

**ANNUAL INFORMATION FORM**  
**Financial Year Ended November 30, 2022**



**February 27, 2023**

## **BASIS OF PRESENTATION**

In this Annual Information Form (the “AIF”):

- references to “Theratechnologies”, the “Company”, the “Corporation”, “we”, “our” and “us” or similar terms refer to Theratechnologies Inc. and its subsidiaries on a consolidated basis, unless otherwise indicated or unless the context requires otherwise;
- *EGRIFTA SV*<sup>®</sup> (tesamorelin for injection) refers to tesamorelin indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. *EGRIFTA SV* is our registered trademark in the United States and this mark is used in the United States to commercialize tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.
- tesamorelin refers to the use of our tesamorelin compound for the potential treatment of nonalcoholic steatohepatitis (“NASH”) in the general population and for the potential treatment of other diseases;
- Trogarzo<sup>®</sup> (ibalizumab-uiyk) refers to a recombinant humanized monoclonal antibody. Trogarzo<sup>®</sup>, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (“HIV-1”) infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen. Trogarzo is a registered trademark of TaiMed Biologics, Inc. (“TaiMed”) and is under licence to us for use in the United States and Canada.
- *THERA Patient Support*<sup>®</sup> is our registered trademark in the United States and it refers to our patients and physicians service desk providing support to these people in connection with our commercialized products.
- *SORTI+ Technology* is our trademark and refers to our licensed platform to develop peptide-drug conjugates (“PDC”).
- References to “\$” and “US\$” are to U.S. dollars and references to “CA\$” or “CAD” are to Canadian dollars;
- all information is provided as of February 27, 2023, except where otherwise stated.

## **FORWARD-LOOKING STATEMENTS**

This AIF 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*<sup>®</sup> and Trogarzo<sup>®</sup>, despite new market entrants;
- our ability and capacity to grow the sales of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> successfully in the United States;
- our capacity to meet supply and demand for our products;
- the market acceptance of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> 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*<sup>®</sup> and Trogarzo<sup>®</sup> by third-party payors in the United States;
- the pricing and reimbursement conditions of other competing drugs or therapies that are or may become available;
- our ability to protect and maintain our intellectual property rights in tesamorelin;
- the filing of a supplemental biologics application (“sBLA”) for an intramuscular method of administration of Trogarzo<sup>®</sup>;
- the approval of an intramuscular method of administration of Trogarzo<sup>®</sup> by the United States Food and Drug Administration (“FDA”);
- the filing of a sBLA with the FDA for a new formulation of tesamorelin (“F8 Formulation”);
- the approval of the F8 Formulation by the FDA;
- Our ability to successfully complete the human factors validation study (“HFS”) and to resubmit a change being effected (“CBE”) supplement with the FDA for *EGRIFTA SV*<sup>®</sup> in the 2023 fiscal year;
- our capacity to meet the undertakings, covenants and obligations contained in the credit agreement entered into with Marathon’s affiliates and not be in default thereof;
- our capacity to find a partner to conduct a Phase 2b/3 clinical trial using tesamorelin for the treatment of NASH in the general population;
- the filing of an amendment to our protocol to resume the conduct of our Phase 1 clinical trial using TH1902 in various types of cancer;
- our capacity to find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed;
- our capacity to pursue the development of other PDCs in the field of oncology;
- our capacity to acquire, in-license, or copromote new products;
- our expectations regarding our financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes;
- our estimates regarding our capital requirements; and
- our ability to meet the timelines set forth herein.

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

- sales of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> in the United States will increase over time;
- our expenses will remain under control;
- our commercial practices in the United States will not be found to be in violation of applicable laws;
- the long-term use of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> will not change their respective current safety profile;
- no recall or market withdrawal of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> 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*<sup>®</sup> and Trogarzo<sup>®</sup> in the United States;
- continuous supply of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> will be available to meet market demand on a timely basis;
- our relations with third-party suppliers of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> will be conflict-free;
- the level of product returns and the value of chargebacks and rebates will not exceed our estimates in relation thereto;
- no biosimilar version of tesamorelin will be approved by the FDA;
- our intellectual property will prevent companies from commercializing biosimilar versions of tesamorelin in the United States;
- we will file a sBLA for the F8 Formulation in the 2023 fiscal year;
- the FDA will approve the F8 Formulation;
- no vaccine or cure will be found for the prevention or eradication of HIV;
- the HFS will be successfully completed and we will resubmit a CBE supplement with the FDA for *EGRIFTA SV*<sup>®</sup> by the end of the 2023 fiscal year;
- the FDA will approve the CBE supplement;
- we will not default under the terms and conditions of the credit agreement entered into with Marathon's affiliates, including meeting the minimum liquidity and revenue target covenants therein;
- we will meet all of the conditions set forth under the credit agreement entered into with Marathon's affiliates to draw down the \$20 million second tranche;
- the interest rate on the amount borrowed from Marathon's affiliates under the credit agreement will not materially vary upwards;
- the Corporation will continue as a going concern;
- we will find a partner to conduct a Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- the FDA will approve the amendments to our protocol allowing us to resume the conduct of our Phase 1 clinical trial using TH1902 in various types of cancer;
- our Phase 1 clinical trial studying TH1902 in various types of cancer will demonstrate positive efficacy and safety results;
- we will find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed;
- our research and development activities will yield positive results;

- the data obtained from our market research on the potential market for *EGRIFTA SV*<sup>®</sup> and on the potential market for Trogarzo<sup>®</sup> in the United States are accurate;
- the timelines set forth herein will not be materially adversely impacted by unforeseen events that could arise subsequent to the date of this AIF;
- our business plan will not be substantially modified; and
- no international event, such as a pandemic or worldwide war, will occur and adversely affect global trade.

Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these risks and uncertainties, the forward-looking statements and circumstances discussed in this AIF 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 “Item 3 - 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 AIF. 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 AIF, and particularly our forward-looking statements, with these cautionary statements.

#### **NON-IFRS AND NON-US GAAP MEASURE**

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

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## SELECTED EVENTS IN FISCAL YEAR 2022 AND 2023 OUTLOOK

*The following summary highlights selected events that occurred in the fiscal year 2022 up to the date of this AIF as well as our business objectives described elsewhere in this AIF for the fiscal year 2023. This summary does not contain all of the information about us and you should carefully read the entire AIF, including the section entitled “Risk Factors”.*

### Commercial Events

- Internalization of commercial and medical affairs teams;
- Ceased operation of Trogarzo<sup>®</sup> in Europe and retuned our commercial rights to TaiMed;
- Conclusion of a credit agreement providing for up to \$100 million term loan;
- Launch of IV Push method of administration of Trogarzo<sup>®</sup>; and
- Execution of agreement providing for the distribution of *EGRIFTA SV*<sup>®</sup> in various countries in the regions of Latin America, Middle East, North Africa, Turkey and Central and Eastern Europe.

### Regulatory Events

- FDA approval of the IV Push method of administration of Trogarzo<sup>®</sup>; and
- Suspension of enrollment in connection with our Phase 1 clinical trial studying TH1902 in various types of cancers.

### Research and Development Events

- Completion of study enrollment for the development of an intramuscular method of administration of Trogarzo<sup>®</sup>.

### 2023 Business Objectives

- To continue growing our revenues in the United States from sales of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> and to manage our expenses to achieve a positive Adjusted EBITDA by year-end;
- To pursue potential product acquisitions, in-licensing transactions, copromotion, or other opportunities to grow our revenues;
- To file a sBLA with the FDA to seek approval of the intramuscular method of administration of Trogarzo<sup>®</sup>;
- To file a sBLA with the FDA to seek approval of the F8 Formulation of tesamorelin;
- To resubmit a CBE supplement with the FDA in relation to the HFS for *EGRIFTA SV*<sup>®</sup> by September 15, 2023;
- To resume our Phase 1 clinical trial studying TH1902 in various types of cancer by filing an amendment to our protocol with the FDA and, once such trial has resumed, to find a partner for TH1902 ; and
- To continue looking for a partner to initiate a Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population.

## ITEM 1 CORPORATE STRUCTURE

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### 1.1 NAME, ADDRESS AND INCORPORATION

We were incorporated under Part IA of the *Companies Act* (Québec), or CAQ, on October 19, 1993 under the name Theratechnologies Inc. We amended our articles on October 20, 1993 by repealing the restrictions applicable to private companies. On December 6, 1993, we again amended our articles to increase the number of directors and to modify our share capital. On March 26, 1997, we further modified our share capital to consist of an unlimited number of common shares and an unlimited number of preferred shares. Finally, on June 21, 2011, we amended our articles to give the power to our directors to appoint a number of additional directors equal to 33.33% of the number of directors elected at the last shareholders meeting preceding any appointment.

On February 14, 2011, the CAQ was abrogated and replaced by the *Business Corporations Act* (Québec), or BCA, and companies governed by Part IA of the CAQ such as us became business corporations governed by the BCA. Accordingly, we did not have to file articles of continuation or amend our existing corporate articles. The BCA was applicable immediately without having to complete any formalities.

Our common shares are listed on the Toronto Stock Exchange, or TSX, under the symbol “TH” and on the U.S. NASDAQ stock market, or NASDAQ, under the symbol “THTX”. See Item 6.1 for a complete description of our authorized share capital.

Our head office and principal place of business are located at 2015 Peel Street, 11<sup>th</sup> Floor, Montreal, Québec, Canada H3A 1T8. Our phone number is (514) 336-7800. Our website is [www.theratech.com](http://www.theratech.com). The information contained on our website is not part of this AIF.

### 1.2 SUBSIDIARIES

As at February 27, 2023, Theratechnologies had the following five wholly-owned subsidiaries:

- **Theratechnologies Europe Limited**, a company governed by the *Companies Act 2014* (Ireland). Theratechnologies Europe Limited provides the services of personnel to Theratechnologies Inc. for its activities in the United States;
- **Theratechnologies U.S., Inc.**, a company governed by the *Delaware General Corporation Law* (Delaware). Theratechnologies U.S., Inc. provides the services of personnel to Theratechnologies Inc. for some of its activities in the United States;
- **Theratechnologies Intercontinental Inc.**, a company governed by the *Business Corporations Act* (Québec). Theratechnologies Intercontinental Inc., formerly Theratechnologies ME Inc., used to control the worldwide rights to commercialize *EGRIFTA*<sup>®</sup>, except in the United States, Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries, and Canada. Theratechnologies Intercontinental Inc. is no longer an active subsidiary;
- **Theratechnologies Europe Inc.**, a company governed by the *Business Corporations Act* (Québec). Theratechnologies Europe Inc., formerly 9176-5057 Québec Inc., used to control the rights to commercialize *EGRIFTA*<sup>®</sup> in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries. Theratechnologies Europe Inc. is no longer an active subsidiary; and
- **Pharma-G Inc.**, a company governed by the *Business Corporations Act* (Québec). Pharma-G Inc. is no longer an active subsidiary.



## ITEM 2 OUR BUSINESS

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### 2.1 OVERVIEW

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

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

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

*EGRIFTA SV*<sup>®</sup> (tesamorelin for injection) is a new formulation of *EGRIFTA*<sup>®</sup> which was originally approved by the FDA in November 2010 and was launched in the United States in January 2011. *EGRIFTA SV*<sup>®</sup> was approved by the FDA in November 2018, was launched in 2019 and has now replaced *EGRIFTA*<sup>®</sup> in such country. *EGRIFTA SV*<sup>®</sup> can be kept at room temperature, comes in a single vial and has a higher concentration resulting in a smaller volume of administration. *EGRIFTA SV*<sup>®</sup> is currently the only approved therapy in the United States for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and our organization has been commercializing this product in this country since May 1<sup>st</sup>, 2014.

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

Trogarzo<sup>®</sup> was also approved by the European Medicines Agency (“EMA”) in September 2019 and is no longer under licence to us in Europe further to our decision to terminate and return to TaiMed our commercialization rights to this product in April 2022. The EMA has since withdrawn the marketing approval of Trogarzo<sup>®</sup> in Europe.

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

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

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

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

## **2.2 THREE-YEAR HISTORY**

### **2022**

- *2023 Fiscal Year Guidance and Key Objectives.* On January 4, 2023, we announced, among other things, revenue guidance between \$90 million and \$95 million for the fiscal year 2023, our key objectives for the fiscal year 2023 consisting of achieving positive Adjusted EBITDA and the creation of an advisory scientific committee whose mandate is to optimize the protocol amendments for the development of TH1902.
- *Voluntary Pause of Phase 1 Clinical Trial Studying TH1902.* On December 1, 2022, we announced our decision to voluntarily pause the enrollment of patients in our Phase 1 clinical trial studying TH1902 and to revisit the study design of this clinical trial.
- *FDA Approval of 30-Second Intravenous Push Method of Administration of Trogarzo®.* On October 3, 2022, we announced that the FDA approved the 30-Second Intravenous Push Method of Administration of Trogarzo®.
- *Closing of Funding of \$40 million Under Credit Agreement.* On July 27, 2022, we announced that we received \$40 million under the terms of a credit agreement with affiliated funds of Marathon Asset Management.
- *Conclusion of Non-Dilutive Term Loan of Up to \$100 million.* On July 13, 2022, we announced that we had entered into a binding commitment with affiliated funds of Marathon Asset Management providing for a non-dilutive term loan of up to \$100 million (the “Marathon Credit Facility”). On February 27, 2023, we entered into a first amendment to the Marathon Credit Facility (the “First Amendment to the Marathon Credit Facility”). The First Amendment to the Marathon Credit Facility and the Marathon Credit Facility are collectively referred to as the “Marathon Credit Facility”. See “Item 9 – Material Contracts – Marathon Credit Facility” below for a description of the Marathon Credit Facility.
- *Strategic Hire Supporting Investor Relations.* On May 31, 2022, we announced the hiring of a new Head of Investor Relations.
- *Initiation of Basket Trial in Phase 1 Clinical Trial Studying TH1902.* On May 10, 2022, we announced the initiation of the recruitment of patients in the basket portion of the first-in-human study of TH1902. The dose of TH1902 was then established at 300 mg/m<sup>2</sup>.
- *Return of European Commercialization Rights of Trogarzo® to TaiMed.* On April 27, 2022, we announced that we notified TaiMed of our decision to return the European commercialization rights to Trogarzo® to TaiMed within the next 180 days pursuant to the terms of the TaiMed Agreement.
- *Launch of an Internal Sales Force.* On February 15, 2022, we announced the launch of our own field force through the hiring of key account managers joining from our long-term contract sales organization. We also announced the hiring of medical science liaison and community liaison personnel as part of the internalization of commercial and medical dedicated personnel.

## 2021

- *Submission of sBLA to the FDA for the IV Push mode of administration of Trogarzo<sup>®</sup>.* On December 6, 2021, we announced the submission of an sBLA to the FDA for the IV Push mode of administration of Trogarzo<sup>®</sup>.
- *Renewal of Shelf Prospectus and ATM Program.* On November 23, 2021, we announced the filing of a short form base shelf prospectus with the Securities and Exchange Commission, or SEC, and Canadian securities regulatory authorities with the intent on filing a prospectus supplement to renew our prospectus supplement of July 23, 2021 relating to our US\$50,000,000 at-the-market, or ATM, facility. Such prospectus supplement was filed on December 16, 2021 and the ATM program was renewed.
- *Conclusion of Agreement for the Reimbursement of Trogarzo<sup>®</sup> in Italy.* On October 26, 2021, we announced that we had reached an agreement with the Italian Medicines Agency for the reimbursement of Trogarzo<sup>®</sup>.
- *Pharmacokinetic Results of Trogarzo<sup>®</sup> similar in IV Push mode of administration of Trogarzo<sup>®</sup> as those in the intravenous mode of administration.* On September 22, 2021, we announced that the pharmacokinetics results of the IV Push mode of administration of Trogarzo<sup>®</sup> were no different than those of the intravenous mode of administration of Trogarzo<sup>®</sup>.
- *ATM Facility.* On July 23, 2021, we announced that we had filed a prospectus supplement to our short form base shelf prospectus with the SEC and Canadian securities regulatory authorities establishing an ATM facility entitling us to issue and sell up to US\$50,000,000 common shares from treasury.
- *Study of Tesamorelin for the Potential Treatment of NASH in the General Population.* On July 15, 2021, we announced that discussions with the FDA and the EMA on our protocol design were completed and provided details on such study design. We also announced that the costs of conducting such study were higher than expected and we had retained a third party to assist in identifying a potential partner. As a result, we announced that the timelines to initiate such study were no longer applicable.
- *Appointment and Election of New Board Members.* On June 23, 2021, we announced that we had appointed Mr. Frank Holler to the Board of Directors. This announcement followed the election of three new members, Mr. Joe Arena, Mr. Andrew Molson and Mr. Alain Trudeau, to the Board of Directors of Theratechnologies during the annual meeting of shareholders of Theratechnologies held on May 13, 2021.
- *Strategic Hire Supporting the Human Resources Activities.* On May 31, 2021, we announced the addition of one new senior member to our executive team, namely Mr. André Dupras acting as Vice President, Human Resources.
- *Strategic Hires Supporting the Commercial Activities.* On March 29, 2021, we announced the addition of two new senior members to our executive team, namely Mr. John Leasure and Mr. Peter Kowal. Mr. Leasure acts as Global Commercial Officer, whereas Mr. Kowal acts as Vice President, HIV-US, Commercial Operations.
- *First Patient Dosed with TH1902 in Phase 1 Clinical Trial.* On March 24, 2021, we announced that a patient had received a first dose of TH1902 as part of the dose-escalating part of our Phase 1 clinical trial evaluating TH1902 in various types of cancer.
- *FDA's Grant of Fast track Designation to TH1902.* On February 4, 2021, we announced that the FDA granted fast track designation to TH1902 as a single agent for the treatment of patients with sortilin positive recurrent advanced solid tumors that are refractory to standard therapy.
- *US\$46 Million Unit Offering.* On January 19, 2021, we announced the closing of a US\$46 million unit offering (the "Offering") at a price of US\$2.75 per unit, each unit being comprised of one common share and one-half common share purchase warrant. Each whole warrant entitles the holders thereof to purchase

one common share at a price of US\$3.18 until January 19, 2024. The Offering resulted in the sale of 16,727,900 units and included the full exercise of the over-allotment option to purchase an additional 2,181,900 units. The announcement related to this Offering was made on January 11, 2021.

- *Preliminary Consolidated Annual Revenues and Update on Research and Development Activities.* On January 7, 2021, we announced consolidated net revenues estimates for our full fiscal year to be between US\$65.8 million and US\$66.1 million. We also announced the receipt of a “Study May Proceed Letter” from the FDA for our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population. Such letter contained a recommendation that we request a meeting with the FDA to discuss questions and comments received on certain aspects of the proposed trial design. We also announced the receipt of a “Study May Proceed” letter from the FDA for our Phase 1 clinical trial using TH1902.

## 2020

- *New Data on the Effect of Tesamorelin on Liver Fibrosis and NASH.* On November 16, 2020, we announced new data on tesamorelin further to a sub-study of the transcriptomic analysis of the liver biopsies resulting from the Phase 2 study evaluating the effect of tesamorelin in people living with HIV-associated NAFLD conducted at MGH. The data showed that the serum levels of three proteins associated with the development of NASH and fibrosis were reduced in tesamorelin patients compared to the placebo group.
- *Appointment of New Directors.* On October 16, 2020, we announced the appointment of Mr. Andrew Molson and Mr. Alain Trudeau as new independent directors to our board of directors.
- *Issuance of U.S. Patent Directed to the Treatment of NASH and/or NAFLD Using Tesamorelin.* On October 13, 2020, we announced that the United States Patent and Trademark Office had issued U.S. patent No. 10,799,562 directed to the treatment of NASH and/or NAFLD in patients using tesamorelin. The patent is scheduled to expire in 2040 and we have an exclusive license with MGH to this patent.
- *Tesamorelin to Be Studied for the Treatment of NASH in General Population.* On September 10, 2020, we announced our plan to pursue the Phase 3 clinical development of tesamorelin for the treatment of NASH in the general population.
- *Commercialization of Trogarzo<sup>®</sup> in Germany.* On September 10, 2020, we announced that Trogarzo<sup>®</sup> would become commercially available in Germany as of September 11, 2020.
- *New Data on the Effects of Tesamorelin on Liver Fat.* On July 23, 2020, we announced new data derived from a sub-analysis of the Phase 2 study evaluating the effect of tesamorelin on the transcriptome of the liver biopsies in people living with HIV-associated nonalcoholic fatty liver disease conducted at MGH. The data showed that tesamorelin had a positive effect on gene expression related to oxidative phosphorylation and decreased gene expression related to inflammation, tissue repair and cell division. Treatment with tesamorelin also showed improvement of genes associated with hepatocellular carcinoma prognosis.
- *Bioequivalence of F8 Formulation with EGRIFTA<sup>®</sup>'s Formulation.* On July 7, 2020, we announced the successful completion of our in-house bioequivalence study evaluating the F8 Formulation of tesamorelin against the formulation used for EGRIFTA<sup>®</sup> (the “F1 Formulation”).
- *Ibalizumab's Effects on HIV-2.* On July 6, 2020, we announced that data obtained from *in vitro* studies using ibalizumab could have some efficacy in patients infected with HIV-2.
- *New Positive Data for Investigational Peptide-Drug Conjugates Targeting Sortilin Positive Cancer.* On May 15, 2020, we announced *in vivo* results regarding TH1902 to assess its effect on triple-negative breast cancer compared to docetaxel alone. These results showed that docetaxel administered alone at one quarter of its maximum tolerated dose had no apparent effect on tumor burden whereas the administration

of TH1902 at a comparable dose led to sustained tumor inhibition. TH1902 also showed a better safety profile than the administration of docetaxel alone. In addition, *in vitro* results obtained in ovarian cancer showed that TH1904 stopped the formation of vasculogenic mimicry at very low doses whereas doxorubicin alone had no effect. Inhibition of vasculogenic mimicry was also observed in a triple-negative breast cancer model with very low doses of TH1902 compared to docetaxel alone.

- *Positive results Announced for Two Investigational Peptide-Drug Conjugates Targeting Sortilin Positive Ovarian Cancer.* On April 27, 2020, we announced *in vivo* results obtained with TH1902 and TH1904. These results showed a high accumulation of both conjugates in ovarian tumors with low accumulation in healthy ovary tissue. TH1902 and TH1904 were found to have better efficacy in the animal model, at equivalent dose, than docetaxel and doxorubicin used alone. No weight loss or decreasing lymphocytes were induced using TH1902 and TH1904.
- *Feedback Received from FDA and EMA on Proposed Clinical Trial Using Tesamorelin for the Treatment of NASH in People Living with HIV.* On March 31, 2020, we announced that we had received feedback from both the FDA and the EMA on our proposed clinical trial seeking to develop tesamorelin for the treatment of NASH in people living with HIV and that further discussions were warranted with these regulatory agencies in order to harmonize their approaches with the aim of filing a common research protocol.
- *Appointment of New President and Chief Executive Officer.* On March 2, 2020, we announced the appointment of Mr. Paul Lévesque as our new president and chief executive officer in replacement of our retiring president and chief executive officer, Mr. Luc Tanguay.
- *Execution of Agreement with Massachusetts General Hospital and Dr. Steven Grinspoon.* On February 4, 2020, we announced the execution of two long-term agreements with Massachusetts General Hospital, or MGH, and Dr. Steve Grinspoon, regarding the assistance to be provided by MGH, through Dr. Steve Grinspoon, in connection with the study design, dosing, study duration and other matters in consideration of certain milestones and royalty payments related to the development of tesamorelin for the treatment of NAFLD and NASH in the HIV patient population. The agreements were subsequently amended to provide for the development of tesamorelin for the treatment of NAFLD and NASH in the general population.
- *In Vitro and In Vivo Data on our Investigational Oncology Peptide-Drug Conjugates Presented at Scientific Conference.* On December 13, 2019, we announced the results from *in vitro* and *in vivo* experiments using TH1902 at the San Antonio Breast Cancer Symposium. Results showed that treatment using TH1902, in combination with docetaxel, improved efficacy and had better tolerability over treatment with docetaxel alone.

### **2.3 OUR 2023 BUSINESS OBJECTIVES**

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

Below is a table detailing our approved products and our pipeline.

	Product	Phase of Development						Milestones
		Preclinical	Phase 1	Phase 2	Phase 3	Approved	Marketed	
HIV	 Trogarzo® (ibalizumab-uiyk) injection 200mg/1.33mL (150 mg/mL)	[Green arrow from Preclinical to Marketed]						Solidify long-acting Trogarzo® positioning
	 EGRIFTA SV® tesamorelin for injection	[Purple arrow from Preclinical to Marketed]						Enhanced patient education and prescriber engagement; Leverage KOL community
HIV	Trogarzo® IV Push Multi-drug resistant HIV-1	[Green arrow from Preclinical to Marketed]						New method of administration launched
	Trogarzo® Intramuscular Multi-drug resistant HIV-1	[Green arrow from Preclinical to Phase 3]						Intramuscular study completed; File sBLA with FDA in 2023
	Tesamorelin F8 HIV-associated lipodystrophy	[Green arrow from Preclinical to Phase 3]						Bioequivalence study completed; File sBLA with FDA in 2023
NASH	Tesamorelin F8 Formulation	[Purple arrow from Preclinical to Phase 2]						Seeking potential partnership to launch Phase 2b/3 clinical trial
Oncology	TH1902 (PDC) SORT1+ Technology™	[Dark blue arrow from Preclinical to Phase 1]						Phase 1 clinical trial voluntarily paused; File amended protocol with FDA in first half of 2023 to resume trial and enrollment

## 2.4 PRODUCTS

### Our Approved Products

#### *EGRIFTA SV® (tesamorelin for injection)*

*EGRIFTA SV®* (tesamorelin for injection) induces the release of growth hormone which causes a reduction in excess visceral abdominal fat (lipohypertrophy) in HIV-infected adult patients without reducing or interfering with subcutaneous fat, and, as such, has no clinically significant effect on undesired loss of subcutaneous fat (lipoatrophy).

*EGRIFTA SV®* is an improved formulation of the original F1 Formulation and is available in the United States only. It was approved by the FDA in November 2018 and was made commercially available to patients in the United States in November 2019. *EGRIFTA SV®* comes in a single vial, can be stored at room temperature and has a higher concentration than the original F1 Formulation, therefore resulting in a smaller volume of administration. No filing has been made in any country seeking the approval of *EGRIFTA SV®*. *EGRIFTA SV®* is injected under the skin into the abdomen once a day.

#### *Lipodystrophy*

Lipodystrophy is characterized by abnormalities in the production and storage of fat. It has two components: lipohypertrophy, abnormal and excessive fat accumulation, and lipoatrophy, the noticeable, localized loss of fat tissue under the skin. In patients with lipohypertrophy, fat accumulation occurs mostly around the waist and may also occur in other regions, including breast tissue and in dorsocervical tissues in the neck, resulting in a “buffalo

hump". Excess fat also appears as lipomas, or benign tumors composed of fat cells. In patients with lipoatrophy, the loss of fat tissue generally occurs in the limbs and facial area.

In HIV-infected patients, lipodystrophy may be caused by the viral infection itself, the use of antiretroviral therapy (not class-specific), presence of hormonal imbalance (growth hormone) and/or microbiome alteration and chronic inflammation. Different pathophysiological mechanisms are involved in the development of lipohypertrophy and lipoatrophy. The most common statistically significant independent risk factors identified for lipohypertrophy are duration of antiretroviral therapy and markers of disease severity, including higher pre-antiretroviral treatment viral load. Other factors include age, genetics, and gender.

### *Tesamorelin*

Tesamorelin is the active peptide comprising *EGRIFTA SV*<sup>®</sup>. Tesamorelin is a stabilized 44 amino acid human growth hormone-releasing factor analogue, or GRF, which was synthesized in our laboratories in 1995 using our long-acting peptide method. Although natural peptides have significant therapeutic potential, they are subject to enzymatic degradation which severely limits their effectiveness in clinical use. Our long-acting peptide method is a peptide stabilization process which increases the target protein's resistance to enzymatic degradation, while maintaining its natural specificity. This usually results in a more stable and efficient compound, which can thus prolong its duration of action. tesamorelin induces growth hormone secretion in a natural and pulsatile way. The clinical results obtained to date using tesamorelin suggest a therapeutic potential in both anabolic and lipolytic indications.

### *Mechanism of Action*

*In vitro*, tesamorelin binds and stimulates human GRF receptors with similar potency as the endogenous GRF. GRF is a hypothalamic peptide that acts on the pituitary somatotroph cells to stimulate the synthesis and pulsatile release of endogenous growth hormone, which is both anabolic and lipolytic. Growth hormone exerts its effects by interacting with specific receptors on a variety of target cells, including chondrocytes, osteoblasts, myocytes, hepatocytes, and adipocytes, resulting in a host of pharmacodynamic effects. Some, but not all these effects, are primarily mediated by insulin-like growth factor one, IGF-1, produced in the liver and in peripheral tissues.

The effects of recombinant human growth hormone, or rhGH, and tesamorelin have been the subject of several clinical trials in the area of HIV-associated lipodystrophy. Based on these clinical trials, the safety profiles of rhGH and tesamorelin appear to be very different. The natural synthesis of growth hormone is regulated by a feedback mechanism preventing its overproduction. Tesamorelin induces optimal activity of the somatotrope function and retains the natural rhythm (pulsatility) of the physiological secretion of growth hormone without interfering with the feedback mechanism mentioned above. With the exogenous administration of rhGH, the feedback mechanisms are short-circuited, which gives rise to higher levels of growth hormone. The side effects associated with rhGH include nerve, muscle or joint pain, swelling due to fluid retention (edema), carpal tunnel syndrome, numbness and tingling of skin and increased risk of diabetes. These side effects are particularly frequent among older people. In addition, rhGH can cause hyperglycemia which makes it contraindicated for patients with diabetes or pre-diabetic conditions.

### ***Trogarzo*<sup>®</sup> (ibalizumab-uiyk) Injection**

Trogarzo<sup>®</sup> is a CD-4 directed post-attachment HIV-1 inhibitor. Trogarzo<sup>®</sup> was approved by the FDA on March 6, 2018 and was made commercially available to patients in the United States on April 30, 2018. In the United States, Trogarzo<sup>®</sup> is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen. Since its approval, Trogarzo<sup>®</sup> was included in the treatment guidelines issued by the International Antiviral Society-United States and the treatment guidelines issued by the U.S. Department of Health and Human Services.

Trogarzo<sup>®</sup> was also approved in Europe by the EMA on September 26, 2019, for the treatment of adults infected with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen.

In connection with our decision to stop the commercialization of Trogarzo<sup>®</sup> in Europe in the fiscal year 2022, we filed a request with the EMA seeking the withdrawal of the marketing authorisation for Trogarzo<sup>®</sup> as an approved product in Europe as of January 1, 2023 and such request was granted by the EMA. A similar request was also filed with the Medicines and Healthcare products Regulatory Agency in the United Kingdom and such request was granted.

As a result of the withdrawal of Trogarzo<sup>®</sup> as an approved product in Europe, our obligation to conduct a pediatric study and any other post-approval studies related to this product have ceased.

However, we are continuing the conduct of our efficacy study in the United States, the PROMISE-US study, as we believe data generated through this study will help the medical community to acknowledge the value of Trogarzo<sup>®</sup> in the United States. The costs of the PROMISE-US study are entirely borne by the Corporation. The PROMISE-US study is aimed primarily at evaluating the long-term efficacy and durability of Trogarzo<sup>®</sup> in combination with other antiretrovirals by comparing the virologic, immunologic and clinical outcomes of patients receiving Trogarzo<sup>®</sup> treatment *versus* matched patients not receiving Trogarzo<sup>®</sup>.

Trogarzo<sup>®</sup> is available as a single dose, 2 mL vial containing 150 mg/mL of ibalizumab-uiyk. Each vial delivers approximately 1.33 mL containing 200 mg of ibalizumab-uiyk. Trogarzo<sup>®</sup> is administered intravenously after diluting the appropriate number of vials in 250 ml of 0.9% Sodium Chloride Injection, USP. Patients receive a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every two weeks. This maintenance dose is either administered intravenously or through the new intravenous push method of administration approved by the FDA in October 2022. The new intravenous push method administers the same drug product, as an undiluted maintenance dose over 30 seconds, eliminating the need for infusion supplies, reducing duration time of dosing and improving convenience for patients and physicians. Further, many HIV clinics previously unable to administer infusions due to State regulation or institutional policies will now be able to administer Trogarzo<sup>®</sup> using this new method. See “Item 2.6 – Research and Development Activities – Ibalizumab – Intramuscular Method of Administration of Trogarzo” below.

Trogarzo<sup>®</sup> was developed by TaiMed and we have an exclusive license to distribute this product in Canada and in the United States. Effective December 15, 2022, we no longer have the commercial rights to distribute Trogarzo<sup>®</sup> in Europe. See “Item 2.5 – Commercialization Activities – *Trogarzo*<sup>®</sup> – General” below.

### *Mechanism of Action*

Unlike other antiretroviral agents, Trogarzo<sup>®</sup> binds primarily to the second extracellular domain of the CD4 receptor, away from major histocompatibility complex II molecule binding sites. It potentially prevents the HIV virus from infecting CD4<sup>+</sup> immune cells while preserving normal immunological function. Trogarzo<sup>®</sup> is active across all major HIV clades and irrespective of tropism. No drug-drug interactions and no cross-resistance with other ART were noted during the clinical trials nor are expected.



## 2.5 COMMERCIALIZATION ACTIVITIES

### *EGRIFTA SV<sup>®</sup> - United States*

#### *General*

*EGRIFTA SV<sup>®</sup>* (tesamorelin for injection) is commercialized in the United States. Prior to November 2019, the date on which *EGRIFTA SV<sup>®</sup>* became commercially available in the United States, *EGRIFTA<sup>®</sup>* (tesamorelin for injection) was also commercialized in the United States and Canada. However, *EGRIFTA<sup>®</sup>* is no longer offered for sale in the United States since being replaced by *EGRIFTA SV<sup>®</sup>* in the 2020 fiscal year. We have also discontinued the sale of *EGRIFTA<sup>®</sup>* in Canada in October 2022. See “Item 2.5 – Commercialization Activities – Marketing and Sales of our Products” below for a description of our commercial infrastructure.

#### *Manufacturing*

We do not own or operate commercial scale manufacturing facilities for the production of *EGRIFTA SV<sup>®</sup>*, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party service providers, Bachem Americas, Inc. (“Bachem”) and Jubilant HollisterStier, General Partnership, (“Jubilant”), for all of our required raw materials, drug substance and finished product for commercial sale and clinical trials.

We currently manufacture *EGRIFTA SV<sup>®</sup>* in a 2 mg/vial formulation and one vial of *EGRIFTA SV<sup>®</sup>* is required to administer a dose of 1.4 mg which is bioequivalent to a 2 mg dose of the original F1 Formulation.

#### *Active Pharmaceutical Ingredient*

We are currently negotiating the renewal of our manufacture and supply agreement with Bachem (the “Bachem Agreement”) relating to the manufacture and supply of the active pharmaceutical ingredient of tesamorelin (the “API”) for *EGRIFTA SV<sup>®</sup>*. However, despite the ongoing negotiations, Bachem has advised us that it would manufacture lots of API, if needed. Bachem is our only validated supplier of raw materials.

#### *Finished Product*

We have an agreement with Jubilant providing for the manufacture and supply of the finished form of *EGRIFTA SV<sup>®</sup>* for commercial sale in the United States and for tesamorelin in connection with clinical trials (the “Jubilant Agreement”). Under the Jubilant Agreement, Jubilant must fill vials with tesamorelin, lyophilize it, label and package those vials and deliver them to locations in accordance with our instructions. See “Item 9 - Material Contracts – Jubilant Agreement” below.

We have an agreement with Lyophilization Services of New England, Inc. (“LSNE”) providing for the manufacture and supply of the finished form of the F8 Formulation pursuant to the terms of a commercial supply agreement with an effective date of May 11, 2020.

#### *Injection Kit*

In connection with the sale of *EGRIFTA SV<sup>®</sup>*, we provide patients with the necessary devices to administer *EGRIFTA SV<sup>®</sup>*. These devices are comprised of syringes, needles and water for injection. In the United States, we have an agreement with Hospira Worldwide, Inc. (“Hospira”) pursuant to which Hospira provides us with sterile water for injection. The packaging of those devices is done through Sharp Clinical Services Inc. (“Sharp”) a third-party service provider. The packaging agreement with Sharp was entered into in August 2017 (the “Sharp Agreement”). See “Item 9 - Material Contracts” below.

## *Distribution*

In connection with the commercialization of *EGRIFTA SV*<sup>®</sup> in the United States, we have entered into various agreements with third-party service providers to distribute our products to patients. The distribution of *EGRIFTA SV*<sup>®</sup> is tightly controlled and is only available through certain selected pharmacies. Below is a summary of our agreements entered into with our third-party service providers forming part of the supply chain of *EGRIFTA SV*<sup>®</sup>.

### *Logistic Service Provider and Distributor*

On November 1<sup>st</sup>, 2017, we entered into an amended and restated master services agreement with RxC Acquisition Company, LLC (“RxCrossroads”) along with two amended and restated statements of work (the “RxCrossroads Agreements”). Under the terms of the RxCrossroads Agreements, RxCrossroads acts as our exclusive third-party logistic service provider for all of our products in the United States and as such, provides us with warehousing and logistical support services, including inventory control, account management, customers support, product return management and fulfillment of orders.

Under the RxCrossroads Agreements, RxCrossroads also acts as our exclusive third-party distributor of our products in the United States. In such role, RxCrossroads purchases products from us and takes title thereto. RxCrossroads’ purchases of our products are triggered by its expectations of market demand over a certain period of time. RxCrossroads fulfills orders received from authorized wholesalers and certain authorized specialty pharmacies and, with respect to *EGRIFTA SV*<sup>®</sup>, delivers it directly to that authorized wholesaler’s client, namely a specialty pharmacy forming part of our network of specialty pharmacies, or directly to those authorized specialty pharmacies. See “Item 9 - Material Contracts – RxCrossroads Agreements” below.

### *Wholesalers*

Our supply chain of *EGRIFTA SV*<sup>®</sup> in the United States is comprised of a limited number of wholesalers through which specialty pharmacies we have contracted with can order *EGRIFTA SV*<sup>®</sup>. These wholesalers accept purchase orders from those specialty pharmacies, purchase *EGRIFTA SV*<sup>®</sup> from RxCrossroads, and resell this product to these specialty pharmacies. Our wholesalers do not handle the physical delivery of *EGRIFTA SV*<sup>®</sup>. The shipping and delivery of *EGRIFTA SV*<sup>®</sup> to those specialty pharmacies is handled by RxCrossroads. To date, we have agreements in place with the following principal wholesalers for *EGRIFTA SV*<sup>®</sup>: Cardinal Health, McKesson Corporation, and Cesar Castillo, Inc. For a description of these agreements, see “Item 9 – Material Contracts” below.

### *Specialty Pharmacies*

We have entered into agreements with various specialty pharmacies across the United States providing them with the right to order *EGRIFTA SV*<sup>®</sup> from our authorized wholesalers and distribute *EGRIFTA SV*<sup>®</sup> to patients in the United States through their networks of local pharmacies.

In addition, a limited number of those specialty pharmacies are authorized to purchase *EGRIFTA SV*<sup>®</sup> directly from RxCrossroads for redistribution within their own retail specialty pharmacy stores.

## **Trogarzo**<sup>®</sup>

### *General*

Trogarzo<sup>®</sup> is under license to us from TaiMed. On March 18, 2016, we entered into a distribution and marketing agreement with TaiMed (the “TaiMed Agreement”) and, on March 6, 2017, we amended and restated the TaiMed Agreement, as further amended. Pursuant to the terms of the TaiMed Agreement, we have the exclusive rights to

commercialize Trogarzo<sup>®</sup> in the United States, in Canada, in the European Union countries as well as in Albania, Iceland, Israel, Liechtenstein, Norway, Russia, Switzerland and Turkey (collectively, the “European Territory”). TaiMed has kept all rights related to the further development of ibalizumab.

On April 27, 2022, we notified TaiMed pursuant to the terms of the TaiMed Agreement that we were terminating our rights to commercialize Trogarzo<sup>®</sup> in the European Territory. Such notice of termination became effective on December 15, 2022.

#### *North American Territory – Terms and Conditions*

In the United States, Trogarzo<sup>®</sup> was approved by the FDA on March 6, 2018.

In Canada, we are responsible, but under no obligation, to seek the approval of Trogarzo<sup>®</sup> from Health Canada. No filing seeking the approval of Trogarzo<sup>®</sup> has been made in Canada and to date, it is unlikely that a filing seeking the approval of Trogarzo<sup>®</sup> in Canada will be made.

We are responsible for all regulatory activities, regulatory filings and communications with the FDA and with Health Canada, if and when applicable, in addition to all commercialization activities in the North American Territory.

The transfer price for sales of Trogarzo<sup>®</sup> in Canada and in the United States has been determined at 52% of its net selling price.

Under the terms of the TaiMed Agreement, we agreed to make the following payments to TaiMed in consideration of the rights granted to us in the North American Territory:

- a cash payment of US\$1,000,000, which cash payment was made on the execution of the TaiMed Agreement in March 2016; and
- a payment of US\$4,000,000 through the issuance of common shares and such payment was made after the first commercial sale of Trogarzo<sup>®</sup> in the United States.

The US\$4,000,000 payment was made on May 15, 2018, and resulted in the issuance of 1,463,505 common shares to TaiMed.

Furthermore, we agreed to make the following one-time milestone payments to TaiMed based on the net sales of Trogarzo<sup>®</sup> in the North American Territory:

- US\$7,000,000 in two annual equal installments once net sales reached an aggregate amount of US\$20,000,000 over four consecutive Theratechnologies’s financial quarters. The first installment of US\$3,500,000 was paid in July 2019 and the last one was paid in June 2020;
- US\$10,000,000 once annual net sales will have reached US\$200,000,000 in any of our financial year;
- US\$40,000,000 once annual net sales will have reached US\$500,000,000 in any of our financial year; and
- US\$100,000,000 once annual net sales will have reached US\$1,000,000,000 in any of our financial year.

We also agreed to pay TaiMed a development milestone of US\$3,000,000 upon the first commercial sale in the North American Territory of a bi-weekly intramuscular, subcutaneous or intravenous-push (either fast or slow) injection formulation. This milestone is payable in two annual equal installments of US\$1,500,000 each, with the first one expected to be paid in the first half of the 2023 fiscal year, while the second one will be paid 12 months after the date of payment of the first installment.

We also agreed to pay TaiMed an additional development milestone as a result of the potential conduct by TaiMed of a phase III trial using Trogarzo<sup>®</sup> with a once every four-week intramuscular, subcutaneous or intravenous-push (either fast or slow) injection formulation. This development milestone would be equal to 50% of all costs associated with the development and approval of such new formulation, subject, however, to a maximum of US\$50,000,000. TaiMed and we must agree on the amount of the milestone after taking into consideration the size of the market for this new formulation of Trogarzo<sup>®</sup> and the market exclusivity related thereto. The TaiMed Agreement contains a provision dealing with a disagreement between the parties on the determination of the amount of this development milestone. This development milestone would be paid quarterly, based on a percentage of net sales then generated by the sale of Trogarzo<sup>®</sup> using this new formulation, and would include a payment of interest on the principal. We are not aware of any development plan for an injection formulation.

### *Manufacturing*

TaiMed is responsible to manufacture and supply Trogarzo<sup>®</sup> to us for each country forming part of the North American Territory. TaiMed has subcontracted the manufacture of Trogarzo<sup>®</sup> to WuXi Apptec Biologics, Inc., (“WuXi”) in China, and to Samsung Biologics Laboratories, in South Korea.

### *Distribution*

We began the distribution of Trogarzo<sup>®</sup> at the end of April 2018.

### *Logistic Service Provider and Distributor*

RxCrossroads acts as our exclusive third-party logistic service provider and exclusive third-party distributor for Trogarzo<sup>®</sup> in the United States under the RxCrossroads Agreements. Orders for Trogarzo<sup>®</sup> are being made directly by a limited number of specialty pharmacies and delivery of Trogarzo<sup>®</sup> is made directly to those specialty pharmacies by RxCrossroads.

### *Specialty Pharmacies and Distributors*

We have entered into agreements with specialty pharmacies, a specialty distributor, and infusion therapy providers that have a large U.S. network capable of handling drug products whose administration is made intravenously. These specialty pharmacies have the capacity to deliver Trogarzo<sup>®</sup> to patients, physicians or infusion centers. Each of those specialty pharmacies purchase Trogarzo<sup>®</sup> from RxCrossroads and deliver it to infusion centers, physicians or patients for home-infusion. Patients are administered Trogarzo<sup>®</sup> at infusion centers, at physicians’ offices or at home with the assistance of nurses.

To provide these services to patients, we entered into agreements with Caremark, LLC (“Caremark”), Accredo Health Group, Inc. (“Accredo”), Option Care Enterprises, Inc. (“Option Care”), Priority Healthcare Distribution, Inc. (“Curascript”), and Walgreen Co. (“Walgreen”). For a description of these agreements, see “Item 9 - Material Contracts” below.

Accredo and Option Care are specialty pharmacies that provide home-infusion services. Curascript is a specialty distributor that can deliver Trogarzo<sup>®</sup> to physicians and Caremark and Walgreen are specialty pharmacies.

In the European Territory, Trogarzo<sup>®</sup> was approved by the EMA on September 26, 2019. Pursuant to the TaiMed Agreement, we were responsible for all regulatory activities, including regulatory filings and communications with the EMA, in addition to all commercialization activities. Since December 15, 2022, we are no longer involved in the commercialization of Trogarzo<sup>®</sup> in the European Territory.

## ***Marketing and Sales of Our Products***

### *North American Territory*

Our marketing and sales activities in the United States for *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> are conducted from our head office in Montreal, Québec, Canada. We have also retained the services of Syneos Health (“Syneos”) to assist us with market access and reimbursement activities in the United States. The market access and reimbursement teams provided by Syneos are solely dedicated to our products. Syneos is a recognized provider of services around the globe. We have renewed our agreement with Syneos and we entered into an amendment to our amended and restated master service agreement in this respect effective as of December 1, 2021 (the “Syneos Agreement”) pursuant to which Syneos will continue providing us with certain services in connection with the commercialization of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> in the United States until November 30, 2024. The Syneos Agreement contains customary representations and warranties, indemnification, confidentiality, intellectual property and termination provisions.

We have contracted with Asembia, LLC (“Asembia”) for the provision of services related, amongst other things, to a call center. The call center, *THERA Patient Support*<sup>®</sup>, guides physicians and patients through the process of initiating treatment under reimbursement. This process, which can be complex and time-consuming, begins with a referral and concludes with the final reimbursement decision. *THERA Patient Support*<sup>®</sup> also helps patients adhering to their treatment and answering questions about our products. See “Item 9 – Material Contracts” below

Trogarzo<sup>®</sup> is not approved in Canada since no filing has been made with Health Canada to seek its approval and, to date, we do not expect seeking its approval for sale in Canada.

### *Other Territories*

#### *EGRIFTA SV*<sup>®</sup>

*EGRIFTA SV*<sup>®</sup> is not approved in any country outside of the United States.

In November 2022, we entered into an agreement with foreign distributors providing them with the exclusive right to distribute *EGRIFTA SV*<sup>®</sup> under named patient programs only in various countries based in the regions of Latin America, Middle East, North Africa and Turkey and Central and Eastern Europe. This agreement has a five-year term. The exclusive distributors have no minimum purchase obligations but have to buy and pay *EGRIFTA SV*<sup>®</sup> in U.S. denominated dollars at a discount to the current list price in the United States or at a discount to the price at which they are entitled to sell it in a country under the named patient program of such country. This agreement does not impose annual minimum purchases on the distributors but contains restrictive covenants regarding the sale of competitive products to *EGRIFTA SV*<sup>®</sup>.

#### *Trogarzo*<sup>®</sup>

Trogarzo<sup>®</sup> was commercially available in the European Territory through our European subsidiary, Theratechnologies Europe Limited, until December 15, 2022, the effective date on which all of our commercialization rights to Trogarzo<sup>®</sup> were returned to TaiMed under the TaiMed Agreement.

Since our decision to return to TaiMed our commercial rights to Trogarzo<sup>®</sup> in the European Territory, we have ceased all activities related to pricing and reimbursement of this product in the various European countries in which such activities were ongoing.

## 2.6 RESEARCH AND DEVELOPMENT ACTIVITIES

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

### **Tesamorelin**

#### *EGRIFTA SV<sup>®</sup> Human Factors Study*

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

#### *F8 Formulation*

We have completed the in-house bioequivalence study of the F8 Formulation. The F8 Formulation is eight times more concentrated than the F1 formulation and twice as concentrated as the current *EGRIFTA SV<sup>®</sup>* formulation. The F8 Formulation has a number of advantages for patients over the F1 formulation: (1) it is intended to be presented in a multidose vial that will be reconstituted once per week; (2) it is expected to be stable at room temperature, even once reconstituted; and (3) the volume of administration will be smaller, approximately 0.2 ml. To date, all process validation batches have been manufactured.

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

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

### *Multi-Dose Pen Injector*

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

### *Tesamorelin for NASH in the General Population*

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

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

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

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

NAFLD includes nonalcoholic fatty liver (“NAFL”), NASH and NASH cirrhosis. NAFLD is the leading cause of liver diseases in the Western world (Central Europe and United States). As the global epidemic of obesity fuels NAFLD prevalence, NASH has become one of the most common liver disorders. In the absence of approved

therapies, NASH remains widely untreated, and has become a critical public health concern with high unmet medical needs.

Without therapeutic intervention, NASH can cause the development of fibrosis, which is the accumulation of non-functional scar tissue, as the body tries to heal itself.

Because this build-up leads to tissue remodeling, development of fibrosis leads to progressive loss of liver function which may ultimately progress to life-threatening conditions such as cirrhosis, liver cancer and ultimately liver failure, a stage where patients have no other choice than undergoing a liver transplantation.

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

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

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

## **Ibalizumab**

### *Intramuscular Method of Administration of Trogarzo®*

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

## **TH1902**

### *Phase 1 Clinical Trial*

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

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



In March 2021, we initiated our Phase 1 clinical trial evaluating TH1902 for the treatment of cancers where the sortilin receptor is expressed. The Phase 1 clinical trial design included a Part A dose escalation study to evaluate the safety, pharmacokinetics, maximum tolerated dose (the “MTD”) and preliminary anti-tumor activity of TH1902 administered once every three weeks in patients with advanced solid tumors refractory to available anti-cancer therapies. Part B of the Phase 1 clinical trial, also known as the “basket trial” consisted in recruiting a total of approximately 70 patients to study the safety and tolerability of TH1902 in the following various solid tumor types, including HR+ breast cancer, triple negative breast cancer, ovarian cancer, endometrial cancer, melanoma, thyroid cancer, small cell lung cancer, and prostate cancer.

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

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

In addition, we reported that the levels of free docetaxel were low, at only 11% of those observed at docetaxel treatment dosage of 75 mg/m<sup>2</sup>. 300 mg/m<sup>2</sup> appeared to be a well-tolerated dose level.

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

- confirmed partial response in one prostate cancer patient with 53% overall reduction in target lesions after three cycles of TH1902 at 300 mg/m<sup>2</sup>, although the prostate specific antigen (“PSA”) continued to progress;
- stabilized disease in a prostate cancer patient with measurable reduction in target lesion sizes (single digit percentages), including one PSA response (the patient was treated with mixed cycles of TH1902 from 420 mg/m<sup>2</sup> to 300 mg/m<sup>2</sup>); and
- stabilized disease in an endometrial cancer patient with measurable reduction in target lesion sizes (single digit percentages) after receiving a total of 11 cycles (the patient’s dose was escalated from 60 mg/m<sup>2</sup> to 360 mg/m<sup>2</sup>).

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

The Corporation is currently studying the data from its Phase 1 clinical trial and has formed a scientific advisory committee (“SAC”) comprised of the study’s principal investigator, and several medical oncologists from across the United States who are leading experts in the end-to-end lifecycle of oncology drug development to help determine the best developmental path forward for TH1902. The meeting of the SAC is scheduled to take place in the latter half of March 2023.

Further to our decision to voluntarily pause the enrollment of patients, we have had discussions with the FDA. Following such discussions, we received a letter from the FDA indicating that our Phase 1 clinical trial was placed

on a partial clinical hold subject to our responses to a list of questions. We intend to respond to the FDA's questions along with the filing of the amended protocol. Questions raised by the FDA were already being addressed by our team as part of our analysis of the data accumulated so far in the Phase 1 clinical trial and we are confident that we will be able to address all of the FDA's questions. The FDA indicated that their review of the protocol amendment would be completed within thirty days of submission.

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

## **SORT1+ Technology™ Platform**

### *Description*

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

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

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

We are no longer conducting research and development work on TH1904, one of our other investigational PDCs. However, we continue the conduct of research and development activities on other PDCs, primarily to advance a PDC using SN38.

Since announcing our decision to voluntarily pause the enrollment of patients in our Phase 1 clinical trial studying TH1902 in various types of cancer, partnership discussions in Greater China regarding the development and commercialization of TH1902 have been paused as well.

### *Acquisition of SORT1+ Technology™ Platform*

We acquired the SORT1+ Technology™ platform following the acquisition of all of the issued and outstanding shares of Katana BioPharma Inc. ("Katana") on February 25, 2019 (the "Katana Agreement"). Katana had the exclusive worldwide rights, through a royalty-bearing licence agreement entered into with Transfert Plus, LP

(“Transfert Plus”), to a technology platform using peptides as a vehicle to specifically deliver cytotoxic agents to sortilin receptors, which are overexpressed on cancer cells (the “Transfert Plus License Agreement”). Katana has since been wound up into Theratechnologies and we became a party to the Transfer Plus License Agreement.

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

#### *Description of the Transfert Plus License Agreement*

Under the Transfert Plus License Agreement, we obtained the exclusive worldwide rights to develop, make, have made, use, sell, offer to sell, distribute, commercialize and import the technology related to the technology platform that uses peptides as a vehicle to deliver existing cytotoxic agents to sortilin receptors which are overexpressed on cancer cells.

The annual maintenance fees payable to Transfert Plus amount to CAD 25,000 for the first five (5) years and to CAD 100,000 thereafter, until royalties become payable beginning with the first commercial sale of a product developed using the licensed technology.

The royalties payable under the Transfert Plus License Agreement vary between 1% and 2.5% on net sales of a product based on the licensed technology. If we enter into a sublicense agreement, we must pay amounts varying between 5% and 15% of the revenues received under such sublicense agreement. The percentage varies based on the timing of the execution of such sublicense agreement.

We must also pay Transfert Plus the following milestone payments upon the occurrence of the following development milestones for the first product developed in the field of oncology:

- (i) first milestone payment: CAD 50,000 upon the successful enrolment of the first patient in the first Phase 1 clinical trial;
- (ii) second milestone payment: CAD 100,000 upon the successful enrolment of the first patient in the first Phase 2 clinical trial;
- (iii) third milestone payment: CAD 200,000 upon the successful enrolment of the first patient in the first Phase 3 clinical trial.

Also, we must pay Transfert Plus CAD 200,000 for each product upon receiving the first approval for such product by a regulatory authority. The approval shall entitle the holder thereof to commercialize the product in the territory in which the approval was obtained.

We must also pay Transfert Plus the same milestone payments upon the occurrence of any of those development milestones for the first product developed outside the field of oncology. See “ITEM 9 – Material Contracts – Transfert Plus License Agreement” below.

## **2.7 COMPETITION**

### ***EGRIFTA SV***<sup>®</sup>

We are not aware of other GRF products indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy being commercialized. However, we are aware that we face indirect competition for

*EGRIFTA SV*<sup>®</sup> from other drugs, such as human growth-hormone, testosterone, insulin sensitizing agents, GLP-1 receptor agonists and sermorelin that may be prescribed by physicians. To our knowledge, the use of these other drugs for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy has not been proven nor approved by the FDA. Other approaches to reduce excess abdominal fat include coping mechanisms such as lifestyle modification (diet and exercise), switching antiretroviral therapy, or liposuction.

## **Trogarzo<sup>®</sup>**

Fostemsavir and Lenacapavir are direct competitors to Trogarzo<sup>®</sup>. Contrary to Fostemsavir which is administered orally twice per day, Trogarzo<sup>®</sup> is a long-acting ARV that only needs to be administered intravenously every two weeks. Lenacapavir has been approved by the FDA in December 2022. Like Fostemsavir, Lenacapavir's indication for use targets the same patient population as that of Trogarzo<sup>®</sup>. Lenacapavir is administered subcutaneously once every six months. In addition, we are aware of other agents including, but not limited to, dolutegravir and darunavir, that are either indicated or commonly used in combination in regimens for the treatment of heavily treatment-experienced patients with MDR HIV-1.

## **Tesamorelin for the Treatment of NASH in the General Population**

There exists no approved medicine for the treatment of NASH. However, there are various compounds currently being studied for the treatment of this disease, some of which are already in Phase 3 clinical trials. These compounds have different mechanisms of action to treat different aspect of the disease, either fat accumulation or inflammation. Tesamorelin has a unique mechanism of action targeting liver fat. However, it has been shown that tesamorelin also improved inflammatory markers. Tesamorelin also benefits from a good safety profile based on more than ten (10) years of use. The development of tesamorelin for the treatment of NASH, if successful, may compete with many potential other drugs for this patient population and we expect strong competition among those companies that will have succeeded in developing and commercializing a medicine for this disease.

## ***SORT1+ Technology<sup>TM</sup>* Platform in Oncology**

The development of novel treatments in oncology is competitive. Many companies are investing in the development of innovative cancer treatments or in finding a cure for cancer. Most of those companies have significant means and scientific experience. Some of those companies are at more advanced development stage of their drugs than us. In addition, there exists a variety of potential targets: some treatment will aim at focusing on one particular cancer type whereas others, like our PDCs, could be used in various types of cancers. Our Phase 1 clinical trial studying TH1902 in various types of cancer has been voluntarily paused and there can be no guarantee that our Phase 1 clinical trial will resume and, to the extent it resumes, that we will observe positive signs of safety and efficacy. Even if successful, by the time we enter the market, there may be approved medicines that would directly compete with TH1902 or any other PDCs we may develop.

## **2.8 GOVERNMENT REGULATION**

### ***Overview***

The research, development, manufacture and marketing of pharmaceutical products are governed by various governmental authorities throughout the world to ensure the efficacy and safety of such products.

Governmental authorities in the United States, Canada, and other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products, such as *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> and any other compound that we may develop. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require

the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or commercialization process, may subject an applicant to administrative or judicial sanctions. Sanctions could include, but are not limited to, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters or other enforcement letters, product recalls, import/export delays, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, and government reimbursement, restitution, disgorgement or civil or criminal penalties.

The text below explains some of the most important features of government regulations that we must follow in connection with the commercialization of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> in the United States.

Government regulations in Canada are similar, albeit not identical to those in the United States.

### ***Sales and Marketing Regulation – United States***

We are subject to various United States requirements relating to the sales and marketing of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> in the United States. The FDA regulates all advertising and promotional activities for prescription drug products under its jurisdiction both prior to and after approval. *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> may be promoted only for their approved indications and in accordance with the provisions of their approved label. Any promotional claims regarding an approved drug must be accurate, not misleading and contain a fair balance of risk and benefit information. The FDA, as well as other government authorities, actively enforces the laws and regulations prohibiting the promotion of inaccurate, misleading or inadequately balanced product claims and the promotion of product for unapproved (i.e., off-label) uses. If we are found to have improperly promoted a prescription drug, we may be subject to significant sanctions. Failure to comply with applicable FDA requirements may subject us to adverse publicity, enforcement action by the FDA, corrective advertising, and the full range of civil and criminal penalties available to the FDA.

The FDA does not regulate the practice of medicine by physicians in their choice of treatment and prescribing decisions.

The marketing of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> within the United States may also be subject to various federal and state laws pertaining to health care “fraud and abuse,” including but not limited to the federal Anti-kickback Statute, Civil Monetary Penalties Law, and False Claims Act and analogous state laws. The federal Anti-kickback Statute prohibits a person from knowingly and willfully offering, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce referring or recommending an individual to another person to receive items or services or to purchase, lease, order, or arrange for any good, facility, item or service payable in whole or in part under a Federal health care program. The Civil Monetary Penalties Law prohibits, among other things, a person from offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of Medicare or Medicaid payable items or services. Sanctions under these laws include civil monetary penalties, imposition of a corporate integrity agreement, exclusion from U.S. federal and state healthcare programs (i.e., those programs will not provide reimbursement or payment coverage for *EGRIFTA SV*<sup>®</sup> and/or Trogarzo<sup>®</sup>), and criminal penalties, including imprisonment; further, an alleged violation of the Anti-kickback Statute could be used as a basis for a federal or state false claims law challenge. The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program, knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly makes a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Generally, claims for drugs prescribed for off-label uses may be considered to be “false claims.” Sanctions under false claims laws include significant civil monetary penalties. In addition, there is ability for private individuals to bring similar actions.

In addition, several states require that companies implement compliance programs or comply with industry ethics codes, adopt marketing spending limits, and report to state governments any gifts, compensation, and other remuneration provided to certain healthcare professionals. Also, the federal Physician Payments Sunshine Act, also known as the Open Payments Act, requires certain manufacturers of drugs, medical devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to record and disclose to the federal government certain transfers of value to physicians and teaching hospitals and ownership and investment interests held by physicians and their immediate family members. Any activities relating to the sale and marketing of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> may be subject to scrutiny under these laws. Failure to make these required reports or comply with these laws can result in civil monetary penalties and/or other sanctions. If the government were to allege or convict us of violating these laws, our business could be harmed. There are a number of states that have similar reporting and disclosure requirements, and failure to comply with these laws could have adverse consequences.

### ***Good Manufacturing Practices***

Drug products must be manufactured and packaged in accordance, among other things, with current good manufacturing practices, or GMPs, and both Bachem and Jubilant, the contract manufacturers of *EGRIFTA SV*<sup>®</sup>, as well as WuXi, the manufacturer of Trogarzo<sup>®</sup>, must adhere to GMPs in connection with the manufacture, labeling, packaging, and any other quality-related functions for these products. If a company wants to make certain changes in its manufacturing equipment, location or process, FDA regulatory review and approval may be required. The FDA often conducts audits of manufacturing sites to ensure that manufacturers comply with quality-related requirements and GMPs. If, as a result of these inspections, it is determined that a manufacturer's equipment, facilities or processes do not comply with the regulations and conditions of product approval, the FDA may issue an FDA-483 list of observations or seek civil, criminal or administrative sanctions and/or remedies against the manufacturer, including seeking corrective action, or requiring suspension of manufacturing operations, which would delay the product and sale of our products.

### ***Good Clinical Practices***

The FDA promulgates regulations and standards, commonly referred to as good clinical practices, or GCPs, for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the trial participants are adequately protected. Our research and development activities are subject to GCPs. The FDA enforces GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If study sites fail to comply with applicable GCPs or other applicable requirements, such as informed consent or Institutional Review Board oversight, the clinical data generated in clinical trials may be deemed unreliable and the FDA may require a sponsor to redo its studies or even stop a study. Where patient safety is at risk, the FDA could impose a clinical hold.

## **2.9 PHARMACEUTICAL PRICING AND REIMBURSEMENT**

In the United States and in other countries, sales of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> will depend in large part on the availability of reimbursement from third-party payors. These payors include both government (such as Federal Medicare and State Medicaid, AIDS Drug Assistance Programs and special needs plans in the United States) and privately managed care organizations as well as pharmacy benefit managers.

These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup>. *EGRIFTA SV*<sup>®</sup> and/or Trogarzo<sup>®</sup> may not be considered cost-effective. It is time consuming and expensive for us, and our commercial partners, to seek reimbursement from

third-party payors. Reimbursement may not be available or sufficient to allow us, or our commercial partners, to sell *EGRIFTA SV*<sup>®</sup> and/or Trogarzo<sup>®</sup> on a competitive and profitable basis.

## **United States**

The U.S. Congress, state legislatures, and federal and state agencies from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our drug products profitably. For example, in March 2010, the Patient Protection and Affordable Care Act, and the associated reconciliation bill, which we refer to collectively as the Health Care Reform Law was enacted, and was a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements (inclusive of price increases) for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of “average manufacturer price” for reporting purposes, which could increase the amount of all Medicaid drug rebates. On January 21, 2016, the Centers for Medicare and Medicaid Services, or CMS, finalized a rule detailing reforms to the rebate and reimbursement systems for Medicaid prescription drugs. This final rule was intended to save taxpayers billions and ultimately improve beneficiary access to prescription drugs. The final rule allowed manufacturers to recalculate the baseline “average manufacturer price” and includes U.S. territories in the calculation of “average manufacturer price” and “best price” effective April 1, 2017. Further, the new law imposed a significant annual fee on companies that manufacture or import certain branded prescription drug products and biologic agents. On December 31, 2020, CMS issued a final rule to support state flexibility to enter into value-based purchasing arrangements, or VBPs, with manufacturers for prescription drugs and to provide manufacturers with regulatory support to enter into VBPs with payers, including Medicaid. This final rule is intended in part to further value-based payment arrangements. Implementation of certain aspects of this final rule were delayed until July 1, 2022. Substantial new provisions affecting compliance also have been enacted, which may require us to modify our business practices with healthcare practitioners, and also may increase our regulatory burdens and operating costs.

The U.S. Medicare program provides payment for many pharmaceuticals under the Medicare Part D program. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both standalone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

Under Part D, government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while Part D applies only to drug benefits for Medicare beneficiaries, state Medicaid programs and private payors may follow Medicare coverage policy limitations in setting their own payment rates. Any reduction in payment that results under Part D may influence decision-making and negotiations for payments from non-governmental payors. Payors are, however, forbidden to negotiate both commercial and Part D agreements together. Negotiations must be kept separate.

The cost of pharmaceuticals continues to generate substantial governmental and third-party private payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, particularly towards specialty pharmacy, the increasing influence of managed care organizations, and additional legislative proposals. For example, CMS issued an interim final rule on November 27, 2020 designed to test whether a Most-Favored-Nation model will help control growth in spending for Medicare Part B drugs

without adversely affecting quality of care. This followed an Executive Order issued in September 2020 that directed the Secretary of DHHS to implement new payment models under the Medicare Part B and Part D programs to curb “unfair” and high drug prices in the United States. Implementation of this interim final rule was blocked by a temporary restraining order and preliminary injunctions through various court actions, and on December 29, 2021, CMS formally rescinded the interim final rule, effective February 28, 2022. Nonetheless, we expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law. The Health Care Reform Law may be modified, amended or repealed at any time and may or may not be replaced with a different law or health care payment system. We are unable to predict the full impact of any such potential modification, amendment or repeal of the Health Care Reform Law.

The passage of the Inflation Reduction Act (IRA) of 2022 shall further impact Medicare reimbursement. The IRA has three key elements reforming Medicare drug pricing policy. The implementation of these changes under the IRA are still forthcoming, so the specific implications for pharmaceutical pricing and reimbursement are yet to be determined. Likewise, we are unable to predict potential modification, amendment, or repeal of the IRA, though some predict that challenges may be made to the Act in 2023 or beyond as different provisions are enacted.

As the first key element, the IRA created a Medicare drug price negotiation program enabling the Secretary of the U.S. Department of Health and Human Services to negotiate the prices of certain costly, single-source drugs or biologics within the Medicare program. Certain drugs are excluded from this negotiation process, such as drugs that are less than 9 years, or biologics less than 13 years, from their FDA-approval or licensure date, and drugs with an orphan designation as their only FDA-approved indication. The first set of these negotiated prices will not take effect until 2026.

Second, the IRA requires drug manufacturers to pay rebates to the federal government for price increases above the rate of inflation for single-source drugs or biologics covered under Medicare Part B and most drugs under Medicare Part D, which already occurs under the Medicaid program. This inflation rebate provision for Medicare Part B took effect at the start of 2023, and such provision for Medicare Part D took effect in 2022 as the starting point for measuring drug price increases, with rebate payments required beginning in 2023.

Third, the IRA restructures the Medicare Part D benefit to limit patients’ out-of-pocket costs and rebalance the bearing of risk for Part D plans and manufacturers. Some of these changes are set to take effect in 2024, while other aspects of this provision will take effect in 2025.

As mentioned previously, industry is still waiting to understand the full implications of these changes and the practical impact on pharmaceutical pricing and reimbursement.

## **2.10 INTELLECTUAL PROPERTY**

As further described below, tesamorelin, the active ingredient of *EGRIFTA SV*®, is protected by patents in the United States and in certain European countries.

Our PDCs stemming from our licensed SORT1+ Technology™ platform are also patent protected in the United States and patent applications have been filed in additional countries.

Trogarzo® is not patent protected but benefits from twelve (12) years of market exclusivity in the United States. See “Regulatory Exclusivity” below.

### ***Our Patent Portfolio***



## *Tesamorelin*

Our current patent portfolio is comprised of the following material patents for tesamorelin:

- In the United States, we own three patents relating to the use of tesamorelin in the treatment of HIV-associated lipodystrophy, which are scheduled to expire in August 2023;
- We also own patents in several other countries relating to the use of tesamorelin in the treatment of HIV--associated lipodystrophy, which are scheduled to expire from May 2023 to October 2025;
- In the United States, we have the exclusive rights to two patents that claim methods for the treatment of NAFL or NASH in a patient, as well as for reducing liver fibrosis and the risk of liver cancer in such patients, via the administration of tesamorelin. These patents are scheduled to expire in 2040;
- In the United States, we also have the exclusive rights to an additional patent application that claims a method for preventing or delaying the onset of cirrhosis or for treating cirrhosis, in a patient suffering from NAFL or NASH, via the administration of tesamorelin. This application, if granted, would be scheduled to expire in 2040;
- We also have the exclusive rights to patent applications in several other countries relating to the treatment of NAFL or NASH in a patient. These applications, if granted, would be scheduled to expire in 2040;
- In the United States and in certain major European countries, we own patents relating to the F8 Formulation, which are scheduled to expire in 2033 and 2034, respectively;
- We have also filed patent applications in the US and Canada related to the use of the F4 formulation in a treatment regimen bioequivalent to the original formulation of EGRIFTA®. These applications, if granted, would be scheduled to expire in 2039; and
- We have also filed a PCT patent application in June 2021 and are currently filing corresponding patent applications in the US and several other jurisdictions, relating to the use of the F8 formulation in a treatment regimen bioequivalent to the original formulation of EGRIFTA®. These applications, if granted, would be scheduled to expire in 2041.

## *SORT1+ Technology™*

Our currently licensed patent portfolio related to the SORT1+ Technology™ platform is comprised of the following material patents:

- In the United States, we have the exclusive rights to a patent relating to conjugates in respect of the SORT1+ Technology™ platform, which is scheduled to expire in 2037;
- In the United States, we also have the exclusive rights to a patent application relating to peptides in respect of the SORT1+ Technology™ platform. This application, if granted, would be scheduled to expire in 2036;
- In Europe, we have the exclusive rights to a patent relating to peptides and conjugates in respect of the SORT1+ Technology™ platform. This patent is scheduled to expire in 2036 and is validated in certain major European countries;

- In Europe, we also have the exclusive rights to a patent application relating to additional peptides and conjugates in respect of the SORT1+ Technology™ platform. This application, if granted, would be scheduled to expire in 2036 and may be validated in certain major European countries;
- We also have exclusive rights to patent applications filed in other countries relating to peptides and conjugates in respect of the SORT1+ Technology™ platform, some of which have already been granted and are scheduled to expire in 2036;
- We also have exclusive rights to patent applications filed in several countries relating to the use of peptides and conjugates in respect of the SORT1+ Technology™ platform for the treatment of cancers involving vascular mimicry, which are typically associated with poor prognosis. Such applications, if granted, would be scheduled to expire in 2039;
- We own patent applications filed in several countries relating to formulations of conjugates in respect of the SORT1+ Technology™ platform. Such applications, if granted, would be scheduled to expire in 2040; and
- We also have exclusive rights to a PCT patent application filed in February 2022 relating to the use of peptides and conjugates in respect of the SORT1+ Technology™ platform for the treatment of cancers comprising Sortilin-expressing cancer stem cells (CSCs), which are typically associated with poor prognosis and often exhibit resistance to common chemotherapeutic approaches. Patent applications may be pursued in numerous jurisdictions stemming from this PCT application. Such applications, if granted, would be scheduled to expire in 2042.

### ***Regulatory Exclusivity***

The regulatory regimes of certain countries and territories such as the United States, Canada and Europe provide market exclusivity for a pharmaceutical product once approved. Data protection provides a person with protection against third parties who may wish to commercialize a product similar to an approved product.

In the United States, the *Drug Price Competition and Patent Term Restoration Act of 1984*, or *Hatch-Waxman Act*, awards, in certain circumstances, non-patent marketing exclusivities to pioneer drug manufacturers. The *Hatch-Waxman Act* provides five years of non-patent marketing exclusivity within the United States to an applicant who gains approval of a NDA for a “new chemical entity,” a drug for which the FDA has not previously approved any other new drug with the same active moiety, which is the molecule or ion responsible for the action of the drug. This marketing exclusivity generally prevents the FDA from approving, in certain circumstances, any abbreviated new drug application, or ANDA, for a generic drug or any 505(b)(2) NDA that references the pioneer drug product. The market exclusivity for *EGRIFTA SV*® in the United States has expired.

In the United States, distinct from exclusivity for drug products, biological products, such as toxins and serums, may be eligible for non-patent exclusivity. Specifically, the *Biologics Price Competition and Innovation Act of 2009*, or the BPCI Act, amended the Public Health Service Act to provide an abbreviated licensure pathway for biological products, or 351(k) application, shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. In turn, the BPCI provides a 4-year exclusivity period from the date of first licensure of the reference product, during which a 351(k) application referencing that product may not be submitted. In addition, FDA may grant a 12-year exclusivity period from the date of first licensure of the reference product, during which approval of a 351(k) application referencing that product may not be made effective. For the first biological product determined to be interchangeable with the reference product for any condition of use, the agency may provide a period of market exclusivity, during which a second or subsequent biological product may not be determined interchangeable with that reference product. However, unlike the process for drug products, FDA will not grant exclusivity for supplements or changes to the reference biological product. Like drug products,

biologic products can receive seven (7) years of market exclusivity for an orphan indication. Finally, FDA may issue an exclusivity period for certain biological products for which pediatric studies are conducted in accordance with a written request.

Trogarzo<sup>®</sup> benefits from twelve (12) years of market exclusivity in the United States.

### ***Our Trademark Portfolio***

*EGRIFTA SV* is our registered trademark in the United States and it is used in this country to commercialize a different formulation of tesamorelin for the treatment of HIV-associated lipodystrophy.

*Trogarzo* is a registered trademark of TaiMed in the United States and in Europe and it is under license to us pursuant to the TaiMed Agreement.

*THERA Patient Support* is our registered trademark in the United States and it is used to designate our call center that assists healthcare professionals and patients in processing referrals, following-up on treatment adherence and answering questions from both healthcare professionals and patients regarding *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup>.

*SORTI+ Technology*<sup>™</sup> is our trademark and we have filed various trademark registration applications for this mark in various trademark offices worldwide.

### ***Other Intellectual Property Portfolio***

Our portfolio of intellectual property contains additional trademarks, pending trademark registrations and domain names associated with our trademarks and pending trademark applications.

### ***Our Policy on Intellectual Property***

Our intellectual property practice is to keep all information relating to proprietary compounds, inventions, improvements, trade secrets, know-how and continuing technological innovation confidential and, where practicable, file patent and trademark applications. In particular, as part of our intellectual property protection practice, we:

- where practicable, file patent applications for any new and patentable invention, development or improvement in the United States and in other countries;
- prosecute all pending patent applications in conformity with applicable patent laws and in a manner that efficiently covers our activities;
- file trademark applications in countries of interest for our trademarks;
- register domain names whose addresses include our trademark names; and
- maintain our intellectual property rights by paying government fees as may be necessary to ensure such rights remain in force.

## **2.11 EMPLOYEES**

As at November 30, 2022, we had 89 employees in Canada, 47 employees in the United States and 8 employees in Ireland. All of our employees are engaged in administration, finance, legal, medical affairs, regulatory, marketing and sales and research and development functions. None of our employees are unionized. We believe the relations with our employees are good.

Through Syneos, as at November 30, 2022, we had an additional 13 persons dedicated to the commercialization of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> in the United States.

## **2.12 FACILITIES**

Our head office is located at 2015 Peel Street, 11<sup>th</sup> Floor, in the City of Montreal, Québec, Canada where we lease a 15,000 square-foot office space. We have a place of business in the United States located at 101 Hudson Street, 21<sup>st</sup> Floor, in the City of Jersey City, New Jersey, where we lease an office space. We also moved our place of business in Ireland to 12 Duke Street, 1<sup>st</sup> Floor, Royal Hibernian Way, Dublin 2 where we lease a 1,765 square-foot office space.

We also conduct our research and development activities in laboratories leased from the Université du Québec à Montréal, in Montreal, Canada, and in laboratories subleased from Repare Therapeutics Inc., in Montréal, Canada.

## **2.13 ENVIRONMENT**

To our knowledge, in the last financial year, environmental issues did not have a material financial or operational impact on our capital expenditures, income or competitive position within the normal course of our operating activities.

## ITEM 3 RISK FACTORS

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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.

### 3.1 RISKS RELATED TO THE CORPORATION'S CASH POSITION

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

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

The Marathon Credit Facility contains various covenants, including a prohibition on the inclusion of a going concern note in the Corporation's Auditors Report. The inclusion of a going concern note in the Corporation's Auditors' Report related to the Corporation's audited consolidated financial statements would trigger an event of default under the Marathon Credit Facility resulting in the interest rate payable on any outstanding loaned amount to be increased by 300 basis points and would allow Marathon to declare such principal amount and interest

thereon immediately due and payable. Marathon would also no longer have the obligation to fund any additional tranches under the Marathon Credit Facility and would have the option to foreclose on all of the assets of the Corporation pursuant to the liens registered against all of the assets of the Corporation.

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

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

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

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

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

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

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

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

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

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

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

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

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

***The Marathon Credit Facility includes significant operating and financial restrictions on the Corporation, any of which could prevent us from capitalizing on business opportunities. In addition, our failure to comply with such restrictions could trigger an event of default which would increase by 300 basis points the interest payable on any loaned amounts under the Marathon Credit Facility and would allow Marathon to declare the outstanding loaned amounts immediately due and payable in addition to providing Marathon with the right to foreclose on all of the assets of the Corporation pursuant to the liens registered against all of the assets of the Corporation. If we are unable to cure an event of default or obtain a waiver from Marathon in relation to such***

*event of default, and if we do not have the financial capacity to repay any amount loaned becoming due and payable, we may have to cease our operations and to resort to insolvency laws.*

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

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

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

### **3.2 RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS**

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

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



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

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

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

Because we expect to be dependent on revenues solely from *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> 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<sup>®</sup> and Trogarzo<sup>®</sup> and a default or a dispute under our agreement, or its termination or non-renewal at term, would materially adversely affect our revenues, business and operating results.***

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

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

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

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

We do not own or operate manufacturing facilities for the production of *EGRIFTA SV*<sup>®</sup> 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*<sup>®</sup>. We will also rely on a single third-party supplier, LSNE for the manufacture of the F8 Formulation. Our agreement with Bachem has expired and we are currently renegotiating the terms and conditions of a new manufacturing agreement. Although we are in discussions with Bachem, our inventory of drug product

is high and potential alternative suppliers and manufacturers have been identified, but we have not entered into any agreements with Bachem yet. Also, we have not qualified alternative manufacturers to date and no assurance can be given that such manufacturers will be qualified in the future or receive necessary regulatory approvals. The replacement of a third-party manufacturer is time-consuming and costly due to the required validation of their capabilities. The validation process includes an assessment of the capacity of such third-party manufacturer to produce the quantities that we may request from time to time, the manufacturing process and its compliance with current good manufacturing practice, or GMP, regulations. In addition, the third-party manufacturer would have to familiarize itself with our technology. Validation of an additional third-party manufacturer takes at least twenty-four (24) months and could take as long as thirty-six (36) months or more. If we fail to renegotiate the terms and conditions of the Bachem Agreement, we may no longer be able to rapidly manufacture tesamorelin for *EGRIFTA SV*<sup>®</sup>, for the F8 Formulation and for our potential Phase 2b/3 clinical trial in NASH. Despite our current level of inventory of tesamorelin, we could incur a shortage of tesamorelin by the time new manufacturers are qualified.

TaiMed is our sole supplier of Trogarzo<sup>®</sup>. TaiMed does not currently own or operate any manufacturing facilities for the production of Trogarzo<sup>®</sup> and must rely on its suppliers, WuXi and Samsung. We are not in a contractual relationship with WuXi and Samsung for Trogarzo<sup>®</sup> and, therefore, we may not be able to interact with any of them in the event they encounter issues which could adversely affect the supply of Trogarzo<sup>®</sup>. 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<sup>®</sup> and, accordingly, materially adversely affect our revenues.

We do not have state licensure in the United States to distribute *EGRIFTA SV*<sup>®</sup>, Trogarzo<sup>®</sup> or any other product we may acquire or in-license and we have not made any application to obtain the licenses required in order to distribute a drug product in the United States. Our supply chain model is based upon that fact and the distribution of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> 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*<sup>®</sup> and Trogarzo<sup>®</sup>, we have not entered into any agreements with them and no assurance can be given that such providers would enter into any agreement with us on terms satisfactory to us.

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

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

Our reliance on single third-party service providers for some of our core business activities exposes us to a number of risks. For instance, we may be subject to delays in, or suspension of, the manufacturing of *EGRIFTA SV*<sup>®</sup>, the F8 Formulation and Trogarzo<sup>®</sup> if a third-party manufacturer: (a) becomes unavailable to us, or to TaiMed, for any

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

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

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

***Significant safety problems may arise with respect to EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> which could result in restrictions in EGRIFTA SV<sup>®</sup>'s or Trogarzo<sup>®</sup>'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*<sup>®</sup> and Trogarzo<sup>®</sup> 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*<sup>®</sup> and/or Trogarzo<sup>®</sup> 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<sup>®</sup> and Trogarzo<sup>®</sup>.***

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

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

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

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

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

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

The biopharmaceutical and pharmaceutical industries are highly competitive and we must compete with pharmaceutical companies, biotechnology companies, academic and research institutions as well as governmental agencies for the development and commercialization of products, most of which have substantially greater financial, technical and personnel resources than us. We believe there is currently few approved drug products competing directly with our approved products. However, with respect to Trogarzo<sup>®</sup>, we face competition from the approval of Fostemsavir and Lenacapavir in the United States. In addition, we are aware of other agents, including dolutegravir and darunavir, that are either indicated or commonly used in combination in regimens to treat heavily-treatment experienced patients with MDR HIV-1. With respect to EGRIFTA SV<sup>®</sup>, 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.

### **3.3 RISKS RELATED TO RESEARCH AND DEVELOPMENT ACTIVITIES**

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

The development of new therapies is highly risky and the results obtained therefrom may not yield any of the anticipated benefits. The development of a product candidate into a new drug requires the conduct of many tests on animals and humans, all of which must comply with stringent regulation and require substantial investments. There can be no assurance that any research and development program designed to develop a new formulation, a

new drug, a new method or route of administration or provide a new treatment, such as the development of the F8 Formulation and the Pen, the development of tesamorelin for the potential treatment of NASH in the general population and the development of our peptide-drug conjugates resulting from our SORT1+ Technology™ platform, will end up generating positive results leading up to an approved formulation, label expansion, new medical device or a new product by a regulatory authority. The failure to develop a new formulation, a new method of treatment, a new method or route of administration or a drug product could hamper the future growth of our business and have long-term adverse effects on our potential revenues and operating results.

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

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

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

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

***those assets, any of which could have a material adverse effect on our long-term potential revenue growth and business prospects.***

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

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

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

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

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

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

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

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

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

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

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

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

Even if the Corporation finds a partner to initiate a Phase 2b/3 clinical trial, there can be no guarantee that the FDA will be satisfied with the responses to the questions and comments asked in connection with the amendments to the protocol filed in February 2022 and allow the initiation of such trial. Even if the FDA or any other regulatory

agency approves the study of tesamorelin for the treatment of NASH in the general population, there can be no guarantee that the results will meet the endpoints of the study and that tesamorelin will be approved for such treatment. Even if the Corporation meets the FDA's primary endpoints and approval is received from the FDA, such approval may be conditioned on conducting additional studies which, if not conducted or if the results therefrom are not positive on certain clinical outcomes, could result in the FDA withdrawing its approval for the use of tesamorelin for the treatment of NASH in the general population.

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

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

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

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

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

If the Corporation incurs any delay in the conduct of a clinical trial or decides to suspend or terminate such trial, this could materially adversely affect the business prospects of the Corporation and its potential long-term revenues derived from the potential sale of its drug candidates. Any delay or suspension of a clinical trial may



also adversely impact the duration of the protection afforded by the issuance of patents covering the drug candidate subject to such clinical trial and lead to earlier entries of competitors in the market.

### **3.4 RISKS RELATED TO OUR INTELLECTUAL PROPERTY**

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

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

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

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

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

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

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

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

or discover our trade secrets through proper means. In addition, the laws of many countries do not protect intellectual property rights to the same extent as the laws of Canada, the United States and the European Patent Convention, and those countries may also lack adequate rules and procedures for defending intellectual property rights effectively.

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

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

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

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

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

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

Because of the difficulty in analyzing and interpreting patents, there can be no guarantee that a third party will not assert that we infringe such third-party's patents or any of its other intellectual property rights. Under such circumstances, there is no guarantee that we would not become involved in litigation. Litigation with any third party, even if the allegations are without merit, is expensive, time-consuming and would divert management's

attention from the daily execution of our business plan. Litigation implies that a portion of our financial assets would be used to sustain the costs of litigation instead of being allocated to further the development of our business.

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

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

### **3.5 REGULATORY RISKS**

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

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

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

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

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

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

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

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

requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

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

### **3.6 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<sup>®</sup> and Trogarzo<sup>®</sup>, our capacity to generate revenues and management's attention to the development of our business.***

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

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

Despite all reasonable efforts to ensure the safety of our products we may be commercializing, it is possible that we or our commercial partners will sell products which are defective, to which patients react in an unexpected manner, or which are alleged to have side effects. The development, manufacture and sale of such products may expose us to potential liability, and the pharmaceutical industry has been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial

condition, business and operating results. A product liability claim could also tarnish our reputation, whether or not such claims are with or without merit.

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

### **3.7 GEO-POLITICAL RISKS**

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

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

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

### **3.8 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<sup>®</sup> and Trogarzo<sup>®</sup>. Security breaches and other disruptions to those information technology systems could cause a violation of privacy laws, exposing us to liability which could cause our business and reputation to suffer.*

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

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

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

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

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

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

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

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

financial condition and operating results. In addition, it could adversely affect the market price of our Common Shares.

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

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

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

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

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

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

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



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

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

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

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

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

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

misstatement of the Corporation's financial statements, which could cause investors to lose confidence in the Corporation's financial statements and cause the trading price of its Common Shares to decline.

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

### **3.9 RISKS RELATED TO OUR COMMON SHARES**

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

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

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

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

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

***Our Common Shares may be delisted from the Nasdaq stock market if the minimum bid price of our Common Shares remains below US\$1.00 per share for 30 consecutive trading days. The delisting of our Common Shares could reduce the liquidity in our Common Shares and could trigger a sell-off from U.S. shareholders. Any***

***reduction in the liquidity of our Common Shares or a sell-off our Common Shares would result in a decline in the price of our Common Shares. Being delisted from the Nasdaq stock exchange could also adversely affect analysts coverage of our Common Shares and prevent us from retaining U.S. investment bankers to raise equity in public offerings.***

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

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

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

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

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

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

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

The trading market for our Common Shares will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our Common Shares, the lack of research coverage may adversely affect the market price of our Common Shares. Furthermore, if one or more of the analysts who do cover us downgrade our Common

Shares or if those analysts issue other unfavorable commentary about us or our business, the price of our Common Shares would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our Common Shares could decrease, which in turn could cause our share price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

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

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

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

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

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

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

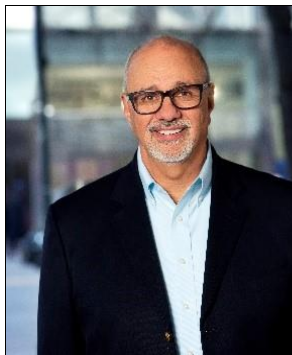
## ITEM 4 DIRECTORS AND EXECUTIVE OFFICERS

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### 4.1 DIRECTORS

The table below sets forth the following information about our directors as of February 27, 2023: his/her name, age, city/province/state of residence, principal occupation, the date each director first became a director of the Corporation, his/her status as an independent director, his/her biography, his/her areas of expertise, his/her memberships on the committees of the Board of Directors, whether he/she acts as director for other public companies or entities involved in the pharmaceutical industry, and the number of common shares (the only voting securities of the Corporation), DSUs, options, common share purchase warrants, or Warrants, and Notes beneficially held or controlled.

Each elected director remains in office until the next annual meeting of shareholders, unless he/she resigns or his/her position becomes vacant following his/her death, destitution or for any other reason before the next annual meeting of shareholders.



**Joseph P. Arena**  
 Age: 68  
 Norristown,  
 Pennsylvania, USA

**Independent**

**Director since:**  
 May 13, 2021

**Areas of Expertise:**  
 - Regulatory Affairs  
 - Drug Development  
 - Medical Education  
 - Management

**Other Directorship:**  
 None

<b>Principal Occupation</b>	Corporate Director
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Joseph Arena was elected to the Board of Directors of Theratechnologies in May 2021.

Joseph Arena was Vice President, Oncology Products, Global Regulatory Affairs at Pfizer, Inc. (“Pfizer”) between 2018 and 2021. In such a role, he managed a team that provided strategic global leadership to Medicine Teams for Pfizer’s portfolio in oncology. The group was responsible for regulatory strategy and registration of products globally. His tasks included providing guidance on the worldwide regulatory requirements for registration of new chemical entities and new claims, identification of pharmaceutical, toxicological and clinical developmental issues and problem resolution, overseeing the preparation of high quality, effective regulatory submissions, providing oversight and input for all communications agencies and leading scientific teams in direct negotiations with agencies on all issues of product development, product registration and labeling (including post-marketing surveillance).

Prior to acting as Vice President, Oncology Products, Global Regulatory Affairs, he acted as Vice President, Cardiovascular and Metabolic Products, between 2016 and 2018 when he joined the Pfizer Worldwide Safety and Regulatory organization. In such a role, he managed a team that provided strategic global leadership to Medicine Teams for Pfizer’s portfolio in Cardiovascular and Metabolic Diseases. The group was responsible for regulatory strategy and registration of products globally.

Prior to joining Pfizer, he was at Merck and Co. Inc. (“Merck”) where he held the role of Vice President, Therapeutic Area Lead Oncology, Immunology and in vitro Diagnostics from 2015 to 2016. His team provided global leadership to development teams for oncology and immunology products and in vitro diagnostics across the portfolio. The group was responsible for regulatory strategy and registration of Merck’s products globally with a focus on the United States, European Union, China and Japan.

Mr. Arena began his career as a research scientist in 1989 at Merck Research Laboratories in Rahway, New Jersey. In 1996, he moved to a position in Regulatory Affairs International focusing primarily on Merck’s cardiovascular products. He eventually assumed management and leadership roles with Regulatory Affairs International, including management of therapeutic areas in Diabetes, Neuroscience, Atherosclerosis and Cardiovascular.


Mr. Arena received his B.S. in Pharmacy from St. John’s University in Queens, New York. After four (4) years in community and hospital settings, he attended the University of Medicine and Dentistry of New Jersey and received a Ph.D. in Pharmacology, followed by a post-doctoral fellowship in the Physiology Department at the University of Rochester in New York.


**Securities Held or Controlled**

Common Shares (#)	DSU (#)	Options (#)	Warrants (#)	Notes (US\$)
15,000	Nil	14,170	Nil	Nil


**Committees of the Board of Directors**


Nil


	<b>Principal Occupation</b>		President and CEO, Ponderosa Capital Inc.		
	<p>Frank A. Holler was appointed to the Board of Directors in June 2021.</p> <p>He is currently the President &amp; CEO of Ponderosa Capital Inc. He previously served as Chairman &amp; CEO of BC Advantage Funds (VCC) Ltd., a venture capital firm investing in emerging technology companies in British Columbia.</p> <p>He also served as President and CEO of Xenon Pharmaceuticals Inc. from 1999 to 2003 after having been President and CEO of ID Biomedical Corporation from 1991 to 1998. In addition, he was a founding director of Angiotech Pharmaceuticals.</p> <p>Prior to working in biotechnology and healthcare, Mr. Holler was a Vice-President of Investment Banking with Merrill Lynch Canada and Wood Gundy Inc. (now CIBC World Markets).</p> <p>Mr. Holler is a member of the board of directors of two additional public companies: Sernova Corp. in Ontario, Canada, and Harvest One Cannabis Inc. in British Columbia, Canada.</p> <p>Mr. Holler holds an MBA and BA (Economics) from the University of British Columbia.</p>				
<b>Frank A. Holler</b> Age: 66 Summerland, B.C., Canada	<b>Securities Held or Controlled</b>				
<b>Independent</b>	<b>Common Shares</b> (#)	<b>DSU</b> (#)	<b>Options</b> (#)	<b>Warrants</b> (#)	<b>Notes</b> (US\$)
<b>Director since:</b> June 23, 2021	39,000	5,300	14,170	Nil	Nil
<b>Areas of Expertise:</b> - Corporate Finance - Life Sciences - Management	<b>Committees of the Board of Directors</b>				
<b>Other Directorship:</b> Sernova Corp.; and Harvest One Cannabis Inc.	Member of Audit Committee				


	<b>Principal Occupation</b>		Corporate Director		
	<p>Gérald A. Lacoste is a retired lawyer with extensive experience in the fields of securities regulation, financing and corporate governance. He was previously Chairman of the Québec Securities Commission (now known as the Autorité des marchés financiers) and was also President and Chief Executive Officer of the Montreal Exchange. During his career, Mr. Lacoste acted as legal counsel to the Canadian Standing Senate Committee on Banking, Trade and Commerce, he chaired the Québec Advisory Committee on Financial Institutions, and was a member of the task force on the capitalization of life insurance companies in Québec. Mr. Lacoste has been a member of the North American Free Trade Agreement arbitration panel and is currently a corporate director.</p>				
	<b>Securities Held or Controlled</b>				
<b>Gérald A. Lacoste</b> Age: 79 Ste-Adèle, Québec, Canada	<b>Common Shares</b> (#)	<b>DSU</b> (#)	<b>Options</b> (#)	<b>Warrants</b> (#)	<b>Notes</b> (US\$)
	100,000	21,936	84,174	Nil	45,000
<b>Independent</b>	<b>Committees of the Board of Directors</b>				
<b>Director since:</b> February 8, 2006	Chair of Nominating and Corporate Governance Committee Member of Audit Committee				
<b>Areas of Expertise:</b> - Securities and - Market Regulations - Corporate Governance - Mergers & - Acquisitions					
<b>Other Directorship:</b> None					





 <p><b>Paul Lévesque</b> Age: 59 Westmount, Québec, Canada</p> <p><b>Non-independent</b></p> <p><b>Director since:</b> April 6, 2020</p> <p><b>Areas of Expertise:</b> - Pharmaceutical Industry - Sales and Marketing - Management - Human Resources</p> <p><b>Other Directorship:</b> None</p>	<b>Principal Occupation</b>		President and Chief Executive Officer of the Corporation		
	<p>Paul Lévesque has built an enviable reputation in the pharmaceutical industry both here and abroad. He is recognized for his track record at delivering growth.</p> <p>Paul has worked in the research-based pharmaceutical industry since 1985. He started with Upjohn Canada and then joined Pfizer Canada in 1992. He went on to occupy increasingly senior positions within the organization including as Vice President of Marketing in Canada and in France, Country Manager for Canada, Chief Marketing Officer for the U.S. in Primary Care and as Regional President in Asia-Pacific for the innovative division of Pfizer.</p> <p>He also assumed the role of Global President and General Manager for the Rare Disease Unit until he joined Theratechnologies on April 6, 2020.</p> <p>Paul carries a passion for bringing to patients therapies in areas of unmet medical needs and will put to contribution his learnings from his 35 years in the pharmaceutical industry.</p> <p>Paul holds a BSc in biochemistry from Laval University and a Diploma in Management from McGill University.</p>				
	<b>Securities Held or Controlled</b>				
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Warrants (#)</b>	<b>Notes (US\$)</b>
	111,200	Nil	1,134,728	20,000	Nil
<b>Committees of the Board of Directors</b>					
N.A.					

	<b>Principal Occupation</b>		Corporate Director		
	<p>From 2008 to 2015, Mr. Littlejohn held the position of CEO and then of advisor to the Chairman and Board Member of the Arab National Investment Company, also known as ANB Invest, in Riyadh, a subsidiary of Arab National Bank. Previously, he was Managing Director of investment banking at Desjardins Securities in Montreal, a position he took after serving six years as Executive Vice-president at Ecopia Biosciences. Mr. Littlejohn also occupied various senior positions in investment banking at TD Securities, Midland Walwyn, BMO Nesbitt Burns and National Bank Financial. He held the position of Interim CEO at Helix BioPharma from October 2015 to January 2016. Mr. Littlejohn also served on the Board of several corporations including Helix BioPharma, ANB Invest, Aegera Pharmaceuticals, Ecopia Biosciences and The Montreal Exchange. Mr. Littlejohn holds a B.A. (Honours Economics), a BCL and a MBA from McGill University. He also completed the Director Education Program provided by the Canadian Institute of Corporate Directors in 2015. He is a retired lawyer of the Quebec Bar.</p>				
<p><b>Gary Littlejohn</b> Age: 67 Lac-Tremblant-Nord, Québec, Canada</p> <p><b>Independent</b></p> <p><b>Director since:</b> October 15, 2018</p> <p><b>Areas of Expertise:</b> - Capital Markets - Corporate governance - Corporate Finance - Risk Management</p> <p><b>Other Directorship:</b> None</p>	<b>Securities Held or Controlled</b>				
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Warrants (#)</b>	<b>Notes (US\$)</b>
19,060	26,456	46,928	Nil	Nil	
<b>Committees of the Board of Directors</b>					
<p>Chair of Compensation Committee Member of Audit Committee</p>					

	<b>Principal Occupation</b>		Corporate Director		
	<p>Ms. Dale MacCandlish Weil has more than 35 years of experience in the commercialization, marketing, sale of consumer products and B2B services. From May 2018 to January 2020, Ms. Weil has been Managing Director of the Montreal Institute for Palliative Care (a branch of the Teresa Dellar Palliative Care Residence) and, in January 2020, she became Executive Director of the Teresa Dellar Palliative Care Residence and of the Montreal Institute for Palliative Care. She spent the prior 18 years of her career in management positions related to health care services such as distribution, pharmaceutical and retail pharmacy services. She worked with McKesson Canada Corporation, or McKesson, since August 1999 where she occupied the position of Vice President and Senior Vice President for various divisions of McKesson. She acted in an advisory role to the President from May 2015 to February 2018. Prior to May 2015, she acted as Senior Vice President Retail Management Services with McKesson from July 2014 to May 2015 and, from November 2011 to June 2014, she acted as Senior Vice President, Integrated Health Care Solutions, Strategy and Business Development with McKesson. Ms. Weil is a member of the board of directors of Tetra Bio-Pharma Inc. in Ontario. Ms. Weil holds a Master's in business administration from McGill University and has obtained her certification as a certified director after successfully completing the ICD Directors Education Program.</p>				
<b>Dale MacCandlish Weil</b> Age: 67 Baie d'Urfé, Québec, Canada	<b>Securities Held or Controlled</b>				
	<b>Independent</b>	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Warrants (#)</b>
<b>Director since:</b> May 16, 2017	31,840	5,531	69,174	Nil	2,000
<b>Areas of Expertise:</b> - Healthcare Industry - Commercialization of products - Management - Strategic Planning	<b>Committees of the Board of Directors</b>				
	Member of Nominating and Corporate Governance Committee				
<b>Other Directorship:</b> Tetra Bio-Pharma Inc.; and Nuvo Pharmaceuticals Inc.					

 <p><b>Andrew Molson</b> Age: 55 Westmount, Québec, Canada</p> <p><b>Independent</b></p> <p><b>Director since:</b> October 15, 2020</p> <p><b>Areas of Expertise:</b> - Communications - Governance</p> <p><b>Other Directorship:</b> Molson Coors Beverage Company; Dundee Corporation</p>	<b>Principal Occupation</b>		Corporate Director		
	<p>Andrew Molson serves as chairman of AVENIR GLOBAL, an organization uniting seven strategic communications firms across Canada, the U.S., Europe and the Middle East. He is also chairman of Molson Coors Beverage Company and a member of the board of directors of Groupe Deschênes Inc., Dundee Corporation and the CH Group Limited Partnership, owner of Evenko and the Montreal Canadiens.</p> <p>He previously served as a director of The Group Jean Coutu PJC Inc. from 2014 to 2018, as Chair of Molson Coors from May 2011 to May 2013 and as its Vice Chair from May 2009 to May 2011. Mr. Molson serves on several non-profit boards, including the Institute for Governance of Private and Public Organizations, Concordia University Foundation, the Québec Blue Cross, the Evenko foundation for emerging talent, the Montreal General Hospital Foundation and the Molson Foundation, a family foundation dedicated to the betterment of Canadian society.</p> <p>Mr. Molson holds a Bachelor of Laws from Laval University (Quebec City). He also holds a Bachelor of Arts from Princeton University and a Master of Science in corporate governance and ethics from University of London (Birkbeck College).</p>				
	<b>Securities Held or Controlled</b>				
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Warrants (#)</b>	<b>Notes (US\$)</b>
	30,000	10,123	27,428	Nil	Nil
<b>Committees of the Board of Directors</b>					
Nil					

 <p><b>Dawn Svoronos</b> Age: 69 Hudson, Québec, Canada</p> <p><b>Independent</b></p> <p><b>Director since:</b> April 8, 2013</p> <p><b>Areas of Expertise:</b> - Pharmaceutical Industry - Commercialization of Drug Products</p> <p><b>Other Directorship:</b> Xenon Pharmaceuticals Inc.; and Adverum Biotechnologies, Inc.</p>	<b>Principal Occupation</b>		Corporate Director – Chair of the Board of the Corporation		
	<p>Ms. Dawn Svoronos worked in the commercial side of the business for the multinational pharmaceutical company Merck &amp; Co. Inc., for 23 years, retiring in 2011. From 2009 to 2011, Ms. Svoronos was President of the Europe/Canada region for Merck and from 2006 to 2009 was President of Merck in Canada. Previously held positions with Merck include Vice-President of Asia Pacific and Vice-President of Global Marketing for the Arthritis, Analgesics and Osteoporosis franchise. Ms. Svoronos is a member of the board of directors of two other public companies: Xenon Pharmaceuticals Inc. in British Columbia, Canada, and Adverum Biotechnologies, Inc. in Redwood City, California.</p>				
	<b>Securities Held or Controlled</b>				
<b>Common Shares</b>	<b>DSU</b>	<b>Options</b>	<b>Warrants</b>	<b>Notes</b>	
(#)	(#)	(#)	(#)	(US\$)	
323,600	855	84,174	Nil	Nil	
<b>Committees of the Board of Directors</b>					
<p>Member of Compensation Committee Member of Nominating and Corporate Governance Committee</p>					

	<b>Principal Occupation</b>	Corporate Director			
	<p>A fellow of the Quebec Chartered Professional Accountant Order, Alain Trudeau has had a distinguished career at Ernst &amp; Young from 1982 to 2019 where he held the position of Managing Partner, Assurance Services, for EY offices in the Province of Quebec from 2008 to 2019. He was also responsible for the audit of many publicly-traded companies.</p> <p>He currently serves on the board of directors of Loto-Québec, the Institut de médiation et d'arbitrage du Québec (IMAQ) and Blue Bridge Trust Company Inc.</p> <p>From 2008 to 2019, Mr. Trudeau was a lecturer at the Collège des administrateurs de sociétés de l'Université Laval in Quebec City.</p> <p>Mr. Trudeau holds a Bachelor of Arts in Accounting from HEC Montréal.</p>				
<p><b>Alain Trudeau</b> Age: 63 Montréal, Québec, Canada</p>	<b>Securities Held or Controlled</b>				
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Warrants (#)</b>	<b>Notes (US\$)</b>
<p><b>Independent</b></p> <p><b>Director since:</b> October 15, 2020</p> <p><b>Areas of Expertise:</b> - Accounting - Finance - Governance</p> <p><b>Other Directorship:</b> None</p>	19,300	33,737	27,428	2,500	Nil
<b>Committees of the Board of Directors</b>					
<p>Chair of Audit Committee Member of Compensation Committee</p>					

#### 4.2 AUDIT COMMITTEE

Our board of directors has established an Audit Committee to review our annual financial statements prior to their approval by the board of directors and also to perform other duties, as is described in the Audit Committee's charter adopted by the board of directors and attached hereto as Appendix A.

As of November 30, 2022, the Audit Committee was composed of four members: Alain Trudeau, its Chair, Gary Littlejohn, Gérald A. Lacoste and Frank Holler. All four are independent and financially literate. The details mentioned hereunder describe the education and experience of the Audit Committee members that is relevant to the performance of their responsibilities, in particular any experience in preparing, auditing, analyzing and evaluating financial statements.

**Alain Trudeau.** Mr. Trudeau holds a Bachelor of Arts in Accounting from HEC Montréal and is a fellow of the Quebec CPA order. From 1982 to 2019, Mr. Trudeau has had a distinguished career at Ernst & Young where he held the position of Managing Partner, Assurance Services, for Ernst & Young offices in the Province of Quebec, from 2008 to 2019. During his career, Mr. Trudeau was responsible for the audit of various publicly-traded companies.

**Gary Littlejohn.** Mr. Littlejohn holds a B.A. (Honours Economics), a BCL and an MBA from McGill University. From 2008 to 2015, Mr. Littlejohn held the position of CEO and then of advisor to the Chairman and Board Member of the Arab National Investment Company, also known as ANB Invest, in Riyadh, a subsidiary of Arab National Bank. Previously, he was Managing Director of investment banking at Desjardins Securities in Montreal, a position he took after serving six years as Executive Vice President and Chief Financial Officer at Ecopia

Biosciences. Mr. Littlejohn also occupied various senior positions in investment banking at TD Securities, Midland Walwyn, BMO Nesbitt Burns and National Bank Financial.


**Gérald A. Lacoste.** Mr. Lacoste has more than 30 years of experience in the fields of securities regulation, corporate finance and corporate governance. Mr. Lacoste was president of the audit committee of Amisco Ltd. from 2002 to 2009 and was also a member of the audit committee of Andromed Inc. from 2004 to 2007. Mr. Lacoste was a member of the audit committee of Génome Québec from 2006 to 2009.


**Frank Holler.** Mr. Holler holds an MBA and BA (Economics) from the University of British Columbia. Prior to joining the Corporation, Mr. Holler was President and CEO of Xenon Pharmaceuticals Inc. from 1999 to 2003 after having been President and CEO of ID Biomedical Corporation from 1991 to 1998. In addition, he was a founding director of Angiotech Pharmaceuticals. Mr. Holler also acted as Vice-President of Investment Banking with Merrill Lynch Canada and Wood Gundy Inc. (now CIBC World Markets).


Each member of the Audit Committee has acquired in-depth financial expertise giving each the ability to read and understand a set of financial statements which presents the breadth and level of complexity of accounting issues that are generally comparable to those that can reasonably be expected to be raised in our financial statements.

### 4.3 EXECUTIVE OFFICERS


The table below sets forth the following information about our executive officers as of February 27, 2023: his/her name, age, city/province/state of residence, his/her principal occupation, the date each Executive Officer joined the Corporation, his/her biography and the number of common shares (the only voting securities of the Corporation), DSUs, options, Warrants and Notes beneficially held or controlled. The information about Mr. Paul Lévesque, the President and Chief Executive Officer of the Corporation, is found in the table above regarding information about our directors.


	<b>Principal Occupation</b>		Vice President, Finance		
	<p>Ms. Marie-Noël Colussi is a graduate of the <i>Université du Québec à Montréal</i> in business administration and is a member of the Quebec Chartered Professional Accountant Order. Prior to joining us, Ms. Colussi worked for eight years with KPMG, an international accounting firm. Ms. Colussi has experience in accounting, auditing, control and taxation, particularly in research and development. She joined us in 1997, and prior to her appointment as Vice President, Finance, she held the position of Director, Accounting and Internal Control and Controller.</p>				
	<b>Securities Held or Controlled</b>				
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Warrants (#)</b>	<b>Notes (US\$)</b>
<b>Marie-Noël Colussi</b> Age: 54  <b>Executive since:</b> May 9, 2002  Laval, Québec, Canada	11,075	3,182	268,092	Nil	10,000


	<b>Principal Occupation</b>		Senior Vice President and Chief Financial Officer		
	<p>Mr. Dubuc brings more than 25 years of experience in investment banking in the healthcare sector and in management. He started his career as a management consultant at Groupe Secor, a well-known Quebec-based consulting firm which is now part of KPMG. He then served as Managing Director, Investment Banking at National Bank Financial. In this role, he headed the healthcare group and was involved in numerous financing and M&amp;A transactions. He later founded a manufacturing company which he sold after seven years of successful operations. Mr. Dubuc holds a M.B.A. from McGill University and a B.Comm. from Concordia University.</p>				
	<b>Securities Held or Controlled</b>				
<b>Philippe Dubuc</b> Age: 56  <b>Executive since:</b> February 24, 2016  Montreal, Québec, Canada	<b>Common Shares</b> (#)	<b>DSU</b> (#)	<b>Options</b> (#)	<b>Warrants</b> (#)	<b>Notes</b> (US\$)
	31,000	Nil	558,414	1,500	25,000

	<b>Principal Occupation</b>		Vice President, Human Resources		
	<p>Mr. André Dupras joined Theratechnologies as Vice President, Human Resources in May 2021. Mr. Dupras brings more than 25 years of experience in Human Resources. Most recently, Mr. Dupras was Vice President, Human Resources at Clementia Pharmaceuticals. Previously, he spent close to 15 years at Pfizer Canada in various leadership roles in Human Resources and Commercialization. He also worked at Bombardier Aerospace as Director of Human Resources and Director of Global Compensation, at Aon Hewitt as a consultant in Compensation and Organizational Effectiveness and at Réno-Dépôt as Director of Human Resources.</p> <p>Mr. Dupras holds a Master's Degree in Management Science (Human Resources) and a Bachelor's Degree in Administration (Marketing and Human Resources). He is a member of the Order of Certified Human Resources Professionals (CHRP, CHRA).</p>				
	<b>Securities Held or Controlled</b>				
<b>André Dupras</b> Age: 59  <b>Executive since:</b> May 31, 2021  Mont-Tremblant, Québec, Canada	<b>Common Shares</b> (#)	<b>DSU</b> (#)	<b>Options</b> (#)	<b>Warrants</b> (#)	<b>Notes</b> (US\$)
	Nil	Nil	141,404	Nil	Nil



 <p><b>Jocelyn Lafond</b> Age: 55</p> <p><b>Executive since:</b> April 16, 2007</p> <p>Montreal, Québec, Canada</p>	<b>Principal Occupation</b>		General Counsel and Corporate Secretary		
	<p>Mr. Lafond has over 20 years of experience in the fields of corporate and securities law. Mr. Lafond holds a law degree from the <i>Université Laval</i> and a Masters Degree in Law from the University of Toronto. He has been a member of the <i>Barreau du Québec</i> since 1992. Prior to joining us in 2007, Mr. Lafond was a partner with the international law firm of Fasken Martineau DuMoulin LLP.</p>				
	<b>Securities Held or Controlled</b>				
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Warrants (#)</b>	<b>Notes (US\$)</b>
18,000	5,000	414,857	Nil	8,000	

 <p><b>John Leasure</b> Age: 58</p> <p><b>Executive since:</b> March 29, 2021</p> <p>Underhill, Vermont, USA</p>	<b>Principal Occupation</b>		Global Commercial Officer		
	<p>John Leasure was hired as Global Commercial Officer in March 2021. He brings extensive experience in Sales, Marketing, Operations and General Management both in the U.S and internationally. He has expertise managing brands across multiple stages of the product life cycle and has launched numerous products in a variety of therapeutic areas.</p> <p>Prior to joining Theratechnologies, John spent 30 years at Pfizer where he led teams in Anti-infectives, Inflammation, Immunology and Oncology. Most recently, John led the Oncology business in Canada where, under his leadership, the business experienced unprecedented growth and launched over 10 new products.</p> <p>He holds a B.A., Business from Gettysburg College in Pennsylvania.</p>				
	<b>Securities Held or Controlled</b>				
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Warrants (#)</b>	<b>Notes (US\$)</b>
5,000	Nil	154,848	Nil	Nil	

	<b>Principal Occupation</b>		Senior Vice President and Chief Medical Officer		
	Dr. Christian Marsolais has over 25 years of experience in the research, development and commercialization of new drugs. He started his career in international pharmaceutical companies, including Sandoz, Biochem and Pfizer, where he held different positions from medical advisor to director clinical research and medical affairs. He was also appointed to the global oncology team at Pfizer, which managed the global oncology portfolio. Dr. Marsolais joined Theratechnologies in 2007 and leads the medical team which was central to the approval of <i>EGRIFTA</i> ® by the FDA. He was also instrumental in the efforts that led to the US and European acquisition of the commercial rights to Trogarzo® and the approval of Trogarzo® by the FDA. More recently, he also led the team to pursue the approval of Trogarzo® in Europe. Dr. Marsolais holds a Ph.D. in biochemistry from the Université de Montréal.				
<b>Christian Marsolais</b> Age: 60  <b>Executive since:</b> May 7, 2007  Town of Mount Royal, Québec, Canada	<b>Securities Held or Controlled</b>				
	<b>Common Shares</b> (#)	<b>DSU</b> (#)	<b>Options</b> (#)	<b>Warrants</b> (#)	<b>Notes</b> (US\$)
	59,297	6,312	680,373	Nil	15,000

#### 4.4 CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS

To our knowledge, except with respect to Mr. Frank Holler, no director and executive officer (a) is, as at February 27, 2023, or has been within the ten (10) years before February 27, 2023, a director or executive officer of any company (including the Corporation) that, while that person was acting in that capacity, (i) was the subject of a cease trade or similar order or an order that denied the relevant company access to any exemption under securities legislation, for a period of more than thirty (30) consecutive days; (ii) was subject to an event that resulted, after the director or executive officer ceased to be a director or executive officer, in the company being the subject of a cease trade or similar order or an order that denied the relevant company access to any exemption under securities legislation, for a period of more than thirty (30) consecutive days; or (iii) within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or (b) has, within the ten (10) years before February 27, 2023, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold his assets.

Mr. Frank Holler was previously the Chair and the Chief Executive Officer of BC Advantage Funds, or BCAF, a venture capital fund investing in emerging technology companies. On July 5, 2013, Allon Therapeutics Inc., or Allon, one of BCAF's publicly traded portfolio companies in which Mr. Holler acted as a director, made a proposal to its creditors under the *Bankruptcy and Insolvency Act* (Canada) and a reorganization of its share structure was approved by the Supreme Court of British Columbia. Following this approval, all of Allon's common shares were acquired by a third party and Allon's common shares were delisted from the Toronto Stock Exchange on June 28, 2013. Mr. Holler ceased acting as a director of Allon effective July 16, 2013.

Mr. Frank Holler was also a director of Contech Enterprises Inc., or Contech, one of the privately held emerging technology companies forming part of the BCAF portfolio. On December 23, 2013, Contech made a proposal to its creditors under the *Bankruptcy and Insolvency Act* (Canada) and a reorganization of its share structure was approved by the Supreme Court of British Columbia on January 26, 2015. The proposal was intended to facilitate a financing by a new lender and a debt restructuring that, taken together, would enable Contech to carry on its

business for the foreseeable future. On March 6, 2015, the Court of Appeal of British Columbia overturned the approval of the proposal by the Supreme Court and placed Contech into bankruptcy. Mr. Holler ceased acting as a director of Contech effective March 6, 2015.

#### **4.5 SECURITIES HELD BY THE DIRECTORS AND EXECUTIVE OFFICERS**

As at February 27, 2023, the total number of common shares (the only securities carrying a voting right) held by our directors and executive officers amounted to 813,372, which represented 0.84% of our outstanding common shares.

## ITEM 5 INTERESTS OF EXPERTS

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KPMG LLP, our auditors, is the only person or company named as having prepared or certified a statement, report or evaluation, included or mentioned in a filing under securities regulations during our most recently completed financial year.

KPMG LLP are the auditors of the Corporation and have confirmed with respect to the Corporation that they are independent within the meaning of the relevant rules and related interpretations prescribed by the relevant professional bodies in Canada and any applicable legislation or regulations and also that they are independent accountants with respect to the Corporation under all relevant U.S. professional and regulatory standards.

### *External Auditors Service Fees*

KPMG LLP have been acting as our auditors since 1993. In addition to performing the audit of our consolidated financial statements, KPMG LLP provided other services to us that were billed or payable in respect of each of our fiscal years ended November 30, 2022 and 2021:

<b>Fees</b>	<b>Fiscal Year Ended November 30, 2022 (CA\$)</b>	<b>Fiscal Year Ended November 30, 2021 (CA\$)</b>
Audit Fees <sup>(1)</sup>	750,615	639,382
Audit-Related Fees <sup>(2)</sup>	53,865	48,943
Tax Fees <sup>(3)</sup>	115,293	170,027
All Other Fees	--	--
<b>Total:</b>	<b>919,773</b>	<b>858,352</b>

- (1) Refers to the aggregate fees billed by our external auditors for audit services, including interim reviews and work performed in connection with securities filings.
- (2) Refers to the aggregate fees billed for professional services rendered by our external auditors for translation.
- (3) Refers to the aggregate fees billed for professional services rendered by our external auditors for tax compliance, transfer pricing, tax advice and tax planning.

## **ITEM 6 SECURITIES OF THE COMPANY**

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### **6.1 AUTHORIZED SHARE CAPITAL**

We are authorized to issue an unlimited number of common shares and an unlimited number of preferred shares issuable in series.

Subject to the priority rights of holders of preferred shares, holders of common shares are entitled to any dividend declared by the board of directors, to one vote per share at meetings of our shareholders and, in the event of our liquidation or dissolution, to participate in the distribution of the assets.

Preferred shares carry no voting rights. Preferred shares may be issued at any time in one or more series. Our articles of incorporation give our board of directors the power to fix the number of preferred shares and the consideration per share, as well as to determine the provisions attached to the preferred shares of each series (including dividends, redemption and conversion rights, if any). The shares of every series of preferred shares will have priority over all our other shares, including common shares, with respect to the payment of dividends and return of capital in the event of our liquidation or dissolution.

The common shares issued represent the total voting rights pertaining to our securities.

### **6.2 DIVIDEND POLICY**

We have never declared or paid cash dividends on our common shares and do not anticipate paying any cash dividends on our common shares in the foreseeable future. We presently intend to retain future earnings, if any, to finance the expansion and growth of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors the board of directors deems relevant. In addition, the terms of any future debt or credit facility may preclude us from paying dividends.

### **6.3 TRANSFER AGENT AND REGISTRAR**

Our transfer agent and registrar in Canada is Computershare Trust Company of Canada which holds, at its Montreal offices, the registers related to our common shares, notes, shareholders and transfers. Our transfer agent and registrar in the United States is Computershare Trust Company NA., which holds at its Canton (MA) offices, the registers related to our common shares, shareholders and transfers.

## ITEM 7 MARKET FOR SECURITIES

### 7.1 PRICE RANGE AND TRADING VOLUME

#### Common Shares

The following table sets forth the price range and trading volume of our common shares on the TSX and on NASDAQ for the periods indicated below. However, you should not view this presentation as an indication that the market price of our common shares will continue at such levels.

Period <sup>(1)</sup>	TSX			NASDAQ		
	High (CA\$)	Low (CA\$)	Volume	High (US\$)	Low (US\$)	Volume
<b>2021</b>						
December	4.30	3.77	604,435	3.37	2.90	2,460,000
<b>2022</b>						
January	3.95	3.47	683,135	3.10	2.77	2,070,000
February	4.14	3.46	498,623	3.26	2.70	1,575,600
March	3.62	2.90	572,974	2.86	2.30	1,639,500
April	3.40	2.89	378,373	2.70	2.26	1,248,700
May	3.18	2.66	404,673	2.72	2.05	1,369,700
June	3.39	2.76	213,186	2.70	2.13	906,200
July	2.98	2.59	302,783	2.39	1.97	770,200
August	2.96	2.50	131,981	2.29	1.90	1,039,000
September	3.33	2.50	584,549	2.45	1.89	1,801,000
October	3.75	2.45	443,821	2.77	1.78	2,971,300
November	3.05	2.40	305,947	2.30	1.74	10,033,700
December	2.93	1.03	1,527,442	2.20	0.77	12,242,000
<b>2023</b>						
January	1.62	1.22	727,819	1.18	0.88	1,334,200
February (to February 24)	1.42	1.14	489,484	1.05	0.84	1,370,000

<sup>(1)</sup> High and low price based on intraday high and low trading prices. Sources for TSX and NASDAQ data in the above table is Bloomberg.

## Notes

The Notes are listed on the TSX under the trading symbol “TH.DB.U”. The following table sets forth certain trading information for our Notes for the periods indicated as reported by the TSX.

Period <sup>(2)</sup>	5.75% Debentures <sup>(1)</sup>		
	High (US\$)	Low (US\$)	Volume
<b>2021</b>			
December	92.00	88.50	63,000
<b>2022</b>			
January	88.50	85.10	1,228,000
February	87.50	85.00	34,000
March	87.50	83.00	13,000
April	85.25	84.90	25,000
May	87.50	83.00	81,000
June	75.50	75.32	8,000
July	90.00	75.50	35,000
August	90.00	88.50	32,000
September	92.00	85.00	77,000
October	90.00	85.00	38,000
November	90.00	87.00	30,000
December	90.00	87.50	12,000
<b>2023</b>			
January	94.49	90.00	97,000
February	94.00	94.00	86,000
(to February 24)			

<sup>(1)</sup> Price per US\$100.00 principal amount of the 5.75% Notes.

<sup>(2)</sup> High and low price based on intraday high and low trading prices.  
Sources for data in the above table is Bloomberg.

## 7.2 PRIOR SALES

The following table summarizes the distribution of securities, other than those listed on a stock exchange, that we issued during the most recently completed financial year, identifying the type of security, the exercise price per security, the number of securities issued, and the date on which the securities were issued.

Date	Type of Security	Price per Security	Number of Securities
December 1, 2021	Options	US\$3.30	269,170
December 1, 2021	Options	CA\$4.21	2,100,219
February 28, 2022	Deferred Share Units <sup>(1)</sup>	CA\$3.67	8,174
May 2, 2022	Deferred Share Units <sup>(1)</sup>	CA\$3.11	14,469
May 10, 2022	Options	US\$2.59	101,672
May 10, 2022	Options	CA\$3.38	30,000
July 19, 2022	Deferred Share Units <sup>(1)</sup>	CA\$2.78	10,792
July 19, 2022	Options	US\$2.20	5,000

<b>Date</b>	<b>Type of Security</b>	<b>Price per Security</b>	<b>Number of Securities</b>
July 19, 2022	Options	CA\$2.83	42,000
October 17, 2022	Deferred Share Units <sup>(1)</sup>	CA\$2.83	21,200
October 20, 2022	Options	US\$2.01	25,000
October 20, 2022	Options	CA\$2.74	5,000

<sup>(1)</sup> The deferred share units are non-dilutive securities. They are redeemable for cash only.



## **ITEM 8    LEGAL PROCEEDINGS**

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In the last financial year, we were not subject to any material legal proceedings and, as at February 27, 2023, we are not subject to any such material proceedings.

## ITEM 9 MATERIAL CONTRACTS

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### Marathon Credit Facility

On July 13, 2022, we announced that we had entered into a binding commitment with affiliated funds of Marathon Asset Management providing for a non-dilutive term loan of up to \$100 million and, on July 20, 2022, the Company executed the Marathon Credit Facility, as amended on February 27, 2023. The Marathon Credit Facility provides for the disbursement of \$100 million in four various tranches. As guarantee for the repayment of the loan, the Company and each of its subsidiaries have granted a first ranking security interest on all of their assets.

The salient features of the Marathon Credit Facility are as follows:

- \$40 million were funded on July 27, 2022 (“Tranche 1 Loan”);
- \$20 million (“Tranche 2 Loan”) to be made available by no later than June 30, 2023, if the Company has had net revenues of at least \$75 million for the 12-month period immediately preceding the funding of the Tranche 2 Loan and if the Company is not in default of its obligations under the loan facility. If the conditions to obtain the Tranche 2 Loan are not met by June 30, 2023, then it nor any other tranche will be available;
- \$15 million (“Tranche 3 Loan”) to be made available by no later than March 31, 2024, if the Tranche 2 Loan has been drawn and the Company has obtained approval from the FDA for its F8 Formulation, has had net revenues of at least \$90 million in the 12-month period preceding the funding of the Tranche 3 Loan and if the Company is not in default of its obligations under the loan facility;
- Up to an additional \$25 million (“Tranche 4 Loan”) to be made available if the Tranche 3 Loan has been drawn and the Company has had at least \$110 million in net revenues as well as at least \$20 million in EBITDA in the 12-month period preceding the funding of the Tranche 4 Loan;
- The Marathon Credit Facility has an initial term of five years (July 27, 2027), or six years if the Tranche 3 Loan is drawn, provides for an interest-only period of 24 months (36 months if the Tranche 3 Loan is drawn), and bears interest at SOFR plus 9.5%. The Tranche 1 Loan and the Tranche 2 Loan are repayable in equal monthly installments on an amortization schedule of 36 months starting in July 2024 (July 2025 if the Tranche 3 Loan is funded on or prior to December 31, 2023);
- The Marathon Credit Facility provides quarterly revenue targets and minimum liquidity covenants. Until the F8 Formulation is approved, the Company must maintain at all times cash, cash equivalents and eligible short-term investments in the amount of \$20 million in specified accounts (which amount will be increased to \$30 million if the Company has not obtained approval from the FDA for the F8 Formulation by March 31, 2024);
- The Marathon Credit Facility restricts the ability to incur additional debt, the acquisitions and disposition of assets as well as in-licensing and out-licensing of products, except in very limited circumstances;
- A breach of the terms and conditions of the Marathon Credit Facility will create an event of default resulting in an increase of 300 basis points on the interest rate payable on the outstanding amounts loaned and provide the lender with the ability to demand immediate repayment of the debt, and not advance any additional tranches; and
- The term loan also includes a covenant prohibiting the inclusion of a going concern explanatory paragraph in the annual report of the independent registered public accounting firm, except in connection with the annual report related to the fiscal year ended November 30, 2022.

### Note Indenture

On June 19, 2018, we entered into a trust indenture with Computershare Trust Company of Canada, or Trustee, providing for the issue of the Notes and governing the terms and conditions of the Notes as well as our rights and

obligations and those of the Trustee. The Notes were issued under a final prospectus dated June 12, 2018. The Notes bear interest at a rate of 5.75% per annum, which will be payable in US dollars in equal instalments semi-annually in arrears on June 30 and December 31 of each year, commencing on December 31, 2018, computed on the basis of a 360-day year composed of twelve 30-day months. The Notes will mature at 5:00 pm (Eastern Time) on June 30, 2023. The Notes are our direct, senior obligations and are not secured by any mortgage, pledge, hypothec or other charge and rank equally and *pari passu* to all of our existing and future senior unsecured and unsubordinated indebtedness. The Note Indenture does not restrict us from incurring additional indebtedness, whether senior secured, *pari passu* or subordinated, for borrowed money or from mortgaging, pledging or charging our assets to secure any indebtedness.

The Notes are convertible at the holder's option into fully-paid, non-assessable and freely-tradeable common shares at any time prior to the close of business on the earliest of (i) the business day immediately preceding the June 30, 2020; (ii) the business day immediately preceding the date specified by us for redemption of the Notes; and (iii) the business day immediately preceding the payment date in the event we are required to offer to repurchase the Notes in connection with a change of control, at a conversion price of US\$14.85 per common share, representing a conversion rate of approximately 67.3401 common shares per US\$1,000 principal amount of Notes. Holders converting their Notes will receive, as the case may be, accrued and unpaid interest thereon for the period from the last interest payment date prior to the date of conversion up to but excluding the date of conversion. Holders converting their Notes will become holders of record of common shares on the business day immediately following the date of conversion. Notwithstanding the foregoing, no Notes may be converted during the five business days preceding June 30 and December 31 of each year.

The Notes may not be redeemed by us before June 30, 2021 (except in certain limited circumstances following a change of control). On or after June 30, 2021 and prior to June 30, 2023, the Notes may be redeemed by us in whole or in part from time to time at our option on not more than 60 days' and not less than 40 days' prior written notice at a redemption price equal to their principal amount plus accrued and unpaid interest thereon, up to, but excluding, the date set for redemption; provided that, as of the date of the notice for redemption, the market price of our common shares is at least 130% of the conversion price of the Notes.

#### Jubilant Agreement

On December 23, 2009, we entered into a supply and manufacturing agreement with Jubilant. This agreement provides for the manufacture and supply of the finished form of *EGRIFTA SV*<sup>®</sup>. Under the agreement, Jubilant must fill vials with tesamorelin, lyophilize it, label and package those vials and deliver them to locations in accordance with our instructions. The agreement contains customary representations and warranties, indemnity provisions and was originally scheduled to expire in May 2020. However, on January 7, 2020, we entered into an amendment to the Jubilant Agreement pursuant to which we amended the minimum quantity of products to purchase for the calendar year 2019-2020 and to extend the term of the agreement until December 31, 2020. The Jubilant Agreement contains a renewal provision providing for automatic successive one-year term renewals unless a party gives the other a written notice within a certain period of time of its intent not to renew the agreement. We are currently renegotiating some of the terms of the Jubilant Agreement.

#### Hospira Agreement

Effective March 19, 2015, we entered into a supply agreement with Hospira. Under this agreement, Hospira is responsible for manufacturing and supplying us with sterile water for injection, filled and finished in plastic vials, in connection with the sale of *EGRIFTA SV*<sup>®</sup> in the United States only. This agreement contains customary representations and warranties, indemnity provisions and was scheduled to expire in December 2016. The agreement has been renewed since for one-year terms pursuant to an automatic one-year term renewal provision. A party is entitled not to renew the term of this agreement by providing the other with a written notice within a certain period of time prior to the renewal term.

#### Sharp Agreement

On August 10, 2017, we entered into a packaging agreement with Sharp to package and ship injection tool kits for *EGRIFTA SV*<sup>®</sup> to our third-party logistic service provider in the United States, RxCrossroads. The agreement contains customary covenants and undertakings for the activities carried out by Sharp, allocation of risk provisions in relation to the packaging of the injection tool kits and indemnity provisions.

#### RxCrossroads Agreements

On November 1<sup>st</sup>, 2017, we entered into an amended and restated master services agreement and amended and restated statements of work agreements with RxCrossroads appointing it as our exclusive third-party logistic service provider and exclusive third-party distributor of *EGRIFTA*<sup>®</sup> and Trogarzo<sup>®</sup> in the United States. Effective November 1<sup>st</sup>, 2019, we amended the amended and restated statement of work agreements to add *EGRIFTA SV*<sup>®</sup> as a new product RxCrossroads was entitled to distribute. The RxCrossroads Agreements will expire in April 2020. The RxCrossroads Agreements contain customary representations and warranties from both parties, indemnification provisions, as well as termination provisions in the event of the occurrence of certain stated events. We are currently discussing the renewal of this agreement.

#### Cardinal Agreements

On August 15, 2014 and on October 23, 2014, we entered into a wholesale drop shipment agreement and a drop ship only services agreement with Cardinal Health appointing Cardinal as a non-exclusive authorized wholesaler for *EGRIFTA*<sup>®</sup> in the United States, or Cardinal Agreements.

The Cardinal Agreements have a one-year term and automatically renew for subsequent one-year period unless a party provides the other with a prior written notice within a certain period of time prior to renewal period of these agreements. The Cardinal Agreements contain customary representations and warranties from both parties, payment terms, indemnification provisions as well as termination provisions in the event of the occurrence of certain events.

#### McKesson Corporation

On May 15, 2014, we entered into a core distribution agreement with McKesson Corporation appointing it as a non-exclusive authorized wholesaler for *EGRIFTA*<sup>®</sup> in the United States, or McKesson Agreement

The McKesson Agreement has an indefinite term but may be terminated at any time by either party upon written notice to the other. However, in the event that we were in the process of being acquired, the McKesson Agreement may not be terminated by us without cause for twelve (12) months following the acquisition. The McKesson Agreement contains customary representations and warranties from both parties, payment terms, indemnification provisions as well as termination provisions in the event of the occurrence of certain stated events.

#### Cesar Castillo, Inc.

On July 12, 2018, we entered into a distribution agreement with Cesar Castillo, Inc. appointing it as a non-exclusive authorized wholesaler for *EGRIFTA*<sup>®</sup> in the territory of Puerto Rico and the U.S. Virgin Islands, or Cesar Castillo Agreement. On November 1<sup>st</sup>, 2018, the Cesar Castillo Agreement was amended to add Trogarzo<sup>®</sup> as a product authorized to be distributed thereunder, and, on October 31, 2019, it was further amended to add *EGRIFTA SV*<sup>®</sup> as a product authorized to be distributed thereunder as well.

The Cesar Castillo Agreement has a three-year term and automatically renew for subsequent one-year terms unless a party provides the other with a prior written notice within a certain period of time prior to a renewal period. The Cesar Castillo Agreement contains customary representations and warranties from both parties, payment terms, indemnification provisions as well as termination provisions in the event of the occurrence of certain events.

#### TaiMed Agreement

See “ITEM 2.5. Commercialization Activities – Trogarzo” above for a description of the TaiMed Agreement.

#### Accredo Agreement

We entered into an amendment to our existing contracted network pharmacy agreement with Accredo on January 2, 2018, or Accredo Agreement, pursuant to which we added Trogarzo<sup>®</sup> as a product that Accredo could purchase from RxCrossroads for resale in the United States and expanded the services to be provided by Accredo to take into consideration the mode of administration of Trogarzo<sup>®</sup>. On December 18, 2019, we further amended the Accredo Agreement to add *EGRIFTA SV*<sup>®</sup> as a product that Accredo could purchase from RxCrossroads for resale in the United States. Prior to that, we entered into a contracted network pharmacy agreement with Accredo, effective November 24, 2015, as amended effective April 12, 2016, in connection with the commercialization of *EGRIFTA*<sup>®</sup>, or the Original Agreement. The Original Agreement appoints Accredo as a non-exclusive authorized purchaser of *EGRIFTA*<sup>®</sup>, contains a description of the services to be provided by Accredo in connection with the purchase and sale of *EGRIFTA*<sup>®</sup> in the United States and customary representations and warranties, provisions relating to indemnification, confidentiality, and audit rights. The Original Agreement had a one-year term with successive one-year term renewal periods. The Original Agreement has been renewed continuously and renews automatically unless a party provides the other with a written notice within an undisclosed time period of its intent not to renew it. The Original Agreement, including the amendments thereto, contains termination provisions based on the occurrence of certain stated events.

#### Option Care Agreement

We entered into a master services agreement, or MSA, and a statement of work, or SOW, with Option Care on January 31, 2018. Pursuant to the terms of the MSA and SOW, Option Care agreed to provide patients with various services in connection with the administration of Trogarzo<sup>®</sup>. The MSA contains, amongst others, customary representations and warranties, provisions relating to indemnification, confidentiality, intellectual property ownership and audit rights of each party. The MSA and the SOW have a two-year term from their effective dates. The MSA and the underlying SOW will renew automatically for successive one-year term periods unless a party provides the other with a written notice within an undisclosed time period of its intent not to renew the MSA and/or the SOW.

#### Curascript Agreement

We entered into an amended and restated wholesale product purchase agreement with Curascript on April 1, 2018 pursuant to which we added Trogarzo<sup>®</sup> as a product available for purchase and resale by Curascript. An additional amendment was entered into on October 31, 2019 pursuant to which we added *EGRIFTA SV*<sup>®</sup> as a product available for purchase and resale by Curascript. No other major changes were made to the original wholesale product purchase agreement we had entered into with Curascript in March 2016. The amended and restated wholesale product purchase agreement has a one-year term and renews automatically for one-year term periods unless a party provides the other with a written notice within an undisclosed time period of its intent not to renew it. The amended and restated wholesale product purchase agreement with Curascript contains, amongst others, customary representations and warranties, provisions relating to the purchase price of Trogarzo<sup>®</sup>, indemnification, confidentiality and audit rights.

#### Walgreen Agreement

We entered into an amended and restated contracted network pharmacy agreement with Walgreen effective March 6, 2018 pursuant to which we added Trogarzo<sup>®</sup> as a product available for purchase and resale by Walgreen. An additional amendment was entered into on November 18, 2019 pursuant to which we added *EGRIFTA SV*<sup>®</sup> as a product available for purchase and resale by Walgreen. No other major changes were made to the original contracted network pharmacy agreement we had entered into with Walgreen in August 2015. The amended and restated contracted network pharmacy agreement has a one-year term and renews automatically for one-year term periods unless a party provides the other with a written notice within an undisclosed time period of its intent not

to renew it. The amended and restated contracted network pharmacy agreement with Walgreen contains, amongst others, customary representations and warranties, provisions relating to the purchase price of Trogarzo<sup>®</sup>, indemnification, confidentiality and audit rights.

#### Syneos Agreement

On December 4, 2016, we entered into an amended and restated master services agreement with Syneos, as amended on December 1, 2021, providing for the main terms and conditions under which Syneos would provide us with services to commercialize *EGRIFTA SV*<sup>®</sup> (*EGRIFTA*<sup>®</sup> at the time) and Trogarzo<sup>®</sup> in the United States. Each of those services has been described in specific project agreements. To date, we have entered into project agreements relating to the provision of managed market, reimbursement and specialty nurses team. The Syneos Agreement contains customary representations and warranties, indemnification, confidentiality, intellectual property and termination provisions. The Syneos Agreement is scheduled to expire on November 30, 2024, unless earlier terminated.

#### Asembia Agreement

On July 15, 2019, we entered into a master services agreement with Asembia, or Asembia Agreement, pursuant to which Asembia agreed to provide us with various services through the entering into of statement of works. The Asembia Agreement contains, amongst others, customary representations and warranties, provisions relating to adverse event reportings, maintenance of cyber-security measures, intellectual property rights, confidentiality and indemnification provisions. The Asembia Agreement is scheduled to expire on July 14, 2022, unless earlier terminated. The Asembia Agreement renews automatically for one-year terms unless a party provides the other with a written notice within a certain period of time of its intent not to renew it. On July 16, 2019, we entered into a statement of work with Asembia pursuant to which Asembia agreed to provide us with the services of a call center, *THERA Patient Support*<sup>®</sup>, for all of our commercialized products in the United States. For a description of our call center, see “Item 2.5 – Commercialization Activities – Marketing and Sales of our Products – North American Territory” above.

#### MGH License Agreement

On February 3, 2020, we entered into an amended and restated license agreement with the MGH, or MGH License Agreement, granting us an exclusive, worldwide, royalty-bearing license under the MGH’s rights to all data, inventions and patents rights, or Proprietary Rights, resulting from the study conducted by the MGH regarding “*Tesamorelin effects on liver fat and histology in HIV*”. Under the terms of the MGH License Agreement, the MGH, through Dr. Steven Grinspoon, agreed to provide services related to the study design related to the study of tesamorelin for the potential treatment of NASH in the HIV population, selection of optimal patient population, dosing, study duration and other safety matters and to participate, if need be, in regulatory meetings with the FDA or the EMA. In consideration, we agreed to make certain milestone payments to the MGH related to the development of tesamorelin and a low single-digit royalty payment on all sales of *EGRIFTA SV*<sup>®</sup> 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 NAFLD or NASH regardless of the patient population. The MGH License Agreement is scheduled to expire on the latest of (i) the date on which all issued patents, if any, and filed patent applications have expired or been abandoned, and (ii) one year after the last sale for which a royalty is due under the MGH License Agreement, unless earlier terminated pursuant to certain customary termination provisions.

#### Transfert Plus License Agreement

On February 25, 2019, we entered into an amended and restated royalty-bearing license agreement with Transfer Plus, or Katana License Agreement, providing us with the exclusive worldwide rights to develop, make, have made, use, sell, distribute, commercialize and import all of the technology related to the oncology platform that

uses peptides as a vehicle to deliver existing cytotoxic agents to sortilin receptors which are overexpressed on cancer cells. The Katana License Agreement contains customary representations and warranties, intellectual property, confidentiality and indemnity provisions. The Katana License Agreement also provides for the payment of milestones and royalties to Transfert Plus. For a description of those milestones and of the royalties, see “Item 2.6 – Research and Development Activities – Oncology Platform” above. The Katana Licence Agreement is scheduled to expire on the latest of (i) February 2039, and (ii) the date of expiry of the last patents to be issued under the agreement or of any of the patents related to any improvements made under the licensed technology, unless earlier terminated pursuant to certain customary termination provisions.

## ITEM 10 ADDITIONAL INFORMATION

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Additional information with respect to our Company, including directors' and officers' compensation, principal holders of our securities and securities authorized for issuance under equity compensation plans, where applicable, is contained in our Management Proxy Circular. Our financial information is provided in our comparative financial statements and Management Discussion & Analysis for our financial year ended November 30, 2022.

Additional information regarding our Company is available on SEDAR at [www.sedar.com](http://www.sedar.com), or upon written request addressed to Jocelyn Lafond, General Counsel and Corporate Secretary, at 2015 Peel Street, 11<sup>th</sup> Floor, Montreal, Québec, Canada H3A 1T8. Except when our securities are in the process of distribution pursuant to a prospectus, we may charge reasonable fees if the request is from a person who does not hold any of our securities.



**AUDIT COMMITTEE CHARTER**

**I. Mandate**

The Audit Committee (the “Committee”) is responsible for assisting the Company’s Board of Directors (the “Board”) in overseeing the following:

- A. the integrity of the Company’s financial statements and related information;
- B. the internal control systems of the Company;
- C. the appointment and performance of the external auditor;
- D. the supervision of the Company’s Risk Management; and
- E. the review and approval of related party transactions.

**II. Obligations and Duties**

The Committee carries out the duties usually entrusted to an audit committee and any other duty assigned from time to time by the Board. Management has the responsibility to ensure the integrity of the financial information and the effectiveness of the Company’s internal controls. The external auditor has the responsibility to verify the fair presentation of the Company’s financial statements; at the same time evaluating the internal control process to determine the nature, extent and timing of the auditing procedures used for the financial statement audit. The Committee has the responsibility to supervise the participants involved in the preparation process of the financial information and to report on this to the Board.

Specifically, the Committee is charged with the following obligations and duties:

- A. Integrity of the Company’s Financial Statements and Related Information
  - 1. Review annual and quarterly consolidated financial statements and all financial information legally required to be disclosed by the Company, i.e. financial information contained in the “Management Discussion and Analysis” report, the Annual Information Form and the press releases, as the case may be, discuss such with management and the external auditor, as applicable, and suggest recommendations to the Board, as the case may be.
  - 2. Approve the interim Financial Statements, the interim “Management Discussion and Analysis” reports and all supplements to these “Management Discussion and Analysis” reports which have to be filed with regulatory authorities.
  - 3. On a periodic basis, review and discuss with management and the external auditor, as applicable, the following:
    - a. major issues regarding accounting principles and financial statement presentations, including any significant changes in the Company’s selection or application of accounting principles, and major issues as to the adequacy of the

Company's internal controls and any special audit steps adopted in light of significant or material control deficiencies;

- b. the effect of regulatory and accounting initiatives, as well as off-balance sheet structures, on the financial statements of the Company; and
  - c. the type and presentation of information to be included in press releases dealing with financial results (paying particular attention to any use of forward-looking information and use of non-GAAP financial measures).
4. Review and discuss reports from the external auditor on:
- a. all critical accounting policies and practices used by the Company;
  - b. all material alternative treatments of financial information within generally accepted accounting principles that have been discussed with management, including the ramifications of the use of such alternate treatments and disclosures and the treatment preferred by the external auditor;
  - c. the external auditor's report to the Committee on the planning of external auditing; and
  - d. the external auditor's report to the Committee on the auditing results.

**B. Supervision of the Company's Internal Control Systems**

1. Review and discuss with management and, when appropriate, provide recommendations to the Board on the following:
  - a. actual financial data compared with budgeted data;
  - b. the Company's internal control system;
  - c. the relationship of the Committee with the management and audit committees of the Company's consolidated subsidiaries. With respect to the subsidiaries, the Committee must:
    - obtain precisions as to the mandate of the audit committees;
    - enquire about internal controls and study related risks;
    - obtain copy of the minutes of the audit committees' meetings; and
    - ensure that the critical accounting policies and practices are identical to the Company's.
2. Study the feasibility of implementing an internal auditing system and when implemented, establish its responsibilities and supervise its work.
3. Establish procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters, and

procedures for the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters.

4. Review and discuss with the Chief Executive Officer and Chief Financial Officer of the Company the process for the certifications to be provided in the Company's public disclosure documents.

C. Appointment and Performance Supervision of the External Auditor

1. Provide recommendations to the Board on the selection of the external auditor to be appointed by the shareholders.
2. Approve in advance and recommend to the Board the external auditor's remuneration and more specifically fees and terms of all audit, review or certification services to be provided by the external auditor to the Company and any consolidated subsidiary.
3. Supervise the performance of the external auditor in charge of preparing or issuing an audit report or performing other audit services or certification services for the Company or any consolidated subsidiary of the Company, where required, and review all related questions as to the terms of its mission and the revision of its mission.
4. Pre-approve all engagements for permitted non-audit services provided by the external auditor to the Company and any consolidated subsidiary, and to this effect and at its convenience, establish policies and procedures for the engagement of the external auditor to provide to the Company and any consolidated subsidiary permitted non-audit services, which shall include approval in advance by the Committee of all audit/review services and permitted non-audit services to be provided to the Company and any consolidated subsidiary by the external auditor.
5. Authorize the Chair of the Committee to pre-approve all engagements for permitted non-audit services provided by the external auditor to the Company and any consolidated subsidiary where such engagements have not been pre-approved by the Committee as set forth above under paragraph 4; *provided, however*, that the upper limit of the amount of such approval shall be determined annually by the Committee; and *provided, further*, that the Chair reports any approval to the Committee at the next meeting of the Committee following the date on which the approval was given by the Chair.
6. At least annually, consider, assess and report to the Board on:
  - a. the independence of the external auditor, including whether the external auditor's performance of permitted non-audit services is compatible with the external auditor's independence;
  - b. the obtaining from the external auditor of a written or verbal statement
    - i) describing all relationships between the external auditor and the Company that may reasonably be thought to bear on their independence; ii) assuring that lead audit partner rotation is carried out, as required by law; and iii) describing any other relationship that may reasonably be thought to affect the independence of the external auditor; and

- c. the evaluation of the lead audit partner, taking into account the opinions of management and the internal auditor.
7. At least annually, obtain and review a report by the external auditor describing:
  - a. the external auditor's internal quality-control procedures; and
  - b. any material issues raised by the most recent internal quality-control review (or peer review) of the external auditor's firm, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years, with respect to one or more independent audits carried out by the external auditor's firm, and any steps taken to deal with any such issues.
8. Resolve any disagreement between management and the external auditor regarding financial reporting.
9. Review the audit process with the external auditor.
10. Meet periodically with the external auditor in the absence of management.
11. Establish procedures with respect to hiring the external auditor's employees and former employees.

D. Supervision of the Company's Risk Management

Review, report and, where appropriate, provide recommendations to the Board on the following:

1. the Company's processes for identifying, assessing and managing risk;
2. the Company's major financial risk exposures and the steps the Company has taken to monitor and control such exposures;
3. the Company's insurance portfolio and the adequacy of the coverage; and
4. the Company's investment policy.

E. Review and Approval of Related Party Transactions

Review, approve and oversee any transaction between the Company and any related person (as defined in NASDAQ Listing Rule 5630) for potential conflicts of interest on an ongoing basis.

### **III. External Advisors**

In discharging its duties and responsibilities, the Committee is empowered to retain external legal counsel or other external advisors, as appropriate. The Company shall provide the necessary funds to secure the services of such advisors.

### **IV. Composition of the Committee**

The Committee is composed of any number of Directors, but no less than three, as may be determined by the Board from time to time by resolution. Each member of the Committee shall be independent from the Company and is financially literate, as determined by the Board and in conformity with applicable laws, rules and

regulations. At least one member of the Committee shall have past employment experience in finance or accounting, requisite professional certification in accounting or other comparable experience that leads to financial sophistication, as determined by the Board. No member of the Committee shall have participated in the preparation of the Company's or any of its subsidiaries' financial statements at any time during the past three years.

**V. Term of the Mandate**

Committee members are appointed by Board resolution to carry out their mandate extending from the date of the appointment to the next annual general meeting of the shareholders or until their successors are so appointed.

**VI. Vacancy**

The Board may fill vacancies at any time by resolution. Subject to the constitution of the quorum, the Committee's members can continue to act even if there is one or many vacancies on the Committee.

**VII. Chair**

The Board appoints the Committee Chair who will call and chair the meetings. The Chair reports to the Board the deliberations of the Committee and its recommendations.

**VIII. Secretary**

Unless otherwise determined by resolution of the Board, the Secretary of the Company shall act as Committee Secretary. The Secretary must attend Committee meetings and prepare the minutes. He/she must provide notification of meetings as directed by the Committee Chair. The Secretary is the guardian of the Committee's records, books and archives.

**IX. Meeting Proceedings**

The Committee establishes its own procedures as to how meetings are called and conducted. Unless it is otherwise decided, the Committee shall meet privately and independently from Management at each regularly scheduled meeting. In the absence of the regularly appointed Chair, the meeting shall be chaired by another Committee member selected among attending participants and appointed accordingly. In the absence of the regularly appointed Secretary, Committee members shall designate someone to carry out this duty.

The Committee shall meet at least four times a year with management and the external auditor, and at least once a year, separately in executive session in the absence of management and the external auditor. At least once a year, as and when applicable, the Committee invites the Chief Financial Officer of each subsidiary to present the financial information and internal control systems related to such subsidiary.

**X. Quorum and Voting**

Unless the Board otherwise specifies by resolution, two Committee members shall constitute an appropriate quorum for deliberation of items on the agenda. During meetings, decisions are reached by a majority of votes from Committee members, unless the quorum is of two members, in which case decisions are made by consensus of opinion.

**XI. Records**

The Committee keeps records that are deemed necessary of its deliberations and reports regularly to the Board on its activities and recommendations.

**XII. Annual Review**

The Committee shall review this Charter at least annually and recommend any proposed changes to the Board for approval.

**XIII. Effective Date**

This charter was adopted by the Directors at its May 3, 2004 Board meeting. It was amended by the Directors during the April 13, 2005, February 8, 2006, February 25, 2015, August 7, 2019 and May 13, 2021 Board meetings.