ANNUAL INFORMATION FORM
Financial Year Ended November 30, 2016

February 7, 2017

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*® (tesamorelin for injection) refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA* is our registered trademark in the United States and in Canada and it is used in those countries to commercialize tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. Other trademarks and service marks appearing in this AIF are the property of their respective holders.
- Tesamorelin refers to the use of our tesamorelin compound for the potential treatment of other diseases;
- Ibalizumab refers to a humanized monoclonal antibody being developed for the potential treatment of multidrug resistant HIV-1 infection;
- all monetary amounts set forth are expressed in Canadian dollars, except where otherwise indicated. References to "$" and "C$" are to Canadian dollars and references to "US$" are to U.S. dollars;
- all information is provided as of February 7, 2017, 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*® and ibalizumab;
- our ability and capacity to grow the sales of *EGRIFTA*® successfully in the United States and Canada;
- our ability and capacity to conduct the post-approval commitments mandated by the United States Food and Drug Administration;
- the ability of our commercial partners, sanofi, BL&H Co., Ltd, AOP Orphan Pharmaceuticals AG, Praxis Pharmaceutical S.A. and PRX Pharma Produtos Farmaceuticos Unipessoal, LDA to commercialize *EGRIFTA*® in Mexico, South Korea, certain European countries, Spain and Portugal;
- whether *EGRIFTA*® will be approved for commercialization in South Korea, Europe, Spain and Portugal, and the timing of obtaining such regulatory approvals;

- whether ibalizumab will be approved for commercialization by the United States Food and Drug Administration and the timing of obtaining such regulatory approval;
- our ability and capacity to continue the manufacture of *EGRIFTA*®;
- our ability and capacity to develop a new formulation for *EGRIFTA*®;
- 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 obtaining, and the timing and amount of, reimbursement by third-party payors for (i) *EGRIFTA*® in Mexico and in other territories; and (ii) ibalizumab in the United States;
- the success and pricing of other competing drugs or therapies that are or may become available;
- our ability to establish and maintain intellectual property rights in *EGRIFTA*®, Tesamorelin and our other product candidates;
- our ability and capacity to commercialize ibalizumab shortly after approval;
- our capacity to acquire or in-license a new product and/or compound;
- our expectations regarding our financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes; and
- our estimates regarding our capital requirements.

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

- sales of *EGRIFTA*® in the United States and Canada will increase over time;
- our commercial practices in the United States and Canada will not be found to be in violation of applicable laws;
- *EGRIFTA*® will receive approval in South Korea, Europe, Spain and Portugal;
- no additional clinical studies will be required to obtain regulatory approvals for *EGRIFTA*® in South Korea, Europe, Spain and Portugal;
- the long-term use of *EGRIFTA*® will not change the current safety profile of *EGRIFTA*®;
- no recall or market withdrawal of *EGRIFTA*® 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*® in the United States and/or Canada;
- continuous supply of *EGRIFTA*® will be available;
- our relations with third-party suppliers of *EGRIFTA*® will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply *EGRIFTA*® to meet market demand and on a timely-basis;

- our intellectual property will prevent any generic company to commercialize a generic form of *EGRIFTA*® in the United States;
- ibalizumab will be approved for commercialization by the United States Food and Drug Administration in 2017;
- our commercial infrastructure will be in place to launch ibalizumab rapidly, if and when approved;
- ibalizumab will be added to the list of reimbursed drugs by private and public payors in the United States, if and when approved for commercialization; 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 2016 AND OUTLOOK

The following summary highlights selected events and our business objectives described elsewhere in this AIF for the fiscal year 2017. 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

- We entered into a distribution and marketing agreement with TaiMed Biologics, Inc. in March 2016 pursuant to which we gained the exclusive right to commercialize and distribute ibalizumab in the United States and Canada;
- We entered into a distribution and licensing agreement with Praxis Pharmaceutical, S.A., or Praxis, in September 2016 pursuant to which we granted Praxis the exclusive right to commercialize and distribute *EGRIFTA*® in Spain; and
- We entered into a distribution and licensing agreement with PRX Pharma Produtos Farmacêuticos Unipessoal, LDA, or PRX, in September 2016 pursuant to which we granted PRX the exclusive right to commercialize and distribute *EGRIFTA*® in Portugal.

Regulatory Events

- Our partner, TaiMed Biologics, Inc. completed its pivotal Phase III trial using ibalizumab and released the primary endpoint results and the preliminary results of the safety and efficacy secondary endpoints of this Phase III trial; and
- Our partner, sanofi, obtained regulatory approval from COFEPRIS, Mexico's health agency, in March 2016 to commercialize *EGRIFTA*® in Mexico in its 1 mg/vial presentation.

Corporate Event

- In December 2016, we closed a public offering of 5,323,000 common shares at a price of $3.10 per common share for gross proceeds of $16,501,300.

2017 Business Objectives

- We will continue our commercialization activities related to *EGRIFTA*® in the United States and Canada with the aim of broadening our market and increasing sales;
- We will conduct pre-commercialization activities, develop our marketing plans and build on our current infrastructure in anticipation of the launch of ibalizumab in the United States in 2017;
- We will also look for acquisitions or in-licensing opportunities of products compatible with our expertise and our commercial platform.

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. 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, 5th 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 of February 7, 2017, Theratechnologies had the following three wholly-owned subsidiaries:

- **Theratechnologies Intercontinental Inc.**, a company governed by the *Business Corporations Act* (Québec). Theratechnologies Intercontinental Inc., formerly Theratechnologies ME Inc., controls 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.**, a company governed by the *Business Corporations Act* (Québec). Theratechnologies Europe Inc., formerly 9176-5057 Québec Inc., controls the rights to commercialize *EGRIFTA*® in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries; and

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

ITEM 2 OUR BUSINESS

2.1 OVERVIEW

We are a specialty pharmaceutical company addressing unmet medical needs to promote healthy living and an improved quality of life among HIV patients.

Our first product, *EGRIFTA*® (tesamorelin for injection), was approved by the FDA in November 2010 and was launched in the United States in January 2011. *EGRIFTA*® was also approved by Health Canada in its 1 mg/vial presentation in March 2015 and was launched in Canada in June 2015. COFEPRIS, Mexico's health agency, also approved *EGRIFTA*® in its 1 mg/vial presentation in March 2016. However, the launch of *EGRIFTA*® in this country will not occur until our commercial partner, sanofi, obtains confirmation that *EGRIFTA*® will be reimbursed by Mexican regulatory authorities.

EGRIFTA® is currently the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Since May 1, 2014, *EGRIFTA*® is marketed exclusively in the United States by us further to regaining all of the commercialization rights to *EGRIFTA*® in the United States from EMD Serono, Inc., or EMD Serono, pursuant to a transfer and termination agreement entered into by and between us and EMD Serono dated December 13, 2013, or the EMD Serono Termination Agreement. Before May 1, 2014, EMD Serono was solely responsible for the commercialization of *EGRIFTA*® in the United States under a collaboration and licensing agreement entered into by and between us and EMD Serono dated October 28, 2008, as amended, or the EMD Serono Agreement.

In Canada, *EGRIFTA*® is marketed exclusively by us.

We have also entered into a distribution and licensing agreement with sanofi dated December 6th, 2010, or the Sanofi Agreement, granting sanofi the exclusive commercialization rights to *EGRIFTA*® in Latin America, Africa and the Middle East. To date, no filing is pending in any of the countries covered under the Sanofi Agreement and Mexico is the only country where *EGRIFTA*® has been approved for commercialization.

In 2015, we entered into a distribution and licensing agreement with AOP Orphan Pharmaceuticals AG, or AOP, for the commercialization of *EGRIFTA*® in certain European countries and we also entered into a similar agreement with BL&H Co, LTD, for the commercialization of *EGRIFTA*® in South Korea.

In March 2016, we entered into a distribution and marketing agreement with TaiMed Biologics, Inc., or TaiMed, pursuant to which we acquired the exclusive right to distribute and commercialize ibalizumab in Canada and in the United States of America. Ibalizumab is an investigational humanized monoclonal antibody currently being developed for the treatment of multidrug resistant, or MDR, HIV-1 infection. The ibalizumab Phase III trial is completed and TaiMed is compiling the data derived from all clinical trials using ibalizumab and assembling the biologics licence application to be filed with the United States Food and Drug Administration, or FDA.

In September 2016, we entered into distribution and licensing agreements with each of Praxis Pharmaceutical S.A. and PRX Pharma Produtos Farmacêuticos Unipessoal, LDA, providing each of those companies with the right to distribute and commercialize *EGRIFTA*® in Spain and Portugal, respectively.

Since October 30, 2012, no more research and development activities regarding the development of compounds have been conducted by us.

2.2 THREE YEAR HISTORY

2016

- *Financing by Way of Prospectus.* On November 14, 2016, we announced the filing of a preliminary short-form prospectus and the execution of an underwriting agreement with a syndicate of underwriters led by Mackie Research Capital Corporation, or Underwriters, in connection with an offering of 5,323,000 common shares at a price of $3.10 per common share for gross proceeds of $16,501,300, or Offering. On December 5, 2016, we announced the closing of the Offering which resulted in gross proceeds to us of $16,501,300.

- *Results from Last Pivotal Phase III Trial Using Ibalizumab.* On May 24, 2016, we announced that the preliminary results for the primary endpoint of the Phase III trial using ibalizumab in patients with MDR HIV-1 indicated that 82.5% of patients enrolled in such Phase III trial had met the primary endpoint of a decrease of ≥ 0.5 $\log_{10}$ in viral load following a 7-day treatment period with ibalizumab. On October 28, 2016, we announced additional preliminary results related to the primary endpoint of the Phase III trial using ibalizumab. During that 7-day period, 60% of patients achieved a decrease of ≥ 1.0 log10 ($p<0.0001$). Finally, on November 10, 2016, we announced the preliminary results of the safety and efficacy secondary endpoints of the 24-week Phase III trial using ibalizumab in patients with MDR HIV-1. The Phase III trial confirmed the safety and efficacy results of ibalizumab observed in the previously completed Phase IIb trial despite the fact that the patient population in the Phase III trial had higher levels of MDR HIV-1 and more advance disease at time of enrollment.

- *Hosting of Analysts Day.* On November 1, 2016, we announced the hosting of a presentation held with healthcare securities analysts in Toronto to provide the healthcare analyst community with a summary of our corporate developments over the last few years, with an overview of our current activities with *EGRIFTA*® and with a detailed review of ibalizumab.

- *End of Patient Treatment for Phase III Trial using Ibalizumab.* On October 24, 2016, we announced that the last patient infected with MDR HIV-1 enrolled in the Phase III trial using ibalizumab had completed the treatment phase of the study.

- *Development of New Single Vial Formulation for EGRIFTA®.* On September 28, 2016, we announced that we would pursue the development of an F4 single vial formulation instead of the 2 mg/vial presentation using the current formulation. The development of the F4 single vial formulation will require the conduct of a bioequivalent program against the current formulation and additional stability testing.

- *Commercialization Agreement for Tesamorelin in Spain and Portugal.* On September 1, 2016, we announced the execution of a distribution and licencing agreement between Theratechnologies Europe Inc. and Praxis Pharmaceutical S.A., or Praxis Agreement, for the distribution and commercialization of *EGRIFTA*® in Spain. Under the terms of the Praxis Agreement, we granted Praxis the exclusive right to commercialize and distribute *EGRIFTA*® in Spain. On that same date, we also announced the execution of a distribution and licencing agreement between Theratechnologies Europe Inc. and PRX Pharma Produtos Farmacêuticos Unipessoal, LDA, or PRX Agreement, for the distribution and

commercialization of *EGRIFTA*® in Portugal. Under the terms of the PRX Agreement, we granted PRX the exclusive right to commercialize and distribute *EGRIFTA*® in Portugal.

- *EGRIFTA*® *not reimbursed in Québec.* On June 9, 2016, we announced that the Government of Québec decided not to include *EGRIFTA*® to the list of reimbursed medications. We sought a review of this decision and, on December 2, 2016, we learned that after the review, the initial decision was maintained.

- *Withdrawal of Marketing Authorization Application in Brazil.* On May 6, 2016, we announced that in conjunction with our commercial partner, sanofi, we decided to withdraw the marketing authorization application for the registration of the 2 mg/vial presentation of tesamorelin in Brazil.

- *Completion of Enrollment for Phase III Trial Using Ibalizumab.* On April 27, 2016, we announced that the enrollment of patients infected with MDR HIV-1 for the Phase III trial using ibalizumab had been completed. The enrollment in the United States reached 36 patients which exceeded the minimum of 30 patients proposed by the FDA.

- *Agreement with TaiMed.* On March 18, 2016, we announced the execution of a 12-year distribution and marketing agreement with TaiMed pursuant to which we acquired the exclusive right to distribute and commercialize ibalizumab, if and when approved, in Canada and in the United States of America. Under the terms of the TaiMed Agreement, TaiMed is responsible to conduct all regulatory activities up to obtaining the approval to commercialize ibalizumab in the United States. Thereafter, we will be responsible to conduct all regulatory and commercialization activities. We are also responsible to conduct all regulatory activities in Canada pre and post-approval of ibalizumab, as well as all commercialization activities in Canada.

- *EGRIFTA*® *Approved in 1 mg/vial Presentation in Mexico*. On March 8, 2016, we announced that COFEPRIS, Mexico health agency, approved the 1 mg/vial presentation of *EGRIFTA*®.

- *Appointment of Chief Financial Officer.* On February 24, 2016, we announced the appointment of Philippe Dubuc as Senior Vice President and Chief Financial Officer of the Corporation.

2015

- *Agreement with BL&H Co., LTD.* On August 31, 2015, we announced the execution of a distribution and licensing agreement with BL&H Co. LTD. for the distribution and commercialization of *EGRIFTA*® in South Korea, or BL&H Agreement. Under the terms of the BL&H Agreement, BL&H is responsible to conduct all regulatory activities to obtain marketing authorizations for *EGRIFTA*® in South Korea.

- *Financing by Way of Prospectus.* On July 24, 2015, we announced the filing of a preliminary short-form prospectus and the execution of an underwriting agreement with a syndicate of underwriters led by Euro Pacific Canada Inc. in connection with an offering of 4,000,000 units at a price of $2.40 per unit for gross proceeds of $9,600,000, or Offering. Each unit consisted of one common share and one-half of a common share purchase warrant exercisable for a period of 24 months from the closing date of the Offering at an exercise price of $3.00. We also granted the underwriters an option to purchase up to 600,000 additional units, representing 15% of the number of units offered under the Offering, at the same price and on

the same terms and conditions as the Offering. On August 6, 2015, we announced the closing of the Offering which resulted in gross proceeds to us of $11,040,000.

- *EGRIFTA® Approved for commercialization in Mexico.* On July 14, 2015, we announced that COFEPRIS approved *EGRIFTA®* in its 2mg/vial presentation. We also announced that our commercial partner, sanofi, would re-submit a file to COFEPRIS to seek approval of the 1mg/vial presentation of *EGRIFTA®*.

- *Launch of EGRIFTA® in Canada.* On June 25, 2015, we announced that a first shipment of *EGRIFTA®* was made to our Canadian distributor and that *EGRIFTA®* would be available to Canadian patients in a few days from such shipment. We also announced that the availability of *EGRIFTA®* in Canada would enable AOP to initiate named-patient sales programs in Europe.

- *Election of David Lilley as a Director.* On May 20, 2015, we announced the election of David Lilley as a new member of the Board of Directors. David Lilley replaced Gilles Cloutier who did not seek re-election at the annual meeting of shareholders held on May 20, 2015.

- *Dismissal of Class Action Motion.* On May 15, 2015, we announced that the Superior Court of Québec authorized 121851 Canada Inc. to discontinue all class proceedings filed under the *Securities Act* (Québec) and the *Civil Code of Québec* against us, a director and a former president and chief executive officer. This follows the decision issued by the Supreme Court of Canada on April 17, 2015 wherein it dismissed 121851 Canada Inc.'s motion for leave to commence an action based on the secondary market liability provisions of the *Securities Act* (Quebec) against us a director and a former president and chief executive officer.

- *EGRIFTA® Approved in 1 mg/vial presentation in Canada.* On March 30, 2015, we announced that Health Canada approved a Supplement to a New Drug Submission for the 1 mg/vial presentation of *EGRIFTA®*.

- *Agreement with AOP.* On February 27, 2015, we announced the execution of a distribution and licensing agreement with AOP Orphan Pharmaceuticals AG for the distribution and commercialization of *EGRIFTA®* in several European countries, or AOP Agreement. Under the terms of the AOP Agreement, AOP is responsible to conduct all regulatory activities to obtain marketing authorizations for *EGRIFTA®* in the countries covered under such agreement.

- *Restructuring of Long-Term Obligation*. On February 17, 2015, we restructured the amount and the payment terms of our initial US $4,000,000 payment due May 1, 2015 as part of our long-term obligation. The amount of the first payment now aggregates US $4,167,808 and is payable in three tranches of US $500,000, US $1,550,548 and US $2,117,260 on May 1, 2015, August 31, 2015 and November 30, 2015, respectively. The balance of the amount and the other payment terms of the long-term obligation remain unchanged.

- *Suspension of SEC Reporting Requirements*. On February 3, 2015, we announced that we filed a Form 15 with the Securities and Exchange Commission of the United States, or SEC, to suspend our reporting obligations in the United States.

2014

- *Resumption of Distribution of EGRIFTA® in the United States*. On September 3, 2014, we announced that a first shipment of *EGRIFTA®* had been sent to our exclusive distributor in the United States, RxC Acquisition Company, or RxCrossroads, to replenish our supply chain.

- *Receipt of $4.1 million from Revenue Canada*. On June 25, 2014, we announced that we received a refund payment of approximately $4.1 million from the Canada Revenue Agency after settling a dispute over our claims of refundable investment tax credits related to our 1994 and 1995 taxation years.

- *Patent Term Extension Granted on Tesamorelin*. On June 9, 2014, the USPTO issued a patent term extension certificate for our compound tesamorelin. As a result, the term of U.S. patent 5,861,379 was extended by five (5) years and is now set to expire in May 2020.

- *Regaining of Commercialization Rights to EGRIFTA® in the United States*. On May 1, 2014, we regained all rights to *EGRIFTA®* in the United States from EMD Serono following the closing on that day of the transaction contemplated by the EMD Serono Termination Agreement.

- *EGRIFTA® Approved for Commercialization in Canada*. On April 30, 2014, we announced that Health Canada issued a NOC for *EGRIFTA®* paving the way for the commercialization of *EGRIFTA®* in Canada. We also announced that we would be filing a SNDS with Health Canada to obtain approval from this regulatory agency to commercialize *EGRIFTA®* in its 1 mg/vial presentation. To date, we have not received a decision from Health Canada on our SNDS.

- *EGRIFTA® Shortage.* On February 14, 2014, we announced that we expected our inventory of *EGRIFTA®* to be depleted in a matter of weeks due to a combination of manufacturing delays and issues observed during the production of new batches of *EGRIFTA®*. We further advised that the ensuing depletion of the inventory would result in a shortage of *EGRIFTA®* and an eventual stock-out and that we were temporarily ceasing to manufacture *EGRIFTA®*.

- *Termination of EMD Serono Agreement.* On December 13, 2013, we entered into the EMD Serono Termination Agreement pursuant to which we regained all commercialization rights to *EGRIFTA®* in the United States on May 1, 2014.

- *Shipment of EGRIFTA® to EMD Serono Resumed*. On December 3, 2013, we resumed shipment of *EGRIFTA®* to EMD Serono following the manufacturing difficulties we had encountered and reported by us on April 11, 2013

2.3 OUR STRATEGY AND OBJECTIVES

Our strategy for value creation in 2017 continues to be focused on growing the sales of *EGRIFTA®* in the U.S. market and on growing our patient base in order to provide a financial foundation that can support the addition of new products. Our objective with respect to *EGRIFTA®* is to continue to grow our net sales revenue and the related cash flow in the United States.

Our objective with respect to ibalizumab is to continue to conduct our pre-commercialization activities, to develop our marketing plans and to build on our current infrastructure in anticipation of the launch of ibalizumab in the United States (if approved) later in the year.

Other objectives include continuing to look for product acquisitions and in-licensing opportunities with respect to products compatible with our expertise and our commercial platform. We will also continue supporting our commercial partners and pursue the development of a new single vial formulation.

2.4 APPROVED PRODUCT AND INVESTIGATIONAL PRODUCTS

EGRIFTA® (tesamorelin for injection) - Our Approved Product

EGRIFTA® (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® is currently available in the United States as a once-daily two unit dose (two vials, each containing 1 mg of tesamorelin) of sterilized lyophilized powder to be reconstituted with sterile water for injection. To administer *EGRIFTA®*, 1 ml is retrieved from each vial into one syringe to prepare a single 2 ml patient self-administered subcutaneous injection. *EGRIFTA®* is injected under the skin into the abdomen once a day.

In connection with its approval, the FDA required the following three post-approval commitments:

- *to develop a single vial presentation of the existing formulation of EGRIFTA®*. The FDA required that this new presentation be available by November 2013 and it was launched in October 2012. As a result of the manufacturing issues we encountered in 2013 with the 2 mg/vial presentation of *EGRIFTA®*, we reverted back to the use of the original 1 mg/vial presentation while working on the further development of the 2 mg/vial presentation. However, due to certain issues we encountered during such development, we proposed to the FDA that we proceed with the development of an F4 single vial formulation instead of the 2 mg/vial presentation using the current formulation to meet the commitment required by the FDA when *EGRIFTA®* was approved. The FDA authorized us to proceed with such formulation. The bioequivalence of this new formulation and additional stability testing must be completed before submitting this new formulation for approval to the FDA for use in the currently approved indication for *EGRIFTA®*.

- *to conduct a long-term observational safety study using EGRIFTA®*. The purpose of the long-term observational study, or Observational Study, required by the FDA is to evaluate the safety of long-term administration of *EGRIFTA®*. The FDA required that the proposed protocol for the Observational Study be filed by the second quarter of 2011 and the FDA subsequently approved the protocol for the Observational Study. We are currently recruiting patients for the Observational Study.

- *to conduct a Phase 4 clinical trial using EGRIFTA®*. The primary purpose of the Phase 4 clinical trial, or Retinopathy Study, is to assess whether *EGRIFTA®* increases the incidence or progression of diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat. The FDA required that the proposed protocols for the Retinopathy Trial be submitted by the second quarter of 2011 and the FDA has now approved the protocol for the Retinopathy Trial. We are currently recruiting patients for the Retinopathy Trial.

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*®. Tesamorelin is a stabilized 44 amino acid human GRF analogue, 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.

Third-Party Studies Evaluating Tesamorelin

On June 9, 2015, we announced a colaboration with the Massachusetts General Hospital that will evaluate the safety and efficacy of tesamorelin in the treatment of HIV-infected patients suffering from non-alcoholic fatty liver disease, or NAFLD, and non-alcoholic steatohepatitis, or NASH. Funding for the clinical trial has been awarded by the U.S. National Institutes of Health, or NIH. The 12 month-parallel, randomized, placebo-controlled study will enroll a total of 60 HIV-infected patients with NAFLD/NASH, who will receive either tesamorelin (2mg/day) or a placebo. The specific aims of the study are to determine the effects of tesamorelin on liver fat, inflammation, fibrosis, and hepatocellular damage seen in conjunction with NASH. At the end of the 12-month period, subjects will enter open-label tesamorelin treatment phase for 6 months. The study is now open for patient recruitment.

On July 23 2014, the results of a study entitled “Effect of Tesamorelin on Visceral Fat and Liver Fat in HIV-Infected Patients with Abdominal Fat Accumulation, A Randomized Clinical Trial” were published in the Journal of the American Medical Association (JAMA) by Dr. Steven K. Grinspoon of the Massachusetts General Hospital (JAMA, 2014;312(4):380-389).

The purpose of the study was to evaluate the effectiveness of a synthetic analog of growth hormone-releasing hormone, tesamorelin, in decreasing the amount of liver fat in antiretroviral-treated HIV-infected men and women with abdominal fat accumulation. This placebo-controlled study enrolled a total of 50 HIV-infected patients at Massachusetts General Hospital in Boston. Participants were randomized to receive tesamorelin, 2mg (n=28), or placebo (n=22), subcutaneously daily for 6 months. This placebo-controlled study demonstrated that, among antiretroviral-treated HIV-infected men and women with abdominal fat accumulation, tesamorelin reduced visceral adipose tissue (VAT) and liver fat over a 6-month period. Fasting glucose increased in the tesamorelin group at 2 weeks but changes at 6 months in fasting glucose and 2-hour glucose were not significant.

We are not currently developing tesamorelin in patients suffering from excessive liver fat, NAFL, or NASH.

F4 Formulation

As part of our commitments with the FDA related to the approval of *EGRIFTA*®, we agreed to develop a single vial formulation of *EGRIFTA*®. We had developed a 2 mg/vial presentation using the 1 mg/vial formulation of *EGRIFTA*® which was withdrawn from the market due to manufacturing issues. Despite our continuous efforts to develop an improved 2 mg/vial presentation of the original formulation, we encountered certain issues and, in order to meet our commitment with the FDA, we proposed to the FDA to substitute the development of the 2 mg/vial presentation of the original formulation with a single vial formulation containing 4 mg/ml of tesamorelin, or F4 Formulation.

The F4 Formulation has previously been used by us in a Phase II program. The F4 Formulation is four times more concentrated than the former 2 mg/vial formulation, thus significantly reducing the volume of administration. The F4 Formulation has also previously been shown to be stable at room temperature which could be a significant improvement over the current formulation as refrigeration by pharmacies and patients would no longer be required. In order to be able to use the F4 Formulation in the current indication of *EGRIFTA*®, we must demonstrate that the F4 Formulation is bioequivalent with the current formulation and conduct additional stability testing. If the F4 Formulation is bioequivalent and the results of our stability testing are satisfactory, we will be submitting the F4 Formulation for approval to the FDA for use in the current indication of *EGRIFTA*®. We have begun work on the development of the F4 Formulation and our goal is to complete the testing and file for FDA approval by the end of 2017.

Ibalizumab – Investigational Product

On March 18, 2016, we entered into the TaiMed Agreement. Pursuant to the terms of the TaiMed Agreement, we have the exclusive rights to commercialize ibalizumab in the United States and in Canada. TaiMed is responsible for the development of ibalizumab and for seeking the approval from the FDA. However, in Canada, we will be responsible, but under no obligation, to seek the approval of ibalizumab from Health Canada.

TaiMed will manufacture and supply ibalizumab to us. The transfer price is determined at 52% of the net selling price of the product and 10% is added for the first manufactured products until an additional amount of US $5,500,000 has been paid.

The terms of the transaction include a US$2,000,000 payment obligation, of which US$1,000,000 was paid in cash at the signature of the agreement and US$1,000,000 will be paid at the commercial launch of ibalizumab through the issuance of 957,169 common shares of Theratechnologies.

A further US$3,000,000 will become due at commercial launch, subject to certain conditions. This amount will be payable as follows: US$2,000,000 in common shares of Theratechnologies at a price to be determined upon FDA approval and US$1,000,000 in common shares of Theratechnologies at a price to be determined upon commercial launch, based on the volume-weighted average trading price of our common shares on the Toronto Stock Exchange prior to each of these dates.

Once sales have reached an aggregate amount of US$20,000,000 over four consecutive quarters, we will make a US$7,000,000 milestone payment (payable in two annual installments). We will also pay these additional sales related milestones: US$10,000,000 once annual sales of ibalizumab reach US$200,000,000, US$40,000,000 once annual sales reach US$500,000,000, and US$100,000,000 once annual sales reach US$1,000,000,000.

We will also pay development milestones to TaiMed. A US$3,000,000 milestone is due upon the approval of the once every two weeks intramuscular route of administration, again payable in two annual installments over one year. TaiMed will also be planning a larger Phase III trial with the once every four weeks intramuscular or subcutaneous route of administration, to address a much broader patient population. This development milestone will consist of an upfront milestone payment of up to US$50,000,000, depending on the size of the newly targeted population, which will be paid quarterly, based on a percentage of net sales generated by the product.

The TaiMed Agreement has a term that will expire on a country-by-country basis. In the United States, the Taimed Agreement will expire 12 years after marketing approval has been obtained and, in Canada, 12 years after marketing approval has been obtained in such country, unless earlier terminated. The TaiMed Agreement contains customary representations and warranties, indemnification provisions and other provisions customarily found in agreements of this nature. Under the TaiMed Agreement, we must meet a certain level of undisclosed minimum sales after an undisclosed period of time following the approval of the drug in the United States.

Following the signing of the TaiMed Agreement, we commissioned a series of market studies internally and through independent external consultants. The main conclusion of these analyses points to a larger potential market than we first expected. We now estimate that approximately 20,000 to 25,000 patients in the United States are currently infected with MDR HIV-1 (the previous estimate was 8,000 to 10,000 patients) and that 50-56% of those patients will experience a virological failure over a period of 48 weeks of treatment. This will likely require physicians to modify their treatment plans and consider adding ibalizumab to their regimens. The research also indicated that an efficacious and safe treatment is badly needed and would be well received by HIV-physicians and third-party payors.

Ibalizumab is an investigational humanized monoclonal antibody currently being developed for the potential treatment of MDR HIV-1 infection. Ibalizumab is the property of TaiMed.

Ibalizumab has received “Breakthrough Therapy” designation from the FDA. This designation is given if a therapy may provide a substantial improvement over what is currently available to address a serious and life-threatening condition. Ibalizumab also received “Orphan Drug” and “Fast Track” designations by the FDA.

Mechanism of Action

Unlike other antiretroviral agents, ibalizumab binds primarily to the second extracellular domain of the CD4 receptor, away from major histocompatibility complex II molecule (MHC II) binding sites. It potentially prevents HIV virus from infecting $CD4^+$ immune cells while preserving normal immunological function. Ibalizumab is active against HIV-1 resistant to all approved antiretroviral agents. Ibalizumab has been tested in Phase I and II clinical trials and the Phase III trial has now been completed.

Description of Phase III Trial

The Phase III trial, or TMB-301, was a single arm, 24-week study of ibalizumab plus optimized background regimen, or OBR, in treatment-experienced patients infected with MDR HIV-1. The primary objective of the study was to demonstrate the antiviral activity of ibalizumab seven days after the first dose of ibalizumab. Patients receiving their current failing antiretroviral therapy (ART), or no therapy, were monitored during a seven-day control period. Thereafter, a loading dose of 2,000 mg of intravenous, or IV, ibalizumab was the only ART added to their regimen. The primary efficacy endpoint was the proportion of patients achieving a ≥ 0.5 $\log_{10}$ decrease in HIV-1 ribonucleic acid seven days after initiating ibalizumab therapy, day 14 of the study. Ibalizumab was continued at doses of 800 mg IV every two weeks through 24 weeks on study treatment. A total of 40 patients were enrolled in the study.

Patients enrolled in the Phase III trial had high pre-existing levels of drug resistance and advanced clinical disease. Patients had a mean HIV-1 viral load of 100,287 copies/mL, with 18% having viral loads above 100,000 copies/mL. The median $CD4^+$ count was 73 cells/ul and 30% had less than 10 $CD4^+$ cells/ul. Close to 90% of patients had MDR HIV-1 with more than one identified mutation conferring resistance to the Nucleoside Reverse Transcriptase Inhibitors, or NRTI, Non-Nucleoside Reverse Transcriptase Inhibitors, or NNRTI, or Protease Inhibitors, or PI, and more than 60% of patients had resistance to at least one Integrase Inhibitor, or INI. Study patients were infected with HIV-1 resistant to more than 75% of all drugs in the NRTI, NNRTI and PI classes and to 1-2 drugs from the INI class, on average. Finally, just over 50% of patients had HIV-1 with resistance to all available drugs from at least three classes of antiretroviral therapies, or ART, 35% from 4 ART classes and 15% from all approved ARTs. A total of 9 patients (23%) discontinued the Phase III trial prior to the completion of the 24 week study treatment (4 non-drug related deaths, 3 withdrawals, and 2 lost to follow-up). The statistical analyses method used for efficacy, intent-to-treat – missing equals failure, or ITT-MEF, represents the most stringent and most conservative data handling convention. The ITT-MEF analysis methodology considers all patients enrolled in the study and any missing values are treated as failure (or no change) in the analysis of the results.

After completion of treatment, patients were offered participation in the expanded access study (TMB-311). Study TMB-311 is also open for U.S. patients with limited options. For more information about TMB-301 (NCT 02475629) and TMB-311 (NCT02707861), please refer to the ClinicalTrials.gov website (www.clinicaltrials.gov).

The phase III trial was the last pivotal clinical trial required by the FDA to complete a biologic license

application, or BLA, submission. TaiMed is currently completing all analysis regarding the clinical trials conducted on ibalizumab with the aim of filing a BLA with the FDA by the end of the first calendar quarter of 2017.

Preliminary Results

The preliminary results related to the primary endpoint of the Phase III trial using ibalizumab showed that patients with MDR HIV-1 experienced a significant decrease in viral load after receiving a loading dose of ibalizumab 2,000 mg IV in addition to their failing ART (or no therapy). Seven days after the loading dose, 83% of patients achieved a ≥ 0.5 $\log_{10}$ decrease from baseline compared with 3% during the seven-day control period. These results were statistically significant ($p<0.0001$). During the same period, 60% of patients achieved a decrease of ≥ 1.0 $\log_{10}$ ($p<0.0001$). The average viral load decrease for the total population was 1.1 $\log_{10}$ ($p<0.0001$). There were no treatment-related serious adverse events or discontinuations reported during the initial seven-day treatment period.

After 24 weeks of treatment, the mean reduction in viral load was 1.6 $\log_{10}$ and a total of 48% of patients had a reduction in viral load of more than 2.0 $\log_{10}$ during this period. At the end of the treatment period using ibalizumab with optimized background regimen, or OBR, the proportion of study participants with undetectable viral load (HIV-1 <50 copies/mL) was 43% (mean viral load reduction of 3.1 $\log_{10}$) and 53% of patients had a viral load lower than 400 copies/mL. The mean viral load of patients at baseline was 100,287 copies/mL.

The safety results in this Phase III trial were consistent with the ones previously observed in the Phase IIb study. Other than for one case of immune reconstitution inflammatory syndrome, an inflammatory response in HIV-infected patients that may be triggered after changing to more active ART, no serious adverse events, or SAEs, were considered to be related to ibalizumab. Most treatment-emergent adverse events reported were mild to moderate in severity. No notable trends in laboratory abnormalities were observed.

Other Investigational Products

We also have the following compounds. All of them are in early development stage and, as of the date of this AIF, all of our research and development activities have been suspended.

TH1173 – Second Generation GRF

In 2012, we pursued and completed preclinical work on TH1173, a GRF peptide. The preclinical safety program has been completed.

New GRF Peptides

In addition to TH1173, we have identified a number of new GRF peptides. These peptides are at the discovery stage.

Acute Kidney Injury

AKI is the acute deterioration of kidney function leading to increased urea waste products and electrolyte imbalance in blood. AKI is common among hospitalized patients and complicates the management of patients in intensive care units. Despite hospitalization and renal replacement, the mortality rate is high for dialyzed patients.

We have developed novel peptides specifically tailored for the prevention or treatment of AKI. One of these peptides, TH0673, is a bifunctional peptide that is currently in preclinical development. We have

tested TH0673 in animal models of AKI and have found that it increases creatinine clearance, improves excretion of nitrogenous waste compounds and limits kidney damage.

Melanotransferrin

In November 2010, we entered into a discovery and collaboration agreement with Université du Québec à Montréal, Gestion Valeo L.P. and Transfert Plus L.P. in connection with research led by Dr. Richard Béliveau seeking to discover short peptide mimics of melanotransferrin for the development of a new cancer treatment. Melanotransferrin is related to the transferrin family of proteins and is expressed normally in melanocytes, but also in several cancer cells. Dr. Béliveau's research has demonstrated that soluble melanotransferrin reduces cell migration, invasion and angiogenesis, which are hallmarks of tumorigenesis and metastasis.

Our research identified several small peptides from the melanotransferrin protein which could replicate the functions of the full length protein. To date, we have assessed the *in vivo* biologic efficacy of these peptides, and the results obtained lead us to believe that these peptides have certain anti-tumoral characteristics. However, further research and development on these peptides, including toxicology and pharmacology studies, need to be conducted.

Under the terms of this agreement, as consideration for our research, we were granted an undivided 50% interest in the short peptide mimics that we discovered and an option to acquire the remaining 50% undivided interest from Transfert Plus L.P. and a 100% interest in the melanotransferrin technology. We exercised the option on July 10, 2013. We had until October 2015 to license our research and development rights for such peptides to a third party, failing which Transfert Plus L.P. was entitled to a 50% undivided interest in the small peptides we discovered and the 100% interest in the melanotransferrin technology. We are currently in discussions with Transfert Plus L.P. in connection with the potential development of these peptides. If we fail to agree on the development strategy (including the contribution to be made by us on such development), we will return our interests to Transfert Plus L.P. in the melanotransferrin technology and our 50% interest in those peptides.

2.5 COMMERCIALIZATION ACTIVITIES

United States

General

Since May 1, 2014, we are responsible for the commercialization of *EGRIFTA*® (tesamorelin for injection) in the United States and the conduct of the Observational Study and Retinopathy Study. We regained our commercialization rights to *EGRIFTA*® pursuant to the EMD Serono Termination Agreement. The EMD Serono Termination Agreement provided for the termination of the EMD Serono Agreement.

Under the terms of the EMD Serono Termination Agreement, we agreed to pay an early termination fee of US $20,000,000, or Early Termination Fee, in equal installments of US $4,000,000 over a five-year period starting on May 1, 2015 and, thereafter, on May 1, 2016, 2017, 2018 and 2019. We also agreed to pay EMD Serono an increasing royalty, or Royalties, based on annual net sales. The Royalties will be paid until a confidential cumulative aggregate amount is reached or until January 1, 2024, the first of these events to occur. We restructured the amount and payment terms of the initial US $4,000,000 payment due May 1, 2015 as part of our long-term obligation. The Early

Termination Fee amounted to US $20,167,808 and the first payment amounted to US $4,167,808 and was payable in three tranches of US $500,000 on May 1, 2015, US $1,550,548 on August 31, 2015 and US $2,117,260 on November 30, 2015. The balance of the amount and the other payment terms of the long-term obligation remain unchanged. The first and second installments aggregating $8,167,808 have been paid, and a balance of US $12,000,000 remains to be paid.

In order to secure the payment of the Early Termination Fee, the Corporation agreed to grant EMD Serono a security interest on its present and future worldwide corporeal and incorporeal movable property related to tesamorelin until such time as the amount of US $20,167,808 has been reimbursed in full to EMD Serono. Thereafter, the Corporation and EMD Serono agreed to reduce the security interest to all present and future corporeal and incorporeal movable property related to tesamorelin in the United States only to secure the payment of the Royalties.

The EMD Serono Termination Agreement contains a five (5) year non-compete undertaking by EMD Serono in favor of the Corporation, customary representations and warranties and indemnity provisions. In addition, the EMD Serono Termination Agreement provides that in the event there occurs a change of control of the Corporation more than eighteen (18) months after May 1, 2014, EMD Serono has the option to receive the payment of all of the unpaid Early Termination Fee.

Manufacturing

We do not own or operate commercial scale manufacturing facilities for the production of our product or any of our compounds, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party service providers for all of our required raw materials, drug substance and finished product for commercial sale and clinical trials and we have entered into supply agreements with those third-party service providers.

We are responsible for the manufacture and supply of tesamorelin to ensure the commercialization of *EGRIFTA*® in the United States and in Canada. We are also responsible for the manufacture and supply of *EGRIFTA*® under the Sanofi Agreement, the AOP Agreement, the BL&H Agreement, the Praxis Agreement and the PRX Agreement.

We currently manufacture *EGRIFTA*® in a 1 mg/vial presentation. This presentation was initially used when we launched *EGRIFTA*® in January 2011 until we switched to a 2 mg/vial presentation pursuant to a post-approval commitment made to the FDA at the time *EGRIFTA*® was approved. As a result of the manufacturing issues we encountered in 2013 with the 2 mg/vial presentation, we reverted back to the use of the original 1 mg/vial presentation. However, we remain committed to the development of a single vial formulation and we have begun working on the F4 Formulation.

Bachem

We have an agreement with Bachem, Inc., an American subsidiary of Swiss-based Bachem AG, providing for the manufacturing and supply of the active pharmaceutical ingredient of tesamorelin, or API, for *EGRIFTA*® for commercial sale in the United States and for clinical programs. Bachem is our only validated supplier of raw materials. The price of tesamorelin manufactured by Bachem has been set under our agreement and is not subject to volatility. The agreement is scheduled to terminate with the expiry of US patent 5,861,379, or May 2020, unless earlier terminated by the parties.

Jubilant

We have an agreement with Jubilant HollisterStier General Partnership providing for the manufacture

and supply of the finished form of *EGRIFTA*® for commercial sale in the United States and for tesamorelin for clinical programs. Under our 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 is scheduled to terminate with the expiry of US patent 5,861,379, or May 2020, unless earlier terminated by the parties. If the agreement is not terminated by the parties prior to its term, it will automatically renew for successive 12-month periods unless a party provides the other with a prior written notice within a confidential time period before the termination of the agreement.

Becton Dickinson

On November 6, 2009, we entered into a supply agreement with Becton Dickinson Canada Inc., or Becton Dickinson. Under this agreement, Becton Dickinson is responsible for supplying us with syringes and hypodermic needles which are provided with *EGRIFTA*® in the United States. The agreement has been in force since 2009 and renews automatically for successive 12-month periods on November of each year unless a party provides the other with a prior written notice within a confidential time period before the renewal of the agreement.

Hospira

On March 19, 2015, we entered into an agreement with Hospira Worldwide, Inc., or 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*® in the United States. The initial term of the agreement expired on December 31, 2016. However, the agreement contained an automatic renewal provision for successive one-year term unless a party provides the other with a prior written notice within a confidential time period before the expiration of the agreement. This agreement automatically renewed on January 1, 2017 for a one-year term pursuant to the automatic renewal provision.

Almac

On February 27, 2015, we entered into an agreement with Almac Pharma Services, or Almac. Under this agreement, Almac is responsible for packaging syringes, needles, sterile water for injection and patient inserts in connection with the sale of *EGRIFTA*® in the United States. The agreement is scheduled to terminate on February 25, 2018.

Distribution

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

RxCrossroads

On May 12, 2014, we entered into a master services agreement with RxCrossroads, along with two 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 warehousing and logistical support services to the Corporation, including inventory control, account management, customers support, product return

management and fulfillment of orders.

Under the RxCrossroads Agreements, RxCrossroads also acts as our exclusive first-party distributor of *EGRIFTA*® in the United States. In such role, RxCrossroads purchases *EGRIFTA*® from us and takes title thereto. RxCrossroads' purchases of *EGRIFTA*® are triggered by its expectations of market demand for *EGRIFTA*® over a certain period of time. RxCrossroads fulfills orders received from authorized wholesalers and delivers *EGRIFTA*® directly to that authorized wholesaler's client, namely a specialty pharmacy forming part of our network of specialty pharmacies.

The RxCrossroads Agreements have a three-year term and will expire on August 25, 2017. 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 events.

H.D. Smith

On September 1, 2014, we entered into a wholesaler services agreement with H.D. Smith, or H.D. Smith Agreement, appointing H.D. Smith as a non-exclusive authorized wholesaler for *EGRIFTA*® in the United States. Under the terms of the H.D. Smith Agreement, H.D. Smith is authorized to accept orders for *EGRIFTA*® from specialty pharmacies, purchase *EGRIFTA*® from RxCrossroads and resell it to those specialty pharmacies.

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 both parties, payment terms, indemnification provisions as well as termination provisions in the event of the occurrence of certain events.

Cardinal

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, or Cardinal Agreements. Under the terms of the Cardinal Agreements, we appointed Cardinal as a non-exclusive authorized wholesaler for *EGRIFTA*® in the United States. As an authorized wholesaler, Cardinal is authorized to accept orders for *EGRIFTA*® from specialty pharmacies, purchase *EGRIFTA*® from RxCrossroads and resell it to those specialty pharmacies.

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 confidential time period prior to the termination or renewal period of the 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

On May 15, 2014, we entered into a core distribution agreement with McKesson, or McKesson Agreement, appointing McKesson as a non-exclusive authorized wholesaler for *EGRIFTA*® in the United States. Under the terms of the McKesson Agreement, McKesson is authorized to accept orders for *EGRIFTA*® from specialty pharmacies, purchase *EGRIFTA*® from RxCrossroads and resell it to those specialty pharmacies.

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 events.

Specialty Pharmacies

We have entered into various agreements with specialty pharmacies across the United States providing for their rights to order *EGRIFTA®* from our authorized wholesalers and distribute *EGRIFTA®* to patients in the United States through their networks of local pharmacies.

Marketing and Sales

Our marketing and sales activities are conducted from our head office in Montreal, Québec, Canada. We have also retained the services of inVentiv Commercial Services, LLC, or inVentiv, to assist us with sales activities in the United States. inVentiv is a recognized provider of commercial, clinical and consulting services around the globe. We have renewed our agreement with inVentiv and we entered into an amended and restated master service agreement in this respect as of December 4, 2016, or inVentiv Agreement, pursuant to which inVentiv will continue providing us with various services in connection with the commercialization of *EGRIFTA®* in the United States. In addition, we sometimes retain inVentiv and other third parties for certain marketing activities.

The services currently provided by inVentiv include the provision of a sales force fully dedicated to *EGRIFTA®,* as well as other staff solely assigned to our business in medical science liaison, reimbursement, and communications with patients and health-care professionals. The communications aspect includes a call center, *EGRIFTA Assist®*, which guides physicians and patients through the process of initiating treatment under reimbursement. This process, which can be complex and time-consuming, begins with a statement of medical necessity and concludes with the final reimbursement decision. inVentiv also assists us with pharmacovigilance activities and with other regulatory matters that may arise from time to time.

The inVentiv Agreement contains customary representations and warranties, indemnification, confidentiality, intellectual property and termination provisions. The inVentiv Agreement is scheduled to expire on November 30, 2019, unless earlier terminated.

Canada

General

EGRIFTA® was approved for commercialization in Canada on April, 30 2014 in its 2 mg/vial presentation and, on March 30, 2015, in its 1 mg/vial presentation.

We have been commercializing *EGRIFTA®* in Canada since June 2015 using our internal team. We currently have one salesperson dedicated to the *EGRIFTA®* operation in Canada. Our initial activities were focused on reimbursement by private drug plans and working with patient groups and key opinion leaders in the medical community to develop awareness of the disease and the availability of *EGRIFTA®* for its treatment.

In the past year, we have turned our attention to seeking reimbursement for EGRIFTA® from the provincial government drug plans. We have filed applications in every province and territory of the country. To date, most of the Maritime provinces along with the provinces of British Columbia, Alberta

and Québec have denied coverage for *EGRIFTA*®. While we have not yet heard from all of the jurisdictions in Canada, we are no longer counting on coverage in any government-sponsored drug plans. Given the small size of the Canadian market, the impact of this on our total revenue is not material. *EGRIFTA*® continues to be available in Canada to cash-paying patients and those with private insurance, who together represent approximately 30-50% of the market, varying from province to province.

The supply chain and commercialization process of *EGRIFTA*® in Canada is as described below.

Manufacturing

The manufacturing components of *EGRIFTA*® for commercialization in Canada are made by Bachem, Jubilant and Becton Dickinson as for the United States under the same agreements as those of the United States. The sterile water for injection is purchased off-the-shelf from a distributor. Since sterile water for injection is easily available in Canada, no formal agreement has been entered into with a third party supplier.

On March 30, 2015, we entered into a packaging agreement with Bellwyck Packaging Inc., or Bellwyck. Under this agreement, Bellwyck is responsible to label the vials of *EGRIFTA*® and place them in boxes ready for shipping and to package syringes, needles, sterile water for injection and patients inserts in the boxes ready for shipping. The agreement is scheduled to terminate on March 30, 2017, unless earlier terminated as a result of a breach by one of the parties or as a result of an insolvency event.

Distribution

On June 3, 2015, we entered into a master services agreement with McKesson Canada Corporation, or McKesson Canada, pursuant to which McKesson Canada is providing us with various services in connection with the commercialization of *EGRIFTA*® in Canada, or McKesson Canada Agreement. The McKesson Canada Agreement is scheduled to terminate on June 3, 2018, unless earlier terminated by the parties in the event of a breach by one party that is not cured within the period prescribed in the agreement, in the event there occurs an insolvency event or in the event *EGRIFTA*® is no longer commercialized in Canada.

Under the terms of the McKesson Canada Agreement, McKesson Canada purchases *EGRIFTA*® from us and resells and distributes *EGRIFTA*® to Canadian pharmacies which form part of its network.

Marketing and Sales

The commercialization of *EGRIFTA*® in Canada is conducted internally.

In addition, McKesson Canada provides the services of a call center, *EGRIFTA Support*®, which guides physicians and patients through the process of initiating treatment with *EGRIFTA*®, which answers questions patients may have regarding *EGRIFTA*® and which helps patients with the reimbursement process.

Latin America, Africa and the Middle East

On December 6, 2010, we entered into the Sanofi Agreement granting sanofi the exclusive commercialization rights to *EGRIFTA*® in Latin America, Africa and the Middle East.

Under the terms of the Sanofi Agreement, we will sell *EGRIFTA*® to sanofi at a transfer price equal to the higher of a percentage of sanofi's net selling price and a predetermined floor price. sanofi will be responsible for conducting all regulatory and commercialization activities for *EGRIFTA*® in the territories covered by to the Sanofi Agreement. We will be responsible for the manufacture and supply of *EGRIFTA*® to sanofi. We have retained all development rights to tesamorelin for other indications and will be responsible for conducting development activities for any additional potential indications. We also granted sanofi an option to commercialize tesamorelin for other indications in the territories mentioned above. If such option is not exercised, or is declined, by sanofi, we may commercialize tesamorelin for such indications on our own or with a third party. The initial term of the Sanofi Agreement extends until December 2020.

To date, Mexico is the only country where a marketing authorization has been issued and is in effect. Sanofi obtained the approval from COFEPRIS, Mexico's health agency, in March 2016 to commercialize *EGRIFTA*® in its 1 mg/vial presentation. Sanofi has not begun any commercialization activity. The next steps in this country consist in filing all documents with the Mexican regulatory authority to seek reimbursement for *EGRIFTA*® under Mexico's drug reimbursement plan. All marketing authorization applications filed in Argentina, Brazil, Colombia, Israel and Venezuela have been abandoned. There are no other marketing authorization applications that have been filed by Sanofi in the territories covered under the Sanofi Agreement.

Europe

On February 25, 2015, we entered into the AOP Agreement granting AOP the right to commercialize and distribute *EGRIFTA*® in the following countries: Austria, Albania, Belarus, Belgium, Bosnia & Hercegovina, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Kazakhstan, Latvia, Lithuania, Luxembourg, Macedonia, Netherlands, Norway, Poland, Romania, Russian Federation, Serbia, Slovak Republic, Slovenia, Sweden, Switzerland, Ukraine and United Kingdom, or collectively, the Territory.

Under the terms of the AOP Agreement, AOP is responsible to conduct all regulatory activities to obtain marketing authorizations for *EGRIFTA*® in the Territory. Prior to obtaining such marketing authorizations, AOP distributes *EGRIFTA*® through named patients sales programs.

We are responsible for the manufacture of *EGRIFTA*® and its supply to AOP at a predetermined transfer price. AOP will pay royalties on net sales of *EGRIFTA*® over a certain price level. The AOP Agreement further provides for a milestone payment upon obtaining marketing authorizations, pricing and reimbursement approvals in countries totalling a certain number of inhabitants, as well as milestone payments upon reaching certain levels of cumulative net sales of *EGRIFTA*® in the territory. Upon execution of the AOP Agreement, we received an upfront payment of 150,000 Euros. Including that upfront payment, milestone payments could potentially reach a combined total of three million Euros. The term of the Agreement varies on a country-by-country basis and extends for seven years from the first sales of *EGRIFTA*® in each country or February 25, 2025, whichever is later.

South Korea

On August 18, 2015, we entered into the BL&H Agreement granting BL&H the right to commercialize and distribute *EGRIFTA*® in South Korea.

Under the terms of the BL&H Agreement, BL&H will be responsible to conduct all regulatory activities to obtain marketing authorizations for *EGRIFTA*® in South Korea. Prior to obtaining such marketing authorizations, BL&H intends to distribute *EGRIFTA*® through named patients sales programs.

We will be responsible for the manufacture of *EGRIFTA*® and its supply to BL&H at a predetermined transfer price. BL&H will pay royalties on net sales of *EGRIFTA*® over a certain price level. The BL&H Agreement further provides for nominal milestone payments upon attaining certain levels of cumulative sales in South Korea. The BL&H Agreement has a 10-year term.

Portugal

On September 1, 2016, we entered into the PRX Agreement granting PRX the exclusive right to commercialize and distribute *EGRIFTA*® in Portugal.

Under the terms of the PRX Agreement, we are responsible to obtain the marketing authorization for EGRIFTA® in Portugal and PRX is responsible to assist us in conducting all regulatory activities to obtain such marketing authorization for *EGRIFTA*® in that country. All costs related to regulatory activities will be borne by PRX. Prior to obtaining a marketing authorization for *EGRIFTA*®, PRX undertook to provide to medical professionals in Portugal all information necessary to allow them to obtain approvals from the competent regulatory authorities to supply *EGRIFTA*® under named patient sales programs, compassionate use programs and/or other similar existing programs. PRX will be solely responsible to commercialize and distribute *EGRIFTA*® in Portugal and will pay for all costs therefor.

We will be responsible for the manufacture of *EGRIFTA*® and its supply to PRX at a pre-determined transfer price. The PRX Agreement further provides that for nominal milestones payments to us upon attaining certain levels of cumulative sales in Portugal. The PRX Agreement prevents PRX from commercializing any other product for the treatment of HIV-associated lipodystrophy. The PRX Agreement further contemplates that PRX will have to purchase a minimum number of vials of *EGRIFTA*® on a yearly basis once marketing authorization for the product has been obtained. The parties have agreed to negotiate such minimum number once marketing authorization has been obtained.

The PRX Agreement contains customary representations and warranties from both parties, indemnification and other customary provisions for agreements of this nature. The PRX Agreement will expire on the later of (i) the seventh year following the date of the first commercial sale of the product or (ii) September 1, 2026. The PRX Agreement will renew automatically for consecutive two-year terms thereafter if all conditions under the PRX Agreement are met.

Spain

On September 1, 2016, we entered into the Praxis Agreement granting Praxis the exclusive right to commercialize and distribute *EGRIFTA*® in Spain.

Under the terms of the Praxis Agreement, we are responsible to obtain the marketing authorization for EGRIFTA® in Spain and Praxis is responsible to assist us in conducting all regulatory activities to obtain such marketing authorization for *EGRIFTA*® in that country. All costs related to regulatory activities will be borne by Praxis. Prior to obtaining a marketing authorization for *EGRIFTA*®, Praxis undertook to provide to medical professionals in Spain all information necessary to allow them to obtain approvals from the competent regulatory authorities to supply *EGRIFTA*® under named patient sales programs, compassionate use programs and/or other similar existing programs. Praxis will be solely responsible to commercialize and distribute *EGRIFTA*® in Spain and will pay for all costs therefor.

We will be responsible for the manufacture of *EGRIFTA*® and its supply to Praxis at a pre-determined

transfer price. The Praxis Agreement further provides that for nominal milestones payments to us upon attaining certain levels of cumulative sales in Spain. The Praxis Agreement prevents Praxis from commercializing any other product for the treatment of HIV-associated lipodystrophy. The Praxis Agreement further contemplates that Praxis will have to purchase a minimum number of vials of *EGRIFTA*® on a yearly basis once marketing authorization for the product has been obtained. The parties have agreed to negotiate such minimum number once marketing authorization has been obtained.

The Praxis Agreement contains customary representations and warranties from both parties, indemnification and other customary provisions for agreements of this nature. The Praxis Agreement will expire on the later of (i) the seventh year following the date of the first commercial sale of the product or (ii) September 1, 2026. The Praxis Agreement will renew automatically for consecutive two-year terms thereafter if all conditions under the Praxis Agreement are met.

Other Territories

We have retained full commercial rights for *EGRIFTA*® in unpartnered territories and we intend to seek partners for the commercialization of *EGRIFTA*® in some of those territories.

2.6 PRE-COMMERCIALIZATION ACTIVITIES

Further to the execution of the TaiMed Agreement, we have begun analyzing the infrastructure needed to launch ibalizumab in the United States, if and when approved. We have also begun reaching out to third party service providers who will assist us in implementing such infrastructure. Setting-up the infrastructure to commercialize ibalizumab means, amongst other things, implementing the supply chain for ibalizumab, defining the territories where HIV-patients and prescribing physicians are the most prevalent, determining the number of people required to detail ibalizumab, if and when approved, assessing the reimbursement by both private and public payors and preparing the packaging and promotional material to be used for ibalizumab.

We have also begun mapping the various medical activities that we intend to undertake in the current year to sensitize medical professionals to the disease aimed to be treated with ibalizumab and began educational medical activities with those professionals in the coming months.

2.7 COMPETITION

The pharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions, many of whom have greater financial, technical and human resources than us. We believe the key competitive factors that affect the commercial success of *EGRIFTA*® are efficacy, safety and tolerability profile, reliability, product acceptance by patients, physicians and other healthcare providers, convenience of dosing, price and reimbursement.

***EGRIFTA*®**

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*® from other drugs, such as human growth-hormone, testosterone, insulin sensitizing agents 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.

Ibalizumab

Although ibalizumab is an investigational drug and has not been approved, we monitor the development activities of other compounds aimed at preventing the entering of HIV virus into human cells. For instance, we are aware that Fuzeon® and Selzentry®, which have been approved by the FDA, are being used to treat MDR HIV-1 patients and that Fostemsavir and Pro-140 are in Phase III clinical development. None of these products have the same mechanism of action as ibalizumab.

2.8 GOVERNMENT REGULATION

Overview

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

Governmental authorities in the United States, Canada, and other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products, such as *EGRIFTA*® 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*® in the United States.

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

Sales and Marketing Regulation

We are subject to various United States requirements relating to the sales and marketing of *EGRIFTA*® 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*® may be promoted only for the approved indications and in accordance with the provisions of the approved label. Ibalizumab may not be promoted since it has not received regulatory approval from the FDA and is an investigational drug only. Any promotional claims regarding an approved drug must also be truthful and not misleading. The FDA, as well as other government authorities, actively enforces the laws and regulations prohibiting the promotion of misleading or unapproved (i.e. off-label) uses and, if we are found to have improperly promoted, we may be subject to significant sanctions. The FDA does not regulate the practice of medicine by physicians in their choice of treatment. 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 marketing of *EGRIFTA*® within the United States is also subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce or reward, the referral of business, including the purchase or prescription of a particular drug that is subject to government reimbursement. Due to the breadth of the statutory provisions, it is possible that we might be challenged under anti-kickback or similar laws. Sanctions under these laws include civil monetary penalties, exclusion from U.S. federal and state healthcare programs (i.e., those programs will not provide reimbursement or payment coverage for *EGRIFTA*®), and criminal penalties including imprisonment. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (including Medicare and Medicaid) claims for reimbursement for drugs or services that are false or fraudulent. 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, several states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits, and report to state governments any gifts, compensation, and other remuneration provided to certain healthcare professionals. Regulations implementing certain provisions of health care legislation require record-keeping and disclosure to the federal government of certain transfers of value to U.S.-licensed physicians and teaching hospitals, otherwise known as the "Sunshine Act". Any activities relating to the sale and marketing of *EGRIFTA*® may be subject to scrutiny under these laws. Failure to make these required reports or comply with these similar states laws can result in civil monetary penalties. If the government were to allege or convict us of violating these laws, our business could be harmed. In addition, there is ability for private individuals to bring similar actions.

Good Manufacturing Practices

Drug products must be manufactured in accordance, among other things, with current good manufacturing practices, or GMP, and both Bachem and Jubilant must adhere to GMP in connection with the manufacture of tesamorelin and the finished product, *EGRIFTA*®. If a company wants to make certain changes in its manufacturing equipment, location or process, 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 GMP. 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 seek civil, criminal or administrative sanctions and/or remedies against the manufacturer, including the issuance of an enforcement letter, seeking corrective action, or requiring suspension of manufacturing operations.

Good Clinical Practices

The FDA promulgates regulations and standards, commonly referred to as good clinical practices, or GCP, 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. Both our Observational Study and Retinopathy Study are subject to GCP. The conduct of the clinical trials using ibalizumab was also subject to GCP. The FDA enforces GCP through periodic inspections of trial sponsors, principal investigators and trial sites. We rely on inVentiv to conduct our Observational Study and our Retinopathy Study. TaiMed was responsible to comply with GCP when it conducted its clinical trials with ibalizumab and we have relied on them for compliance with GCP. If our study sites fail to comply with applicable GCP or other applicable requirements, such as informed consent or Institutional Review Board oversight, or if the clinical trials conducted by TaiMed failed to comply with GCP, the clinical data generated in our clinical trials or in TaiMed's clinical trials may be deemed unreliable and the FDA may require us or TaiMed, as the case may be, to redo our studies or

stop a study and, in the case of TaiMed, refuse to approve ibalizumab. Where patient safety is at risk, the FDA could impose a clinical hold.

2.9 PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the United States and in other countries, sales of *EGRIFTA*® and our other product candidates will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities (such as Medicare and Medicaid in the United States), managed care providers, private health insurers and other organizations.

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 product candidates. We, or our commercial partners, may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of *EGRIFTA*® and ibalizumab (if and when approved). *EGRIFTA*® and/or ibalizumab 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 to sell *EGRIFTA*® and/or ibalizumab (if and when approved) 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 *EGRIFTA*® and any other drug product profitably. For example, in March 2010, President Obama signed into law the *Patient Protection and Affordable Care Act*, and the associated reconciliation bill, which we refer to collectively as the *Health Care Reform Law*, 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 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 Medicaid drug rebates we must pay to states. On January 21, 2016, the Centers for Medicare and Medicaid Services (CMS) finalized a rule detailing reforms to the rebate and reimbursement systems for Medicaid prescription drugs. This final rule is intended to save taxpayers billions and ultimately improve beneficiary access to prescription drugs. The final rule potentially allows manufacturers to recalculate the baseline "average manufacturer price" and includes US territories in the calculation of "average manufacturer price" and "best price" effective April 1, 2017. Further, the new law imposes a significant annual fee on companies that manufacture or import certain branded prescription drug products and biologic agents. 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 most 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 stand-alone 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 often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results under Part D may result in a similar reduction in 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 payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations, and additional legislative proposals. Indeed, 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.

The Health Care Reform Law may be repealed and may or may not be replaced with a different law or health care payment system.

Countries other than the United States and Canada

Outside of the United States, sales of *EGRIFTA*® and other drug products 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 country and are given different weight depending on the countries' attitudes towards providing public healthcare and the government's willingness to pay for these new drugs. We or our commercial partners 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 many jurisdictions, 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 country and in other countries, the evaluation of what a fair price would be based on the condition that is being treated and innovative quality of the new drug.

Many countries have initiated cost-cutting measures which have been reflected in reduced budgets for drugs, higher discounts imposed on manufacturers and price negotiations between authorities and manufacturers among other actions. We expect the current reimbursement evaluation process and pricing policies to keep evolving in ways that we may not foresee.

Pursuant to the Sanofi Agreement, the AOP Agreement, the BL&H Agreement, the Praxis Agreement

and the PRX Agreement, each of sanofi, AOP, BL&H, Praxis and PRX are responsible for identifying and obtaining possible reimbursements under government programs in the territories covered under their respective agreements.

2.10 INTELLECTUAL PROPERTY

Our Current Patent Portfolio

Our current patent portfolio is comprised of patents and patent applications for the following compounds:

Tesamorelin

- In the United States, we own US patent 5,861,379 covering the composition of matter of tesamorelin, which is scheduled to expire in May 2020 after having obtained a patent term extension certificate from the USPTO for such patent. In addition, we own three issued United States patents relating to the use of tesamorelin in the treatment of HIV-associated lipodystrophy, which are scheduled to expire in 2023, as well as a patent relating to the use of tesamorelin in the treatment of mild cognitive impairment that is scheduled to expire in 2025. Furthermore, we have a patent set to expire in 2027 that relates to the use of tesamorelin in the improvement of muscle function in subjects suffering from severe wasting. Finally, we have a patent on a new formulation of tesamorelin scheduled to expire in 2033. This new formulation is different from the F4 Formulation which is not protected by patent.

- In Canada, we own a patent relating to the use of tesamorelin in the treatment of metabolic conditions associated with fat accumulation and/or hypercholesterolemia, including HIV-associated lipodystrophy, which is scheduled to expire in October 2024, as well as a patent relating to the use of tesamorelin in the treatment of mild cognitive impairment that is set to expire in May 2023.

- In Mexico, we own one patent related to the use of tesamorelin in the treatment of HIV-associated lipodystrophy which is scheduled to expire in October 2025.

TH1173

- We have obtained from the USPTO and the IMPI (Mexico Patent Office) patents covering the composition of matter of TH1173, which are scheduled to expire in 2032. Corresponding patent applications are currently pending in Canada, Europe, Japan, China, Brazil, Argentina and Venezuela, and patents stemming from these applications, if granted, would also expire in April 2032.

Acute Kidney Injury

- We have obtained from the USPTO a patent covering the composition of matter of TH0673 which is scheduled to expire in September 2031.

Melanotransferrin

- In the United States, we own a patent covering the composition of matter of melanotransferrin-related peptides, which is scheduled to expire in October 2032. Our property right in such patent is now subject to the ongoing discussions we have with Transfert Plus L.P. in connection with the future development of such peptides. We have also pending applications

relating to melanotransferrin-related peptides from which national patent applications were filed in Canada, Europe, Mexico and South Korea. If such patents are granted, they would be scheduled to expire in 2032.

Our Trademarks & Other Intellectual Property

EGRIFTA® is our registered trademark in the United States and in Canada and it is used in those countries to commercialize tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

EGRIFTA Assist® 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 statements of medical necessity and answering questions from both healthcare professionals and patients regarding *EGRIFTA*®. An application has been filed for the trademark *EGRIFTA Support*™ in Canada and it is used for the same purpose as in the United States.

We have obtained registration for the name *EGRIFTA*® in many of the countries covered by the Sanofi Agreement, the AOP Agreement, the BL&H Agreement, the PRX Agreement, the Praxis Agreement, and in many other countries worldwide. The use of the *EGRIFTA* trademark for tesamorelin intended for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the jurisdictions where we or our commercial partners intend to commercialize *EGRIFTA*® generally requires the approval of the regulatory authorities reviewing the marketing authorization application in such jurisdictions and the approval of the local intellectual property agency. In certain countries, such as in Canada, registration of a trademark may not occur until a declaration of use of the product for which a trademark is sought is filed with the appropriate intellectual property agency of such countries. A declaration of use can be filed once a product is approved for commercialization. We have also reserved certain domain names in order to support our trademark *EGRIFTA*®.

Our Policy on Intellectual Property

Our portfolio of intellectual property contains additional pending trademark registrations and domain names.

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:

- perform surveillance of third party patents and patent applications in order to identify any third party patent or third party patent application which, if granted, could be infringed by our activities;

- 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 in countries of interest; and

- maintain our intellectual property rights by paying government fees as may be necessary to ensure such rights remain in force.

Regulatory Exclusivity

The regulatory regimes of the United States and Canada may provide market exclusivity for a pharmaceutical product. Data protection and patent term extension for holders of patents provide a person with additional protection against third parties who may wish to commercialize a product similar to an approved product.

Data Protection

In the United States, the *Drug Price Competition and Patent Term Restoration Act of 1984*, also known as the *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.

An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications, stability, analytical methods, manufacturing process validation data, quality control and bioequivalence. Rather than demonstrating safety and effectiveness, an ANDA applicant must demonstrate that its product is bioequivalent to an approved reference drug. ANDAs generally cannot be submitted for products that are not bioequivalent to the referenced drug or that do not have the same labeling as the reference drug.

When the FDA approves an NDA (or a 505(b)(2) NDA), it lists the approved drug in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", also known as the "Orange Book". With limited exception, the FDA also lists patents identified by the NDA applicant as claiming the drug or an approved method of using the drug.

Any applicant who files an ANDA must certify to the FDA with regard to each relevant patent that: (1) no patent information has been filed with the FDA; (2) the patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the patent is invalid, unenforceable, or will not be infringed upon by the manufacture, use or sale of the drug product for which the ANDA is submitted. This last certification is known as a Paragraph IV certification. A notice of the Paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. The applicant may determine there are other applicable patent certifications, depending on the facts.

As mentioned above, generally, an ANDA (or a 505(b)(2) NDA) may not be submitted prior to the expiry of the five year regulatory exclusivity period applicable to a drug product made of a "new chemical entity". However, the submission of an ANDA with a Paragraph IV certification is permitted after four years and, if a patent infringement is brought by the patent owner within 45 days from receipt of the certification notice, the FDA is prevented from approving that ANDA until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent or such shorter or longer period as may be ordered by a court. An ANDA applicant that is sued for

infringement may file a counterclaim to challenge the listing of the patent or information submitted to the FDA about the patent. This 30-month stay applied regardless of whether there is any underlying non-patent market exclusivity. In addition, a patent infringement claim can be brought after 45 days, but it will not affect the FDA review.

FDA may grant three years of exclusivity if an NDA application or supplement to an approved NDA contains reports of new clinical investigations (not bioavailability studies). FDA may also grant pediatric exclusivity of six months, added to an underlying exclusivity or patent, in certain cases.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Competitors, however, may receive approval of different active moieties for the same orphan indication or obtain approval for the same active moiety for a different indication. Orphan drug designation does not shorten the FDA review process or ensure FDA approval. It is also possible that, even if FDA approves a new drug application that has orphan drug designation, it might not grant orphan drug exclusivity.

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 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.

If approved by the FDA, we expect that ibalizumab will benefit from a 12-year exclusivity period.

In Canada, the Food and Drug Regulations provide an eight year market exclusivity period to a Notice of Compliance (NOC) holder who markets an innovative drug in Canada.

Patent Term Extension

In the United States, the *Hatch-Waxman Act* permits patent term extension for one patent per approved drug of up to five years for patent term lost during product development and the FDA

regulatory review process. However, patent term extension cannot extend the remaining patent term beyond a total of 14 years from the product's approval date. The patent term extension period is generally one-half the time between the effective date of an Investigational New Drug Application, or IND, and the submission date of an NDA plus the time between the submission date of an NDA and the NDA. We have obtained a five year patent term extension with respect to US patent 5,861,379 covering the composition of matter of tesamorelin.

In Canada, in the context of the Comprehensive Economic and Trade Agreement, or CETA, between Canada and Europe, amendments to Canadian laws are intended to be passed to provide up to a two year patent term extension period under certain conditions. We are aware that the Canadian government has begun working on amending its laws to provide such patent term extension period but are unable to predict when such laws will become in force.

2.11 EMPLOYEES

As at November 30, 2016, we had 26 employees and, as at the date hereof, we have 24 employees. All of our employees are employed in Canada and engaged in administration, finance, regulatory and business development functions. None of our employees are unionized. We believe the relations with our employees are good.

Through inVentiv, we have an additional 30 persons dedicated to the commercialization of *EGRIFTA*® in the United States.

2.12 FACILITIES

We currently carry out our activities at 2015 Peel Street, 5th Floor, in the City of Montreal, Québec, Canada. We lease a 7,496 square-foot office space. We no longer have laboratory facilities in our premises.

2.13 ENVIRONMENT

To our knowledge, environmental protection requirements do not have a significant 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 common shares or common share purchase warrants, 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 adversely affect our business, financial condition, operating results or prospects. As a result, the trading price of our common shares and common share purchase warrants could decline and you could lose all or part of your investment.

3.1 RISKS RELATED TO THE COMMERCIALIZATION OF *EGRIFTA*®

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

Our ability to generate revenue and sustain growth is currently based on the commercialization of one product, *EGRIFTA*®, in the United States.

Our success in commercializing *EGRIFTA*® in the United States 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*® by third-party payors;
- to maintain the registration of *EGRIFTA*® on U.S. governmental forms as a drug available for purchase in the United States;
- to ensure that adequate supplies of *EGRIFTA*® are available;
- to maintain conflict-free relationships with our principal third-party suppliers of services, namely our agent in the United States, inVentiv, our manufacturers, Bachem, and Jubilant, and our wholesalers, RxCrossroads, H. D. Smith, Cardinal, and McKesson;
- to comply with all laws and regulations in the United States that pertain to the commercialization of a pharmaceutical product; and
- to defend our intellectual property rights against third-parties.

Our success in commercializing *EGRIFTA*® in the United States will also depend on:

- the capacity of inVentiv, in collaboration with us, to retain qualified, motivated and talented sales representatives and other key individuals instrumental in the commercialization of *EGRIFTA*® in the United States; 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 *EGRIFTA*® to customers in the United States will increase in the future. If sales of *EGRIFTA*® to customers 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*® for the foreseeable future, any negative developments relating to this product, 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.

We rely on third parties for the manufacture, distribution and commercialization of EGRIFTA® 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 *EGRIFTA*®, namely its manufacturing, its distribution and its 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 replaced.

We do not own or operate manufacturing facilities for the production of *EGRIFTA*®, tesamorelin or any of our other compounds, 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 our commercial sales and for the conduct of the Observational Study and the Retinopathy Study mandated by the FDA. Although potential alternative suppliers and manufacturers have been identified, we have not entered into any agreements with them nor have we qualified these vendors to date and no assurance can be given that such suppliers 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.

We do not have state licensure in the United States to distribute *EGRIFTA*® and we do not currently intend to pursue applications to obtain the licenses required in order to distribute a drug product in every American state. Our supply chain model is based upon that fact and the distribution of *EGRIFTA*® in the United States is done through RxCrossroads which currently holds all state licensure required to distribute a drug product in every American state. We have not identified another third-party service provider that could replace RxCrossroads in the event that it becomes unable to distribute *EGRIFTA*®. The replacement of RxCrossroads would be time-consuming and might not be successful if we are unable to agree on the terms and conditions of a commercial agreement with another third-party service provider.

We do not employ sales or medical service liaison personnel in the United States in connection with the commercialization of *EGRIFTA*® in this territory. We rely on inVentiv to provide us with all of the services related to the commercialization of *EGRIFTA*®, namely sales personnel, medical science liaison personnel, reimbursement specialists and other individuals whose roles and functions pertain to the commercialization of *EGRIFTA*®. In addition, we rely on inVentiv for the conduct of the Observational Study and the Retinopathy Study. Although we are aware that there exists other third-party services providers that could provide the same services as inVentiv, 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 inVentiv, 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.

Our reliance on one third-party service provider 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*® and tesamorelin if a third-party manufacturer:

- becomes unavailable to us 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*® in the United States if RxCrossroads:

- becomes unavailable to us for any reason, including as a result of its failure to meet applicable laws;
- 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
- fails to perform its contractual obligations under our agreement.

We may be subject to a decrease in sales of *EGRIFTA*® in the United States or may face reimbursement challenges if inVentiv:

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

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

New safety or drug interaction issues may arise as *EGRIFTA*® is 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 or drug interaction 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 or drug interaction 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 or drug interaction problems could also result in product recalls, restrictions on the product's permissible uses, or withdrawal of the product from the United States market and/or a

rejection of the pending marketing authorization applications in other countries. If new safety or drug interactions issues are discovered, sales of *EGRIFTA®* may decrease resulting in a material adverse effect on our business, financial condition and operating results.

Our levels of revenues are highly dependent on obtaining patient reimbursement for EGRIFTA®.

Market acceptance and sales of *EGRIFTA®* 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®*.

Sales of *EGRIFTA®* to patients benefitting from U.S. funded reimbursement programs represent an important part of all sales of *EGRIFTA®*. Denial of coverage for *EGRIFTA®* under any of the current programs, or delays in obtaining coverage for *EGRIFTA®* under any of these programs, would materially adversely affect our revenues.

In addition, we cannot be sure that reimbursement by insurers, government or others will be available for *EGRIFTA®* in other territories. If reimbursement is not available, sales of *EGRIFTA®* may be adversely affected. Sales of *EGRIFTA®* may also be adversely affected if reimbursement is available to a limited number of patients. Under the Sanofi Agreement, the AOP Agreement, the BL&H Agreement, the PRX Agreement and the Praxis Agreement, each of sanofi, AOP, BL&H, PRX and Praxis are responsible for seeking reimbursement of *EGRIFTA®* in each country where marketing authorization could be obtained and, as a result, we have no control over whether, or what level of, reimbursement could be achieved. If reimbursement is not available or is available only in a limited manner, the commercialization of *EGRIFTA®* may not be successful and this could have a material adverse effect on our revenues and future prospects.

Even though EGRIFTA® is approved for sale in the United States and Canada, revenue that we generate from its sales may be limited.

Sales of *EGRIFTA®* or any future products for which we obtain marketing approval from the FDA, Health Canada or other regulatory authorities will depend upon the acceptance of such product 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 in the

absence of third-party coverage;

- the product price; and
- the effectiveness of sales and marketing efforts.

If *EGRIFTA*® does not achieve adequate sales, we may not generate sufficient revenue from this product to remain profitable. Moreover, if we do not generate sufficient revenue from the sale of *EGRIFTA*®, we may default on our payment obligations under the EMD Serono Termination Agreement and EMD Serono could exercise its rights under its security interest over all of our tesamorelin-related assets.

Our ability to grow our revenues from sales of EGRIFTA® in countries outside of the United States will be limited if we, sanofi, AOP, BL&H, PRX, Praxis or any other future commercial partner do not obtain market approval and reimbursement coverage or experience significant delays in the efforts to obtain market approval and reimbursement coverage for EGRIFTA®.

In order for *EGRIFTA*® to be commercialized outside of the United States, Canada and Mexico, it is necessary to obtain regulatory approval from the appropriate regulatory authorities. The regulatory authority of each country has its own rules and regulations and the requirements and timing for regulatory approval vary widely from country to country and may, in some cases, be different or more rigorous, than requirements in the United States or Canada.

Sanofi has obtained a marketing authorization for *EGRIFTA*® in Mexico only. However, sanofi has not begun commercializing *EGRIFTA*® in this country and has advised us that it will not begin commercialization until *EGRIFTA*® is reimbursed by Mexico's public plans.

Revenue growth will be affected if sanofi does not obtain reimbursement coverage for *EGRIFTA*® in Mexico.

In Europe, we have entered into the AOP Agreement where AOP is responsible for seeking marketing approval for *EGRIFTA*® in the countries covered by the AOP Agreement. To date, AOP is analyzing the file that we submitted to the FDA and has not made any filings with any of the regulatory authorities of those countries. We have also entered into the PRX Agreement and the Praxis Agreement where both PRX and Praxis are analyzing the file we submitted to the FDA to guide us in seeking approval for *EGRIFTA*® in Portugal and Spain. No filing has been initiated in those countries.

In South Korea, we entered into the BL&H Agreement where BL&H is responsible for seeking marketing approval for *EGRIFTA*®. To date, BL&H is analyzing the file that we submitted to the FDA to assess whether the file contains sufficient data to seek marketing approval for *EGRIFTA*® in South Korea.

In both Europe (including Portugal and Spain) and South Korea, if we, AOP and BL&H do not obtain marketing authorizations to commercialize and distribute *EGRIFTA*®, it could have an adverse effect on our revenue growth, operating results and business prospects.

In addition, even if *EGRIFTA*® is approved in all or some of the countries where marketing authorization applications are filed, or are intended to be filed, there is no assurance that *EGRIFTA*® will be successfully commercialized in any of those countries.

The overall commercialization success of *EGRIFTA*® outside the United States and Canada will depend on several factors, including:

- receipt of regulatory approvals for *EGRIFTA*® from regulatory agencies in the territories in which we wish to expand the commercialization of *EGRIFTA*®;
- reimbursement of *EGRIFTA*® by both private and public plans;
- market acceptance of *EGRIFTA*® by the medical community, patients and third-party payors;
- the amount of resources devoted by ourselves, sanofi, AOP, BL&H, PRX, Praxis and any other potential commercial partner, and their local agents in certain countries, to commercialize *EGRIFTA*® in those countries;
- maintaining manufacturing and supply agreements to ensure the availability of commercial quantities of *EGRIFTA*® through validated processes;
- the number of competitors in these other markets; and
- protecting and enforcing our intellectual property and avoiding patent infringement claims.

The non-approval or lack of commercial success of *EGRIFTA*® in major markets outside the United States would decrease our capacity to grow revenues and could affect our operating results.

We are dependent on collaboration and licensing agreements for the commercialization of EGRIFTA® in Latin America, Africa and the Middle East, certain European countries and South Korea. These agreements place the commercialization of EGRIFTA® in these markets outside of our control.

Although each of our collaboration and licensing agreements with sanofi, AOP, BL&H, PRX and Praxis contain provisions governing their responsibilities as partners for the commercialization of *EGRIFTA*® in their respective territories, our dependence on these commercial partners is subject to a number of risks, including:

- our limited control of the amount and timing of resources that they will be devoting to the commercialization, marketing and distribution of *EGRIFTA*®, including obtaining third-party patient reimbursement coverage, which could adversely affect our ability to obtain or maximize revenues;
- disputes or litigation that may arise between us and them, which could adversely affect the commercialization of *EGRIFTA*®, all of which would divert our management's attention and our resources;
- sanofi, AOP, BL&H, PRX or Praxis not properly defending our intellectual property rights or using them in such a way as to expose us to potential litigation, which could, in both cases, adversely affect the value of our intellectual property rights;
- corporate reorganizations or changes in business strategies of sanofi, AOP, BL&H, PRX or Praxis which could adversely affect their willingness or ability to fulfill their obligations under our agreement; and
- sanofi, AOP, BL&H, PRX or Praxis being found in breach of local laws.

Our collaboration and licensing agreements may be terminated by sanofi, AOP, BL&H, PRX and Praxis in the event of a breach by us of our obligations under such agreement, including our obligation to supply *EGRIFTA*®, for which we rely on third parties. If any of sanofi, AOP, BL&H, PRX and Praxis terminates its agreement with us or fails to effectively commercialize *EGRIFTA*®, for any of the foregoing or other reasons, we may not be able to replace any of them in those markets and the occurrence of any of the abovementioned events would affect our operating results.

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 that we have currently no direct competitors with an approved product indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. However, we face competition from companies selling human growth hormone, testosterone, insulin sensitizing agents and sermorelin as those products may be prescribed by physicians. New competitive products could also come on the market. In addition, a company could file an ANDA with the FDA with the aim of selling and marketing a generic version of *EGRIFTA*®.

3.2 RISKS RELATED TO IBALIZUMAB

Ibalizumab is an investigational drug that may never be approved by the FDA. If ibalizumab is not approved for commercialization by the FDA, our growth and profitability could be materially adversely affected. Even if approved, significant restrictions limiting its use could have a material adverse effect on our business, financial condition and operating results.

Ibalizumab is an investigational drug for which the pivotal Phase III trial was completed in 2016. TaiMed, as owner of this drug, is compiling the data from all clinical trials conducted with ibalizumab and assembling all of the documentation required to file a BLA with the FDA.

Although ibalizumab was designated a "Breakthrough Therapy" by the FDA, and although TaiMed has followed the regulatory requirements in connection with the conduct of clinical trials, there can be no guarantee that the FDA will approve ibalizumab for commercialization. Even if the results obtained to date appear positive, these results could prove to be unsatisfactory to the FDA from a safety, efficacy and/or quality standpoint and the FDA could refuse to approve ibalizumab. Even if the FDA approves ibalizumab, the indication for which ibalizumab can be used could be restricted, limiting the patient population and market to be addressed by ibalizumab. The non-approval of ibalizumab or the imposition of a significant limitation of use on ibalizumab would have a material adverse effect on our potential growth and profitability.

In addition, the non-approval of ibalizumab by the FDA or the imposition of significant restrictions on its use would have a material adverse effect on our business, financial condition and operating results given the pre-commercialization expenses related to ibalizumab to be incurred in the financial year 2017. Even a significant delay in filing the BLA, or in the issuance of a decision from the FDA, could have a material adverse effect on our business, financial condition and operating results.

We are relying on TaiMed for the preparation and submission of the BLA with the FDA pursuant to the terms and conditions of the TaiMed Agreement. Any error by TaiMed in assembling the BLA documents or in analyzing the data resulting from the clinical trials using ibalizumab could delay the filing of the BLA and/or the issuance of a decision by the FDA, and could result in ibalizumab not being approved by the FDA. Any one or all of these occurrences would have a material adverse effect on our business, financial condition and operating results.

Pursuant to the terms of the TaiMed Agreement, TaiMed is responsible for all regulatory activities related to the conduct of the clinical trials using ibalizumab and for obtaining the marketing authorization from the FDA to commercialize ibalizumab in the United States. Our sole right on ibalizumab prior to obtaining marketing authorization from the FDA is to conduct pre-commercialization activities in anticipation of the approval of ibalizumab. Although we are consulted

and have discussions with TaiMed on the preparation of the BLA, we have no right to intervene in the preparation of the BLA and in communicating with the FDA prior to the potential approval of ibalizumab. Therefore, we are relying solely on TaiMed for the preparation, filing and negotiation of the BLA. If TaiMed fails to adequately prepare the BLA, to file it on a timely basis or to negotiate effectively with the FDA, any one or all of these occurrences will have a material adverse effect on our business, financial condition and operating results.

The manufacturer retained by TaiMed is WuXi AppTec, or WuXi, a Chinese-based company, which has not been audited by the FDA in connection with the manufacture of ibalizumab. If WuXi does not pass the FDA inspection in connection with the manufacture of ibalizumab, the decision by the FDA on ibalizumab may be withheld or delayed or the FDA could decide to refuse to approve ibalizumab for commercialization, any one or all of these occurrences will have a material adverse effect on our business, financial condition and operating results.

Prior to approving a new drug, the FDA inspects the proposed manufacturer. In the case of ibalizumab, we were informed by TaiMed that the inspection will occur around May 2017, after the filing of the BLA. No date has been determined yet. During the course of the inspection, the FDA will attend to the manufacture of at least one batch of ibalizumab to ensure compliance with FDA rules, regulation and GMP.

The outcome of the inspection, if objectionable conditions are observed, may result in the FDA providing the manufacturer with a FDA Form 483 citing the list of observations which require corrective actions. The FDA renders a final classification of the inspection based on the documented observations and the compliance status of the manufacturer's establishment at the time of inspection. Based on its findings, the FDA will have discretion to require that all corrective actions and measures be made prior to issuing a decision on ibalizumab. If corrective actions or measures need to be implemented, the FDA may seek a second inspection confirming that any actions or measures taken meet its requirements. Implementing corrective measures, if necessary, planning an FDA inspection and, ultimately, doing the inspection and the issuance of the final inspection report by the FDA resulting therefrom takes time. If WuXi's inspection results in the FDA requiring major corrective actions, it is likely that the timing on the issuance of a decision by the FDA on the approval of ibalizumab for commercialization will be delayed. WuXi could also decide to not implement these corrective measures if the cost of implementing them is too high or if it has other business priorities. In such circumstances, the FDA will not approve ibalizumab until TaiMed can manufacture ibalizumab with a manufacturer that passes an FDA inspection. Delays in the decision to approve or to not approve ibalizumab in the United States will have a material adverse effect on our business, financial condition and operating results.

3.3 RISKS RELATED TO RESEARCH AND DEVELOPMENT ACTIVITIES

In connection with its approval of EGRIFTA®, the FDA has required the Observational Study and the Retinopathy Study.

The Observational Study is to evaluate the safety of long-term administration of *EGRIFTA®* and the Retinopathy Study is to assess whether *EGRIFTA®* increases the incidence or progression of diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat. Both studies are currently recruiting patients and since May 1, 2014, we have assumed responsibility for completing these studies. There can be no assurance that the two studies will be successfully completed or that the results of the studies will be positive. In the event that the studies are not completed or that the results are unfavorable, the FDA could prohibit the future sale, or put restrictions on future sale of *EGRIFTA®* in the United States, either of which would have a material adverse effect on our business, financial condition and operating results.

We have suspended all significant research and development activities related to our compounds and the discovery of new peptides until we have sufficient funds to invest in our research and development programs. We may never resume these activities, which could materially adversely affect our long-term growth and could cause us to rely solely on EGRIFTA® as a revenue-generating asset indefinitely.

Our portfolio of compounds is very limited and these compounds are at early stages of development. As a result of business plan revisions announced in October 2012, we suspended all significant long-term research and development activities on our compounds and the discovery of new peptides. There is no assurance that we will resume these activities and our long-term growth could be materially adversely affected.

In addition, even if we resume research and development of our compounds, there can be no assurance that these compounds will reach the clinical trial phase, obtain positive results in clinical trials, obtain regulatory approval or, if approved, be successfully commercialized.

We rely on third-party service providers to conduct the Observational Study and the Retinopathy Study for EGRIFTA® as well as our preclinical studies and clinical trials if the research and development activities related to our compounds are resumed. The failure by any of these third parties to comply with their obligations may delay the studies which could have an adverse effect on our research and development programs.

We have limited human resources to conduct preclinical studies and clinical trials and will have to rely on third-party service providers to conduct our studies and trials and carry out certain data gathering and analyses in the future. inVentiv has been retained to conduct the Observational Study and the Retinopathy Study mandated by the FDA. The preclinical, or non-clinical, studies must be conducted in compliance with good laboratory practice, or GLP, regulations. Clinical trials must comply with good clinical practice, or GCP, requirements, which are ethical and scientific quality standards for conducting, recording and reporting clinical trials to assure the integrity of study data and that the rights, safety and wellbeing of trial participants are protected. If our third-party service providers become unavailable for any reason, including as a result of the failure to comply with the rules and regulations governing the conduct of preclinical studies and clinical trials, operational failures such as equipment failures or unplanned facility shutdowns, or damage from any event such as fire, flood, earthquake, business restructuring, labour dispute or insolvency or, if they fail to perform their contractual obligations pursuant to the terms of our agreements with them, such as failing to perform the testing, compute the data or complete the reports further to the testing, we may incur delays which may be significant in connection with our post-approval commitments with the FDA for *EGRIFTA®* and/or the planned timing of our trials and studies which could adversely affect the timing of the development program of a compound or the filing of an application seeking marketing approval in a jurisdiction where we rely on third-party service providers to make such filing. In addition, where we rely on such third-party service provider to help in answering any questions raised by a regulatory agency during its review of one of our applications, the unavailability of such third-party service provider may adversely affect the timing of the review of an application and could ultimately delay the approval. If the damages to any of our third-party service providers are material, or, for any reason, such providers do not operate in compliance with GLP or GCP regulations or are unable or refuse to perform their contractual obligations, we would need to find alternative third-party service providers.

If we needed to change or select new third-party service providers, the planned working schedule related to preclinical studies and/or clinical trials could be delayed since the number of competent and reliable third-party service providers of preclinical and clinical work in compliance with GLP and GCP regulations is limited. In addition, if we needed to change or select new third-party service providers to carry out work in response to a regulatory agency review of one of our applications, there may be

delays in responding to such regulatory agency which, in turn, may lead to delays in commercializing a product candidate.

Any selection of new third-party service providers to carry out work related to preclinical studies and clinical trials would be time-consuming and would result in additional delays in receiving data, analysis and reports from such third-party service providers which, in turn, would delay the filing of documents with the FDA in connection with the Observational Study and the Retinopathy Study. These delays could also postpone the filing of any NDA, or its equivalent, with FDA or comparable regulatory agencies for the purposes of obtaining regulatory approval to commercialize our product candidates. Furthermore, such delays could increase our expenditures to develop a compound and materially adversely affect our business, financial condition and operating results.

The conduct of clinical trials requires the enrolment of patients and difficulties in enrolling patients could delay the conduct of our clinical trials or result in their non-completion.

The conduct of clinical trials requires the enrolment of patients. We may have difficulties enrolling patients for the conduct of the Observational Study and the Retinopathy Study mandated by the FDA or our future clinical trials as a result of design protocol, the size of the patient population, the eligibility criteria to participate in the clinical trials, the availability of competing therapies, the patient referral practices of physicians and the availability of clinical trial sites. Difficulty in enrolling patients for our clinical trials could result in the cancellation of clinical trials or delays in completing them. Once patients are enrolled in a clinical trial, the occurrence of any adverse drug effects or side effects observed during the trial could result in the clinical trial being cancelled. Any of these events would have material adverse consequences on the timely development of our compounds, the filing of an NDA, or its equivalent, with FDA or comparable regulatory agencies and the commercialization of such compounds. Moreover, if we are unable to complete the Observational Study and the Retinopathy Study within the time mandated by the FDA because we have difficulties enrolling patients for these studies, the FDA could withdraw *EGRIFTA*® from the market. Under these circumstances, our revenues and operating results would be materially adversely affected and we could be in default under our payment obligations to EMD Serono.

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.

Although we have received patents from the USPTO for the treatment of HIV-related lipodystrophy with tesamorelin, there can be no guarantee that, in the other countries where we filed patent applications for the treatment of HIV-related lipodystrophy, we will receive a patent or obtain granted claims of similar breadth to those granted by the USPTO.

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*®, or other product candidates, 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. The fact that we own patents for tesamorelin and 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.

For example, EMD Serono has listed a patent held by one of its affiliates in the Orange Book under the *Hatch-Waxman Act* with respect to *EGRIFTA*® in HIV-associated lipodystrophy. With the termination of the EMD Serono Agreement, EMD Serono could assert that such patent would be infringed by our continued sale of *EGRIFTA*® in the United States. To counter that risk, we have obtained a non-exclusive license from EMD Serono's affiliate under the EMD Serono Termination Agreement in order to continue selling *EGRIFTA*® in the United States. If we are in default under the EMD Serono Termination Agreement and such default is not cured within the agreed upon time, EMD Serono's affiliate could terminate our non-exclusive license. The termination of that license could prevent us from selling *EGRIFTA*® in the United States if we were found to infringe the patent listed by one of EMD Serono's affiliates in the Orange Book and this could have a material adverse effect on our business, financial condition and operating results.

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 wilful 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.

We have not been served with any notice alleging that we infringe a third-party patent, but 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®. We may also be subject to enforcement action if we engage in the promotion of ibalizumab prior to obtaining regulatory approval.

Our promotional materials and training methods must comply with the *Federal Food, Drug and Cosmetic Act*, as amended, of the United States, or FFDCA, and other applicable laws and regulations, including restraints and prohibitions on the promotion of off-label, or unapproved, use. Physicians may prescribe *EGRIFTA®* 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 *EGRIFTA®*, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of *EGRIFTA®* 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 ibalizumab in the United States and in Canada prior to obtaining regulatory approval since it is an investigational drug. Promotional activities may begin in one of those countries once a drug is approved by the FDA, in the United States, and Health Canada, in Canada. We are only allowed to conduct certain medical activities surrounding the disease aimed to be treated with ibalizumab, if approved. If we are found to violate these rules, the FDA or Health Canada could delay the issuance of a decision regarding the approval or non-approval of ibalizumab and we could be subject to fines or other penalties.

There exist similar laws in Canada that we must comply with in connection with our commercialization of *EGRIFTA®* there.

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 payers 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
- Non-U.S. and U.S. state 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 payer, 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 of 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 *EGRIFTA*® in the United States, which could harm the commercial success of *EGRIFTA*® 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*® or manufacturing processes, withdrawal of *EGRIFTA*® from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material and 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 of 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®, our capacity to generate revenues and management's attention to the development of our business.

We rely on sanofi, AOP, BL&H, PRX and Praxis to commercialize and to obtain and maintain regulatory approvals of *EGRIFTA*® in the territories covered under our distribution and licensing agreements with each of them. We also rely on third-party service providers for sales, marketing and distribution activities in the United States and to manufacture *EGRIFTA*® for commercialization and tesamorelin for our clinical trials. Under those agreements, 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 sanofi, AOP, BL&H, PRX and Praxis and 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 one commercial partner per territory and single third-party service providers, each of whom performing key services for the success of our business plan. In addition, under the terms of the EMD Serono Termination Agreement, we have granted EMD Serono a security interest over all of our tesamorelin-related assets. If we are in breach of the EMD Serono Termination Agreement by failing to meet our payment obligations to EMD Serono, EMD Serono has the right to seize all of those tesamorelin-related assets. Unless we are able to generate sufficient revenues from *EGRIFTA*® or other assets, a breach of the payment provisions under the EMD Serono Termination Agreement by us will have a

material adverse effect on our business and could lead to recourses under insolvency laws.

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 *EGRIFTA*® and our other product candidates, 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 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, Latin America, Africa, the Middle East, Europe and South Korea and elsewhere subject us to additional risks, including:

- 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 labour 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 labour 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.

The election of a new government in the United States could result in amendments to existing laws, or enactment of new laws, that could materially adversely affect the commercialization of *EGRIFTA®* and/or ibalizumab (if approved).

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 have contracted a debt under the EMD Serono Termination Agreement and collateralized all of our assets related to tesamorelin (including EGRIFTA®) in connection therewith. We may not be able to sell the collateralized assets if we need capital and our breach of the payment obligations under the EMD Serono Termination Agreement could allow EMD Serono to seize those assets, all of which would have a material adverse effect on our business.

Under the terms of the EMD Serono Termination Agreement, as amended, we agreed to pay an early termination fee of US $20,167,808, or Early Termination Fee, over a five-year period. The first payment of US $8,167,808 has been made. The three other payments of US $4,000,000 are payable on each of May 1, 2017, 2018 and 2019. We also agreed to pay EMD Serono a confidential increasing royalty, or Royalties, based on annual net sales beginning in 2016. The Royalties will be paid until a confidential cumulative aggregate amount is reached or until January 1, 2024, the first of these events to occur.

In order to secure the payment of the Early Termination Fee, we granted EMD Serono a security interest on our present and future worldwide corporeal and incorporeal movable property related to tesamorelin until such time as the amount of US $20,167,808 has been reimbursed in full to EMD Serono. Thereafter, the Corporation and EMD Serono agreed to reduce the security interest to all present and future corporeal and incorporeal movable property related to tesamorelin in the United States only to secure the payment of the Royalties.

The granting of a security interest over our present and future worldwide corporeal and incorporeal movable property related to tesamorelin could prevent us from being able to dispose of these assets in the event we need additional capital to meet our obligations or expand our business. In addition, if we fail to meet our payment obligations to EMD Serono, EMD Serono may seize the assets subject to the security interest and, to the extent we have no other revenue-generating products, we could have to discontinue our operations and could resort to insolvency laws.

We generated a profit from our operation in the last fiscal year but there can be no guarantee that we will achieve consistent profitability.

We generated a profit of $410,000 in the fiscal year ended November 30, 2016. Our profitability will mainly depend on our capacity to maintain the commercialization of *EGRIFTA*® successfully in the United States through a low-cost and effective distribution network, the recruitment and retention of talented personnel by inVentiv, the deployment of an effective marketing campaign and through continued reimbursement coverage for *EGRIFTA*® under U.S. Medicare and Medicaid programs and under private-health insurers programs.

There is no guarantee that we or our commercial partners will succeed in commercializing *EGRIFTA*® and that *EGRIFTA*® and our product candidates will ever receive approval for commercialization in any jurisdictions and outside of the United States, Canada and Mexico. In addition, 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 require additional funding and may not be able to raise the capital necessary to fund all or part of our capital requirements, including resuming the research and development programs of our compounds and their commercialization.

We may need financing in order to fund all or part of our capital requirements to sustain our growth, to resume research and development of new and current compounds, to conduct clinical programs, to develop our marketing and commercial capabilities and to meet our compliance obligations with various rules and regulations to which we are subject. However, the market conditions or our business performance may 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 equity capital by way of public or private equity offerings in the future. In such a case, we would have to use other means of financing, such as issuing debt instruments or 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 manufacturing, managerial and scientific personnel. We have entered into employment agreements with our executive officers and granted options to all of our executive officers and employees as a retention mechanism, but such agreements and options do not guarantee that our executive officers and 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, inVentiv, has hired sales representatives and other qualified individuals to assist us with the commercialization of *EGRIFTA*® in the United States. Although these individuals are not our employees, the loss of any of those individuals and the inability of inVentiv to attract and retain these individuals could have a material adverse effect on the commercialization of *EGRIFTA*® 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 completion of a clinical program, discovery of a new product candidate, filing of an application to obtain regulatory approval, beginning of commercialization of a product, announcement of additional clinical programs for a product candidate or 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 the nature of the results obtained during a clinical trial or during a research phase, 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, onerous lease provision 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 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 and/or common share purchase warrants could decline in value or fluctuate significantly.

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*® in the United States and Canada;
- the approval, or non-approval, of ibalizumab in the United States;
- the approval, or non-approval, of *EGRIFTA*® in South Korea or certain European countries;
- supply issues with *EGRIFTA*®;
- 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 of regulatory submissions and approvals;
- 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 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.

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, the EMD Serono Termination Agreement 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 EMD Serono Termination Agreement provides that in the event there occurs a change of control of the Corporation more than eighteen (18) months after May 1, 2014, EMD Serono has the option to accelerate the payment of all of the unpaid Early Termination Fee.

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 7, 2017: his/her name, age, province/state of residence, principal occupation, the year 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, DSUs and options 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.

Gérald A. Lacoste
Age: 73
Rivière-Rouge, 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 is currently a corporate director and is a member of the North American Free Trade Agreement arbitration panel.

Securities Held or Controlled

Common Shares (#)	DSU (#)	Options (#)
85,000	20,042	45,000

Committees of the Board of Directors

Chair of Nominating and Corporate Governance Committee
Member of Audit Committee

David D. Lilley
Age: 59
Morrisville, North Carolina
United States

Independent Director

Areas of Expertise:
- Pharmaceutical Industry
- Research & Development

Other Directorship:
SFJ Pharmaceuticals, Inc.

Principal Occupation	Corporate Director

David D. Lilley has been actively involved in a number of different roles in the pharmaceutical industry on a worldwide basis. He has worked in both the pharma and services sectors of the industry and has been involved in both the development and commercialization of prescription medicines. He has been acting as managing partner of Pleasanton Pharma Ventures since 2014. From 2008 to 2010, he was executive vice president of Campbell Alliance where he created and oversaw strategic relationships with clients new to the firm. Prior to that, he spent 12 years (1996-2008) at Quintiles International, or Quintiles, where he held various executive positions. During his tenure at Quintiles, he was initially responsible for leading the global marketing and business development. He later was appointed to be global president of Innovex UK Ltd., the contract sales and marketing division of the company. He also oversaw a number of strategic acquisitions with a focus on new services or geographic expansion. David holds a degree in Medicinal Chemistry from the University of London.

Securities Held or Controlled

Common Shares (#)	DSU (#)	Options (#)
Nil	Nil	15,000

Committees of the Board of Directors

Member of Nominating and Corporate Governance Committee

Paul Pommier
Age: 74
Laval, Québec, Canada

Independent Director since:
January 6, 1997

Areas of Expertise:
- Corporate Finance
- Securities
- Mergers & Acquisitions

Other Directorship:
None

Principal Occupation	Corporate Director

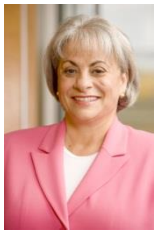
Mr. Paul Pommier worked for more than 25 years at National Bank Financial Inc., his last position being Senior Executive Vice President, Corporate and Government Finance. Throughout his career, he oversaw public and private financings, mergers and acquisitions, as well as the marketing of investment offerings. Under his leadership, National Bank Financial Inc. developed notable expertise in tax-shelter financings.

Securities Held or Controlled

Common Shares (#)	DSU (#)	Options (#)
375,100	120,314	45,000

Committees of the Board of Directors

Chair of Audit Committee
Member of Compensation Committee



Dawn Svoronos
Age: 63
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.

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 sits on the Board of Directors of two other public companies: PTC Therapeutics, Inc. in New Jersey, U.S.A., and Xenon Pharmaceuticals Inc. in British Columbia, Canada.

Securities Held or Controlled

Common Shares (#)	**DSU (#)**	**Options (#)**
200,000	Nil	65,000

Committee of the Board of Directors

Member of Nominating and Corporate Governance Committee
Member of Compensation Committee

Jean-Denis Talon [(1)]
Age: 75
Montreal, Québec, Canada

Independent Director since:
May 10, 2001

Areas of Expertise:
- Human Resources
- Governmental Relations
- Mergers & Acquisitions

Other Directorship:
None

Principal Occupation	Corporate Director

Mr. Jean-Denis Talon had a successful career with AXA Insurance over a period of more than 20 years, ultimately becoming President and Chief Executive Officer. He was Chairman of the Board of AXA Canada until September 2011. Mr. Talon is also a former President of the Financial Affairs Committee at the Insurance Bureau of Canada.

Securities Held or Controlled

Common Shares (#)	**DSU (#)**	**Options (#)**
120,000	3,000	45,000

Committees of the Board of Directors

Chair of Compensation Committee
Member of Audit Committee

Luc Tanguay [(2)]
Age: 58
Town of
Mount Royal,
Québec, Canada

Non-independent Director since:
December 6, 1993

Areas of Expertise:
- Corporate Finance
- Securities
- Mergers & Acquisitions

Other Directorship:
None

Principal Occupation	President and Chief Executive Officer of the Corporation

Mr. Luc Tanguay has been active in the biotechnology industry for over 20 years. As a member of our senior management since 1996, he has contributed to our growth by facilitating access to public and private capital funding. A member of the board of directors since 1993, he has held various management positions since joining the Company. Prior to joining us, Mr. Tanguay had a career in investment banking at National Bank Financial Inc. Mr. Tanguay obtained his M. Sc. Finance from the University of Sherbrooke.

Securities Held or Controlled

Common Shares (#)	DSU (#)	Options (#)
230,000	27,572	735,000

(1) Mr. Talon was a member of the board of directors of Toptent Inc., or Toptent, from August 1, 2007 to November 26, 2009. On December 3, 2009, Toptent filed a notice of intention to make a proposal under the *Bankruptcy and Insolvency Act* (Canada), or Bankruptcy Act. Subsequently, on May 7, 2010, Toptent filed a proposal under the Bankruptcy Act. The proposal was accepted by Toptent's creditors on May 20, 2010.

(2) Mr. Tanguay was a member of the board of directors of Ambrilia Biopharma Inc., or Ambrilia, from August 22, 2006 to March 30, 2010. On July 31, 2009, Ambrilia obtained court protection from its creditors under the *Companies' Creditors Arrangement Act* (Canada), or CCAA. The purpose of the order issued by the court granting Ambrilia protection from its creditors was to provide Ambrilia and its subsidiaries the opportunity to restructure its affairs. On July 31, 2009, the TSX halted the trading of Ambrilia's shares pending its review of Ambrilia's meeting the requirements for continuous listing. On January 31, 2011, the TSX decided to delist the common shares of Ambrilia at the close of market on March 4, 2011 for failure to meet the continued listing requirements of the TSX. The common shares remain suspended from trading. On April 8, 2011, Ambrilia announced that it would seek permission to terminate the protection granted by the Superior Court pursuant to the CCAA and, upon permission of the Court, it would file for bankruptcy pursuant to the Bankruptcy Act. On April 12, 2011, Ambrilia went bankrupt.

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, 2016, the Audit Committee was composed of three members: Paul Pommier, its Chair, Jean-Denis Talon and Gérald A. Lacoste. All three 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.

Paul Pommier. Mr. Pommier holds an MBA degree and has more than 25 years of experience in the financial field, notably in public and private company financings, as well as in merger and acquisition activities. While acting as a director of Royal Aviation Inc., he was also a member of its audit committee.

Jean-Denis Talon. Mr. Talon has more than 20 years of experience in the insurance field as a senior officer. Mr. Talon acted as a member of the audit committee of AXA Canada from March 1995 to April 2008. He has been a member of the audit committee of InnovAssur since March 1999 and acted as Chair of its audit committee from November 1999 until September 2011.

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.

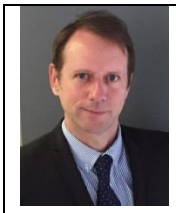
Each member of the Audit Committee has acquired in-depth financial expertise giving each the ability to read and understand a set of financial statements which presents the breadth and level of complexity of accounting issues that are generally comparable to those that can reasonably be expected to be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

4.3 EXECUTIVE OFFICERS

The table below sets forth the following information about our executive officers as of February 7, 2017: his/her name, age, province/state of residence, his/her principal occupation, the year each Executive Officer joined the Corporation, his/her biography and the number of common shares, DSUs and options beneficially held or controlled. The information about Mr. Luc Tanguay, the President and Chief Executive Officer of the Corporation, is found in the table above regarding information about our directors.

Marie-Noël Colussi
Age: 48
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. Prior to joining us, Ms. Colussi worked for eight years with KPMG, a major 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, in February 2002, she held the positions of Director, Accounting and Internal Control and Controller.		
Securities Held or Controlled		
Common Shares (#)	**DSU (#)**	**Options (#)**
10,075	3,182	81,000



Philippe Dubuc
Age: 50
Montreal, Québec, Canada

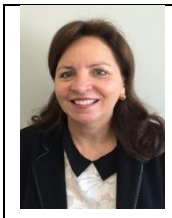
Principal Occupation	Senior Vice President and Chief Financial Officer

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.

Mr. Dubuc joined Theratechnologies in February 2016.

Securities Held or Controlled

Common Shares (#)	**DSU (#)**	**Options (#)**
13,000	Nil	175,000



Lyne Fortin
Age: 57
Laval, Québec, Canada

Principal Occupation	Senior Vice President and Chief Commercial Officer

Ms. Fortin has over 30 years of experience in the commercialization of pharmaceutical products for human health. She has been in executive level positions at Merck Canada for 13 years until 2011. In these roles she was responsible for Marketing and Sales of product portfolios in diverse therapeutic areas. She also managed all the commercial support functions which included marketing and sales research, sales training, sales operations, manufacturing planning, Office of Compliance, Sigma and change management. From 2005 to 2009, she was appointed to the Merck Marketing Committee for Europe, Middle-East, Africa and Canada to advance commercial practices and became a member of the Board of Directors of Merck Canada in 2007 until 2011. From 2011 to 2013, she acted as consultant to the biopharmaceutical industry advising clients on commercial matters. She was appointed Chief Commercial Officer of our Corporation in December 2013.

Ms. Fortin graduated from the *Université de Montréal* with a Certificate in Chemistry in 1978 and a Bachelor degree in Pharmacy in 1982 (Member of the Order of Pharmacists of Québec since 1983). She obtained a MBA from Concordia University in 1984.

Securities Held or Controlled

Common Shares (#)	**DSU (#)**	**Options (#)**
26,150	Nil	175,000

Jocelyn Lafond
Age: 49
Verdun, Québec, Canada

Principal Occupation	Vice President, Legal Affairs, 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 (#)**
1,000	5,000	300,000

Christian Marsolais
Age: 54
Town of Mount Royal, Québec, Canada

Principal Occupation	Senior Vice President and Chief Medical Officer	
Dr. Christian Marsolais has over 15 years of experience in clinical research for large pharmaceutical companies, such as Sandoz Canada Inc. and BioChem Therapeutics Inc. Before joining us in 2007, Dr. Marsolais held various positions at Pfizer Global Pharmaceuticals, where he was appointed Director of Medical Affairs, Therapeutic Areas, in 2004. In this position, Dr. Marsolais was responsible for the clinical program and scientific initiatives development, as well as the integration of the Scientific Affairs and Clinical Research for the oncology and HIV Franchise. Dr. Marsolais holds a Ph.D. in Biochemistry from the *Université de Montréal*.		
Securities Held or Controlled		
Common Shares (#)	**DSU (#)**	**Options (#)**
24,197	6,312	326,000

4.4 CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS

Except as described above in notes 1 and 2 to the table found under "Item 4 – Directors and Executive Officers – Directors", to our knowledge, no director and executive officer (a) is, as at February 7, 2017, or has been within the ten (10) years before February 7, 2017, 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 7, 2017, 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.

4.5 SECURITIES HELD BY THE DIRECTORS AND EXECUTIVE OFFICERS

As at February 7, 2017, the total number of common shares (the only securities carrying a voting right) held by our directors and executive officers amounted to 1,080,522, which represented 1.5% of our outstanding common shares.

ITEM 5 INTERESTS OF EXPERTS

KPMG LLP, our auditors, is the only person or company who is 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 and its partners are independent in accordance with the auditor's rules of professional conduct in the jurisdiction of Québec.

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 and they billed us the following fees in respect of each of our fiscal years ended November 30, 2016 and 2015:

Fees	**Fiscal year ended November 30, 2016 ($)**	**Fiscal year ended November 30, 2015 ($)**
Audit Fees[(1)]	217,000	211,000
Audit-Related Fees[(2)]	43,750	44,120
Tax Fees[(3)]	16,975	16,000
Total:	**277,725**	**271,120**

(1) Refers to the aggregate fees billed by our external auditors for audit services.
(2) Refers to the aggregate fees billed for professional services rendered by our external auditors for translation.
(3) Refers to the aggregate fees billed for professional services rendered by our external auditors for tax compliance, 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 is Computershare Trust Company of Canada which holds, at its Montreal offices, the registers related to our common shares, shareholders and transfers.

ITEM 7 MARKET FOR SECURITIES

7.1 TRADING PRICE AND VOLUME

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

Period	Price		Volume
	$ High	$ Low	
February 1 to February 7, 2017	$3,45	$3,23	324,952
January 2017	$3.32	$2.75	2,156,800
December 2016	$3.05	$2.61	1,699,700
November 2016	$3.60	$2.87	3,512,100
October 2016	$3.50	$2.75	2,708,700
September 2016	$2.99	$2.44	2,196,700
August 2016	$2.70	$2.35	1,857,600
July 2016	$2.86	$2,32	2,741,200
June 2016	$3.74	$2.46	6,200,900
May 2016	$3.25	$2.01	6,332,500
April 2016	$2.24	$1.92	4,187,500
March 2016	$2.08	$1.26	4,013,600
February 2016	$1.69	$1.37	1,079,500
January 2016	$1.90	$1.33	1,258,900
December 2015	$1.90	$1.43	1,709,700

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

Period	Price		Volume
	$ High	$ Low	
February 1 to February 7, 2017	$0.61	$0.55	16,175
January 2017	$0.89	$0.61	11,750
December 2016	$0.70	$0.70	500
November 2016	$0.95	$0.65	21,875
October 2016	$0.86	$0.52	115,500
September 2016	$0.64	$0.40	23,475
August 2016	$0.54	$0.40	603,650

July 2016	$0.50	$0.36	42,750
June 2016	$1.03	$0.50	304,200
May 2016	$0.75	$0.40	42,700
April 2016	--	--	125
March 2016	$0.395	$0.24	6,000
February 2016	--	--	--
January 2016	--	--	--
December 2015	--	--	125

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
April 4, 2016	Stock Options	$2.01	535,000
July 12, 2016	Stock Options	$2.45	85,000
November 21, 2016	Stock Options	$3.10	5,000

ITEM 8 LEGAL PROCEEDINGS

In the last financial year, we were not subject to any legal proceedings and, as at February 7, 2017, we are not subject to any such proceedings.

InVentiv Agreement

On December 4, 2016, we entered into an amended and restated master services agreement with inVentiv providing for the main terms and conditions under which inVentiv would provide us with services to commercialize *EGRIFTA*® in the United States. Each of those services has been described in specific project agreements. We have entered into project agreements relating to the provision of a sales force and medical science liaison personnel, the operation of our *EGRIFTA Assist*® call center and regulatory and reimbursement support. For a description of these agreements, see "Item 2 – Our Business – Section 2.5 – Commercialization Activities – United States – Marketing and Sales".

PRX Agreement

On September 1, 2016, we entered into the PRX Agreement granting PRX the exclusive right to commercialize and distribute *EGRIFTA*® in Portugal. For a description of this agreement, see "Item 2 – Our Business – Section 2.5 – Commercialization Activities – Portugal".

Praxis Agreement

On September 1, 2016, we entered into the Praxis Agreement granting Praxis the exclusive right to commercialize and distribute *EGRIFTA*® in Spain. For a description of this agreement, see "Item 2 – Our Business – Section 2.5 – Commercialization Activities – Spain".

TaiMed Agreement

On March 18, 2016, we entered into the TaiMed Agreement pursuant to which we were granted the exclusive right to commercialize and distribute ibalizumab, if and when approved, in the United States and in Canada. For a description of this agreement, see "Item 2 – Our Business – Section 2.4 – Approved Product and Investigational Products – Ibalizumab – Investigational Product".

AOP Agreement

On February 25, 2015, we entered into the AOP Agreement granting AOP the right to commercialize and distribute *EGRIFTA*® in several European countries. For a description of this agreement, see "Item 2 – Our Business – Section 2.5 – Commercialization Activities – Europe".

Almac Agreement

On February 27, 2015, we entered into an agreement with Almac pursuant to which Almac is responsible for packaging syringes, needles, sterile water for injection and patient inserts in connection with the sale of *EGRIFTA*® in the United States. This agreement is scheduled to terminate on February 25, 2018.

BL&H Agreement

On August 18, 2015, we entered into the BL&H Agreement granting BL&H the right to commercialize and distribute *EGRIFTA*® in South Korea. For a description of this agreement, see "Item 2 – Our Business – Section 2.5 – Commercialization Activities – South Korea".

McKesson Canada Agreement

On June 3, 2015, we entered into the McKesson Canada Agreement pursuant to which McKesson Canada is providing us with various services in connection with the commercialization of *EGRIFTA*® in Canada. For a description of this agreement, see, "Item 2 – Our Business – Section 2.5 – Commercialization Activities – Canada – Distribution".

EMD Serono Termination Agreement, as amended

On December 13, 2014, we entered into an agreement terminating our collaboration and licensing agreement with EMD Serono. On February 17, 2015, we entered into an amendment to the EMD Serono Termination Agreement with EMD Serono to restructure the amount and the payment terms of our first installment of the Early Termination Fee under the original EMD Serono Termination Agreement. For a description of these agreements, see “Item 2 – Our Business – Section 2.5 – Commercialization Activities – United States – General”.

RxCrossroads Agreements

On May 12, 2014, we have entered into a master services agreement and statements of work agreements with RxCrossroads appointing it as exclusive our exclusive first-party logistic and first-party distributor of *EGRIFTA*® in the United States. For a description of the RxCrossroads Agreements, see “Item 2 – Our Business – Section 2.5 - Commercialization Activities – United States – Distribution - RxCrossroads”.

H.D. Smith Agreement

On September 1, 2014, we entered into a wholesaler services agreement with H.D. Smith appointing H.D. Smith as a non-exclusive authorized wholesaler for *EGRIFTA*® in the United States. For a description of the H.D. Smith Agreement, see “Item 2 – Our Business – Section 2.5 - Commercialization Activities – United States – Distribution - H.D. Smith”.

Cardinal Agreement

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 appointing Cardinal as a non-exclusive authorized wholesaler for *EGRIFTA*® in the United States. For a description of the Cardinal Agreement, see “Item 2 – Our Business – Section 2.5 - Commercialization Activities – United States – Distribution - Cardinal”.

McKesson Agreement

On May 15, 2014, we entered into a core distribution agreement with McKesson appointing McKesson as a non-exclusive authorized wholesaler for *EGRIFTA*® in the United States. For a description of the McKesson Agreement, see “Item 2 – Our Business – Section 2.5 - Commercialization Activities – United States – Distribution - McKesson”.

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, 2016.

Additional information regarding our Company is available on SEDAR at www.sedar.com, or upon written request addressed to Jocelyn Lafond, Vice President, Legal Affairs, and Corporate Secretary, at 2015 Peel Street, 5th 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.

APPENDIX A – 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; and

D. the supervision of the Company's Risk Management.

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 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 pro-forma information or information adjusted by means of non-generally accepted accounting principles).

4. Review and discuss reports from the external auditor on:

b. . all critical accounting policies and practices used by the Company;

c. 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;

d. the external auditors' report to the Committee on the planning of external auditing; and

e. the external auditors' 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.

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. 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.

6. 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.

7. Resolve any disagreement between management and the external auditor regarding financial reporting.

8. Review the audit process with the external auditor.

9. 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.

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.

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.

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. Chairman

The Board appoints the Committee Chairman who will call and chair the meetings**.** The Chairman 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 Chairman. 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 Chairman, 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, 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. 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 and February 25, 2015 Board meetings.