# ANNUAL INFORMATION FORM
## Financial Year Ended November 30, 2021


**February 23, 2022**

## BASIS OF PRESENTATION

In this Annual Information Form, or 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*® (tesamorelin for injection) refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected 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 patients with lipodystrophy.
- tesamorelin refers to the use of our tesamorelin compound for the potential treatment of nonalcoholic steatohepatitis, or NASH, in the general population and for the potential treatment of other diseases;
- Trogarzo® (Ibalizumab-uiyk) refers to the humanized monoclonal antibody ibalizumab indicated (i) in the United States, for the treatment of human immunodeficiency virus type 1, or HIV-1, infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen and, (ii) in Europe, in combination with other antiretroviral(s), 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. Trogarzo is a registered trademark of TaiMed Biologics, Inc. and is under licence to us for use in the United States, Canada and in European countries.
- *THERA Patient Support*® 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.
- *SORT1+ Technology* is our trademark and refers to our licensed platform to develop peptide-drug conjugates, or 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 23, 2022, 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*® and Trogarzo®;
- our ability and capacity to grow the sales of *EGRIFTA SV*® and Trogarzo® successfully in the United States;
- our capacity to meet supply and demand for our products;

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

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

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

- our commercial practices in the United States and the countries of the European Union where we commercialize our products will not be found to be in violation of applicable laws;
- the long-term use of *EGRIFTA SV*® and Trogarzo® will not change their respective current safety profile;
- no recall or market withdrawal of *EGRIFTA SV*® and Trogarzo® will occur;
- no laws, regulation, order, decree or judgment will be passed or issued by a governmental body negatively affecting the marketing, promotion or sale of *EGRIFTA SV*® and Trogarzo® in countries where such products are commercialized;
- continuous supply of *EGRIFTA SV*® and Trogarzo® will be available;
- our relations with third-party suppliers of *EGRIFTA SV*® and Trogarzo® will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply *EGRIFTA SV*® and Trogarzo® to meet market demand on a timely basis;
- no biosimilar version of tesamorelin will be approved by the FDA;
- our intellectual property will prevent companies from commercializing biosimilar versions of tesamorelin in the United States;
- Trogarzo® will be added to the list of reimbursed drugs by countries of the European Union and the United Kingdom;
- the integration of U.S. employees into our U.S. subsidiary will not be disruptive to our business and will strengthen our commercial and medical affairs capabilities in the United States;
- the FDA will approve the F8 Formulation;
- no vaccine or cure will be found for the prevention or eradication of HIV;
- we will succeed in developing the Pen or any other device for use with the F8 Formulation and the FDA will approve the use of such device for the F8 Formulation;
- we will have the financial means or will find a partner to conduct a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- the FDA will approve the amendments to our current Phase 3 trial protocol evaluating the use of tesamorelin for the potential treatment of NASH in the general population;
- we will succeed in recruiting patients and in conducting our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- we will succeed in recruiting and in conducting our Phase 1 clinical trial studying TH1902 in various types of cancers;
- our Phase 1 clinical trial studying TH1902 in various types of cancer will demonstrate strong efficacy results;
- we will succeed in entering into a partnership agreement with a third party for TH1902 in Greater China;
- our research and development activities will yield positive results;

- the data obtained from our market research on the potential market for the treatment of NASH in the general population and on the potential market for Trogarzo® in the United States and in the European Union are accurate;
- our European infrastructure is adequate to successfully launch and commercialize Trogarzo® in key European countries;
- the timelines set forth herein will not be materially adversely impacted by unforeseen events that could arise subsequent to the date of this AIF; and
- our business plan will not be substantially modified.

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

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## SELECTED EVENTS IN FISCAL YEAR 2021 AND OUTLOOK

*The following summary highlights selected events that occurred in the fiscal year 2021 up to the date of this AIF as well as our business objectives described elsewhere in this AIF for the fiscal year 2022. 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**

- Launch of Trogarzo® in Italy;
- US $50,000,000 at-the-market facility in place; and
- Internalization of commercial and medical teams effective March 14, 2022.

**Regulatory Events**

- Filing of a supplemental biologics license application, or sBLA, with the FDA for the IV Push mode of administration of Trogarzo®;
- FDA's grant of "Fast Track" designation to TH1902;
- Initiation of Phase 1 clinical trial studying TH1902 in various types of cancers; and
- Postponement of Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population until additional financing or a partner is secured.

**Research and Development Events**

- Additional pre-clinical data using TH1902 in various types of cancer showed that TH1902 could potentially treat sortilin-expressed cancers; and
- Initiation of the development of additional PDC using new payloads, including SN38.

**Governance and Talent Acquisition Events**

- Election and appointment of three (3) new independent directors to our board of directors;
- Hiring of a Global Commercial Officer and a Vice President, HIV-US, Commercial Operations; and
- Hiring of a Vice President, Human Resources.

**2022 Business Objectives**

- We intend to continue growing our revenues in the United States from sales of *EGRIFTA SV*® and Trogarzo®;
- We intend to successfully obtain commercially attractive pricing and reimbursement for Trogarzo® in key European countries and launch Trogarzo® in some of these countries;
- We intend to launch the IV Push mode of administration of Trogarzo®;
- We intend to pursue the development of an intra-muscular mode of administration of Trogarzo®;
- We intend to secure additional financing or find a partner to initiate a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- We intend to initiate Part B of our Phase 1 clinical trial studying TH1902 in various types of cancer;
- We intend to seek potential partners for our SORT1+ Technology™ platform in markets where we are not planning on developing and conducting clinical trials;

- We intend on pursuing potential product acquisitions, in-licensing transactions or other opportunities complementary to our business;
- We plan on retaining and attracting a pool of diverse talents at all levels to participate and contribute to the successful execution of our business strategy and objectives; and
- We plan on managing our financial position to ensure we can successfully execute on our 2022 business strategy and objectives.

## ITEM 1 CORPORATE STRUCTURE

### 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, 11th Floor, Montreal, Québec, Canada H3A 1T8. Our phone number is (514) 336-7800. Our website is www.theratech.com. The information contained on our website is not part of this AIF.

### 1.2 SUBSIDIARIES

As at February 23, 2022, Theratechnologies had the following five wholly-owned subsidiaries:

- **Theratechnologies Europe Limited,** a company governed by the *Companies Act 2014* (Ireland). Theratechnologies Europe Limited is responsible to commercialize Trogarzo® in Europe;

- **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.**[1], 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*®, except in the United States, Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries, and Canada;

- **Theratechnologies Europe Inc.**[1], 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*® in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries; and

- **Pharma-G Inc.**[1], a company governed by the *Business Corporations Act* (Québec). Pharma-G Inc. is no longer an active subsidiary.

[1] We plan on winding-up those wholly owned subsidiaries into Theratechnologies Inc. in 2022.

## ITEM 2 OUR BUSINESS

### 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 from our existing and future assets in North America and Europe 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*® in the United States, and Trogarzo® in the United States, the European Union, the United Kingdom and Israel.

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

Trogarzo® (ibalizumab-uiyk) injection was approved by the FDA in March 2018 and was made commercially available in the United States in April 2018. Trogarzo® was also approved by the EMA in September 2019 and is commercially available in Germany and in Italy. It is also available in France and Spain through access programs. Trogarzo® was also approved in Israel in January 2022. Trogarzo® is under licence to us following our entering into an amended and restated distribution and marketing agreement, as amended, or TaiMed Agreement, with TaiMed Biologics, Inc., or TaiMed, pursuant to which we acquired the exclusive right to distribute and commercialize ibalizumab in Canada, in the United States, in Europe and in certain other countries. Trogarzo® was the first HIV treatment approved with a new mechanism of action in more than 10 years. The treatment is infused every two weeks. It is a long-acting antiretroviral, or ARV, therapy that can lead to an undetectable viral load in combination with other ARVs.

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

Our plan to initiate a Phase 3 clinical trial to study tesamorelin for the treatment of NASH in the general population has been postponed until we can secure additional financings or find a partner. We have initiated our Phase 1 clinical trial using TH1902 in various types of cancer and the ongoing Part A of such Phase 1 is aimed at finding the maximum tolerated dose of TH1902. We plan on initiating Part B of the Phase 1 clinical trial in the current fiscal year to evaluate the potential anti-tumor activity of TH1902 in patients with endometrial, ovarian, triple-negative breast cancer and other cancer types.

To date, we have completed the in-house bioequivalence study of the F8 Formulation and have begun the development of a multi-dose pen injector intended to be used with the F8 Formulation. We plan on filing an sBLA seeking the approval of the F8 Formulation in the first half of the current fiscal year.

We have also filed an sBLA with the FDA for the IV Push mode of administration of Trogarzo® and have begun enrolling patients for the development of an intramuscular mode of administration of Trogarzo®.

## 2.2 THREE-YEAR HISTORY

### 2021

- *Submission of sBLA to the FDA for the IV Push mode of administration of Trogarzo®*. On December 6, 2021, we announced the submission of an sBLA to the FDA for the IV Push mode of administration of Trogarzo®.

- *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® in Italy.* On October 26, 2021, we announced that we had reached an agreement with the Italian Medicines Agency for the reimbursement of Trogarzo®.

- *Pharmacokinetic Results of Trogarzo® similar in IV Push mode of administration of Trogarzo® 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® were no different than those of the intravenous mode of administration of Trogarzo®.

- *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 ad 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, or 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® in Germany.* On September 10, 2020, we announced that Trogarzo® 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®'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®*, or 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.

**2019**

- *Commercialization of EGRIFTA SV® in the United States.* On November 25, 2019, we announced that *EGRIFTA SV*™ was commercially available in the United States.

- *Publication of NASH Study Results in The Lancet HIV Journal.* On October 11, 2019, we announced that results from a clinical trial conducted at the Massachusetts General Hospital on the effects of tesamorelin on nonalcoholic fatty liver disease, or NAFLD, in HIV-patients had been published in *The Lancet HIV Journal*.

- *Common Shares Listed on U.S. NASDAQ Stock Market.* On October 10, 2019, we announced that our common shares began trading on the U.S. NASDAQ stock market under the symbol "THTX".

- *Trogarzo® Approved by the EMA.* On September 26, 2019, we announced that the EMA approved Trogarzo® for commercialization in European Union countries.

- *Worldwide Distribution Rights of EGRIFTA® Regained.* On August 8, 2019, we announced the termination of all of our distribution and licensing agreements with our international commercial partners regarding their rights to distribute *EGRIFTA®* and, as a result, we regained all worldwide distribution rights to *EGRIFTA®*.

- *Tesamorelin to be Developed for the Treatment of NASH in HIV Patient Population.* On June 17, 2019, we announced that we would pursue the development of tesamorelin for the potential treatment of NASH in people living with HIV.

- *EMA Issues Good Manufacturing Practice Certificates to WuXi*. On March 20, 2019, we announced that the EMA issued good manufacturing practice certificates to WuXi Apptec for its manufacturing sites of

Trogarzo® in Wuxi City, China, and in Shanghai, China.

- *FDA Authorizes Study for a New Mode of Administration of Trogarzo®.* On March 4, 2019, we announced that we were informed by TaiMed that the FDA authorized a study protocol to evaluate an intravenous slow-push formulation of Trogarzo®.

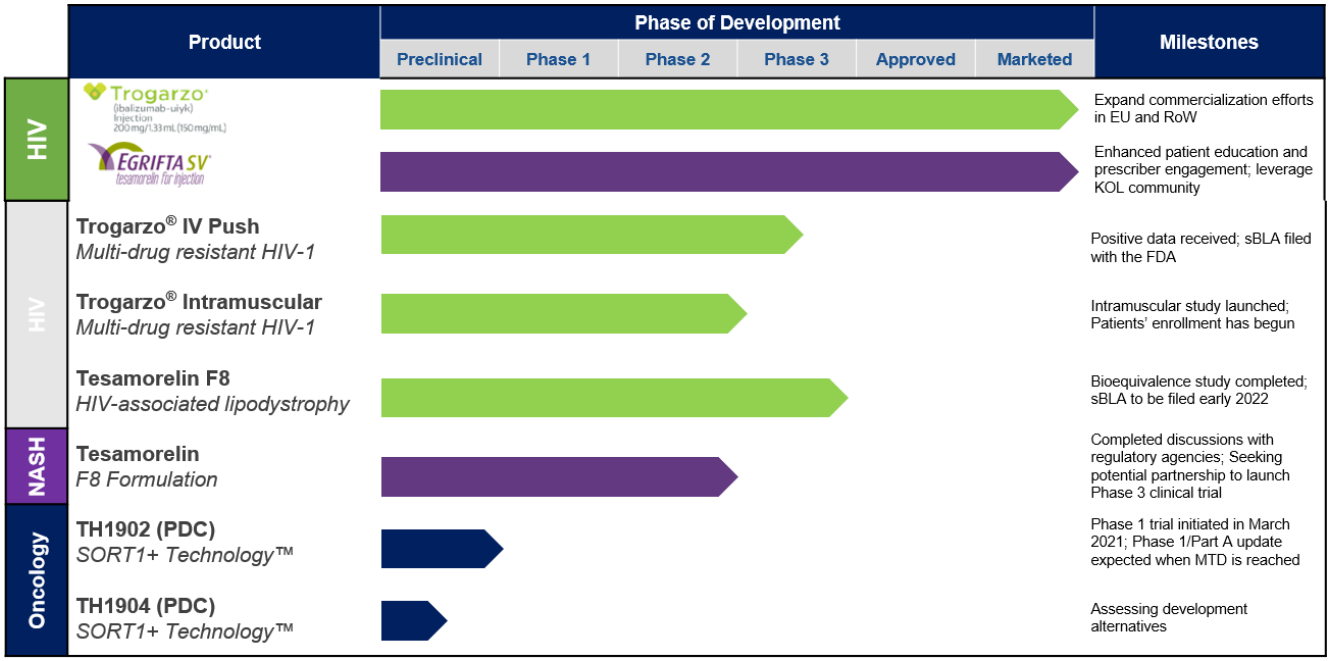
- *Acquisition of Oncology Platform.* On February 25, 2019, we announced the acquisition of all of the issued and outstanding common shares of Katana BioPharma Inc., or Katana. Katana had exclusive worldwide rights through a licence agreement entered into with Transfer Plus L.P. to the development and commercialization of a targeted oncology technology platform. The technology platform uses peptides as a vehicle to deliver existing cytotoxic agents to sortilin receptors which are overexpressed in cancer cells.

- *Appointment of General Manager for our European Subsidiary.* On February 11, 2019, we announced the appointment of Mr. Conor Walshe as the general manager of our wholly-owned subsidiary, Theratechnologies Europe Limited (formerly Theratechnologies International Limited).

## 2.3 OUR 2022 BUSINESS STRATEGY AND OBJECTIVES

Our business strategy in 2022 is focused on: increasing sales of *EGRIFTA SV®* and Trogarzo® in the United States; obtaining commercially attractive pricing and reimbursement of Trogarzo® in key countries of the European Union and launching Trogarzo® therein; launching the F8 Formulation and the IV Push mode of administration in the U.S.; continuing Part 1b of our Phase 1 clinical trial studying TH1902 in various types of cancer; beginning a Phase 3 clinical trial using tesamorelin for the potential treatment of NASH in the general population after having secured additional financing or having found a partner; continuing pursuing potential product acquisitions, in-licensing transactions or other similar opportunities complementary to our business; seeking potential partners for our licensed SORT1+ Technology™ platform in countries where we do not intend to develop and conduct clinical trials; retaining and attracting a pool of talent to participate and contribute to the successful execution of our business strategy and objectives; and managing our financial position to ensure we can successfully execute on our 2022 business strategy and objectives.

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




## 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 abdominal fat (lipohypertrophy) in HIV-infected 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), or both. Recent data suggest that 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®*. 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® (ibalizumab-uiyk) Injection***

Trogarzo® is a CD-4 directed post-attachment HIV-1 inhibitor. Trogarzo® 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® 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® 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® was also approved by the EMA on September 26, 2019. In Europe, Trogarzo® is indicated for the treatment of adults infected with multi-drug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen.

In connection with the marketing authorization application of Trogarzo®, the EMA agreed with our proposed conduct of a paediatric investigation plan, or PIP, comprised of two studies: the first study is to evaluate pharmacokinetics, pharmacodynamics, safety and tolerability of Trogarzo® in children from 6 to less than 18 years of age with HIV-1 infection in order to provide pharmacokinetics and pharmacodynamics data to support the extrapolation of efficacy from adults, or PK/PD Study; and the second study is a modelling and simulation study to evaluate the use of Trogarzo® in the treatment of HIV-1 infection resistant to at least 1 agent in 3 different classes in children from 6 to less than 18 years of age, or Population PK Study. The Population PK Study will rely on the data generated from different clinical trials conducted with adults and those generated from the PK/PD Study conducted in children.

In August 2018, prior to the approval of Trogarzo® by the EMA, we obtained a deferral to conduct the PIP and a waiver to conduct the PK/PD Study and the Population PK Study in children who are less than 6 years old. The deferral required that we complete the PIP in children aged from 6 to less than 18 years of age by June 2022. In February 2021, we filed a request with the EMA seeking to defer the PK/PD Study to June 2023 from June 2022 and to defer the Population PK Study to June 2024 from June 2022. The EMA rejected our request and the PIP must be completed by June 2023. Up to 12 patients will be enrolled in order to complete the PIP and each patient must be treated over a period of 24 weeks with a four-week follow-up.

As part of the approval of Trogarzo®, the EMA requested that we conduct a post-authorisation efficacy study, or PROMISE, according to a protocol to be agreed with the EMA. In July 2020, we agreed on the final terms of this protocol. The PROMISE study is aimed primarily at evaluating the long-term efficacy and durability of Trogarzo® in combination with other antiretrovirals by comparing the virologic, immunologic and clinical outcomes of patients receiving Trogarzo® treatment *versus* matched patients not receiving Trogarzo®. The PROMISE study should be conducted over a five-year period and the enrollment of patients began in December 2021. We expect the costs of the PROMISE study to be approximately 4,000,000 euros. The costs are to be borne as to 52% by TaiMed and as to 48% by us. As a result of this requirement in Europe, we decided to initiate a similar study in the United States, or PROMISE-US. We believe that data gathered from the PROMISE-US study will form part of the data submitted to the EMA. The costs of the PROMISE-US study will be entirely borne by the Corporation.

Trogarzo® is currently commercially available in Germany and in Italy. It is also available in certain other European countries through access programs. We are working on obtaining pricing and reimbursement conditions in key European countries and we anticipate launching Trogarzo® sequentially in countries where the product will be reimbursed.

Trogarzo® is available as a single dose, 2 mg/vial containing 200 mg of ibalizumab-uiyk. Trogarzo® 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. See "Item 2.6 – Research and Development Activities – Ibalizumab – IV-Push Form of Administration of Trogarzo" below.

Trogarzo® was developed by TaiMed and we have an exclusive license to distribute this product in Canada, the United States, Europe and certain other additional countries. See "Item 2.5 – Commercialization Activities – *Trogarzo*® – General" below.

*Mechanism of Action*

Unlike other antiretroviral agents, Trogarzo® 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 $CD4^+$ immune cells while preserving normal immunological function. Trogarzo® 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.

## 2.5 COMMERCIALIZATION ACTIVITIES

### *EGRIFTA SV® - United States*

*General*

*EGRIFTA SV®* (tesamorelin for injection) is commercialized in the United States. Prior to November 2019, the date on which *EGRIFTA SV®* became commercially available in the United States, *EGRIFTA®* (tesamorelin for injection) was also commercialized in the United States. However, *EGRIFTA®* is no longer offered for sale in the United States since being replaced by *EGRIFTA SV®* in the 2020 fiscal year. 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®*, 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., or Bachem, and Jubilant HollisterStier, General Partnership, or Jubilant, for all of our required raw materials, drug substance and finished product for commercial sale and clinical trials.

We currently manufacture *EGRIFTA SV®* in a 2 mg/vial formulation and one vial of *EGRIFTA SV®* 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, or Bachem Agreement, relating to the manufacture and supply of the active pharmaceutical ingredient of tesamorelin, or API, for *EGRIFTA SV®*. 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. See "Item 9 - Material Contracts – Bachem Agreement" below.

*Finished Product*

We have an agreement with Jubilant providing for the manufacture and supply of the finished form of *EGRIFTA SV®* for commercial sale in the United States and for tesamorelin in connection with clinical trials, or 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.

*Injection Tool Kit*

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

*Distribution*

In connection with the commercialization of *EGRIFTA SV*® 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*® 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*®.

*Logistic Service Provider and Distributor*

On November 1st, 2017, we entered into an amended and restated master services agreement with RxC Acquisition Company, LLC, or RxCrossroads, along with two amended and restated statements of work, or 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*®, 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*® in the United States is comprised of a limited number of wholesalers through which specialty pharmacies we have contracted with can order *EGRIFTA SV*®. These wholesalers accept purchase orders from those specialty pharmacies, purchase *EGRIFTA SV*® from RxCrossroads, and resell this product to these specialty pharmacies. Our wholesalers do not handle the physical delivery of *EGRIFTA SV*®. The shipping and delivery of *EGRIFTA SV*® to those specialty pharmacies is handled by RxCrossroads. To date, we have agreements in place with the following wholesalers for *EGRIFTA SV*®: H.D. Smith, LLC., Cardinal Health, McKesson Corporation, Morris & Dickson Co., LLC, 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*® from our authorized wholesalers and distribute *EGRIFTA SV*® 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*® directly from RxCrossroads for redistribution within their own retail specialty pharmacy stores.

**Trogarzo®**

*General*

Trogarzo® is under license to us from TaiMed. On March 18, 2016, we entered into a distribution and marketing agreement with TaiMed and, on March 6, 2017, we amended and restated the TaiMed Agreement, as further amended on November 6, 2018. Pursuant to the terms of the TaiMed Agreement, we have the exclusive rights to

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

Effective November 5, 2019, we re-amended the TaiMed Agreement to set forth some of the obligations of the parties in connection with the payment of expenses and the delivery terms of Trogarzo® in the European Territory.

The TaiMed Agreement will expire on a country-by-country basis 12 years after marketing approval for ibalizumab has been obtained in each country, unless earlier terminated. The TaiMed Agreement contains customary representations and warranties, indemnification provisions and other provisions customarily found in agreements of this nature.

*North American Territory – Terms and Conditions*

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

In Canada, we are responsible, but under no obligation, to seek the approval of Trogarzo® from Health Canada. No filing seeking the approval of Trogarzo® has been made in Canada and no decision has been made yet regarding a filing in Canada.

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® 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® 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® 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 will be payable in two annual equal installments of US$1,500,000 each,

with the first one being paid 30 days after the first sale of such new formulation in the North American Territory, while the second one will be paid 12 months thereafter.

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® 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® 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® using this new formulation, and would include a payment of interest on the principal.

*Manufacturing*

TaiMed is responsible to manufacture and supply Trogarzo® to us for each country forming part of the North American Territory and European Territory. Since TaiMed has no manufacturing facility, TaiMed has subcontracted the manufacture of Trogarzo® to WuXi Apptec Biologics, Inc., or WuXi, in China.

*Distribution*

We began the distribution of Trogarzo® 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® in the United States under the RxCrossroads Agreements. Orders for Trogarzo® are being made directly by a limited number of specialty pharmacies and delivery of Trogarzo® is made directly to those specialty pharmacies by RxCrossroads.

*Specialty Pharmacies*

We have entered into agreements with specialty pharmacies 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® to patients, physicians or infusion centers. Each of those specialty pharmacies purchase Trogarzo® from RxCrossroads and deliver it to infusion centers, physicians or patients for home-infusion. Patients are administered Trogarzo® 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 Accredo Health Group, Inc., or Accredo, Option Care Enterprises, Inc., or Option Care, Priority Healthcare Distribution, Inc., or Curascript, and Walgreen Co., or 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 pharmacy that can deliver Trogarzo® to physicians and Walgreen is a specialty pharmacy.

*European Territory – Terms and Conditions*

In the European Territory, Trogarzo® was approved by the EMA on September 26, 2019. Pursuant to the TaiMed Agreement, we are responsible for all regulatory activities, including regulatory filings and communications with the EMA, in addition to all commercialization activities.

The transfer price for sales occurring in a country forming part of the European Territory is set at (i) 52% of the net selling price of Trogarzo® in such country on annual net sales in such country up to, or equal to, US$50,000,000 and (ii) an amount equal to 57% of the net selling price of Trogarzo® in such country on the portion of annual net sales of Trogarzo® in the European Territory that exceeds annual net sales of Trogarzo® in the European Territory of US$50,000,000.

Under the terms of the TaiMed Agreement, we agreed to issue to TaiMed 906,077 common shares in consideration of the rights granted to us in the European Territory. The common shares were issued on March 17, 2017.

Furthermore, we agreed to make the following one-time milestone payments to TaiMed based on the net sales of Trogarzo® in the European Territory:

- US$10,000,000 to be paid in two annual equal installments upon the date of the first commercial sale of Trogarzo® in the European Territory. The first installment of US$5,000,000 was payable twelve (12) months after the first commercial sale of Trogarzo® in the European Territory and was paid in October 2021. The second installment of US$5,000,000 is payable twelve (12) months after first achieving aggregate net sales of US$50,000,000 in the European Territory over four (4) consecutive Theratechnologies' financial quarters;
- US$10,000,000 upon achieving aggregate net sales of Trogarzo® of US$150,000,000 over four consecutive financial quarters (based on our fiscal year);
- US$20,000,000 upon achieving aggregate net sales of Trogarzo® of US$500,000,000 over four consecutive financial quarters (based on our fiscal year); and
- US$50,000,000 upon achieving aggregate net sales of Trogarzo® of US$1,000,000,000 over four consecutive financial quarters (based on our fiscal year).

*Manufacturing*

The manufacture of Trogarzo® for the European Territory is made by WuXi, TaiMed's designee. In the European Territory, Trogarzo® is being supplied and delivered to us in brite stock form. We have agreed to take charge of quality testing and release of Trogarzo® in the European Territory as well as the packaging and labeling of the finished product. We have entered into various agreements with third party suppliers that assist us with those tasks.

*Distribution*

We are responsible for the importation of Trogarzo® into the European Territory.

On July 9, 2020, our European subsidiary, Theratechnologies Europe Limited, entered into a pre-wholesaling services agreement with Loxxess Pharma GmbH, or Loxxess, pursuant to which Loxxess agreed to act as our third-party service logistic provider, or Loxxess Agreement, in certain key European countries, including Germany, France, Italy, Austria, The Netherlands, Portugal, Switzerland, the United Kingdom, Norway, Sweden, Finland and Denmark. Loxxess is also capable of serving other European countries. Pursuant to the Loxxess Agreement, Loxxess receives customers'orders, stores, packages and ships Trogarzo® to European hospitals and

pharmacies. Loxxess is also responsible, on our behalf, to collect payments of the goods sold to those hospitals and pharmacies. The hospitals and pharmacies dispense Trogarzo® to patients. See "Item 9 – Material Contracts - Loxxess Agreement".

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

*North American Territory*

Our marketing and sales activities in the United States for *EGRIFTA SV*® and Trogarzo® are conducted from our head office in Montreal, Québec, Canada. We have also retained the services of Syneos Health, or Syneos, to assist us with sales, market access and medical affairs activities in the United States. Syneos is a recognized provider of commercial, clinical and consulting 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, or Syneos Agreement, pursuant to which Syneos will continue providing us with various services in connection with the commercialization of *EGRIFTA SV*® and Trogarzo® in the United States until November 30, 2024. In addition, we sometimes retain Syneos and other third parties for certain marketing activities.

The services currently provided by Syneos comprise a sales force team fully dedicated to *EGRIFTA SV*® and Trogarzo®, a medical science liaison team solely assigned to our medical activities, a community liaison team educating patient's associations on HIV, a managed market team solely dedicated to the reimbursement of our products with both public and private payors.

Effective March 14, 2022, we will cease relying on Syneos to provide us with a sales force team, a medical science liaison team and a community liaison team. Top performers forming part of these teams will become employees of our U.S. subsidiary and will be managed directly by us. We are currently finalizing our in-house infrastructure to welcome these new employees.

The Syneos Agreement contains customary representations and warranties, indemnification, confidentiality, intellectual property and termination provisions.

We have contracted with Asembia, LLC, or Asembia, for the provision of services related, amongst other things, to a call center. The call center, *THERA Patient Support*®, 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*® also helps patients adhering to their treatment and answering questions about our products. See "Item 9 – Material Contracts" below

Trogarzo® is not approved in Canada since no filing has been made with Health Canada to seek its approval and no decision has been made yet in regard to seeking its approval in Canada.

*European Territory*

*EGRIFTA SV*®

*EGRIFTA SV*® is not approved in Europe and, therefore, is not available in this territory.

*Trogarzo*®

Trogarzo® became commercially available in Germany in September 2020 and in Italy in December 2021. Our European subsidiary, Theratechnologies Europe Limited, has also retained the services of Syneos in Europe to

assist with the commercialization of Trogarzo®. In the European Territory, Syneos provides us with the services of a medical director, medical science liaison personnel for France, Italy and Spain, and one key account manager.

Currently, Trogarzo® can only be promoted in Italy, the only country where we entered into an agreement with regulatory authorities with respect to its pricing and reimbursement conditions, but is available in other countries, such as France and Spain, through access programs. Although Trogarzo® is commercially available in Germany to patients, we can no longer promote it as of September 2021 since no agreement has been reached yet with German regulatory authorities on its pricing and reimbursement conditions. We are continuing our efforts on obtaining pricing and reimbursement conditions for Trogarzo® in other key European countries and it is anticipated that Trogarzo® will be launched sequentially as public reimbursement is obtained in those key European countries.

We have obtained pricing and reimbursement conditions for Trogarzo® in Israel and are still in negotiation with Norwegian regulatory authorities in relation to the pricing and reimbursement conditions of Trogarzo® in this territory.

## 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**

*F8 Formulation*

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

We intend to file an sBLA with the FDA to seek approval of the bioequivalence of the F8 Formulation in early 2022 for the treatment of lipodystrophy in people living with HIV.

We also intend to use the F8 Formulation in our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population.

*Multi-Dose Pen Injector*

In the last fiscal year, 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 working on the Pen. As a result, no timeline has been set for the filing of an sBLA with the FDA in relation to the Pen.

*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, or IND, with the FDA for a Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH

and we received a "Study May Proceed" letter for such Phase 3 clinical trial from the FDA in December 2020. The letter contained a recommendation that the Corporation 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.

We have already entered into an agreement with Worldwide Clinical Trials, Inc., or WCT, a contract research organization with experience in implementing large and late-stage clinical trials, to assist with the potential conduct of our Phase 3 clinical trial, or WCT Agreement. See "ITEM 9 – Material Contracts – WCT Agreement" below.

On July 15, 2021, we also announced that the final Phase 3 clinical trial design would result in higher costs than what we had expected and, as a result, we were assessing our options to best execute this program, including seeking a potential partner. An external U.S.-based biopharma advisory firm was retained for that purpose. To date, we are still continuing to seek a partner and to assess additional options, such as certain forms of financing.

In order to further de-risk the Phase 3 trial, the Corporation intends to submit an amended protocol to the FDA. The new protocol will include a Phase 2b/3 seamless study design where the first 350 or so patients' data will be analyzed by a data monitoring committee to assess the efficacy of tesamorelin on a smaller subset of patients. A decision will then be made whether to continue the study until the full number of patients (1,094) have completed 18 months of treatment. This will not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH, but it will inform the continuation of enrollment while providing an indication of benefit to patients.

NAFLD includes nonalcoholic fatty liver, or 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.

*VAMOS Study*

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

**Ibalizumab**

*IV-Push Form of Administration of Trogarzo®*

TaiMed has completed the research and development activities of the IV Push mode of administration of Trogarzo® and, in December 2021, we filed an sBLA with the FDA in relation thereto. The FDA has accepted our filing and has provided a target action date of October 3, 2022 in accordance with the *Prescription Drug User Fee Act* (PDUFA). The IV Push mode of administration of Trogarzo® is a more convenient form of administration. It can be infused within 30 seconds without dilution compared to the 15-minute infusion time of the current intravenous mode of administration. We believe this mode of administration will represent a marked improvement for patients. Under the terms of the TaiMed Agreement, we are entitled to commercialize this new form of administration of Trogarzo® if, and when, approved. We expect launching this new mode of administration in 2022.

*Intra-Muscular Administration of Trogarzo®*

In addition to the development of the IV-Push mode of administration of Trogarzo®, we began enrolling patients to study an intra-muscular mode of administration of Trogarzo®. The study will consist of assessing the safety and pharmacokinetic levels of Trogarzo® when administered intra-muscularly using a syringe. Under the terms of the TaiMed Agreement, we are entitled to commercialize this new form of administration of Trogarzo® if, and when, approved.

*Post-Approval Requirements*

In addition to the foregoing research and development work on new modes of administration of Trogarzo®, we began enrolling patients for the conduct of the PROMISE study requested by the EMA and have decided to initiate the PROMISE-US study in the United States. We will also conduct the PIP as per the requirements of the EMA. See "Item 2 – Our Business – Products – Trogarzo" above for a description of these programs.

**TH1902**

*Acquisition of SORT1+ Technology™ Platform*

The research and development activities carried out on our TH1902 PDC and other PDCs stem from our acquisition of all of the issued and outstanding common shares of Katana Biopharma Inc., or Katana, on February 25, 2019. Katana had the exclusive worldwide rights, through a royalty-bearing licence agreement, entered into with Transfert Plus, LP, or Transfert Plus, to a technology platform *(SORT1+ Technology™*) using peptides as a vehicle to specifically deliver cytotoxic agents to sortilin receptors, which are overexpressed on cancer cells, or Transfert Plus License Agreement. Katana was wound up into Theratechnologies in May 2019 and we are now a party to the Transfer Plus License Agreement.

Pursuant to the terms and conditions of the share purchase agreement dated February 25, 2019, as amended on August 12, 2019, the purchase price, or Purchase Price, for all of the issued and outstanding common shares of Katana was set at CAD 6,900,000 and was payable as to a maximum of CAD 2,600,000 in cash and through the issuance of common shares on the execution date of the agreement, or Up-Front Payment, and at later dates through the issuance of common shares based on the attainment of two development milestones. The first development milestone of CAD 2,000,000, or Second Installment, was payable on the date that a Phase 1 clinical trial is initiated using one of the peptides developed through the oncology platform, whereas the second development milestone of up to CAD 2,300,000, or Third Installment, is payable upon our decision to pursue the development of the peptide studied in the Phase 1 clinical trial if the results of such study warrant the pursuit of its development.

On the closing date, we paid to Katana's shareholders the Up-Front Payment as to CAD 2,592,800 in cash and issued 900 common shares having an aggregate value of CAD 7,200.

The Purchase Price was subject to an upward adjustment aggregating CAD 1,080,000 upon obtaining a subsidy, or Subsidy, from the *Consortium Québécois sur la Découverte du Médicament* and the Canadian Cancer Society to pursue the research and development work on the oncology platform. The Subsidy was obtained and, in October 2019, we paid an amount of CAD 500,000 in cash to the former Katana's shareholders. The balance of the payment resulting from the receipt of the Subsidy (CAD 580,000) will be paid through the issuance of common shares simultaneously to the payment of the Third Installment.

On March 23, 2021, we paid the Second Installment to the former shareholders of Katana through the issuance of 481,928 common shares.

*Description of Transfert Plus Licence 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.

*Research and Development Activities*

We are currently developing a platform of new proprietary peptides for cancer drug development targeting SORT1 receptors called SORT1+ Technology™. 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 our 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 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.

In December 2020, we filed an IND application with the FDA for the 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, a Phase 1 clinical trial was initiated evaluating TH1902 for the treatment of cancers where the sortilin receptor is expressed. The Phase 1 clinical trial design includes a Part A dose escalation study to evaluate the safety, pharmacokinetics, maximum tolerated dose, or MTD, and preliminary anti-tumor activity of TH1902 administered once every three weeks in patients with advanced solid tumors refractory to available anti-cancer therapies.

Part A of the Corporation's Phase 1 study evaluating its novel investigational proprietary PDC TH1902 for the treatment of sortilin positive cancers is progressing as planned. The Corporation is in the final stages of such Phase 1/Part A dose escalation study. As per the study protocol, the MTD is established once a significant adverse event is observed in two or more patients. In total, four patients in the trial have been administered significant doses of TH1902 at 420 mg/m$^2$, equivalent to nearly two times the indicated therapeutic dose of docetaxel. To date, we have observed a dose limiting toxicity, or DLT, (grade 4 neutropenia lasting more than 7 days) in one patient, as well as other adverse events after more than one cycle at 420 mg/m$^2$. As a result, we have decided to pursue the study at a lower dose of 300 mg/m$^2$ (or approximately 1.5 times the usual dose of docetaxel). We currently are enrolling patients at the 300 mg/m$^2$ dose to confirm the absence of DLTs following the first cycle. Once MTD has been established, the study protocol allows for immediate initiation of enrollment of a larger open label basket trial. The basket trial will further assess the safety and tolerability of TH1902. Additionally, the preliminary anti-tumor activity of TH1902 will be evaluated for all patients as per the response evaluation criteria in solid tumors. Based on additional research we have conducted on the Sortilin receptor, we have submitted an amendment to the Phase 1 protocol to the FDA to include the following solid tumor types: Hormone Receptor-Positive (HR+) Breast Cancer, Triple Negative Breast Cancer, Ovarian Cancer, Endometrial Cancer, and Melanoma with approximately 10 patients per tumor type. In addition, one arm will be added to include a mix of tumor types including Thyroid, Small Cell Lung, Prostate and potential other high Sortilin expressing cancers with 15 patients in total. The original trial design consisted of 40 patients across a selection of solid tumors, including colorectal and pancreatic cancer. The plan is now to enroll a total of approximately 70 patients in the basket trial to evaluate the potential anti-tumor activity of TH1902.

The research and development work using TH1904 (peptide-drug conjugated to doxorubicin) has slowed down. However, we have begun working on other PDCs, primarily to advance a PDC using SN38.

*Partnership Activities*

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

## 2.7 COMPETITION

### *EGRIFTA SV®*

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®* 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 approved by the FDA or Health Canada. Other approaches to reduce excess abdominal fat include coping mechanisms such as lifestyle modification (diet and exercise), switching antiretroviral therapy, or liposuction.

### Trogarzo®

Fostemsavir, which was approved by the FDA in July 2020 and by the EMA in February 2021, is a direct competitor to Trogarzo®. Contrary to Fostemsavir which is administered orally twice per day, Trogarzo® is a long-acting ARV that only needs to be administered intravenously twice per month. In addition, we are aware that dolutegravir and darunavir, for instance, are commonly used in regimens for the treatment of MDR HIV-1. We are aware that a NDA and a marketing authorization application have been filed with the FDA and the EMA, respectively, for Lenacapavir.

### 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™* 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 peptide-drug conjugates, could be used in various types of cancers. Since we are only beginning our Phase 1 clinical trial, there can be no guarantee that TH1902 will yield positive results when administered into humans and, even if successful, by the time we enter the market, there may be approved medicines that would directly compete with our peptide-drug conjugates. Despite the potential competition in this field, we believe that cancer resistance will not be eradicated and that there will be patients in need of our peptide-drug conjugates, if approved.

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

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*® and Trogarzo® 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*® and Trogarzo® 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*® and Trogarzo® 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*® and/or Trogarzo®), 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, 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*® and Trogarzo® 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.

***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*®, as well as WuXi, the manufacturer of Trogarzo®, 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.

Similarly to the U.S., in the European Union, both marketing authorization holders and manufacturers of medicinal products must comply with European Union GMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union. In addition, importers are responsible to ensure that the third country manufacturer complies with GMP. The manufacturing process for medicinal products in the European Union is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. In the European Union, national competent authorities are responsible for inspecting manufacturing sites located within their own territories. Manufacturing sites outside the European Union are inspected by the national competent authority of the Member State where the European Union importer is located, unless a mutual recognition agreement, or MRA, is in place between the EU and the country concerned. If an MRA applies, the authorities mutually rely on each other's inspections. After inspecting a manufacturing site, EU competent authorities issue a GMP certificate or a non-compliance statement, which is entered in the EudraGMDP database. In the context of the Covid-19 pandemic, for sites in the EEA, GMP certificates and time-limited manufacturing and import authorizations are automatically extended until the end of 2021. This does not waive manufacturers' and importers' obligations to comply with GMP standards. For new sites and facilities within and outside the EEA that have not been inspected or where an inspection is required, a remote inspection by the relevant competent authorities may be carried out pending the resumption of onsite inspections.

***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.

Similarly, in the European Union, the conduct of clinical trials is governed by Directive 2001/20/EC which imposes obligations and procedures that are similar to those in the United States. The European Union Good Clinical Practice rules and European Union Good Laboratory Practice obligations must also be respected during conduct of the trials. Clinical trials must be approved by the competent regulatory authorities and the competent Ethics Committees in the EU Member States in which the clinical trials take place. All entities conducting clinical trials in the European Union will be required to comply with the requirements of the new EU Clinical Trials Regulation (Regulation (EU) No 536/2014), which is due to come into application in 2021. The new EU Clinical Trials Regulation, which will replace the EU Clinical Trials Directive, including national legislation that was put in place to implement the Directive, introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the European Union, including a new coordinated procedure for authorization of clinical trials that is reminiscent of the mutual recognition procedure for marketing authorization of medicinal products, and an increased obligation on sponsors to publish clinical trial results. This will be carried out via a Clinical Trials Information System, or CTIS. CTIS will contain the centralized EU portal and database for clinical trials envisaged by the Regulation and will be used by clinical trial sponsors as a single-entry point in the EU to obtain approval for clinical trials based on applications and for monitoring clinical trials during their life cycle, including the submission of summary of results. The EMA will set up and maintain CTIS, in collaboration with the Member States and the European Commission. The timing of the Regulation's application is dependent on confirmation of full functionality of CTIS through an independent audit and it is anticipated that the CTIS will go live in December 2021. Once launched, CTIS will be immediately available for authorities and clinical trial sponsors, while a three-year phased transition period from the current Directive 2001/20/EC to the Regulation will apply. The authorization and oversight of clinical trials remains the responsibility of Member States, with the EMA managing CTIS and supervising content publication on the EMA's website.

## 2.9 PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the United States and in other countries, sales of *EGRIFTA SV*® and Trogarzo® 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*® and Trogarzo®. *EGRIFTA SV*® and/or Trogarzo® 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*® and/or Trogarzo® 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 has been delayed pursuant to a final rule issued by CMS on November 19, 2021. 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.

**European Union**

In the European Union, sales of Trogarzo® will depend in part on the availability and level of reimbursement from third-party payors. Third-party payors can be public or private or a combination of both. In order to obtain public reimbursement, prescription drugs are often evaluated by specialized bodies in a country. This process is in many cases independent of marketing approval and the time to carry out the evaluation differs in each country, often extending beyond the initial regulatory approval date of the drug.

The requirements and aspects considered during the assessment of a new prescription drug are not necessarily the same in each EU Member State and are given different weight depending on the EU Member States' attitudes towards providing public healthcare and the government's willingness to pay for these new drugs. We could be required to conduct specific health economic and other studies or analyses in order to satisfy such requirements. The decision to comply with such requirements will depend on the prospects of obtaining a positive opinion and the costs involved in the process and the profitability of the market.

In the European Union, the requirements governing drug pricing vary widely from country to country. In many EU Member States, pricing plays an important role in the evaluation of prescription drugs for reimbursement and in most cases, there are price controls that can include, but are not limited to, reference pricing to drugs sold within the EU Member States and in other EU Member States, the evaluation of what a fair price would be based on the condition that is being treated and the innovative quality of the new drug.

The sole legal instrument at the European Union level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC, or Price Transparency Directive. The aim of the Price Transparency Directive is to ensure that pricing and reimbursement mechanisms established in EU Member States are transparent and objective, do not hinder the free movement and trade of medicinal products in the European Union and do not hinder, prevent or distort competition on the market. The Price Transparency Directive does not, however, provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual EU Member States. Neither does it have any direct consequence for pricing or levels of reimbursement in individual EU Member States. The national authorities of the individual EU Member States are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Individual EU Member States adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other EU Member States adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market, including volume-based arrangements and reference pricing mechanisms. Further, an increasing number of EU Member States use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States. These countries include France, Germany and Sweden. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the

healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA will often influence the pricing and reimbursement status for specific medicinal products within individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of a specific medicinal product varies between the EU Member States.

The HTA process in the EU Member States was previously solely governed by the national laws of these countries. However, in November 2021, the EU Parliament adopted Regulation (EU) 2021/2282) on HTA, or HTA Regulation. The HTA Regulation came into force in January 2022 and will become applicable from January 2025. The purpose of the HTA Regulation is to create a more harmonised mandatory approach to HTA, involving permanent co-operation between national HTA authorities. The three-year delayed application period aims to ensure that there is enough time to set up the organisational framework of the HTA Regulation and to adopt the implementing and delegated acts and methodological guidance documents provided for by the HTA Regulation. The delayed application will also give Member States time to adjust their national HTA legislation and processes to the new HTA Regulation as needed, and stakeholder organisations, in particular health technology developers, will have time to familiarise and comply with the requirements of the new framework.

## 2.10 INTELLECTUAL PROPERTY

As further described below, tesamorelin, the active ingredient comprising *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 and ten (10) years of market exclusivity in the European Territory. 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 2023;
- In the United States, we have the exclusive right to two patents that claim a method for the treatment of NAFLD or NASH in a patient via the administration of tesamorelin. These patents are 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; and
- We have also filed additional patent applications related to the bioequivalence of certain formulation of tesamorelin to the original formulation of *EGRIFTA*®.

*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 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 being 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; and

- We own a PCT patent application filed in December 2020 that relates to formulations made with peptides and conjugates in respect of the SORT1+ Technology™ platform, from which patent applications may be pursued in numerous jurisdictions. Such applications, if granted, would be scheduled to expire in 2040.

***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® benefits from twelve (12) years of market exclusivity in the United States.

In Europe, regulatory data exclusivity is independent of a product's patent position. Under the community code for medicinal products (*Directive 2001/83/EC (as amended) and Regulation (EC) 762/2004*), new medicinal products are entitled to eight years regulatory data exclusivity from the date on which the product is granted a marketing authorization in the European Union. During that period, generic applicants cannot file applications referring to the innovator's safety and efficacy data. At the end of that eight-year period, generic or biosimilar applicants may file and the competent authorities may review applications, however, the innovator is granted a further two years of market exclusivity before any approved generic or biosimilar product may be placed on the market. This period of market exclusivity can be extended by a further year if a new therapeutic indication that provides a significant clinical benefit is approved during the first eight years of data exclusivity.

*Regulation (EC) No. 141/2000 (as amended*), or Orphan Regulation, contains additional data exclusivity provisions for "orphan medicinal products". These are products intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union; or that without incentives is unlikely to generate sufficient return to justify the necessary investment needed for its development. An orphan designation can be granted only if there is no satisfactory method of diagnosis, prevention or treatment of the condition authorized in the European Union, or if the product will be of significant benefit.

If a medicine is approved as a designated orphan medicine, the product will benefit from 10 years' market exclusivity, from date of receipt of a marketing authorization from the European Commission, during which regulators cannot accept applications for similar medicinal products for the same indication, unless they offer a significant clinical benefit (i.e., in terms of safety or efficacy). To benefit from market exclusivity, a medicine must maintain its orphan designation at the time of marketing authorization. A medicine that has multiple orphan designations for different conditions will benefit from separate market exclusivity periods pertaining to its different orphan designations. To benefit from market exclusivity, a medicine must maintain its orphan designation at the time of marketing authorization. Article 8(2) of the Orphan Regulation establishes the possibility for Member States to request that the market exclusivity be reduced from ten to six years, under certain circumstances. Article 8(3) of the Orphan Regulation describes three types of derogations from the market exclusivity provided to orphan medicinal products where a marketing authorization may be granted, for the same therapeutic indication, to a similar medicinal product: (a) consent of the original marketing authorization holder; (b) inability of the original marketing authorization holder to supply sufficient quantities; and (c) the second medicinal product is safer, more effective or otherwise clinically superior.

The European Medicine Agency's CHMP may issue the marketing authorization/extension to the marketing authorization, in circumstances where the CHMP conclude that the marketing authorization application is not similar to an authorized orphan medicinal product or if similar, that one of the derogations provided for in the Orphan Regulation claimed by the applicant applies, provided that the marketing authorization applicant can prove the quality, safety and efficacy of the medicinal product. However, if the CHMP conclude that the applicant product is similar to an authorized orphan medicinal product and none of the derogations apply, the CHMP will make a recommendation to refuse the marketing authorization /extension to the marketing authorization, irrespective of the quality, safety or efficacy of the medicinal product. The 10-year period of market exclusivity of an approved orphan product does not preclude a second, similar product, which has been authorized by way of derogation under Article 8(3) of the Orphan Regulation, to benefit from a new 10-year period of orphan market exclusivity, as long as it also fulfils the designation requirements set out in Article 3(1) of the Orphan Regulation. When the period of market exclusivity for an indication ends, the orphan designation for that indication expires

and the European Commission removes it from the Community register of orphan medicinal products. Once all of the orphan designations associated with an approved medicine have expired or been withdrawn by the sponsor, the medicine ceases to be classified as an orphan medicine and no longer benefits from the orphan incentives.

The *Paediatric Regulation (EC) No. 1901/2006* also provides specific incentives for the development of products with paediatric indications. If a product is approved on the basis of a dossier that includes paediatric clinical trial data generated in accordance with an approved paediatric investigation plan, the applicant will benefit from one of two periods of exclusivity: (1) if the product is an orphan medicine, it will benefit from an additional two years of orphan drug exclusivity (i.e., a total of 12 years' orphan exclusivity); or (2) if the product is not an orphan medicine and is eligible for patent term extension (referred to as a supplementary protection certificate, or SPC) the patent term will be extended by six months. The paediatric-use marketing authorization, or PUMA, is a type of marketing authorization which applicants request for a medicinal product which is already authorized but is no longer covered by a patent or SPC and will be exclusively developed for use in children. This type of marketing authorization will cover the indication and appropriate formulation for the paediatric population and the development of this medicine in children will follow a paediatric investigation plan. Once issued, a PUMA will benefit from 10 years of market exclusivity (made up of 8 years data exclusivity and an additional two years marketing exclusivity) as an incentive for the development in children. The existing marketing authorization procedures including the centralised, Mutual Recognition Procedure, Decentralised Procedure, or national procedure are used for PUMA applications.

Trogarzo® benefits from ten (10) years of market exclusivity in the European Territory.

***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 licence 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*® and Trogarzo®.

*SORT1+ Technology*™ 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, 2021, we had 70 employees in Canada, four employees in the United States and 13 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, 2021, we had an additional 48 persons dedicated to the commercialization of *EGRIFTA SV*® and Trogarzo® in the United States and seven persons dedicated to the commercialization of Trogarzo® in the European Territory.

## 2.12 FACILITIES

Our head office is located at 2015 Peel Street, 11th Floor, in the City of Montreal, Québec, Canada where we lease a 15,000 square-foot office space. We conduct our European activities from premises located at 2 Hume Street, 4th Floor, Dublin 2, Ireland, where we lease a 1,765 square-foot office space.

We also conduct some of our research and development activities at laboratories leased from the Université du Québec à Montréal, in Montreal, Canada.

## 2.13 ENVIRONMENT

To our knowledge, environmental issues do 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

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 COVID-19 PANDEMIC

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

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

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

- patients' limited access to the Corporation's treatments and products;
- diversion of healthcare resources prioritizing the treatment of patients suffering from COVID-19;
- delays or difficulties in enrolling patients in the Corporation's clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials;
- interruption of key clinical trial activities;
- risk that participants enrolled in the Corporation's clinical trials will acquire COVID-19 while the clinical trial is ongoing;
- limitations in employee resources that would otherwise be focused on the commercialization of the Corporation's products and the conduct its clinical trials;
- delays in receiving authorizations from regulatory authorities to approve a drug candidate or to initiate the Corporation's planned clinical trials;

- delays in clinical sites receiving the supplies and materials needed to conduct the Corporation's clinical trials;

- changes in local regulations as part of a response to the COVID-19 pandemic which may require the Corporation to change the ways in which its clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether;

- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;

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

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

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

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

## 3.2 RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS

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

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

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

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

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

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

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

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

- to maintain conflict-free relationships with our principal third-party suppliers of services, namely our agent in the United States and in the European Union (Syneos), our manufacturers, (TaiMed and Jubilant),

our distributor in the United States (RxCrossroads) and in Europe (Loxxess), as well as other specialized third parties; and

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

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

- the capacity of Syneos, in collaboration with us, to retain qualified, motivated and talented sales representatives and other key individuals instrumental in the commercialization of our products; and
- the capacity of our third-party suppliers to comply with all laws and regulations applicable to the conduct of their respective businesses.

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

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

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

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

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

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

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

We do not own or operate manufacturing facilities for the production of *EGRIFTA SV*® and tesamorelin, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on

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

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

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

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

Part of our commercial team in the United States and in the European Territory dedicated to the commercialization of our products in these territories is provided by Syneos. In the United States, after March 14, 2022, Syneos will continue to provide us with services related to managed market and certain functions supporting our medical team

in connection with the commercialization of our products. In Europe, Syneos provides us with medical science liaison personnel. Although we are aware that there exists other third-party services providers that could provide the same services as Syneos, we have not entered into any agreements with them nor conducted any audit on them. If we need to find another third-party service provider for some or all of the services provided by Syneos, it will be time-consuming and will be disruptive to our business. In addition, there can be no assurance that we will be able to find such third-party service provider if we are unable to agree on the terms and conditions of an agreement with them.

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

Our reliance on single third-party service providers for each of our core business activities exposes us to a number of risks. For instance, we may be subject to delays in, or suspension of, the manufacturing of *EGRIFTA SV*® and Trogarzo® if a third-party manufacturer:

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

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

- RxCrossroads or Loxxess becomes unavailable to us for any reason, including as a result of its failure to meet applicable laws;
- RxCrossroads or Loxxess experiences warehousing problems or other operational failure, such as unplanned facility shutdown or damage from any event, including fire, flood, earthquake, business restructuring or insolvency; or
- RxCrossroads or Loxxess fails to perform its contractual obligations under our agreement.

We may be subject to a decrease in sales of our products in the United States or in the European Territory or we may face reimbursement challenges if Syneos:

- becomes unavailable to us for any reason, including as a result of its incapacity to motivate and retain the employees working on the commercialization of *EGRIFTA SV*® and/or Trogarzo®;
- experiences compliance issues with the FDA or the EMA; or
- fails to perform its contractual obligations under our agreement.

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

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

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

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

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

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

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

Even if Trogarzo® is reimbursed, in EU Member States, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment in the European Union. Certain of these changes could impose limitations on the prices we will be able to charge for Trogarzo® or the amounts of reimbursement available for Trogarzo® from governmental agencies or third-party payors. Further, an increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as "reference prices"

to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our potential revenues and profitability from Trogarzo®. Moreover, in order to obtain reimbursement for Trogarzo® in some EU Member States, we may be required to conduct clinical trials that compare the cost-effectiveness of Trogarzo® to other available therapies. There can be no assurance that Trogarzo® will obtain favorable pricing and reimbursement status in any EU Member States.

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

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

- demonstrated product safety, including the prevalence and severity of side effects, and effectiveness as a treatment that addresses a significant unmet medical need;
- storage requirements, dosing regimen and ease of administration;
- the availability of competitive alternatives;
- our ability to obtain and maintain sufficient third-party coverage for reimbursement from government health care programs, including U.S. Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness and ability of patients to pay out-of-pocket for medications;
- the product price; and
- the effectiveness of sales and marketing efforts.

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

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

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

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

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

## 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.***

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

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

The Corporation held discussions with the FDA and the EMA to finalize its Phase 3 clinical trial design, which discussions concluded in July 2021. As a result of such discussions, the trial design will result in higher costs than what the Corporation had previously estimated. The Corporation has decided to postpone the initiation of its Phase

3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population until it can secure additional resources to execute its program and has initiated a search to find a partner for that purpose.

There can be no guarantee that the Corporation will be able to initiate its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH if it is unable to secure substantial additional resources, either from a financing, a partnership or other means that it could resort to. In addition, the Corporation may not be able to find a partner to help with securing additional resources. Even if the Corporation finds a partner, the terms and conditions pursuant to which such partner may be interested in assisting the Corporation may not be suitable to the Corporation or may be unfavorable. Under such circumstances, the Corporation may decide to forego the search of a partner and turn to alternative sources of financing. If the Corporation is unable to secure additional resources, it may further postpone the initiation of its Phase 3 clinical trial until it can secure additional resources, review and amend its current protocol to reduce the costs associated with the study of tesamorelin for the potential treatment of NASH, or may cancel its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population. If the Corporation is unable to, or does not proceed with, the development of tesamorelin for the treatment of NASH in the general population, it could have a material adverse effect on its potential long-term revenues, growth and prospects.

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

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

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

***The development of TH1902 for the potential treatment of various types of sortilin-expressing cancers is still uncertain since results obtained from preclinical in vivo development work may not translate into human subjects. The goal of the Phase 1 clinical trial evaluating TH1902 is to determine the MTD that can be administered to human subjects and determine if any adverse side effects will be observed from the injection of TH1902 in human subjects. If the Corporation is unable to demonstrate similar results as obtained from its preclinical work, or if patients enrolled in the clinical trial are subject to serious adverse side effects, the***

***Corporation may have to discontinue its Phase 1 clinical trial. Any interruption or halt in the Corporation's Phase 1 clinical trial would materially adversely affect the development of its SORT1+ Technology™ platform, reduce its pipeline of drug candidates and could materially adversely affect its long-term growth and prospects.***

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

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

***We will require substantial capital to pursue the development of our product pipeline, including the conduct of our Phase 3 clinical trial for the development of tesamorelin for the treatment of NASH in the general population and the development of TH1902 in various types of cancer. If we are unable to generate cash flow from our commercial operations or are unable to access capital if, and when, needed, we may have to delay, suspend or cancel our Phase 3 clinical trial, Phase 1 clinical trial or the development of any of our product candidates, the result of which would have a material adverse effect on our long-term growth, potential revenue growth and our business prospects.***

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

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

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

types of cancer, we could have to enroll a large number of patients. Such a Phase 2 clinical trial could be very expensive and require capital.

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

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

The beginning or completion of clinical trials may be delayed or prevented for several reasons, including, among others:

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

In addition, clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. A sponsor may decide to suspend or terminate its clinical trial, or regulatory agencies could order a sponsor to do so for several reasons, including, among others:

- Failure to conduct the clinical trial in accordance with the regulatory requirements of a sponsor's study protocol; and
- Inspections of the clinical study operations or study sites by regulatory agencies that would reveal deficiencies or violations requiring a sponsor to undertake corrective actions (to the extent any are available).

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

***Regulatory agencies have not approved the F8 Formulation as being bioequivalent to the Corporation's original formulation of EGRIFTA®. Under such circumstances, the Corporation may have to conduct additional clinical studies to prove the bioequivalence of the F8 Formulation against the original formulation, resulting in additional spending and delays in the use of the F8 Formulation.***

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

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

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

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

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

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

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

## 3.4 RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

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

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

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

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

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

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

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

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

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

able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property and to compete with us.

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

## 3.5 REGULATORY RISKS

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

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

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

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

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal healthcare program's anti-kickback law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FFDCA and similar laws regulating advertisement and labeling; and
- European Union's, EU Member States' and U.S. States' law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

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

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

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

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

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

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

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

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

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

## 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:

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

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

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

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

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

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

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

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

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

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

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

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

As at November 30, 2021, we had negative operating cash flow of US$14,477,000. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay investments and capital expenditures, seek additional capital or restructure or refinance our debt. These measures may not be successful and may not permit us to meet our scheduled debt service obligations. In the absence of such cash flows and resources, we could face substantial liquidity problems and we could have to resort to insolvency laws to seek protection from our creditors.

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

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

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

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our key employees and on our ability to be able to attract, retain and motivate qualified commercial, managerial and scientific personnel. We have entered into employment agreements with our executive officers and provided them, as well as to other key employees, with long-term incentives as a retention mechanism, but such agreements and incentives do not guarantee that our executive officers and other key employees will remain employed by us for any significant period of time, or at all. In addition, we have a limited workforce to pursue our business plan and the loss of any of our key employees could materially adversely affect our business. Our third-party service provider, Syneos, has hired qualified individuals to assist us with the commercialization of *EGRIFTA SV*® and Trogarzo® in the United States. Syneos has also hired, amongst others, medical science liaison personnel in the European Territory. Although these individuals are not our employees, the loss of any of those individuals and the inability of Syneos to attract and retain these individuals could have a material adverse effect

on the commercialization of *EGRIFTA SV*® and Trogarzo®, and, accordingly, our business, financial condition and operating results. In addition, it could adversely affect the market price of our common shares.

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

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

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

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

The preparation of our consolidated financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, our management evaluates our critical and other significant estimates and assumptions, including among others, those associated with revenue and deferred revenue, stock option plan, income taxes, and contingent liabilities such as clinical trial expenses, recoverability of inventories, recoverability of tax credits and grants receivable and capitalization of development expenditures. Any significant differences between our actual results and our estimates and assumptions could negatively impact our reported financial position, operating results and cash flows.

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

Pursuant to the Corporation's accounts and revenue recognition policies, the product revenue recognized quarter over quarter by the Corporation is net of estimated allowances for discounts, returns, rebates and chargebacks, including potential clawbacks in certain jurisdictions when pricing terms are based on temporary use 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.

***If we identify a material weakness in our internal controls over financial reporting, our ability to meet our reporting obligations and the trading price of our common shares could be negatively affected.***

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under Canadian securities laws to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we determine that our internal controls over our financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial results, and the price of our common shares could be negatively affected.

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

## 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.***

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

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

Our revenues and expenses have fluctuated in the past and are likely to do so in the future. These fluctuations could cause our share price to decline. Some of the factors that could cause revenues and expenses to fluctuate include the following:

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

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

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

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

turn could cause our share price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

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

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

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

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

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

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

## ITEM 4 DIRECTORS AND EXECUTIVE OFFICERS

### 4.1 DIRECTORS

The table below sets forth the following information about our directors as of February 23, 2022: 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: 67
Norristown,
Pennsylvania, USA

**Independent**

**Director since:**
May 13, 2021

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

**Other Directorship:**
None

| **Principal Occupation** | Corporate Director |
|---|---|

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$) |
|---|---|---|---|---|
| 7,500 | Nil | 14,170 | Nil | Nil |

**Committees of the Board of Directors**

Nil

**Frank A. Holler**
Age: 65
Summerland, B.C., Canada

**Independent**

**Director since:**
June 23, 2021

**Areas of Expertise:**
- Corporate Finance
- Life Sciences
- Management

**Other Directorship:**
Sernova Corp.; and Harvest One Cannabis Inc.

| **Principal Occupation** | President and CEO, Ponderosa Capital Inc. |
|---|---|

Frank A. Holler was appointed to the Board of Directors in June 2021.

He is currently the President & CEO of Ponderosa Capital Inc. He previously served as Chairman & CEO of BC Advantage Funds (VCC) Ltd., a venture capital firm investing in emerging technology companies in British Columbia.

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.

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).

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.

Mr. Holler holds an MBA and BA (Economics) from the University of British Columbia.

**Securities Held or Controlled**

| Common Shares (#) | DSU (#) | Options (#) | Warrants (#) | Notes (US$) |
|---|---|---|---|---|
| Nil | Nil | 14,170 | Nil | Nil |

**Committees of the Board of Directors**

Member of Audit Committee

**Gérald A. Lacoste**
Age: 78
Ste-Adèle,
Québec, Canada

**Independent**

**Director since:**
February 8, 2006

**Areas of Expertise:**
- Securities and Market Regulations
- Corporate Governance
- Mergers & Acquisitions

**Other Directorship:**
None

| **Principal Occupation** | Corporate Director |
|---|---|

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.

**Securities Held or Controlled**

| Common Shares (#) | DSU (#) | Options (#) | Warrants (#) | Notes (US$) |
|---|---|---|---|---|
| 100,000 | 21,936 | 84.174 | Nil | 45,000 |

**Committees of the Board of Directors**

Chair of Nominating and Corporate Governance Committee
Member of Audit Committee

**Paul Lévesque**
Age: 58
Westmount, Québec, Canada

**Non-independent**

**Director since:**
April 6, 2020

**Areas of Expertise:**
- Pharmaceutical Industry
- Sales and Marketing
- Management
- Human Resources

**Other Directorship:**
None

| **Principal Occupation** | President and Chief Executive Officer of the Corporation |
|---|---|

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.

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.

He also assumed the role of Global President and General Manager for the Rare Disease Unit until he joined Theratechnologies on April 6, 2020.

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.

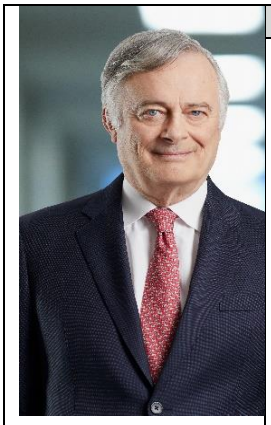
Paul holds a BSc in biochemistry from Laval University and a Diploma in Management from McGill University.

**Securities Held or Controlled**

| Common Shares (#) | DSU (#) | Options (#) | Warrants (#) | Notes (US$) |
|---|---|---|---|---|
| 111,200 | Nil | 1,134,728 | 20,000 | Nil |

**Committees of the Board of Directors**

N.A.



**Gary Littlejohn**
Age: 66
Lac-Tremblant-Nord, Québec, Canada

**Independent**

**Director since:**
October 15, 2018

**Areas of Expertise:**
Capital Markets
Corporate governance
Corporate Finance
Risk Management

**Other Directorship:**
None

| **Principal Occupation** | Corporate Director |
|---|---|

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.

**Securities Held or Controlled**

| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
|---|---|---|---|---|
| 19,060 | 6,850 | 46,928 | Nil | Nil |

**Committees of the Board of Directors**

Chair of Compensation Committee
Member of Audit Committee

**Dale MacCandlish Weil**
Age: 66
Baie d'Urfé,
Québec, Canada

**Independent**

**Director since:**
May 16, 2017

**Areas of Expertise:**
- Healthcare Industry
- Commercialization of products
- Management
- Strategic Planning

**Other Directorship:**
Tetra Bio-Pharma Inc.

| **Principal Occupation** | Corporate Director |
|---|---|

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.

**Securities Held or Controlled**

| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
|---|---|---|---|---|
| 31,840 | 5,531 | 69,174 | Nil | 2,000 |

**Committees of the Board of Directors**

Member of Nominating and Corporate Governance Committee

**Andrew Molson**
Age: 54
Westmount, Québec, Canada

**Independent**

**Director since:**
October 15, 2020

**Areas of Expertise:**
- Communications
- Governance

**Other Directorship:**
Molson Coors Beverage Company;
Dundee Corporation

| **Principal Occupation** | Corporate Director |
|---|---|

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.

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.

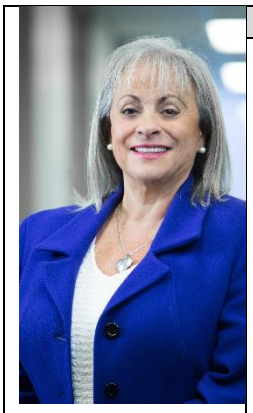
Mr. Molson holds a Bachelor of Laws from Laval University (Quebec City). He also holds a Bachelor of Arts from Princeton University and a Master of Science in corporate governance and ethics from University of London (Birkbeck College).

**Securities Held or Controlled**

| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
|---|---|---|---|---|
| 30,000 | Nil | 27,428 | Nil | Nil |

**Committees of the Board of Directors**

Nil



**Dawn Svoronos**
Age: 68
Hudson,
Québec, Canada

**Independent Director since:**
April 8, 2013

**Areas of Expertise:**
- Pharmaceutical Industry
- Commercialization of Drug Products

**Other Directorship:**
Xenon Pharmaceuticals Inc.;
PTC Therapeutics, Inc.;
Global Blood Therapeutics, Inc.;
Adverum Biotechnologies, Inc.

| **Principal Occupation** | Corporate Director – Chair of the Board of the Corporation |
|---|---|

Ms. Dawn Svoronos worked in the commercial side of the business for the multinational pharmaceutical company Merck & 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 four other public companies: Xenon Pharmaceuticals Inc. in British Columbia, Canada, PTC Therapeutics, Inc. in New Jersey, U.S.A., Global Blood Therapeutics, Inc. in San Francisco, California, and Adverum Biotechnologies, Inc. in Redwood City, California.

**Securities Held or Controlled**

| Common Shares (#) | DSU (#) | Options (#) | Warrants (#) | Notes (US$) |
|---|---|---|---|---|
| 273,600 | 855 | 134,174 | Nil | Nil |

**Committees of the Board of Directors**

Member of Compensation Committee
Member of Nominating and Corporate Governance Committee

**Alain Trudeau**
Age: 62
Montréal, Québec, Canada

**Independent**

**Director since:**
October 15, 2020

**Areas of Expertise:**
- Accounting
- Finance
- Governance

**Other Directorship:**
None

| **Principal Occupation** | Corporate Director |
|---|---|

A fellow of the Quebec Chartered Professional Accountant Order, Alain Trudeau has had a distinguished career at Ernst & 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.

He currently serves on the board of directors of the Montréal Inc. Foundation, the Institut de médiation et d'arbitrage du Québec (IMAQ) and Blue Bridge Trust Company Inc.

From 2008 to 2019, Mr. Trudeau was a lecturer at the Collège des administrateurs de sociétés de l'Université Laval in Quebec City.

Mr. Trudeau holds a Bachelor of Arts in Accounting from HEC Montréal.

**Securities Held or Controlled**

| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
|---|---|---|---|---|
| 19,300 | 14,131 | 27,428 | 2,500 | Nil |

**Committees of the Board of Directors**

Chair of Audit Committee
Member of Compensation Committee

## 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, 2021, 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.

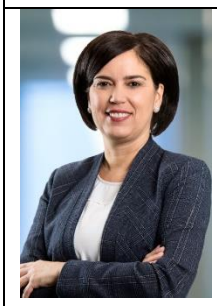
**Gérald A. Lacoste.** Mr. Lacoste has more than 30 years of experience in the fields of securities regulation, corporate finance and corporate governance. Mr. Lacoste was president of the audit committee of Amisco Ltd. from 2002 to 2009 and was also a member of the audit committee of Andromed Inc. from 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 23, 2022: 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.

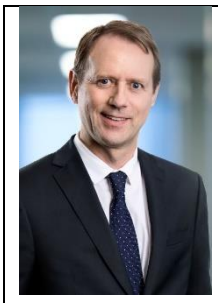


**Marie-Noël Colussi**
Age: 53

**Executive since:**
May 9, 2002

Laval, Québec, Canada

| **Principal Occupation** | | | Vice President, Finance | |
|---|---|---|---|---|
| Ms. Marie-Noël Colussi is a graduate of the *Université du Québec à Montréal* 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. | | | | |
| | **Securities Held or Controlled** | | | |
| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
| 11,075 | 3,182 | 238,092 | Nil | 10,000 |



**Philippe Dubuc**
Age: 55

**Executive since:**
February 24, 2016

Montreal, Québec, Canada

| **Principal Occupation** | Senior Vice President and Chief Financial Officer |
|---|---|

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&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.

| | **Securities Held or Controlled** | | | |
|---|---|---|---|---|
| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
| 31,000 | Nil | 558,414 | 1,500 | 25,000 |

**André Dupras**
Age: 58

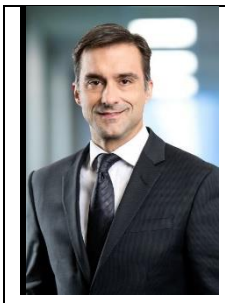
**Executive since:**
May 31, 2021

Mont-Tremblant, Québec, Canada

| **Principal Occupation** | Vice President, Human Resources |
|---|---|

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.
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).

| | **Securities Held or Controlled** | | | |
|---|---|---|---|---|
| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
| Nil | Nil | 141,404 | Nil | Nil |



**Jocelyn Lafond**
Age: 54

**Executive since:**
April 16, 2007

Montreal, Québec, Canada

| **Principal Occupation** | General Counsel and Corporate Secretary |
|---|---|

Mr. Lafond has over 20 years of experience in the fields of corporate and securities law. Mr. Lafond holds a law degree from the *Université Laval* and a Masters Degree in Law from the University of Toronto. He has been a member of the *Barreau du Québec* since 1992. Prior to joining us in 2007, Mr. Lafond was a partner with the international law firm of Fasken Martineau DuMoulin LLP.

| | **Securities Held or Controlled** | | | |
|---|---|---|---|---|
| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
| 18,000 | 5,000 | 434,857 | Nil | 8,000 |

**John Leasure**
Age: 57

**Executive since:**
March 29, 2021

Underhill, Vermont, USA

| **Principal Occupation** | Global Commercial Officer |
|---|---|

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.

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.

He holds a B.A., Business from Gettysburg College in Pennsylvania.

| | **Securities Held or Controlled** | | | |
|---|---|---|---|---|
| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
| 5,000 | Nil | 154,848 | Nil | Nil |

**Christian Marsolais**
Age: 59

**Executive since:**
May 7, 2007

Town of Mount Royal, Québec, Canada

| **Principal Occupation** | 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 *EGRIFTA*® 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.

| | **Securities Held or Controlled** | | | |
|---|---|---|---|---|
| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
| 59,297 | 6,312 | 680,373 | Nil | 15,000 |

**Conor Walshe**
Age: 48

**Executive since:**
March 19, 2019

Rathmines, Ireland

| **Principal Occupation** | General Manager, Theratechnologies Europe Limited |
|---|---|

Mr. Walshe is based at the Theratechnologies European head office in Dublin, Ireland. Prior to joining our European subsidiary, Mr. Walshe was General Manager and Vice President, Operations and Commercial, at Aralez Plc. Prior to Aralez Plc, Mr. Walshe spent more than 15 years in the pharmaceutical industry including at Perrigo Plc, Elan Plc and Venn Life Sciences where he was called upon to serve, among others, as CFO, Senior Vice President Commercial and Financial Operations and in product management. Mr. Walshe is a Chartered Accountant. He holds a Bachelor of Commerce and a Master in Business Studies from the University College in Dublin. He also obtained a diploma in IFRS from the Institute of Chartered Accountants and in Advanced International Corporate Finance from INSEAD.

| | **Securities Held or Controlled** | | | |
|---|---|---|---|---|
| **Common Shares (#)** | **DSU (#)** | **Options (#)** | **Warrants (#)** | **Notes (US$)** |
| Nil | Nil | 223,333 | Nil | Nil |

## 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 23, 2022, or has been within the ten (10) years before February 23, 2022, 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 23, 2022, 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 23, 2022, the total number of common shares (the only securities carrying a voting right) held by our directors and executive officers amounted to 716,872, which represented 0.75% of our outstanding common shares.

## ITEM 5 INTERESTS OF EXPERTS

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, 2021 and 2020:

| **Fees** | **Fiscal Year Ended November 30, 2021 (CA$)** | **Fiscal Year Ended November 30, 2020 (CA$)** |
|---|---:|---:|
| Audit Fees[(1)] | 639,382 | 497,667 |
| Audit-Related Fees[(2)] | 48,943 | 89,175 |
| Tax Fees[(3)] | 170,027 | 54,563 |
| **Total:** | **858,352** | **641,405** |

(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 and accounting consultations.

(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

### 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.

| | TSX | | | NASDAQ | | |
|---|---|---|---|---|---|---|
| **Period[(1)]** | **High (CA$)** | **Low (CA$)** | **Volume** | **High (US$)** | **Low (US$)** | **Volume** |
| **2020** | | | | | | |
| December | 3.23 | 2.68 | 1,780,000 | 2.54 | 2.09 | 2,810,000 |
| **2021** | | | | | | |
| January | 4.16 | 2.72 | 4,910,000 | 3.25 | 2.13 | 7,880,000 |
| February | 4.13 | 2.82 | 6,660,000 | 3.25 | 2.20 | 25,200,000 |
| March | 4.98 | 3.67 | 3,670,000 | 3.99 | 2.92 | 7,490,000 |
| April | 5.34 | 4.18 | 1,590,000 | 4.25 | 3.35 | 3,670,000 |
| May | 4.60 | 4.02 | 775,359 | 3.82 | 3.27 | 2,140,000 |
| June | 4.83 | 4.18 | 744,182 | 3.95 | 3.4834 | 1,950,000 |
| July | 4.85 | 4.12 | 1,220,000 | 3.9599 | 3.2181 | 3,730,000 |
| August | 4.60 | 4.00 | 721,528 | 3.68 | 3.18 | 2,930,000 |
| September | 5.61 | 4.45 | 905,298 | 4.46 | 3.46 | 5,130,000 |
| October | 4.79 | 4.24 | 399,290 | 3.79 | 3.36 | 1,890,000 |
| November | 4.62 | 4.01 | 766,060 | 3.65 | 3.16 | 2,160,000 |
| December | 4.30 | 3.77 | 604,435 | 3.37 | 2.90 | 2,460,000 |
| **2022** | | | | | | |
| January | 3.95 | 3.47 | 683,135 | 3.10 | 2.77 | 2,070,000 |
| February (to February 22) | 4.14 | 3.61 | 313,887 | 3.26 | 2.85 | 1,260,000 |

(1) 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.

| | 5.75% Debentures[1] | | |
|---|---|---|---|
| **Period[2]** | **High (US$)** | **Low (US$)** | **Volume** |
| **2020** | | | |
| December | 75.00 | 61.10 | 223,000 |
| **2021** | | | |
| January | 83.00 | 80.00 | 52,000 |
| February | 89.00 | 80.00 | 175,000 |
| March | 91.00 | 82.00 | 338,000 |
| April | 90.50 | 82.00 | 165,000 |
| May | 91.00 | 88.00 | 344,000 |
| June | 91.00 | 87.50 | 11,000 |
| July | 92.00 | 91.00 | 221,000 |
| August | 96.00 | 91.00 | 48,000 |
| September | 92.00 | 88.00 | 91,000 |
| October | 91.50 | 87.50 | 55,000 |
| November | 91.75 | 87.50 | 51,000 |
| December | 92.00 | 88.50 | 63,000 |
| **2022** | | | |
| January | 88.50 | 85.10 | 43,000 |
| February (to February 22) | 85.00 | 85.00 | 19,000 |

(1) Price per US$100.00 principal amount of the 5.75% Notes.
(2) 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 |
|---|---|---|---|
| January 19, 2021 | Warrants[1] | US$3.18 | 8,363,950 |
| February 26, 2021 | Stock Options | CA$3.93 | 1,019,331 |
| February 26, 2021 | Stock Options | US$3.10 | 81,093 |
| February 26, 2021 | Deferred Stock Units[2] | CA$3.89 | 5,784 |
| July 27, 2021 | Stock Options | US$3.48 | 21,515 |
| July 27, 2021 | Stock Options | CA$4.32 | 38,500 |
| July 27, 2021 | Deferred Stock Units | CA$4.38 | 10,275 |
| October 15, 2021 | Deferred Stock Units | CA$4.38 | 6,850 |

(1) The Warrants were issued on January 19, 2021 and formed part of units issued by way of prospectus. Each unit was comprised of one common share and one-half of one common share purchase warrant, each whole warrant entitling the holder thereof to purchase one common share at a price of US$3.18 at any time until January 19, 2024.

(2) The deferred stock units are non-dilutive securities. They are redeemable for cash only.

## ITEM 8 LEGAL PROCEEDINGS

In the last financial year, we were not subject to any material legal proceedings and, as at February 23, 2022, we are not subject to any such material proceedings.

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.

Bachem Agreement

We are currently renegotiating the terms of our agreement with Bachem which has now expired. This agreement provides for the manufacturing and supply of the active pharmaceutical ingredient of tesamorelin for *EGRIFTA SV*® and for the conduct of clinical trials. Bachem is our only validated supplier of raw materials. Despite the ongoing renegotiation of this agreement, Bachem has indicated to us that it could manufacture lots of tesamorelin, if needed.

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*®. 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*® 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*® 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 1st, 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*® and Trogarzo® in the United States. Effective November 1st, 2019, we amended the amended and restated statement of work agreements to add *EGRIFTA SV*® 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.

H.D. Smith Agreement

On September 1st, 2014, we entered into a wholesaler services agreement with H.D. Smith LLC., or H.D. Smith Agreement, appointing H.D. Smith as a non-exclusive authorized wholesaler for *EGRIFTA*® in the United States, or H.D. Smith Agreement.

The H.D. Smith Agreement has a one-year term and automatically renews for subsequent one-year period unless a party provides the other with a prior written notice within a confidential time period prior to the termination or renewal period of the agreement. The H.D. Smith Agreement contains customary representations and warranties from parties, payment terms, indemnification provisions as well as termination provisions in the event of the occurrence of certain stated events.

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*® 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*® 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.

Morris & Dickson Agreement

On March 21, 2018, we entered into a drop ship services agreement with Morris & Dickson Co. LLC appointing it as a non-exclusive authorized wholesaler for *EGRIFTA*® in the United States, or M&D Agreement.

The M&D Agreement has a one-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 M&D 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.

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*® in the territory of Puerto Rico and the U.S. Virgin Islands, or Cesar Castillo Agreement. On November 1st, 2018, the Cesar Castillo Agreement was amended to add Trogarzo® as a product authorized to be distributed thereunder, and, on October 31, 2019, it was further amended to add *EGRIFTA SV*® 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® 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®. On December 18, 2019, we further amended the Accredo Agreement to add *EGRIFTA SV*® 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*®, or the Original Agreement. The Original Agreement appoints Accredo as a non-exclusive authorized purchaser of *EGRIFTA*®, contains a description of the services to be provided by Accredo in connection with the purchase and sale of *EGRIFTA*® 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®. 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® 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*® 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®, 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® 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*® 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®, indemnification, confidentiality and audit rights.

Loxxess Agreement

On July 9, 2020, our European subsidiary, Theratechnologies Europe Limited, entered into the Loxxess Agreement pursuant to which Loxxess agreed to act as our third-party service logistic provider for Trogarzo® in certain key European countries, including Germany, France, Italy, Austria, The Netherlands, Portugal, Switzerland, the United Kingdom, Norway, Sweden, Finland and Denmark. Loxxess has also indicated to us that it is capable of serving various additional countries, including Israel and Turkey. Pursuant to the Loxxess Agreement, Loxxess receives customers'orders, stores, packages and ships Trogarzo® to European hospitals and pharmacies. Loxxess is also responsible, on our behalf, to collect payments of the goods sold to those hospitals and pharmacies. The Loxxes Agreement contain customary representations and warranties, covenants, risk allocation provisions in respect of the activities carried out by Loxxes and indemnity provisions. The Loxxess Agreement has a one-year term and is scheduled to expire in July 2021 but renews automatically for additional one-year terms unless a party provides the other with a written notice within a certain period of time preceding the expiry of the term of its intent not to renew. Unless a party is in default under the terms of the Loxxess Agreement before the end of the term and such default is not cured within the period set forth in the Loxxess Agreement, or unless the parties decide not to renew the Loxxess Agreement, this agreement will be automatically renewed in July 2021 for an additional one-year term.

Syneos Agreement

On December 4, 2016, we entered into an amended and restated master services agreement with Syneos, as amended on February 3, 2020, providing for the main terms and conditions under which Syneos would provide us with services to commercialize *EGRIFTA SV*® (*EGRIFTA*® at the time) and Trogarzo® in the United States and

Trogarzo® in Europe. Each of those services has been described in specific project agreements. We have entered into project agreements relating to, amongst others, the provision of a sales force, medical science liaison and community liaison personnel, and reimbursement support personnel. 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, 2021, 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®*, 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®* 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.

WCT Agreement

On December 18, 2020, we entered into a master services agreement with WCT to define the terms and conditions pursuant to which we would retain the services of WCT to assist us with the conduct of our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the gensral population. The agreement provides for the entering of statements of work whenever services would be required from WCT. The agreement contains provisions relating to the quality of the services to be provided, covenants and undertakings of the parties in relation to services to be performed, customary representations and warranties, confidentiality, ownership of intellectual property and indemnification. The agreement has a three-year term and is scheduled to expire on December 18, 2023, subject to automatic renewal for one-year terms, unless a party provides the other with a written notice within a certain period of time preceding the expiry of the term of its intent not to renew.

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

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, 2021.

Additional information regarding our Company is available on SEDAR at www.sedar.com, or upon written request addressed to Jocelyn Lafond, General Counsel and Corporate Secretary, at 2015 Peel Street, 11th 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.