars)

	Three-month periods ended November 30		Years ended November 30		
	2021	2020	**2021**	2020	2019[(1)]
Net loss	(9,901)	(5,549)	(31,725)	(22,667)	(12,496)
Add (deduct):					
Depreciation and amortization	2,189	2,192	8,748	8,520	7,495
Lease inducement and amortization	-	-	-	-	238
Net finance costs	1,817	1,424	6,426	4,694	3,983
Income taxes	19	16	63	16	-
Share-based compensation for stock option plan	405	259	1,932	1,427	1,087
(Reversal) write-down of inventories	(30)	241	(30)	917	16
Adjusted EBITDA	(5,501)	(1,417)	(14,586)	(7,093)	323

(1) The Company adopted IFRS-16 – Leases, using the modified retrospective approach, effective for Fiscal 2020, beginning on December 1, 2019. Accordingly, comparative figures for Fiscal 2019 have not been restated.

RISKS AND UNCERTAINTIES

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

RISKS RELATED TO THE COVID-19 PANDEMIC

The ongoing COVID-19 pandemic could have a material adverse effect on our 2022 business strategy and objectives, the result of which could adversely impact the sales of our products, our revenues, results of operation and the conduct of our clinical trials and other research and development activities.

The outbreak of COVID-19, its recent variants and any other outbreaks of contagious diseases or other adverse public health developments, could have a material adverse effect on the successful implementation of our 2022 business strategy and objectives, the result of which could materially adversely impact the sales of our products, our revenues, results of operation and the conduct of our clinical trials and other research and development activities. The outbreak of COVID-19 has resulted in governmental authorities implementing numerous measures to try to contain the pandemic, such as travel bans and restrictions, quarantines, increased border and port controls and closures, and shutdowns. Although most industrialized countries are relaxing some of the restrictive measures, there remains considerable uncertainty regarding the consequences such relaxed measures may have on the pandemic and the population worldwide as well as on the reimplementation of potential future measures.

As COVID-19 continues to be present and spread around the globe, the Corporation may experience disruptions that could severely impact its business and clinical trials, including:

- patients' limited access to the Corporation's treatments and products;
- diversion of healthcare resources prioritizing the treatment of patients suffering from COVID-19;
- delays or difficulties in enrolling patients in the Corporation's clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials;
- interruption of key clinical trial activities;
- risk that participants enrolled in the Corporation's clinical trials will acquire COVID-19 while the clinical trial is ongoing;
- limitations in employee resources that would otherwise be focused on the commercialization of the Corporation's products and the conduct its clinical trials;
- delays in receiving authorizations from regulatory authorities to approve a drug candidate or to initiate the Corporation's planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct the Corporation's clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require the Corporation to change the ways in which its clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;

- interruptions or delays in efforts to acquire data needed to support patent claims or otherwise expand the Corporation's intellectual property portfolio; and

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

The COVID-19 pandemic has significantly increased economic and demand uncertainty throughout North America and Europe. The COVID-19 pandemic has caused disruption and volatility in the global capital markets, which, depending on further developments, could impact the Corporation's capital resources and liquidity in the future, including the availability of financing on attractive terms, if at all.

The extent to which COVID-19 could impact the Corporation's operations, financial condition, liquidity, results of operations, and cash flows is still highly uncertain and will depend on future developments. Such developments may include the geographic spread and duration of COVID-19, the severity of the disease and the actions that may be taken by various governmental authorities and other third parties in response to the pandemic.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS

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

Our ability to generate revenue and sustain growth is currently based on the commercialization of *EGRIFTA SV®* and Trogarzo® in the United States and on Trogarzo® in Europe.

Our success in generating sales revenue from *EGRIFTA SV®* and Trogarzo® in the United States and from Trogarzo® in Europe will depend on our capacity:

- to pursue the deployment of a commercialization strategy that will be accepted by patients, healthcare professionals and third-party payors;

- to maintain reimbursement coverage for *EGRIFTA SV®* and Trogarzo® by third-party payors;

- to obtain commercially attractive pricing for Trogarzo® and obtain reimbursement therefor in major European countries;

- to maintain the registration of *EGRIFTA SV®* and Trogarzo® on U.S. governmental forms as drugs available for purchase in the United States;

- to ensure that adequate supplies of *EGRIFTA SV®* and Trogarzo® are available;

- to maintain conflict-free relationships with our principal third-party suppliers of services, namely our agent in the United States and in the European Union (Syneos), our manufacturers, (TaiMed and Jubilant), our distributor in the United States (RxCrossroads) and in Europe (Loxxess), as well as other specialized third parties; and

- to defend our intellectual property rights regarding tesamorelin against third parties.

Our success in commercializing our products in the United States and in the European Territory will also depend on:

- the capacity of Syneos, in collaboration with us, 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 and in the European Territory 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 from *EGRIFTA SV*® and Trogarzo® for the foreseeable future, any negative developments relating to these products, such as safety or efficacy issues, manufacturing issues, the introduction or greater acceptance of competing products, or adverse regulatory or legislative developments, or our inability to successfully manage any of the abovementioned factors, will have a material adverse effect on our business and our future business prospects.

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

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

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

RxCrossroads for such discounts to which RxCrossroads' clients are entitled to and this may materially adversely affect our level of revenues and operating results for the year.

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

We have a single third-party service provider for each of our core business activities pertaining to the commercialization of our products, namely their manufacturing, distribution and commercialization. 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*®. Our agreement with Bachem has expired and we are currently renegotiating the terms and conditions of a new manufacturing agreement. Although we are in discussions with Bachem, our inventory of drug product is high and potential alternative suppliers and manufacturers have been identified, but we have not entered into any agreements with Bachem yet. Also, we have not qualified alternative manufacturers to date and no assurance can be given that such manufacturers will be qualified in the future or receive necessary regulatory approvals. The replacement of a third-party manufacturer is time-consuming and costly due to the required validation of their capabilities. The validation process includes an assessment of the capacity of such third-party manufacturer to produce the quantities that we may request from time to time, the manufacturing process and its compliance with current good manufacturing practice, or GMP, regulations. In addition, the third-party manufacturer would have to familiarize itself with our technology. Validation of an additional third-party manufacturer takes at least twenty-four (24) months and could take as long as thirty-six (36) months or more. If we fail to renegotiate the terms and conditions of the Bachem Agreement, we may no longer be able to rapidly manufacture tesamorelin for *EGRIFTA SV*® and for our potential Phase 3 clinical trial in NASH. Despite our current level of inventory of tesamorelin, we could incur a shortage of tesamorelin by the time new manufacturers are qualified.

TaiMed is our sole supplier of Trogarzo®. TaiMed does not currently own or operate any manufacturing facilities for the production of Trogarzo® and must rely on its sole supplier, WuXi. We are not in a contractual relationship with WuXi for Trogarzo® and, therefore, we may not be able to interact with Wuxi 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 do not currently intend to pursue applications to obtain the licenses required in order to distribute a drug product in the United States. Our supply chain model is based upon that fact and the distribution of *EGRIFTA SV*® and Trogarzo® in the United States is done through RxCrossroads which currently holds all state licensure required to distribute a drug product in every American state. Although potential alternative third-party service providers have been identified to replace RxCrossroads in the event that it becomes unable to distribute *EGRIFTA SV*® and Trogarzo®, we have not entered into any agreements with them and no assurance can be given that such providers would enter into any agreement with us on terms satisfactory to us.

In the European Territory, we hold a wholesale distribution authorization but do not have any warehouse and structure to store, pack and ship Trogarzo®. We do not currently intend to open a warehouse and do not have the infrastructure to carry out the activities set forth above. Therefore, we are relying on Loxxess to carry out these activities. We have not entered into a long-term commercial agreement with Loxxess. The Loxxess Agreement is a one-year term agreement that automatically renews at the end of its term unless a party provides the other with a prior written notice of its intent not to renew such agreement within a certain period of time. Although we have identified other third-party logistic service providers in the European Territory, if the Loxxess Agreement is terminated unilaterally by Loxxess, or if we decide to terminate such agreement, there can be no assurance that we would succeed in entering into agreements with those other third-party logistic service providers on terms satisfactory to us. Our failure to enter into long-term commercial agreements with those third-party logistic service providers would disrupt our supply and distribution chain and would delay the commercialization of Trogarzo® in the European Territory. All such events would result in a material adverse effect on our business, revenues and financial conditions.

Part of our commercial team in the United States and in the European Territory dedicated to the commercialization of our products in these territories is provided by Syneos. In the United States, after March 14, 2022, Syneos will continue to provide us with services related to managed market and certain functions supporting our medical team in connection with the commercialization of our products. In Europe, Syneos provides us with medical science liaison personnel. Although we are aware that there exists other third-party services providers that could provide the same services as Syneos, we have not entered into any agreements with them nor conducted any audit on them. If we need to find another third-party service provider for some or all of the services provided by Syneos, it will be time-consuming and will be disruptive to our business. In addition, there can be no assurance that we will be able to find such third-party service provider if we are unable to agree on the terms and conditions of an agreement with them.

Finally, we retain contract research organizations, or CROs, to support us with the conduct of our 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 an sBLA or NDA seeking the approval of our products.

Our reliance on single third-party service providers for each 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:

- becomes unavailable to us, or to TaiMed, for any reason, including as a result of the failure to comply with GMP regulations;
- experiences manufacturing problems or other operational failures, such as labour disputes, equipment failures or unplanned facility shutdowns required to comply with GMP, or damage from any event, including fire, flood, earthquake, business restructuring, labour disputes or insolvency; or
- fails to perform its contractual obligations under our agreement, such as failing to deliver the quantities requested on a timely basis or not meeting product specifications.

We may also be subject to distribution disruption and interrupted sales of *EGRIFTA SV®* and Trogarzo® in the United States, or of Trogarzo® in the European Territory, if:

- RxCrossroads or Loxxess becomes unavailable to us for any reason, including as a result of its failure to meet applicable laws;
- RxCrossroads or Loxxess experiences warehousing problems or other operational failure, such as unplanned facility shutdown or damage from any event, including fire, flood, earthquake, business restructuring or insolvency; or
- RxCrossroads or Loxxess 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 in the European Territory or we may face reimbursement challenges if Syneos:

- 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®;
- experiences compliance issues with the FDA or the EMA; or
- fails to perform its contractual obligations under our agreement.

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

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

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

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

Market acceptance and sales of *EGRIFTA SV*® and Trogarzo® substantially depend on the availability of reimbursement from third-party payors such as governmental authorities, including U.S. Medicare and Medicaid, managed care providers, and private insurance plans and may be affected by healthcare reform measures in the United States and elsewhere. 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. funded reimbursement programs represent the most important part of our sales. Denial of coverage for any of those products under any of the current programs would materially adversely affect our revenues.

In the European Territory, sales of Trogarzo® will be highly dependent on agreeing on a commercially attractive pricing with regulatory authorities and obtaining reimbursement for Trogarzo®. The process of seeking reimbursement for a new drug is complex and varies from one EU Member State to another. In many EU Member States, pricing plays an important role in the evaluation of prescription drugs for reimbursement. There can be no assurance that Trogarzo® will be reimbursed by all or any EU Member State, or that we will be able to negotiate a pricing that will be commercially attractive to us in any or all of the EU Member States.

Even if Trogarzo® is reimbursed, in EU Member States, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment in the European Union. Certain of these changes could impose limitations on the prices we will be able to charge for Trogarzo® or the amounts of reimbursement available for Trogarzo® from governmental agencies or third-party payors. Further, an increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our potential revenues and profitability from Trogarzo®. Moreover, in order to obtain reimbursement for Trogarzo® in some EU Member States, we may be required to conduct clinical trials that compare the cost-effectiveness of Trogarzo® to other available therapies. There can be no assurance that Trogarzo® will obtain favorable pricing and reimbursement status in any EU Member States.

Even though EGRIFTA SV® and Trogarzo® are approved for sale in one or more territories, revenue that we generate from their sales may be limited.

Sales of *EGRIFTA SV®* and Trogarzo® will depend upon the acceptance of such products by the medical community, including physicians, patients and third-party payors. The degree of market acceptance of any of our products will depend on a number of factors, including:

- demonstrated product safety, including the prevalence and severity of side effects, and effectiveness as a treatment that addresses a significant unmet medical need;
- storage requirements, dosing regimen and ease of administration;
- the availability of competitive alternatives;
- 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;
- the willingness and ability of patients to pay out-of-pocket for medications;
- the product price; and
- the effectiveness of sales and marketing efforts.

If our products do not achieve adequate sales, we may not generate sufficient revenue in order to become profitable.

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

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

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

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

RISKS RELATED TO RESEARCH AND DEVELOPMENT ACTIVITIES

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

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

The conduct of the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population will be costly and the Corporation has decided to secure additional resources, including finding a partner, prior to initiating such clinical trial, all of which will result in a postponement of the initiation of such trial. Although the Corporation has begun the search for a potential partner, 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 will need to look for alternatives to secure additional resources but there can be no guarantee that the Corporation will secure such resources in an amount sufficient to initiate or complete its Phase 3 clinical trial. Moreover, the Corporation has no meaningful Phase 2 clinical data evaluating tesamorelin for the treatment of NASH in the general population and any result obtained from the conduct of one Phase 3 clinical trial will have to show substantial evidence that tesamorelin is safe and effective for the treatment of NASH in the general population. Finally, the Corporation's decision to design its Phase 3 clinical trial to meet the FDA's primary endpoints may prevent the Corporation from seeking approval of tesamorelin for the treatment of NASH in the general population from the EMA since the primary endpoint for this agency is different from that of the FDA. If the Corporation is unable to secure additional resources to initiate its Phase 3 clinical trial, or find alternatives to pursue this trial, the conduct of such trial could be cancelled. If the Corporation is unable to meet the endpoints of its Phase 3 clinical trial, it will not receive approval for tesamorelin for the treatment of NASH in the general population. And, even if the Corporation meets the endpoints of Part 1 of the Phase 3 clinical trial and obtains a conditional approval letter from the FDA, the Corporation could lose such approval if Part 2 of the Phase 3 clinical trial is unable to show evidence on the resolution of certain clinical outcomes. 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.

The Corporation held discussions with the FDA and the EMA to finalize its Phase 3 clinical trial design, which discussions concluded in July 2021. As a result of such discussions, the trial design will result in higher costs than what the Corporation had previously estimated. The Corporation has decided to postpone the initiation of its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population until it can secure additional resources to execute its program and has initiated a search to find a partner for that purpose.

There can be no guarantee that the Corporation will be able to initiate its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH if it is unable to secure substantial additional resources, either from a financing, a partnership or other means that it could resort to. In addition, the Corporation may not be able to find a partner to help with securing additional resources. 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 suitable to the Corporation or may be unfavorable. Under such circumstances, the

Corporation may decide to forego the search of a partner and turn to alternative sources of financing. If the Corporation is unable to secure additional resources, it may further postpone the initiation of its Phase 3 clinical trial until it can secure additional resources, review and amend its current protocol to reduce the costs associated with the study of tesamorelin for the potential treatment of NASH, or may cancel its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population. 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 prospects.

Even if the Corporation secures additional resources to initiate its Phase 3 clinical trial, there can be no guarantee that the FDA will approve tesamorelin for the treatment of NASH in the general population since the FDA recommended the Corporation to conduct a Phase 2 clinical trial to generate data resulting from the use of tesamorelin in patients suffering from NASH and since the Corporation must meet the primary endpoints set forth by the FDA in its guidelines. Given the lack of Phase 2 data resulting from the use of tesamorelin in patients suffering from NASH, the data from the Phase 3 clinical trial will have to demonstrate substantial evidence of the safety and effectiveness of tesamorelin for the treatment of NASH in the general population. In addition, even if the Corporation meets the FDA's primary endpoints of the clinical trial and receives approval from the FDA, such approval will be conditional upon completing Part 2 of the Phase 3 clinical trial. If Part 2 of the Phase 3 clinical trial does not show positive evidence on certain clinical outcomes, the FDA could withdraw its approval on the use of tesamorelin for the treatment of NASH in the general population. Finally, if the Corporation is unable to show substantial evidence that tesamorelin is safe and effective for the treatment of NASH in the general population through the conduct of one Phase 3 clinical trial, the FDA could require the Corporation to conduct an additional study.

The Corporation has decided to design its Phase 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 development of TH1902 for the potential treatment of various types of sortilin-expressing cancers is still uncertain since results obtained from preclinical in vivo

development work may not translate into human subjects. The goal of the Phase 1 clinical trial evaluating TH1902 is to determine the MTD that can be administered to human subjects and determine if any adverse side effects will be observed from the injection of TH1902 in human subjects. If the Corporation is unable to demonstrate similar results as obtained from its preclinical work, or if patients enrolled in the clinical trial are subject to serious adverse side effects, the Corporation may have to discontinue its Phase 1 clinical trial. Any interruption or halt in the Corporation's Phase 1 clinical trial would materially adversely affect the development of its SORT1+ Technology™ platform, reduce its pipeline of drug candidates and could materially adversely affect its long-term growth and prospects.

Clinical failure can occur at any stage of clinical development. The Corporation's Phase 1 clinical trial may not replicate results obtained from its preclinical *in vivo* work and we may not be able to determine the MTD into human subjects as a result of difficulty in enrolling patients, patients' responsiveness to TH1902's serious adverse side effects or patient deaths.

TH1902 is being developed as a potential treatment for severe, various life-threatening cancers that express SORT1 receptor. The Phase 1 clinical trial is being conducted with patients that are more prone than healthy subjects to exhibit certain diseases or adverse events. Some of these patients face life-threatening situations and may die during our Phase 1 clinical trial. If patients have serious adverse side effects from the administration of TH1902, it may become difficult to discern whether certain events or symptoms observed in those patients are directly related to TH1902. In the event of the death of a patient, the Corporation may have to suspend its Phase 1 clinical trial to determine whether such patient's death is associated with the administration of TH1902. The suspension period could be lengthy since an investigation will need to be conducted to determine its causation. In the event the death of a patient is found not to be associated with TH1902, which would lead to the continuation of the Phase 1 clinical trial, the FDA may nonetheless require that the Corporation amend its Phase 1 clinical trial design by imposing various safety measures, the effect of which would be to increase its costs. In addition, the Corporation may have difficulty enrolling additional patients to resume the trial as a result of such death. The amendment of a Phase 1 clinical trial design, the obligation to add additional safety measures or the difficulty in enrolling additional patients would cause delays and increase the costs associated with the Corporation's current Phase 1 clinical trial. If the death of a patient is found to be related to TH1902, the Corporation may have to halt or completely cease its Phase 1 clinical trial which could lead to the abandonment of the development of our SORT1+ Technology™ platform. The abandonment of the development of the Corporation's SORT1+ Technology™ platform would reduce its pipeline of drug candidates and could materially adversely affect its long-term growth and prospects.

We will require substantial capital to pursue the development of our product pipeline, including the conduct of our Phase 3 clinical trial for the development of tesamorelin for the treatment of NASH in the general population and the development of TH1902 in various types of cancer. If we are unable to generate

cash flow from our commercial operations or are unable to access capital if, and when, needed, we may have to delay, suspend or cancel our Phase 3 clinical trial, Phase 1 clinical trial or the development of any of our product candidates, the result of which would have a material adverse effect on our long-term growth, potential revenue growth and our business prospects.

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

Our proposed Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population will require the enrollment of over 2,000 patients and our study will be conducted over many years. The costs associated with the enrollment of patients, the monitoring of a study and the monitoring of clinical sites are expensive and such costs are directly proportional to the number of patients enrolled in a study over the duration of such study. Therefore, we expect the Phase 3 clinical trial to cost multi-millions of dollars.

To the extent that the results obtained in our Phase 1 clinical trial are positive, the development of TH1902 could accelerate, especially as a result of the recent decision of the FDA to grant "Fast Track" designation to TH1902. The number of patients that we may have to enroll to move to a Phase 2 clinical trial would be based, among other things, on our development strategy. For instance, if we were to decide to study TH1902 concurrently, in various types of cancer, we could have to enroll a large number of patients. Such a Phase 2 clinical trial could be very expensive and require capital.

We intend to fund the development of our Phase 3 clinical trial, Phase 1 clinical trial and the development of other product candidates through cash flows resulting from the sales of our products and through other sources of financing, such as public offerings, private placements or the conclusion of partnerships. However, if our sales do not generate sufficient cash flows, or if we incur delays in recruiting patients or are faced with unexpected expenses in the conduct of our operations, we may not have enough cash to fund our research and development activities. In addition, market conditions may not be favorable to resort to public or private financing and, even if favorable, the terms of such financing may not be attractive to us. If we are unable to generate sufficient cash flows from our operations, do not have access to public or private financing, or are unable to conclude partnerships to fund our research and development activities, we may have to delay, suspend or cancel the conduct of our clinical trials and the development of our product candidates. Any delay, suspension or cancellation of the development of our product candidates would have a material adverse effect on our long-term growth, potential revenue growth and business 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:

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:

- Negative results from the Corporation's clinical trial resulting in a failure to meet the endpoints of its clinical trial;
- 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;
- Any breach of the terms of any contract research organization agreement by us or by our third-party suppliers that have responsibility to assist us with the conduct of our clinical trials;
- Inadequate quantity or quality of the active pharmaceutical ingredient or other materials necessary to conduct clinical trials;
- 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;
- Severe or unexpected adverse drug effects experienced by patients;
- 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;
- 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
- 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 agencies have not approved the F8 Formulation as being bioequivalent to the Corporation's original formulation of EGRIFTA®. Under such circumstances, the Corporation may have to conduct additional clinical studies to prove the bioequivalence of the F8 Formulation against the original formulation, resulting in additional spending and delays in the use of the F8 Formulation.

The Corporation has conducted studies to assess the bioequivalence of the F8 Formulation against the original 1 mg/vial formulation of *EGRIFTA®*. These studies were conducted based on the current FDA regulation to show the bioequivalence of formulations. The Corporation has not yet filed an sBLA with the FDA seeking the approval of the F8 Formulation for commercial use although this is planned for the first half of calendar year 2022.

In addition, the Corporation has manufactured one process validation batch of the F8 Formulation only and is therefore currently unable to determine whether the manufacturing process will be stable and allow the commercial use of the F8 Formulation, even if approved by the FDA as being bioequivalent to the original formulation.

If the FDA does not approve the F8 Formulation as being bioequivalent to the original formulation, the Corporation would have to conduct additional testing using the F8 Formulation which would delay the time by which the Corporation could commercialize the F8 Formulation and which would require the Corporation to incur additional expenses, all of which could adversely affect the Corporation's financial condition or results of operations. Furthermore, the non-approval of the F8 Formulation would prevent the Corporation from using the Pen currently under development.

The development of a multi-dose pen injector for the F8 Formulation is risky, and its commercial use is subject to the approval of regulatory agencies. There can be no guarantee that the development of the multi-dose pen injector will be successful or, even if successful, that it will be approved for commercial use by regulatory agencies. The failure to obtain approval of the multi-dose pen injector using the F8 Formulation could reduce our competitive advantage vis-à-vis other potential medicine for the treatment of NASH in the general population and also result in lower sales of tesamorelin approved for the treatment of lipodystrophy in patients living with HIV.

The Corporation has undertaken through third-party service providers the development of the Pen for the F8 Formulation. Although the Pen is already used with other drugs, some development is required to adapt its delivery system to the F8 Formulation dosing. The development of a device is complex, subject to failure, and there can be no guarantee that it will result in an approved drug-device for commercial use. Any issues encountered in developing the Pen could delay its use in the development of tesamorelin for the treatment of NASH in the general population and reduce the likelihood of such device being approved for use in the treatment of NASH in the general population. Consequently, the Corporation could have to conduct additional clinical trials using the device and incur unplanned capital expenditures, thereby affecting its financial condition.

The Corporation could lose its competitive advantage *vis-à-vis* other potential medicine for the treatment of NASH in the general population if it is unable to develop or obtain approval of the Pen for its F8 Formulation. The Corporation could also reduce the potential growth of its tesamorelin-related franchise for the treatment of HIV-associated lipodystrophy if it is unable to introduce a Pen using the F8 Formulation for the treatment of such disease. Any delays in getting the Pen approved, or the non-approval thereof, will have a material adverse effect on the Corporation's sales growth, financial results and business prospects.

Finally, the development of the Pen relies on agreements with single third-party service providers and exposes the Corporation to the risks faced by these third-party service providers, such as failure by these third parties to comply with applicable laws, the loss of their operating licenses, the loss of key personnel, a shutdown of their facilities as a result of financial condition, COVID-19 or other *force majeure* issues, as well as their failure to perform their contractual obligations under the agreements with the Corporation. The occurrence of any of those instances would have a material adverse effect on the Corporation's business, results of operations and financial condition.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

Because the patent and trademark position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope, validity, and enforceability of patents and trademarks cannot be predicted with certainty. Patents and trademarks, if issued, may be challenged, invalidated or circumvented. For example, if our patents are invalidated or found to be unenforceable, we would lose the ability to exclude others from making, using or selling the inventions claimed. Moreover, an issued patent does not guarantee us the right to use the patented technology or commercialize a product using

that technology. Third parties may have blocking patents that could be used to prevent us from developing our compounds, selling our products or commercializing our patented technology. Thus, patents that we own may not allow us to exploit the rights conferred by our intellectual property protection.

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

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

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

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

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

Our capacity to commercialize *EGRIFTA SV*® and Trogarzo® will depend, in part, upon our ability to avoid infringing third party patents and other third-party intellectual property rights. The biopharmaceutical and pharmaceutical industries have produced a multitude

of patents and it is not always easy for participants, including us, to determine which patents cover various types of products, processes of manufacture or methods of use. The scope and breadth of patents is subject to interpretation by the courts and such interpretation may vary depending on the jurisdiction where the claim is filed and the court where such claim is litigated. For instance, the fact that we own patents for the treatment of HIV-related lipodystrophy in certain jurisdictions does not guarantee that we are not infringing one or more third-party patents in such jurisdictions and there can be no guarantee that we will not infringe or violate third-party patents and other third-party intellectual property rights in the United States or other jurisdictions.

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

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

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

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

REGULATORY RISKS

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

Our promotional materials and training methods must comply with the *Federal Food, Drug and Cosmetic Act*, as amended, of the United States, or FFDCA, as well as with laws in the European Union, including EU Member States laws, and 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 or other regulatory agencies, such as Health Canada and the EMA, 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 since none of those products have been approved in this territory. Promotional activities may begin once a drug is approved by Health Canada, in Canada.

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:

- 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;

- 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;

- 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;
- the FFDCA and similar laws regulating advertisement and labeling; and
- European Union's, EU Member States' and 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, or DOJ, scrutinizes interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time and resource consuming and can divert management's attention from the business. Additionally, if a healthcare provider settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Over the past few years, a number of pharmaceutical and other healthcare companies have been

prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips or items and gifts of value to prescribers, “sham” consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

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

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

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

LITIGATION RISKS

If we fail to comply with our contractual obligations, undertakings and covenants under our agreements with our commercial partners and third-party service providers, we may be exposed to claims for damages and/or termination of these agreements, all of which could materially adversely affect the commercialization of

EGRIFTA SV® and Trogarzo®, our capacity to generate revenues and management's attention to the development of our business.

We rely on third-party service providers for sales, marketing, 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 TaiMed as well as with 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.

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

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

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

GEO-POLITICAL RISKS

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

International business relationships in the United States, Europe, China, Taiwan and elsewhere subject us to additional risks, including:

- disruptions of important government services;

- differing regulatory requirements for drug approvals in foreign countries;
- potentially reduced protection for intellectual property rights, including unexpected changes in the rules governing patents and their enforcement;
- potential third-party patent rights in foreign countries;
- 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;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- foreign taxes;
- 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;
- workforce uncertainty in countries where labor unrest is more common than in the United States and Canada;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or epidemic such as the one related to the coronavirus.

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

OTHER RISKS RELATED TO OUR BUSINESS

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

In the ordinary course of business, we rely upon information technology and networks, most of which are managed by third parties, to process, transmit and store electronic information to manage and support our business decisions and strategy. We have no

control and access over the information technology systems of third-party service providers where most of this information is stored and we are unable to assess whether appropriate measures have been implemented to prevent or limit a security breach of their information technology systems.

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

In connection with the commercialization of our products and with the conduct of clinical trials, we must comply with privacy laws of various countries. For instance, in Europe, we have to comply with the European Union General Data Protection Regulation, or GDPR. The GDPR introduced data protection requirements in the European Union 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. The GDPR has increased the responsibility of all parties collecting personal data. As we continue to build our infrastructure in Europe, we will continue to optimize our systems to ensure compliance with the GDPR. However, our efforts to comply with the GDPR may not be successful and could increase our costs of doing business. In addition, data protection authorities of the various EU Member States may interpret the GDPR differently adding a layer of complexity in implementing adequate compliance measures.

The secure and uninterrupted operation of third-party information technology systems and of ours is material to our business operations and strategy. Unauthorized access to data files held in our information technology systems or those of third parties could result in inappropriate use, change or disclosure of sensitive and/or personal data of our customers, employees, suppliers and patients. Any such access, disclosure or other loss of information could subject us to litigation, regulatory fines, penalties or reputational damages, any of which could have a material adverse effect on our competitive position, reputation, business, financial condition and operating results.

We did not generate a profit from our operation in the last fiscal year and there can be no guarantee that we will achieve consistent profitability.

We did not generate a profit in the fiscal year ended November 30, 2021. Our profitability will mainly depend on our capacity to maintain the commercialization of *EGRIFTA SV*® and Trogarzo® successfully in the United States and Trogarzo® in the European Territory through a low-cost and effective distribution network, the recruitment and retention of talented personnel by Syneos, the deployment of an effective marketing campaign and through continued reimbursement coverage for *EGRIFTA SV*® and Trogarzo® under U.S. Medicare and Medicaid programs and under private-health insurers programs in the United States. The obtaining of reimbursement of Trogarzo® in key European countries will also impact our capacity to be profitable.

There is no guarantee that we will continue succeeding in growing sales of *EGRIFTA SV*® and Trogarzo® in the United States. In addition, there is no guarantee that we will be able to successfully launch, commercialize and obtain reimbursement of Trogarzo® in key European countries. 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 sustain profitability.

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

Our ability to make payment on the Notes and our overall indebtedness will depend on future financial and operating performance, which is subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We may be unable to maintain a level of positive cash flows from operating activities sufficient to pay the principal and interest on our Notes. In addition, if our share price remains below the conversion price of the Notes, the Notes are unlikely to be converted and we will have to pay all accrued interest thereon and their principal on their maturity date (June 30, 2023).

As at November 30, 2021, we had negative operating cash flow of $14,477,000. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay investments and capital expenditures, 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.

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

We may need financing in order to fund all or part of our capital requirements to sustain our growth, to develop our marketing and commercial capabilities, to meet our compliance obligations with various rules and regulations to which we are subject, to conduct our research and development activities, including our Phase 3 clinical trial studying tesamorelin for the treatment of NASH and our Phase 1 clinical trial studying TH1902 for various types of cancers, and to in-license or acquire new molecules or approved products. However, our business performance may prevent us from generating enough cash-flow to meet our obligations and the market conditions may also prevent us from having access to the public market in the future at the times or in the amounts necessary. Therefore, there can be no guarantee that we will be able to continue to raise additional capital by way of public or private offerings in the future. In such a case, we would have to use other means of financing, such as entering into private financing or credit agreements, the terms and conditions of which may not be favorable to us. In addition, the issuance and sale of substantial amounts of equity, or other securities, or the perception that such issuances and sales may occur could adversely affect the market price of our common shares.

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

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our key employees and on our ability to be able to attract, retain and motivate qualified commercial, managerial 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. Our third-party service provider, Syneos, has hired qualified individuals to assist us with the commercialization of *EGRIFTA SV*® and Trogarzo® in the United States. Syneos has also hired, amongst others, medical science liaison personnel in the European Territory. Although these individuals are not our employees, the loss of any of those individuals and the inability of Syneos to attract and retain these individuals could have a material adverse effect on the commercialization of *EGRIFTA SV*® and Trogarzo®, and, accordingly, 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 development 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 milestones or our commercial objectives on time.

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 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 deferred revenue, stock option plan, income taxes, and contingent liabilities such as clinical trial expenses, recoverability of inventories, recoverability of tax credits and grants receivable and capitalization of development expenditures. 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.

If we identify a material weakness in our internal controls over financial reporting, our ability to meet our reporting obligations and 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 the financial information we report contains material errors.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under Canadian securities laws to report annually on our internal control over financial reporting. 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. If we determine that our internal controls over our financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial results, and the price of our common shares could be negatively affected.

If we cannot conclude that we have effective internal controls over our financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the Canadian regulatory authorities.

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.

Since our initial public offering in Canada, our valuation and share price have fluctuated immensely and have had no meaningful relationship to current or historical financial results, asset values, book value or many other criteria based on conventional measures of the value of common shares. In the past, the market price of our common shares has fluctuated and will continue to fluctuate due to various factors including the risk factors described herein and other circumstances beyond our control. An investment in our

common shares could decline in value or fluctuate significantly. Any decline in value or fluctuation in the market price of our common shares could also affect the market price of the Notes and the value of the warrants issued in the Offering.

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:

- the level of sales of *EGRIFTA SV*® in the United States;
- the level of sales of Trogarzo® in the United States;
- the level of sales of Trogarzo® in the European Territory;
- supply issues with *EGRIFTA SV*® or Trogarzo®;
- default under the terms of our Notes;
- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals or allowances to commercialize product candidates;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize our product candidates;
- the outcome of any litigation;
- payment of fines or penalties for violations of laws;
- foreign currency fluctuations;
- the timing of achievement and the receipt of milestone or royalty payments from future third parties; and
- failure to enter into new or the expiration or termination of current agreements with third parties.

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

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

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

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

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

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

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

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

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