UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 40-F/A
(Amendment No. 1)

(Check One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended November 30, 2011 **Commission file number 001-35203**

THERATECHNOLOGIES INC.

(Exact name of Registrant as specified in its charter)

QUEBEC
(Province or other jurisdiction of incorporation or organization)

2834
(Primary Standard Industrial Classification Code Number (if applicable))

Not applicable
(I.R.S. Employer Identification Number (if applicable))

2310 Alfred-Nobel Blvd., Montreal, Quebec, Canada, H4S 2B4
(514) 336-7800
(Address and Telephone Number of Registrant's Principal Executive Offices)

CT Corporation System, 111 8th Avenue, New York, NY 10011
(212) 894-8800
(Name, address (including zip code) and telephone number (including area code) of agent for service in the United States)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Name of each exchange on which registered
Common Shares	**The NASDAQ Stock Market LLC**

Securities registered or to be registered pursuant to Section 12(g) of the Act. None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None.

For annual reports, indicate by check mark the information filed with this Form:

☒Annual Information Form ☐ Audited Annual Financial Statements

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: as of November 30, 2011, 60,865,266 common shares of the Registrant were issued and outstanding.

Indicate by check mark whether the Registrant by filing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934 (the "Exchange Act"). If "Yes" is marked, indicate the file number assigned to the Registrant in connection with such Rule.

Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files).

Yes ☐ No ☐

PRINCIPAL DOCUMENT

The Annual Information Form dated February 27, 2012 for the fiscal year ended November 30, 2011, filed as Exhibit 99.1 to this annual report on Form 40-F/A is hereby incorporated by reference.

SIGNATURES

Pursuant to the requirements of the Exchange Act, the Registrant certifies that it meets all of the requirements for filing on Form 40-F and has duly caused this annual report to be signed on its behalf by the undersigned, thereto duly authorized, on February 28, 2012.

Theratechnologies Inc.

By: /S/ JOHN MICHEL T. HUSS
Name: **John Michel T. Huss**
Title: **President and Chief Executive Officer**

EXHIBIT INDEX

Exhibit	Description
99.1	Annual Information Form dated February 27, 2012 for the fiscal year ended November 30, 2011
99.2	Sections of the Management Proxy Circular dated April 14, 2011 entitled: • Information Relating to the Annual and Special Meeting - Voting Securities and Principal Holders • Compensation - Executive Compensation • Compensation - Other Information (Incorporated by reference to Exhibit 99.28 to the Registrant's Registration Statement on Form 40-F filed on June 13, 2011.)
99.3	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
99.4	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
99.5	Section 1350 Certification of Chief Executive Officer
99.6	Section 1350 Certification of Chief Financial Officer
99.7	Form 52-109F1 - Certification of Chief Executive Officer
99.8	Form 52-109F1 - Certification of Chief Financial Officer

ANNUAL INFORMATION FORM
Financial Year Ended November 30, 2011

February 27, 2012

FORWARD-LOOKING STATEMENTS

This Annual Information Form, or 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 ability, and the ability of our commercial partners, to commercialize *EGRIFTA*™ in the United States and other territories;
- whether we will receive regulatory approvals for tesamorelin from regulatory agencies in territories other than the United States in which we wish to expand the commercialization of tesamorelin, and the timing and costs of obtaining such regulatory approvals;
- our recognition of milestones, royalties and other revenues from our commercial partners related to future sales of *EGRIFTA*™;
- the continuation of our collaborations and other significant agreements with our existing commercial partners and our ability to establish and maintain additional development collaborations;
- our estimates of the size of the potential markets for *EGRIFTA*™, tesamorelin and our other product candidates;
- the rate and degree of market acceptance of *EGRIFTA*™ and our other product candidates;
- our success in obtaining, and the timing and amount of, reimbursement for *EGRIFTA*™ and our other product candidates;
- the benefits of tesamorelin and our other product candidates as compared to others;
- the success and pricing of other competing drugs or therapies that are or may become available;
- our ability to maintain and establish intellectual property rights in tesamorelin and our other product candidates;
- the manufacturing capacity of third-party manufacturers, including the manufacturer of tesamorelin in commercial quantities;
- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes; and
- our need for additional financing and our estimates regarding our capital requirements and future revenues and profitability.

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:

- tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy will receive approval in territories other than the United States covered in our commercialization agreements;

- no additional clinical studies will be required to obtain said regulatory approval of tesamorelin;
- sales of *EGRIFTA*™ in the United States will increase;
- our relations with third-party suppliers of *EGRIFTA*™ will be conflict-free and that such third-party suppliers will have the capacity to manufacture and supply *EGRIFTA*™ to meet market demand and on a timely-basis;
- we will obtain positive results from our program for the development of new GRF peptides; 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 events 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 these risks in greater detail under the heading "Risk Factors". 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.

This AIF also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry and target indications. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

BASIS OF PRESENTATION

We obtained the industry, market and competitive position data in this AIF from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. Certain statistical data and other information regarding the size of our potential markets are based on industry publications and/or derived from our own internal analysis of such industry publications. While we believe our internal company research is reliable and the market definitions, methodology and hypotheses we use are appropriate, such research, analysis, methodology or definitions have not been verified by an independent source. We cannot and do not provide any assurance as to the accuracy or completeness of such information. Market forecasts, in particular, are likely to be inaccurate, especially over long periods of time.

In this AIF, the use of *EGRIFTA*™ refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy regardless of the trade name used for such product in any particular territory. *EGRIFTA*™ is the trade name used in the United States for tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA*™ is our trademark. Other trademarks and service marks appearing in this AIF are the property of their respective holders.

All monetary amounts set forth in this AIF 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.

In this AIF, references to “Theratechnologies”, the “Company”, the “Corporation”, “we”, “our” and “us” refer to Theratechnologies Inc. and its subsidiaries, unless the context otherwise states.

All information provided in this AIF is provided as of February 27, 2012, except where otherwise stated.

TABLE OF CONTENTS

SELECTED EVENTS SINCE FISCAL YEAR-END 2010

The following summary highlights selected events contained elsewhere in this AIF. 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

- our commercial partner launched *EGRIFTA*™ in the United States.
- we entered into commercialization agreements for *EGRIFTA*™ with the following partners and for the following territories:
  - Sanofi (Latin America, Africa and Middle East)
  - Ferrer (Europe, Russia, South Korea, Taiwan, Thailand, and certain central Asian countries)
  - Actelion (Canada)

Regulatory Events

- we or our commercial partners filed marketing authorization applications for *EGRIFTA*™ in the following countries:
  - Argentina
  - Brazil
  - Canada
  - Europe
  - Israel
  - Mexico

Research & Development Event

- we announced the discovery of a new growth-hormone releasing factor peptide.

Corporate Event

- we listed our common shares on the NASDAQ Global Market (ticker: THER).

ITEM 1 CORPORATE STRUCTURE

1.1 NAME, ADDRESS AND INCORPORATION

We were incorporated under the name Theratechnologies Inc. on October 19, 1993 under Part IA of the *Companies Act* (Québec) (now the *Business Corporations Act* (Québec)) by Certificate of Incorporation. 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. Our common shares are listed on the Toronto Stock Exchange, or TSX, under the symbol "TH" and on the NASDAQ Global Market, or NASDAQ, under the symbol "THER". See Item 6.1 for a complete description of our authorized share capital.

Our head office is located at 2310 Alfred-Nobel Boulevard, Montréal, Québec, Canada H4S 2B4. 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 27, 2012, Theratechnologies had the following four 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;
- **Theratechnologies Canada Inc.**, a company governed by the *Business Corporations Act* (Québec). Theratechnologies Canada Inc. controls the rights to commercialize *EGRIFTA*™ in Canada; and
- **Pharma-G Inc.**, a company governed by the *Business Corporations Act* (Québec). Pharma-G Inc. is no longer an active subsidiary.

2.1 OVERVIEW

We are a specialty pharmaceutical company that discovers and develops innovative therapeutic peptide products with an emphasis on growth-hormone releasing factor, or GRF, peptides. Our strategy is to leverage our expertise in the field of metabolism and GRF peptides to address serious health disorders while remaining actively involved in the commercialization of our future products. Our first product, *EGRIFTA*™ (tesamorelin for injection), was approved by the United States Food and Drug Administration, or FDA, in November 2010. *EGRIFTA*™ is currently the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Based on our analysis of 20 independent medical studies published from 2000 to 2004, we estimate that excess abdominal fat in HIV-infected patients affects approximately 29% of HIV-infected patients treated with antiretroviral therapies and approximately 12% of untreated patients. In HIV-infected patients, lipodystrophy may be caused by the viral infection itself, the use of antiretroviral therapy, or both. Lipodystrophy is characterized by abnormalities in the production and storage of fat, which lead to excess abdominal fat, or lipohypertrophy, and the loss of fat tissue, or lipoatrophy, generally occurring in the limbs and facial area.

Excess abdominal fat in HIV-infected patients is associated with significant health risks beyond the mortality risk of the HIV infection itself. These health risks include metabolic disturbances such as hyperlipidemia, an increase in the amount of fat in the blood (such as triglycerides and cholesterol), and hyperglycemia, an increase in the amount of sugar in the blood, characterized by insulin resistance, both of which lead to increased risks of cardiovascular disease and diabetes. While there is evidence that suggests that lipoatrophy may be reduced with certain newer HIV therapies, we are not aware of any evidence showing that any currently-marketed HIV therapy reduces lipohypertrophy or the incidence of lipohypertrophy.

EGRIFTA™ is currently marketed exclusively in the United States by EMD Serono Inc., or EMD Serono, an affiliate of Merck KGaA, Darmstadt, Germany, pursuant to a collaboration and licensing agreement. We have also entered into distribution and licensing agreements for *EGRIFTA*™ with Sanofi Winthrop Industrie S.A., or Sanofi, granting Sanofi the exclusive commercialization rights in Latin America, Africa and the Middle East and with Ferrer Internacional S.A., or Ferrer, granting Ferrer the exclusive commercialization rights in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries. More recently, we have entered into a supply, distribution and licensing agreement for *EGRIFTA*™ with Actelion Pharmaceuticals Canada Inc., or Actelion, granting Actelion the exclusive commercialization rights in Canada. For a description of these agreements, see Item 2.5. Using data compiled by the United States Center for Disease Control published in 2008, or CDC, and the World Health Organization and UNAIDS published in 2008, or WHO/UNAIDS, we estimate that in 2012 there will be approximately 190,000 HIV-infected patients treated with antiretroviral therapies with lipohypertrophy in the United States, 170,000 in Europe, and 180,000 in Latin America, or 540,000 patients in total. We also estimate that in 2012, there will be an additional 47,000 HIV-infected untreated patients with lipohypertrophy in the United States, 42,000 in Europe, and 28,000 in Latin America, or an additional 117,000 patients in total.

In January 2011, EMD Serono launched *EGRIFTA*™ in the United States. EMD Serono's launch program consisted of medical education, advertising, marketing and promotion through their experienced sales force, and supporting market access through co-pay programs, reimbursement education and support for payors. In addition, during the course of the year, EMD Serono launched a direct-to-consumer campaign.

EGRIFTA™ is the trade name used for our first marketed product using our most advanced compound, tesamorelin. Tesamorelin is a GRF analogue that stimulates the synthesis and pulsatile release of endogenous growth hormone. Tesamorelin was synthesized using our internally-developed peptide stabilization method. This method increases a protein's resistance to enzymatic degradation, which prolongs its duration of action and enhances its effectiveness in clinical use. We believe this compound and future GRF peptides that we are developing can be used in a number of additional high-value indications. Clinical data have shown tesamorelin to have both lipolytic (fat-burning) and anabolic (muscle-building) properties. Our initial development of *EGRIFTA*™ focused on the lipolytic properties of the compound.

To solidify our leadership position in the field of GRF therapeutics, we have embarked on a program to discover new generations of GRF peptides. We believe that GRF compounds have the potential to improve patient outcome in many high-value indications, such as various types of wasting, certain abdominal obesity-related diseases, mild cognitive impairment or growth hormone replacement therapies. We also believe that we can improve the route of administration of GRF peptides to make them quicker and easier to use for patients. To date, we have synthesized approximately 250 GRF peptides and, in October 2011, we identified a new GRF peptide with similar potency and efficacy to *EGRIFTA*™. Pre-clinical feasibility studies to explore new modes of administration with this new GRF peptide are ongoing.

2.2 RECENT DEVELOPMENTS

Since the end of our most recently completed financial year, we have been engaged in the following activities:

- *Execution of Supply, Distribution and Licensing Agreement for EGRIFTA*™ for the Canadian Market. On February 21, 2012, we announced the execution, through Theratechnologies Canada Inc., of a supply, distribution and licensing agreement with Actelion granting it the exclusive distribution rights to *EGRIFT*A™ in Canada for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. For a description of this agreement, see Item 2.5.
- *Discontinuation of COPD In-House Clinical Program for EGRIFTA™ and Corporate Reorganization*. On December 7, 2011, we announced that we were discontinuing our in-house clinical program in muscle wasting in COPD. This decision resulted in the lay-off of 37 employees. On that same date, we also announced that we were accelerating the development of our new GRF peptide. The overall objective of the restructuring is to achieve positive earnings before interest, taxes, depreciation and amortization by 2013. Finally, on that same date, we announced that Mr. Jean de Grandpré was retiring from the board of directors after 18 years with us.

2.3 THREE YEAR HISTORY

2011

- *Applications for Registration of EGRIFTA™ in Certain South American and Latin American Countries*. On October 19, 2011, September 1, 2011 and August 31, 2011, we announced that our commercial partner, Sanofi, filed marketing authorization applications for *EGRIFTA*™ in Mexico, Argentina and Brazil, respectively.
- *Identification of Second Generation GRF Peptide*. On October 6, 2011, we announced our discovery of a new GRF peptide with similar potency and efficacy to tesamorelin. The discovery of this new GRF peptide could be suitable for the treatment of a broader range of medical indications and different methods of administration than the one currently used for tesamorelin. We are conducting pre-clinical feasibility studies to explore new modes of administration with this new GRF peptide.

- *Results of Independent Study on Cognitive Function*. On July 19, 2011, we announced the results of an independent study conducted by Dr. Michael V. Vitiello of the University of Washington in Seattle evaluating the effect of tesamorelin on cognitive function in healthy older adults and older adults with mild cognitive impairment. The study was conducted on 152 older adults, half of whom were cognitively normal and half of whom were diagnosed with amnestic mild cognitive impairment. The study showed that tesamorelin improved executive function in both cognitively normal healthy older adults and in adults with MCI.
- *New Drug Submission in Canada*. On June 20, 2011, we announced the filing of a new drug submission, or NDS, in Canada for *EGRIFTA*™ and, on August 16, 2011, we announced that the Therapeutic Products Directorate of Health Canada, or TPD, accepted to review the NDS.
- *Listing of Our Shares on NASDAQ*. On June 13, 2011, we announced that our common shares would begin trading on June 15, 2011 on the NASDAQ Global Market, or NASDAQ, under the ticker symbol "THER". The listing of our common shares on NASDAQ was made regardless of our decision on March 8, 2011 of not pursuing our intended public offering in the United States.
- *Application for Registration of EGRIFTA™ in Europe*. On June 6, 2011, we announced that our commercial partner, Ferrer, filed a marketing authorization application, or MAA, with the European Medicines Agency, or EMA, for *EGRIFTA*™. On June 27, 2011, we also announced that the MAA had been accepted for review by the EMA. If approved, *EGRIFTA*™ will receive marketing authorization for the 27 European Union member countries as well as for Iceland, Liechtenstein and Norway. Since the filing of the MAA, we have assisted Ferrer in answering questions issued by the EMA.
- *Evaluation of R&D Business Model.* On June 2, 2011, we announced that we had revisited our research and development, or R&D, business model to further rely on third parties in the public and private arena to help us bring our R&D projects forward. The restructuring of our R&D business model led to a workforce reduction affecting 24 employees.
- *COPD Indication for EGRIFTA*™. On February 22, 2011, we announced a new clinical program in muscle wasting in COPD using tesamorelin. The program was to be conducted in stable ambulatory COPD patients with muscle wasting in the Global Initiative for Chronic Obstructive Lung Disease, or GOLD, stage II and III severity experiencing decreased functionality in daily activities. The multi-center Phase 2 study was to evaluate two different doses using a new formulation of tesamerelin in approximately 200 patients.
- *Execution of Distribution and Licensing Agreement for EGRIFTA™ for the European Market.* On February 3, 2011, we announced the execution, through Theratechnologies Europe Inc., of a distribution and licensing agreement with Ferrer granting it the exclusive commercialization rights of tesamorelin in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. For a description of this agreement, see Item 2.5.
- *Execution of Distribution and Licensing Agreement for EGRIFTA™ for the Latin American, African and Middle Eastern Markets.* On December 6, 2010, we announced the execution, through Theratechnologies Intercontinental Inc., of a distribution and licensing agreement with Sanofi granting it the exclusive distribution rights to *EGRIFTA*™ in Latin America, Africa and the Middle East for the reduction of excess abdominal fact in HIV-infected patients with lipodystrophy. For a description of this agreement, see Item 2.5.

- *Discontinuation of AKI Program.* In the course of the year, we have decided to discontinue our pre-clinical development of our TH0673 peptide in the field of acute kidney injury. This decision was made after further analysis of the development program for such peptide.

2010

- *FDA Approval Received for EGRIFTA™*. On November 11, 2010, we announced that the FDA approved *EGRIFTA™* as the first and only drug indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy (abdominal lipohypertrophy). The FDA approval triggered a US$25 million milestone payment pursuant to our collaboration and licensing agreement with EMD Serono.
- *Appointment of New President and Chief Executive Officer*. On September 1, 2010, we announced the appointment of Mr. John-Michel T. Huss as President and Chief Executive Officer of the Company, following the retirement of Mr. Yves Rosconi, effective November 30, 2010. Mr. Huss assumed his position on December 1, 2010.
- *Execution of Research Collaboration Agreement with UQAM, Gestion Valeo and Transfert Plus.* On November 16, 2010, we entered into a research collaboration agreement with the Université du Québec à Montréal, or UQAM, Gestion Valeo, L.P., or Gestion Valeo, and Transfert Plus, L.P, or Transfert Plus, with the goal of discovering short peptide mimics of melanotransferrin with the hope of developing a novel cancer treatment. For a description of this agreement, see "Melanotransferrin peptides (Anti-cancer compounds)" at Item 2.5.
- *Adoption of Shareholder Rights Plan.* On February 10, 2010, we announced that our board of directors had adopted a shareholder rights plan, effective as of such date. The plan was later ratified by our shareholders at our annual meeting held on March 23, 2010. The plan is designed to provide adequate time for the board of directors and the shareholders to assess an unsolicited takeover bid for Theratechnologies, to provide the board of directors with sufficient time to explore and develop alternatives for maximizing shareholder value if a takeover bid is made, and to provide shareholders with an equal opportunity to participate in a takeover bid and receive full and fair value for their common shares. For a description of the plan, see ITEM 9.

2009

- *Advisory Committee Reviews NDA for Tesamorelin.* On November 5, 2009, we announced that the Endocrinologic and Metabolic Drugs Advisory Committee of the FDA would be reviewing our New Drug Application, or NDA, for tesamorelin in the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.
- *Filing of NDA for Tesamorelin*. On June 1, 2009, we announced the filing of an NDA with the FDA for tesamorelin, an analogue of the growth hormone-releasing factor, proposed for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

2.4 OUR STRATEGY

Our goal is to leverage our expertise in the field of metabolism and GRF peptides to become a leading specialty pharmaceutical company with the necessary infrastructure to take innovative therapeutic peptides through all phases of research and development up to commercialization. Key elements of this strategy include:

Maximize the global commercial potential of EGRIFTA™

In order to maximize the commercial potential of *EGRIFTA*™ we have entered into licensing agreements with EMD Serono, Sanofi, Ferrer and Actelion for different territories around the world. We intend to continue to support our commercial partners to ensure the successful commercialization of *EGRIFTA*™ in their respective territories. This will include regulatory support, manufacture and supply of *EGRIFTA*™.

In compliance with the request made by the FDA when it approved *EGRIFTA*™, we have developed a new presentation of *EGRIFTA*™ which is quicker and easier to use than its current presentation.

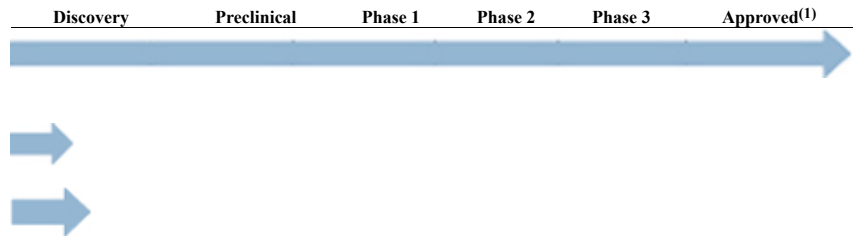
We are also developing a new and more concentrated formulation of tesamorelin. Compared to our current formulation, this new formulation requires a smaller volume of injection and could be stable at room temperature. In addition, this new formulation could potentially be used with a new delivery device such as a pen, to facilitate patient self-administration. We expect the new presentation and the new formulation will have a positive impact on our manufacturing capacity and will significantly reduce our unit costs. In addition, the new formulation could extend the life cycle of *EGRIFTA*™.

Solidify our position as a leader in the field of novel GRF products and other peptides

As a result of the research and development work conducted this year, we announced in October 2011 our discovery of a new GRF peptide with similar potency and efficacy to *EGRIFTA*™. We will continue working on the development of this new GRF peptide and we are targeting the second half of the calendar year 2013 to begin phase 1 trials.

2.5 OUR PRODUCT AND PRODUCT CANDIDATES

The following table provides an overview of our product and product candidates and their current stages of development:



(1) *EGRIFTA*™ has been approved in the United States only.

EGRIFTA™ - Our Lead Product

EGRIFTA™ 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.

For the purposes of FDA approval, *EGRIFTA™* was evaluated in two clinical trials involving 816 HIV-infected adult men and women with lipodystrophy and excess abdominal fat. In both studies, patients treated daily with *EGRIFTA™* experienced greater reductions in abdominal fat as measured by CT scan and greater improvements in belly appearance distress, compared with patients receiving another injectable solution (placebo). Once the treatment was terminated, the patients' condition reversed to its status prior to the beginning of the treatment. The most commonly reported adverse effects in the studies included reactions due to the release of endogenous hormone, such as joint pain (arthralgia), pain in the extremities, swelling in the lower limbs and muscle pain (myalgia), injection site reactions such as skin redness (erythema), itching (pruritis) and pain and clinically manageable changes in blood sugar control. Our clinical trials did not seek to measure any potential cardiovascular benefits of *EGRIFTA™* on cardiovascular events. Since the launch of *EGRIFTA™* in the United States, our review of the pharmacovigilance data did not reveal any new safety concerns. These data are consistent with the known safety profile of *EGRIFTA™*.

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

- *to develop a single vial presentation of the existing formulation of EGRIFTA™*. We have developed a new presentation of *EGRIFTA™* which is quicker and easier to use than its current presentation. In the new presentation, *EGRIFTA™* will be available as a single unit dose (one vial containing 2 mg of tesamorelin) of sterile, lyophilized powder to be reconstituted with sterile water for injection. The FDA required that this new presentation be available by November 2013 and we expect it to be commercially available before that date. The development of the new presentation is complete and the dossier has been filed and approved by the FDA.
- *to conduct a long-term observational safety study using EGRIFTA™*. The purpose of the long-term observational study required by the FDA is to evaluate the safety of long-term administration of *EGRIFTA™*.
- *to conduct a Phase 4 clinical trial using EGRIFTA™*. The primary purpose of the Phase 4 clinical trial, or Retinopathy Trial, 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 long-term observational safety study and Phase 4 clinical trial be submitted by the second quarter of 2011. Under the terms of our collaboration and licensing agreement, EMD Serono is responsible for finalizing, filing and obtaining approval of such protocols. To date, the protocols for the long-term observational safety study and the Retinopathy Trial have been filed and the FDA approved the protocol relating to the Retinopathy Trial. The protocol relating to the long-term observational safety study is still under review by the FDA. In the last financial year, we have supported EMD Serono in developing and finalizing such protocols.

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.

Excess abdominal fat in HIV-infected patients is associated with significant health risks beyond the mortality risk of the HIV infection itself. These health risks include metabolic disturbances such as hyperlipidemia, an increase in the amount of fat in the blood (such as triglycerides and cholesterol), and hyperglycemia, an increase in the amount of sugar in the blood, characterized by insulin resistance, both of which lead to increased risks for cardiovascular disease and diabetes.

In HIV-infected patients, lipodystrophy may be caused by the viral infection itself, the use of antiretroviral therapy, or both. While there is evidence that suggests that lipoatrophy may be reduced with certain newer HIV therapies, we are not aware of any evidence showing that any currently-marketed HIV therapy reduces lipohypertrophy or the incidence of lipohypertrophy. 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, markers of disease severity and protease inhibitor use. Other factors include age, genetics, and gender.

Market Opportunity

Based on our analysis of 20 independent medical studies published from 2000 to 2004, we estimate that excess abdominal fat in HIV-infected patients affects approximately 29% of HIV-infected patients treated with antiretroviral therapies. According to a separate 2003 independent medical study, we estimate that an additional 12% of untreated HIV-infected patients are also affected by excess abdominal fat.

Based on the above-mentioned data, we have identified the following potential markets for *EGRIFTA™*.

- *United States*. The United States market represents the largest commercial opportunity for *EGRIFTA™*. We estimate the prevalence of HIV/AIDS in the United States will rise to 1.3 million people in 2012. Of this amount, approximately 650,000 people will be treated for HIV/AIDS and, of those patients treated, approximately 190,000 will suffer from excess abdominal fat. In addition, approximately 47,000 untreated patients will suffer from excess abdominal fat.
- *Europe*. We estimate the prevalence of HIV/AIDS in Europe will rise to 1.4 million people in 2012. Of this amount, approximately 590,000 people will be treated for HIV/AIDS and, of those patients treated, approximately 170,000 will suffer from excess abdominal fat. In addition, approximately 42,000 untreated patients will suffer from excess abdominal fat.
- *Latin America*. We estimate the prevalence of HIV/AIDS in Latin America will rise to 2.2 million people in 2012. Of this amount, approximately 630,000 people will be treated for HIV/AIDS and, of those patients treated, approximately 180,000 will suffer from excess abdominal fat. This number is proportionately lower than the other territories due to a lower percentage of diagnosed and treated patients. With approximately 60,000 treated patients who will suffer from excess abdominal fat, Brazil offers the largest market in Latin America for *EGRIFTA™*. In addition, approximately 28,000 untreated patients will suffer from excess abdominal fat.
- *Canada.* We estimate that of all the patients treated for HIV/AIDS in Canada, approximately 10,000 will suffer from excess abdominal fat. In addition, approximately 3,000 untreated patients will suffer from excess abdominal fat.

We estimate that the total number of patients diagnosed with and treated for HIV/AIDS who will suffer from excess abdominal fat in our primary target markets will be 540,000 in 2012. We estimate that an additional 117,000 untreated patients may develop lipohypertrophy in such markets.

The foregoing information is based on historical data from the CDC for the United States, and WHO/UNAIDS for Europe, Latin America and Canada. We used the historical growth rates derived from that data to estimate the prevalence of HIV/AIDS in 2012.

EGRIFTA™ Commercialization Activities

EMD Serono launched *EGRIFTA™* in the United States in January 2011. We are working closely with Sanofi, Ferrer and Actelion to obtain regulatory approval for and the subsequent commercialization of *EGRIFTA™*. Each of our commercial partners were chosen due to their commercial and regulatory capabilities in their respective territories. We have also filed a NDS with TPD in June 2011 seeking regulatory approval for *EGRIFTA™* in Canada. TPD accepted to review our NDS in August 2011. The regulatory activities related to this filing will be carried out by Actelion.

EMD Serono Agreement - United States

On October 28, 2008, we entered into a collaboration and licensing agreement granting EMD Serono the exclusive commercialization rights to *EGRIFTA™* for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the United States.

Under the terms of the agreement, EMD Serono has the exclusive right to conduct *EGRIFTA™* commercialization activities in the United States. We are responsible for the manufacturing and supply of *EGRIFTA™* and for the development of a new formulation. The agreement also entitles us to conduct additional clinical programs to develop tesamorelin for potential additional indications. EMD Serono has the option to commercialize products resulting from such additional clinical programs in the United States. If EMD Serono exercises this option, it will pay half of the development and regulatory costs incurred and to be incurred by us in connection with such additional clinical programs. If EMD Serono decides not to exercise its option, we have the right to commercialize tesamorelin for such indications on our own or with third parties. We also have the option to co-promote any product resulting from such clinical programs under terms and conditions to be agreed with EMD Serono. This agreement extends until the expiration of the last valid claim based on a patent right (including patent applications) controlled by us in the United States covering *EGRIFTA™* or any other product based on an additional indication for tesamorelin that EMD Serono has elected to commercialize under the agreement.

We may receive up to US$215 million in upfront and milestone payments in addition to royalties and revenues from the sale of *EGRIFTA™* to EMD Serono. To date, we have received US$65 million which includes an upfront payment and regulatory milestone payments of US$57 million and an equity investment of US$8 million. Future milestone payments will be made based on the achievement of certain sales milestones. We will also be entitled to receive royalties at an increasing rate based on achieving specified levels of annual net sales of *EGRIFTA™* in the United States.

We made our first delivery of *EGRIFTA™* to EMD Serono on December 13, 2010. In January 2011, EMD Serono launched *EGRIFTA™* in the United States. EMD Serono executed a launch program consisting in increasing disease awareness through medical education to doctors, patient advocacy and advertising, marketing and promotion through their experienced sales force, and supporting market access through patient support, co-pay programs, reimbursement education and support for payors. In addition, during the course of the year, EMD Serono launched a direct-to-consumer campaign.

As at November 30, 2011, we received royalty and license fees revenue of $ 1,423,000 from EMD Serono for the sale of *EGRIFTA*™ in the United States for the period covering January 1, 2011 to September 30, 2011. Under the agreement, royalties on sales are paid quarterly in arrear based on a calendar year. In addition, as the supplier of *EGRIFTA*™ to EMD Serono, we reported revenues generated from the supply of *EGRIFTA*™ to EMD Serono of $ 8,351,000 as at November 30, 2011.

Sanofi Agreement - Latin America, Africa and the Middle East

On December 6, 2010, we entered into a distribution and licensing agreement granting Sanofi, a subsidiary of Sanofi-aventis S.A., the exclusive commercialization rights to *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Latin America, Africa and the Middle East.

Under the terms of the 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*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories subject to the agreement. We will be responsible for the manufacture and supply of *EGRIFTA*™ to Sanofi. We have retained all development rights to *EGRIFTA*™ 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 this agreement extends until December 2020.

To date, Sanofi has filed marketing authorization applications in Israel, Brazil, Argentina and Mexico. We expect Sanofi to file similar applications in Columbia and Venezuela in the first half of 2012.

Ferrer Agreement - Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries

On February 3, 2011, we entered into a distribution and licensing agreement granting Ferrer the exclusive commercialization rights to *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

Under the terms of the agreement, we will sell *EGRIFTA*™ to Ferrer at a transfer price equal to the higher of a percentage of Ferrer's net selling price and a predetermined floor price. Ferrer will be responsible for conducting all regulatory and commercialization activities in connection with *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories subject to the agreement. We will be responsible for the manufacture and supply of *EGRIFTA*™ to Ferrer. We have retained all development rights to *EGRIFTA*™ for other indications and will be responsible for conducting development activities for any additional potential indications. We have the option to co-promote *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories. Ferrer has the option to enter into a co-development and commercialization agreement using tesamorelin for potential additional indications. The terms and conditions of such a co-development and commercialization agreement will be negotiated based on any additional program chosen for development. This agreement extends until the later of the expiration of the last valid claim based on a patent right (including patent applications) controlled by us covering a product licensed under the agreement or ten years from the date of the first commercial sale of *EGRIFTA*™ for each country covered by the agreement.

On June 6, 2011, we announced that Ferrer had filed a MAA with the EMA using the centralized marketing authorization procedure. On June 27, 2011, we announced that the EMA accepted to review the MAA. If *EGRIFTA*™ is approved by the EMA, the approval will be valid in the 27 European Union member countries as well as in Iceland, Liechtenstein and Norway. To date, we are assisting Ferrer in answering questions issued by the EMA resulting from the filing of the MAA.

Actelion Agreement - Canada

On February 20, 2011, we entered into a supply, distribution and licensing agreement granting Actelion the exclusive commercialization rights to *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Canada.

Under the terms of the agreement, we will sell *EGRIFTA*™ to Actelion at a transfer price equal to the higher of a percentage of Actelion's net selling price and a predetermined floor price. Actelion will be responsible for conducting all regulatory and commercialization activities for *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Canada subject to the agreement. We will be responsible for the manufacture and supply of *EGRIFTA*™ to Actelion. We have retained all development rights to *EGRIFTA*™ for other indications and will be responsible for conducting development activities for any additional potential indications. We also granted Actelion an option to commercialize tesamorelin for other indications in Canada. If such option is not exercised, or is declined, by Actelion, we may commercialize tesamorelin for such indications on our own or with a third party. The initial term of this agreement extends until the later of (i) the expiration of the last valid claim based on a patent right (including patent applications) controlled by us in Canada covering *EGRIFTA*™ or any other product based on an additional indication for tesamorelin that Actelion has elected to commercialize under the agreement and (ii) 10 years from the date of the first commercial sale of *EGRIFTA*™.

Unpartnered Territories

We have retained full commercial rights for *EGRIFTA*™ in certain territories. In those territories, we may commercialize *EGRIFTA*™ in collaboration with commercial partners.

Tesamorelin - Our Lead Compound

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. *EGRIFTA*™ has demonstrated the ability to significantly reduce visceral adipose tissue, increase muscle mass and reduce waist circumference.

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 July 19, 2011, we announced the results of an independent study entitled "Cognitive Effects of GHRH in Healthy Older Adults and Patients with MCI: Results of a Controlled Trial". This independent study was led by Dr. Michael V. Vitiello of the University of Washington in Seattle and the results were presented at the 2011 Alzheimer's Association International Conference on Alzheimer's Disease Conference held July 16-21 in Paris, France.

This single-center, randomized, double-blind, placebo-controlled Phase 2 clinical trial evaluated the effect of tesamorelin on cognitive function in healthy older adults and older adults with mild cognitive impairment, or MCI, also known as pre-Alzheimer's syndrome.

A total of 152 older adults, half of whom were cognitively normal and half of whom were diagnosed with amnestic MCI, received either tesamorelin or a placebo. The study showed that tesamorelin improved executive function (response inhibition, set-shifting, and working memory) in both cognitively normal healthy older adults and in adults with MCI. Tesamorelin also improved delayed verbal recall in adults with MCI.

Currently, tesamorelin is not indicated for treatments related to MCI.

Also, we expect results from the study led by Dr. Steven Grinspoon of the Massachusetts General Hospital and entitled "Physiologic Effects of Long-Term GHRH 1-44 in Abdominal Obesity" to be published in the first half of the calendar year 2012. The purpose of this study is to evaluate the effectiveness of synthetic growth-hormone releasing hormone in decreasing the amount of abdominal fat and improving cardiovascular function in people who are obese.

Currently, we are not developing tesamorelin in patients suffering from MCI and in patients suffering from obesity.

Other Product Candidates

Novel Growth Hormone-Releasing Factor Peptides

To date, we have synthesized approximately 250 different compounds and, in October 2011, we announced the discovery of a second generation GRF peptide with similar potency and efficacy to tesamorelin. We are pursuing pre-clinical feasibility studies with this new peptide. If the results of all studies we intend to pursue are positive, we believe that this new peptide could be used in various indications, such as various types of wastings, certain abdominal obesity-related diseases, mild

cognitive impairment or growth hormone replacement therapies. In addition, this new GRF peptide could be administered through more patient-friendly routes of administration than tesamorelin. To date, we are unable to assess the cost related to the complete development of this new peptide given that we have not determined the indication in which we intend to pursue the development of this new GRF peptide. For a description of the development of a drug, see "Government Regulation" at Item 2.9.

Other Discovery Activities - Melanotransferrin Peptides (Anti-cancer compounds)

In November 2010, we entered into a discovery and collaboration agreement with the UQAM, Gestion Valeo and Transfert Plus 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. We have identified 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. The results obtained lead us to believe that these peptides have certain anti-tumoral characteristics. We need to conduct further research and development on these peptides, including toxicology and pharmacology studies.

2.6 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 a patent covering the composition of matter (tesamorelin), which is scheduled to expire in 2015. We have applied for a patent term extension requesting an extension of five years to this patent term. If our request for patent term extension for the entire five year term is granted, the patent protection for tesamorelin in the United States would be extended until 2020. In addition, we own an issued United States patent relating to the use of tesamorelin in the treatment of HIV-associated lipodystrophy, which is scheduled to expire in 2023. Because tesamorelin qualifies as a new chemical entity, we benefit from data protection for a five year period for *EGRIFTA*™ ending November 2015. See "Regulatory Exclusivity".
- In Europe, tesamorelin is covered by granted patents scheduled to expire in 2016. In the event of receipt of marketing approval from the EMA, we intend to apply for supplementary protection certificates, or SPCs, in certain countries which, if granted, could extend the patents covering tesamorelin in the countries where SPCs are approved until 2021. We have also filed two patent applications relating to the use of tesamorelin in the treatment of HIV-associated lipodystrophy where, if such patents were granted, they would be scheduled to expire in 2023 and 2025, respectively. As discussed below, the first time a new product is approved in Europe, the regulation provides for a 10 year exclusivity period. Assuming approval in 2012, we would benefit from protection until 2022. See "Regulatory Exclusivity".
- We have obtained a patent covering the composition of matter (tesamorelin) in Brazil that expires in 2019.

- We have filed United States and international Patent Cooperation Treaty applications, relating to combination therapies of tesamorelin with certain drugs indicated for the treatment of HIV which, if patents issued from these applications were granted, would be scheduled to expire in 2030.

Novel GRF Peptides

- We have recently filed a United States provisional patent application relating to new GRF analogues. Patents claiming priority to this application may be pursued and, if such patents were granted, they would be scheduled to expire in 2032.

Melanotransferrin

- We have filed a United States provisional patent application relating to melanotransferrin-related peptides. Patents claiming priority to this application may be pursued and, if such patents were granted, they would be scheduled to expire in 2032.

Our Trademarks & Other Intellectual Property

EGRIFTA™ is the registered trademark used for tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the United States.

We have obtained registration for *EGRIFTA*™ in Europe, Japan, Australia, Norway, Switzerland, Mexico and Lebanon and have filed trademark applications for this trademark in other countries. The use of the trademark in each jurisdiction generally requires the approval of the regulatory authorities in such jurisdictions.

Other trademarks related to tesamorelin have been filed as part of our business strategy. We have also reserved certain domain names in order to support future activities.

Our Policy on Intellectual Property

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

- 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 Europe may provide market exclusivity for a pharmaceutical product. Data protection and patent term extension provide a patent holder 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 New Drug Application, or 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 prevents the FDA from approving, in certain circumstances, any abbreviated new drug application for a generic drug or any 505(b)(2) NDA. See "Government Regulation - United States - FDA Process" below.

In Europe, when a product based on a new compound is approved, the EMA grants a 10 year exclusivity period beginning on the date of such approval. When the same compound is approved for a second indication within the first eight years of this 10 year period, the exclusivity period is extended by one year, providing a total exclusivity period of 11 years for the compound.

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 applied for a patent term extension with respect to tesamorelin.

In the European Union, SPCs for medicinal products are governed by *Regulation 469/2009* with effect from May 2009. An SPC has the effect of extending the term of a patent relating to protection of a particular medicinal product by compensating the patentee for some lost patent protection caused by the length of time taken to obtain marketing authorisation for the product in question. An SPC is a national right, available in member states of the European Union by application to the national patent office of each state for which a certificate is desired. The SPC must be based on a patent but since an SPC is only granted in respect of a very specific active ingredient in a product, it is generally of rather more limited scope than the patent on which it is based. Typically, the term of the SPC is equal to the period which has elapsed between filing of the patent application and grant of the first European Union marketing authorisation less five years. The term of the SPC may not, generally, exceed five years. However, some European Union legislation regarding pediatric medicines provides for a six-month extension of the basic SPC term in certain circumstances. The SPC takes effect on expiry of the basic patent. In each country for which SPC protection is sought, a separate SPC application must be filed within six months of the grant of the first marketing authorisation in that country for the active ingredient(s) in question.

2.7 MANUFACTURING

We do not own or operate commercial scale manufacturing facilities for the production of our product or any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and finished product for clinical trials and commercial sale.

We are responsible for the manufacture and supply of tesamorelin to ensure the commercialization of *EGRIFTA*™ under our agreements with EMD Serono, Sanofi and Ferrer. As part of our agreement with EMD Serono, we are required to maintain certain levels of inventory. In order to fulfill these contractual obligations, we have negotiated and entered into various third-party supply agreements.

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 for clinical programs and *EGRIFTA*™ for commercial sale in the United States.

Draxis

We have an agreement with Draxis Pharma, a division of Draxis Specialty Pharmaceuticals, Inc., or Draxis, providing for the manufacture and supply of the finished form of tesamorelin for clinical programs and *EGRIFTA*™ for commercial sale. Under our agreement, Draxis must fill vials with tesamorelin, lyophilize it, label and package those vials and deliver them to locations in accordance with our instructions.

We have identified and initiated discussions with possible secondary suppliers of these products. We believe that there are alternate sources of supply for these products that will be able to satisfy our needs and will be able to receive FDA qualification. We expect our new presentation as well as our new formulation of tesamorelin will significantly increase our production capacity for *EGRIFTA*™ due to the smaller quantity of vials, shorter manufacturing process times and increased batch sizes.

We have also entered into the following manufacturing agreements as a result of our undertakings under the distribution and licensing agreement with EMD Serono wherein we agreed to supply the injection tool kits for *EGRIFTA*™ namely:

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.

Hospira

On March 26, 2009, we entered into a development and supply 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.

ABAR

On January 5, 2010, we entered into a supply agreement with Gruppo Cartotecnico ABAR Litofarma S.R.L., or ABAR, an Italian company, in order to ensure the commercial supply of pharmaceutical mass market folding boxes for the sale of *EGRIFTA*™ in the United States.

2.8 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 will affect the development and commercial success of *EGRIFTA*™ and our product candidates are efficacy, safety and tolerability profile, reliability, product acceptance by physicians and other healthcare providers, convenience of dosing, price and reimbursement. Also, the development of new treatment methods for the indications we are targeting could render our drugs non-competitive or obsolete. We are not aware of other GRF products being commercialized or in development for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy although we may face indirect competition for *EGRIFTA*™ from other drugs that may be prescribed by physicians. 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 nor any other regulatory authority.

2.9 GOVERNMENT REGULATION

Overview

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

Governmental authorities in the United States at the federal, state and local level, 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 other product candidates that we are developing. 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 United States or foreign requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. Sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

On November 10, 2010, the FDA approved *EGRIFTA*™ as the first approved treatment for excess abdominal fat in HIV-infected patients with lipodystrophy. Our other product candidates must receive regulatory approval from the FDA or other relevant foreign regulatory authorities before they may legally be marketed in the United States or other countries.

In Canada, these activities are governed by the provisions of the *Food and Drugs Act* and its regulations, which is enforced by TPD and the Food Branch of Health Canada.

United States - FDA Process

Before new pharmaceutical products may be sold in the United States, clinical trials of the product candidates must be conducted and the results submitted to the FDA for approval. The drug approval process requires, among other things, a demonstration of product safety and efficacy. Generally, a demonstration of safety and efficacy includes preclinical testing and clinical trials of product candidates. The testing, manufacture and marketing of pharmaceutical products in the United States requires the approval of the FDA. The FDA enforces laws and regulations which apply to preclinical testing, clinical trials, and manufacture of these products. The drug approval process in the United States is described in brief below.

Pre-Clinical Testing: Before testing of any compounds with potential therapeutic value in human subjects may begin in the United States, stringent government requirements for pre-clinical data must be satisfied. Pre-clinical testing includes laboratory evaluations of product pharmacology and toxicity in animal studies of the drug candidates. In parallel, the chemistry of the drug candidates must be elucidated and their manufacturing, including formulation and stability, clearly defined and controlled.

Investigational New Drug Application: Among other things, pre-clinical testing results obtained from animal studies and in vitro studies, are submitted to the FDA as part of an IND application and are reviewed by the FDA prior to the commencement of human clinical trials. An IND sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. Unless the FDA objects to an IND (referred to as a clinical hold), the IND becomes effective 30 days following its receipt by the FDA. Once trials have commenced, the FDA may stop the trials at any time by placing them on "clinical hold" because of safety concerns or noncompliance. If the FDA issues a clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. Accordingly, we cannot be sure that submission of a IND will result in the FDA allowing clinical trials to begin or that, once began, issues will not arise that suspend or terminate such trials.

Clinical Trials: Clinical trials involve the administration of the drug to healthy human volunteers or to patients under the supervision of a qualified investigator pursuant to an FDA-approved protocol. Each clinical trial must be conducted under the auspices of an Institutional Review Board, or IRB, that considers, among other things, ethical factors, the safety of human subjects and approves the patient informed consent, which must be agreed to by all participants prior to participation in the clinical trial. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the FDA for review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Human clinical trials are typically conducted in three sequential phases, although the phases may overlap with one another.

All phases of clinical trials must be conducted in conformance with Good Clinical Practices, or GCP, which are ethical and scientific quality standards for conducting, recording, and reporting clinical trials to assure that the rights, safety, and well-being of trial participants are protected, and the FDA's regulations for the protection of human subjects.

Phase 1 Clinical Trials: Phase 1 clinical trials represent the initial administration of the investigational drug to a small group of healthy human subjects or, more rarely, to a group of select patients with the targeted disease or disorder. The goal of Phase 1 clinical trials is typically to test for safety, dose tolerance, absorption, bio-distribution, metabolism, excretion and clinical pharmacology and, if possible, to gain early evidence regarding efficacy.

Phase 2 Clinical Trials: Phase 2 clinical trials involve a small sample of the actual intended patient population and seek to assess the efficacy of the drug for specific targeted indications, to determine dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.

Phase 3 Clinical Trials: Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, Phase 3 clinical trials are initiated to establish further clinical safety and efficacy of the investigational drug in a broader sample of the

patient population with the target disease or disorder at geographically dispersed study sites in order to determine the overall risk-benefit ratio of the drug and to provide an adequate basis for regulatory approval and product labeling.

New Drug Application: All data obtained from a comprehensive development program including research and product development, manufacturing, pre-clinical and clinical trials and related information are submitted in an NDA to the FDA. In addition to reports of the trials conducted under the IND, the NDA includes information pertaining to the preparation of the new drug, chemistry manufacturing and controls, or CMC, analytical methods, details of the manufacture of finished products and proposed product packaging and labeling. The submission of an application is no guarantee that the FDA will find the application complete and accept it for filing. The FDA may refuse to file the application and request additional information rather than accept the application for filing, in which case, the application must be resubmitted with the supplemental information. The re-submitted application is also subject to review before the FDA accepts it for filing. Once an application is accepted for filing, an FDA review team - medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts - evaluates whether the studies the sponsor submitted show that the drug is safe and effective for its proposed use and whether the applicant's manufacturing complies with Good Manufacturing Practices, or GMP, to assure and preserve the product's identity, strength, quality and purity. As part of the approval process, the FDA will inspect the facility or facilities where the product is manufactured. The FDA review process may be extended by FDA requests for additional information or clarification. In some cases, the FDA may decide to expedite the review of new drugs that are intended to treat serious or life threatening conditions and demonstrate the potential to address unmet medical needs.

As part of its review, the FDA may refer the application to an advisory committee for evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Under legislation enacted in 2007, the FDA may determine that a risk evaluation and mitigation strategy, or REMS, is necessary to ensure that the benefits of a new product outweigh its risks. If required, a REMS may include various elements, such as publication of a medication guide, patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug.

In reviewing an NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval. The FDA may require larger or additional clinical trials, leading to unanticipated delay or expense. Even if such additional information and data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials may be subject to different interpretation, and the FDA may interpret data differently than the applicant. The receipt of regulatory approval often takes a number of years, involving the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. The FDA may require, as a condition of approval, restricted distribution and use, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, or restrictions on direct-to-consumer advertising or commitments to conduct additional research post-approval. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. In addition, changes in FDA approval policies or requirements may occur, or new regulations may be promulgated, which may result in delay or failure to receive FDA approval.

Changes to an approved product, such as adding a new indication, making certain manufacturing changes, or changing manufacturers or suppliers of certain ingredients or components requires review and approval of the FDA.

Under the *Hatch-Waxman Act*, the U.S. Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products. The *Hatch-Waxman Act* requires NDA applicants and NDA holders to provide certain information about patents related to the drug for listing in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations", commonly known as the Orange Book. The *Hatch-Waxman Act* allows for, under certain circumstances, an abbreviated NDA, or ANDA, where an applicant seeks to determine that its proposed product is biologically equivalent to the reference drug. ANDA applicants do not have to conduct extensive clinical trials to prove the safety or efficacy of the drug product; rather, they are required to conduct less rigorous bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original listed drug. In addition, in certain cases, an application for marketing approval may include information regarding safety and efficacy of a proposed drug that comes from studies not conducted by or for the applicant and for which the applicant has not obtained a specific right to reference those studies. Such applications, known as a 505(b)(2) NDA, are permitted for new drug products that incorporate previously approved active ingredients, even if the proposed new drug incorporates an approved active ingredient in a novel formulation or for a new indication. Section 505(b)(2) also permits the FDA to rely for such approvals on literature or on a finding by the FDA of safety and/or efficacy for a previously approved drug product. In addition, a 505(b)(2) NDA for changes to a previously approved drug product may rely on the FDA's finding of safety and efficacy of the previously approved product coupled with new clinical information needed by FDA to support the change. FDA approval of the NDA or ANDA is required before marketing of the product may begin in the United States.

The *Pediatric Research Equity Act*, or PREA, requires NDAs (or NDA supplements) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to contain data assessing the safety and efficacy for the claimed indication in all relevant pediatric subpopulations. Data to support dosing and administration also must be provided for each pediatric subpopulation for which the drug is safe and effective. FDA may grant deferrals for the submission of data, or full or partial waivers from the PREA requirements. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation, as described below, has been granted.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-Approval Studies and Registries: Post-approval studies, also referred to as Phase 4 clinical trials are studies that are conducted after a product has been approved. These trials can be conducted for a number of purposes, including to collect long-term safety information or to collect additional data about a specific population. As part of a product approval, the FDA may require that certain Phase 4 studies be conducted post-approval, and in these cases these Phase 4 studies are called post-marketing commitments.

Adverse Event Reporting: Regulatory authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product's use and, potentially, withdrawal or suspension of the product from the market. Furthermore, in September 2007 the *Food and Drug Administration Amendments Act of 2007* was enacted, which provides the FDA with expanded authority over drug products after approval. This legislation enhances the FDA's authority with respect to post-marketing safety surveillance including, among other things, the authority to require additional post-approval studies or clinical trials and mandate label changes as a result of safety findings, including the development and implementation of a REMS.

Orphan Drug Designation

Under the *Orphan Drug Act*, the FDA may grant orphan designation to a drug intended to treat a "rare disease or condition," which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales in the United States of the drug. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in, or shorten the duration of the regulatory review and approval process.

If a drug that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different drugs for the indication for which the orphan product has exclusivity or may obtain approval for the same drug but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug designated as an orphan drug receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in the European Union.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for market, including a fast track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review

and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Non-U.S. Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations governing clinical studies and commercial sales and distribution of our products in other jurisdictions around the world. Whether or not we obtain FDA approval for a product, we must obtain approvals from the comparable regulatory authorities of foreign countries before we can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from country to country. In some international markets, additional clinical trials may be required prior to the filing or approval of marketing applications within the country.

In the European Union, medicinal products must be authorized either through the decentralized procedure by the competent authorities of the European Union Member States, or through the centralized procedure by the European Commission following an opinion by the EMA. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products with a new active substance indicated for the treatment of certain diseases such as neurodegenerative disorder or diabetes and products designated as orphan medicinal products, and optional for those products which are highly innovative or for which a centralized process is in the interest of patients. The decentralized approval procedure provides for approval by one or more “concerned” member states based on an assessment of an application performed by one member state, known as the reference member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials (draft summary of product characteristics, draft labeling and package leaflet) to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state’s assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state objects to approval of the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states. In many European Union countries, pricing and reimbursement negotiations must also take place before the product is sold in their national market between the company marketing the product and the competent national authorities.

In order to obtain approval for commercializing new drugs in Canada, we must satisfy many regulatory conditions. We must complete preclinical studies in order to file a Clinical Trial Application, or CTA, in Canada. We then receive different clearance authorizations to proceed with Phase 1 clinical trials, which can then lead to Phase 2 and Phase 3 clinical trials. Once all three phases of trials are completed, we file a registration file named a New Drug Submission, or NDS, in Canada. If the NDS demonstrates that the product was developed in accordance with the regulatory authorities' rules, regulations and guidelines and demonstrates favourable safety, efficacy and receives a risk/benefit analysis, then the regulatory authorities issue a notice of compliance, which allows us to market the product.

Good Manufacturing Practices

The FDA, the EMA, the competent authorities of the European Union Member States and other foreign regulatory agencies regulate and inspect equipment, facilities, and processes used in the manufacturing of pharmaceutical and biologic products prior to approving a product. Among the conditions for NDA or equivalent foreign approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures adhere to the FDA's or other competent authorities' current GMP. Before approval of an NDA or equivalent foreign approval, the FDA or other competent authority may perform a pre-approval inspection of a manufacturing facility to determine its compliance with GMP and other rules and regulations. In complying with GMP, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance. Similarly, NDA or equivalent foreign approval may be delayed or denied due to GMP non-compliance or other issues at contract sites or suppliers included in the NDA or equivalent foreign approval, and the correction of these shortcomings may be beyond our control. Facilities are also subjected to the requirements of other government bodies, such as the U.S. Occupational Safety & Health Administration and the U.S. Environmental Protection Agency.

If, after receiving clearance from regulatory agencies or competent authorities, a company makes certain changes in manufacturing equipment, location, or process, additional regulatory review and approval may be required. Our third-party suppliers must adhere to GMP and product-specific regulations enforced by the FDA or other competent authorities following product approval. The FDA, the European Union and other national competent authorities and regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities and processes following the initial approval of a product. If, as a result of these inspections, it is determined that our suppliers' equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions and/or remedies against them, including the suspension of manufacturing operations.

Good Clinical Practices

The FDA, the EMA and other competent authorities promulgate regulations and standards, commonly referred to as 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. The FDA, the European Union and other foreign national competent authorities and regulatory agencies enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. We rely on third-party service providers to conduct our clinical trials. If our study sites fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications.

Good Laboratory Practices

The FDA and other regulatory authorities promulgate regulations and standards, commonly referred to as Good Laboratory Practices, or GLP, for the conduct of non-clinical, commonly referred to as "preclinical," non-human studies to provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. Compliance with GLP is intended to assure regulatory authorities of the quality and integrity of the results obtained during the preclinical studies. Before we may test our product candidates on humans in clinical trials, we must first conduct preclinical testing, including animal studies, in accordance with GLP. The FDA or other regulatory authorities may inspect the testing facilities where our pre-clinical studies are conducted. The results of preclinical studies in the United States, Europe or other countries, not conducted in accordance with GLP, might be inadmissible in support of an NDA in the United States, or comparable applications in other countries.

United States Sales and Marketing

Our commercial partner, EMD Serono, is subject to various United States regulations relating to the sales and marketing of *EGRIFTA*™ in the United States. The FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA actively enforces the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The FDA does not regulate the practice of medicine by physicians in their choice of treatment, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, and the full range of civil and criminal penalties available to the FDA.

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, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our commercial partners' practices might be challenged under anti-kickback or similar laws. 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 reimbursed drugs or services that are false or fraudulent.

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 physicians. The recently enacted health care reform legislation will require record-keeping and disclosure to the federal government of payments to physicians commencing in 2012. Any activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to allege or convict our commercial partner of violating these laws, our business could be harmed. In addition, there is ability for private individuals to bring similar actions.

Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities.

2.10 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 the Centers for Medicare & Medicaid Services in the United States), managed care providers, private health insurers and other organizations. We believe *EGRIFTA*™ will achieve a high degree of physician and payor acceptance, driven by our product's safety and efficacy, the lack of approved alternative therapies for these patients and the prominent medical and social need to treat HIV/AIDS patients.

However, 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*™ or our other product candidates. *EGRIFTA*™ or our other product candidates 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*™ or our other product candidates on a competitive and profitable basis.

United States

Pursuant to our agreement with EMD Serono, they are responsible for identifying and obtaining possible reimbursements under such government programs in the United States. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products 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* revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, beginning in 2011, 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, or EMD Serono, to modify our business practices with healthcare practitioners. We will not know the full effects of the *Health Care Reform Law* until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the *Health Care Reform Law*, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and also may increase our regulatory burdens and operating costs.

The *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, or MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, and included a major expansion of the prescription drug benefit under a new Medicare Part D. Medicare Part D went into effect on January 1, 2006. 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. Unlike Medicare Part A and B, 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.

It is not clear what effect the MMA will have on the prices paid for *EGRIFTA*™ and our other product candidates. Some studies indicate that Part D lowered the average price and increased the utilization of prescription drugs by Medicare beneficiaries. 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 the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

There are also laws that govern a company's eligibility to participate in Medicare and Medicaid reimbursements. For example, a company may be debarred from participation if it is found to have violated federal anti-kickback laws, which could have a significant effect on a company's ability to operate its business.

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. At the present time, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, the U.S. Congress is considering passing legislation that would lift the ban on federal negotiations. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could harm our business, financial condition and results of operations.

Some third-party payors also require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

Europe and other countries covered by our agreements

Outside of the United States, sales of *EGRIFTA*™ and our other product candidates will depend in part on the availability and level of reimbursement from third-party payers. Third-party payers 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, particularly in Europe, 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.

In Latin America, Brazil has a formal price procedure through Agência Nacional de Vigilância Sanitoria (ANVISA) which determines the price of a pharmaceutical based on five reference countries, including the United States. However, there is uncertainty in pricing of pharmaceutical drugs in Latin America in general.

Pursuant to our agreements with Sanofi and Ferrer, each is responsible for identifying and obtaining possible reimbursements under such government programs in their respective territories.

2.11 EMPLOYEES

As at November 30, 2011, we had 69 employees and, as at the date hereof, we have 33 employees. All of our employees are employed in Canada and engaged in administration, finance, research and development, regulatory and business development functions. None of our employees are unionized. We believe the relations with our employees are good.

2.12 FACILITIES

We carry out our activities at 2310 Alfred-Nobel Boulevard in the Technoparc Montréal in Ville Saint-Laurent, Québec, Canada. We lease a 36,400 square-foot building, which houses both offices and laboratories which enable us to conduct small-scale peptide manufacturing, discovery and manage preclinical and clinical research.

The facilities contain laboratories which enable us to conduct small-scale peptide manufacturing, discovery and preclinical research. Peptide compounds are synthesized by our pharmaceutical development department using manual and semiautomatic methods with reactors of different sizes (from 50 to 8000 ml) and also a 12-channel automated peptide synthesizer. The peptides are purified using preparative high performance liquid chromatography, or HPLC, comprising either the Dynamic Axial Compression column, or a number of pre-packed columns. The final peptides are dried to a solid form using lyophilization equipment. The analyses on the quality of the peptides are done using a variety of equipment including HPLC instruments Agilent 1100 and 1200, UV spectrophotometers and a water content analyzer.

We also have discovery and preclinical research laboratories which include two cell culture rooms and several chemical hoods. A Mesoscale chemiluminometer (Sector PR100) is used for sensitive immunological and cell-based assays. Several HPLC instruments for preformulation and purity determinations, scintillation spectrophotometers for radioactivity measurements, and fluorospectrophotometers and colorimetric plate readers for cell-based screens and immunoassays enable in-house discovery and preclinical research. A designated laboratory section is equipped to conduct studies according to GLP.

2.13 ENVIRONMENT

To our knowledge, at our current development stage, 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.

Before you invest in our common shares, you should understand the high degree of risk involved. You should consider carefully the following risks and uncertainties described below before you decide to purchase our common shares. 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 could decline and you could lose all or part of your investment.

3.1 RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCT AND PRODUCT CANDIDATES

Our commercial success depends largely on the commercialization of EGRIFTA™; the failure of EGRIFTA™ to obtain commercial acceptance would have a material adverse effect on us.

Our ability to generate revenues in the future is primarily based on the commercialization of *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. In the short-term, these revenues should be primarily derived from the U.S. market alone. Although we have entered into a collaboration and licensing agreement with EMD Serono for the commercialization of *EGRIFTA*™ in the United States and the launch of *EGRIFTA*™ was made in January 2011, there can be no assurance that sales of *EGRIFTA*™ in the United States will increase or remain the same. In addition, there is no assurance that *EGRIFTA*™ will be successfully commercialized in any other country. Although we are developing new GRFpeptides, these peptides are at earlier stages of development and none of them may reach the clinical trial phase, obtain regulatory approval or, even if approved, be successfully commercialized.

The overall commercialization success of *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy will depend on several factors, including:

- receipt of regulatory approvals for *EGRIFTA*™ from regulatory agencies in the territories other than the United States in which we wish to expand the commercialization of tesamorelin;
- market acceptance of *EGRIFTA*™ by the medical community, patients and third-party payors (such as governmental health administration authorities and private health coverage insurers);
- the amount of resources devoted by our commercial partners to commercialize *EGRIFTA*™ in their respective territories;
- maintaining manufacturing and supply agreements to ensure the availability of commercial quantities of *EGRIFTA*™ through validated processes;
- the number of competitors in our market; and
- protecting and enforcing our intellectual property and avoiding patent infringement claims.

The inability to successfully commercialize *EGRIFTA*™ in the United States for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the short term would delay our capacity to generate revenues and would have a material adverse effect on our financial condition and operating results.

We are or will be dependent on a limited number of collaboration and licensing agreements for the commercialization of EGRIFTA™ in the United States, Europe, Latin America, Africa, the Middle East and Canada. These agreements place the commercialization of EGRIFTA™ in these markets outside of our control.

Although our collaboration and licensing agreements with EMD Serono, Sanofi, Ferrer and Actelion contain provisions governing their respective responsibilities as partners for the commercialization of *EGRIFTA*™ in their respective territories, our dependence on these partners to commercialize *EGRIFTA*™ is subject to a number of risks, including:

- our limited control of the amount and timing of resources that our commercial partners will be devoting to the commercialization, marketing and distribution of tesamorelin, including obtaining patient reimbursement for *EGRIFTA*™, which could adversely affect our ability to obtain or maximize our royalty payments;
- disputes or litigation that may arise between us and our commercial partners, which could adversely affect the commercialization of tesamorelin, all of which would divert our management's attention and our resources;
- our commercial partners 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; and
- corporate reorganizations or changes in business strategies of our commercial partners, which could adversely affect a commercial partner's willingness or ability to fulfill its obligations under its respective agreement.

Our collaboration and licensing agreements may be terminated by our partners in the event of a breach by us of our obligations under such agreements, including our obligation to supply *EGRIFTA*™, for which we rely on third parties. Our collaboration and licensing agreement with EMD Serono can also be terminated by EMD Serono for their convenience on 180 days notice to us. Such a termination could have an adverse effect on our revenues related to the commercialization of *EGRIFTA*™ in the United States. In addition, 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. In the event of a termination of our agreement with EMD Serono, EMD Serono could assert that such patent would be infringed by our continued sale of *EGRIFTA*™ in the United States. Any such assertion would divert our management's attention and, if successful, could expose us to damages or require us to obtain a license from EMD Serono in order to continue selling *EGRIFTA*™ in the United States, all of which could have a material adverse effect on our results of operations, cash flows and financial conditions.

If any one of our commercial partners terminates their agreement with us or fails to effectively commercialize *EGRIFTA*™, for any of the foregoing or other reasons, we may not be able to replace the commercial partner and any of these events would have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our share price to decline.

We are responsible for reporting to our commercial partners all adverse events derived from the use of EGRIFTA™ and our failure to meet this obligation may subject us to a breach of our agreements and result in our commercial partners being subject to fines from regulatory agencies. The occurrence of any such events would be detrimental to our business.

Regulations governing the commercialization of a pharmaceutical product require the holders of the regulatory dossier of an approved pharmaceutical product to report to regulatory agencies in the countries where such product received approval all adverse events related to the use of such product regardless of its country of origin pursuant to certain timelines. Under the terms of our agreements with our commercial partners, we agreed to act as the entity collecting from each of our commercial partners all adverse events related to the use of our products in each country where such product is approved and disseminate it to all our commercial partners who, as owner of the regulatory dossier, must report such adverse events to the regulatory agencies of their respective countries.

The method of communicating adverse events from all our commercial partners to us and from us to them requires the set-up of certain systems, the standards of which are regulated. To date, not all of those systems are in place since we must agree with our commercial partners on those. If we fail to set-up those systems or if our commercial partners are not being provided the information required pertaining to the adverse events of our products on a timely basis, this may subject us to a breach of our commercial agreements and result in our commercial partners being fined by regulatory agencies. In such events, our relationship with our commercial partners will be adversely affected and this may have an adverse effect on our revenue, business and operating results.

We rely on third parties for the manufacture and supply of EGRIFTA™ and tesamorelin and such reliance may adversely affect us if the third parties are unable or unwilling to fulfill their obligations.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We do not own or operate manufacturing facilities for the production of tesamorelin or any of our other product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third parties to manufacture and supply all of our required raw materials, drug substance and drug product for our preclinical research, clinical trials and commercial sales. For tesamorelin for clinical studies and *EGRIFTA*™ for commercial sales, we are currently using, and relying on, single suppliers and single manufacturers for starting materials and the final drug substance. Although potential alternative suppliers and manufacturers have been identified, we have not qualified these vendors to date and no assurance can be given that such suppliers will be qualified in the future or receive necessary regulatory approval.

Our reliance on third-party manufacturers exposes us to a number of risks. 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 equipment failures or unplanned facility shutdowns required to comply with GMP, or damage from any event, including fire, flood, earthquake, business restructuring or insolvency; or
- fails to perform its contractual obligations under our agreement, such as failing to deliver the quantities requested on a timely basis.

Any delay in or suspension of the supply of *EGRIFTA*™ could delay or prevent the sale of *EGRIFTA*™ and, accordingly, adversely affect our revenues and results of operations. In addition, any manufacturing delay or delay in delivering *EGRIFTA*™, or delay in entering into additional commercial agreements for the manufacture and supply of our drug substance and drug product, may result in our being in default under our collaboration agreements. If the damage to a supplier’s manufacturer

facility is extensive, or, for any reason, it does not operate in compliance with GMP or the third-party manufacturer is unable or refuses to perform its obligations under our agreement, we would need to find an alternative third-party manufacturer. The selection of a replacement third-party manufacturer would be time-consuming and costly since we would need to validate the manufacturing facility of such new third-party manufacturer. The validation process would include an assessment of the capacity of such third-party manufacturer to produce the quantities that we may request from time to time, the manufacturing process and its compliance with GMP. In addition, the third-party manufacturer would have to familiarize itself with our technology. Any delay in finding an alternative third-party manufacturer of tesamorelin and *EGRIFTA*™ could result in a shortage of such analogue or product, which could materially adversely affect our business and results of operations.

Even though EGRIFTA™ was launched in the United States, 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 or other regulatory authorities will depend upon the acceptance of such product by the medical community, including physicians, patients and health care payors. The degree of market acceptance of any of our products will depend on a number of factors, including:

- acceptance of the product by physicians and patients as safe and effective treatments and addressing a significant unmet medical need;
- product price;
- the effectiveness of the sales and marketing efforts of our commercial partners (or ours);
- storage requirements and ease of administration;
- dosing regimen;
- safety and efficacy;
- prevalence and severity of side effects;
- competitive products;
- the ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness and ability of patients to pay out-of-pocket in the absence of third-party coverage.

If *EGRIFTA*™ does not achieve adequate sales level, we may not generate sufficient revenue from this product, and we may not be able to achieve profitability.

We have no internal sales, marketing or distribution capabilities so we must rely on strategic alliance agreements with third parties for the sale and marketing of EGRIFTA™ or any future products.

We currently have no internal sales, marketing or distribution capabilities and we rely on our commercial partners to market and sell *EGRIFTA*™ in their respective territories. Our agreements with our commercial partners contain termination provisions which, if exercised, could delay or suspend the commercialization of *EGRIFTA*™ or any future products.

In the event of any such termination, in order to continue commercialization, we would be required to build our own sales force or enter into agreements with third parties to provide such capabilities. We currently have limited marketing capabilities and we have limited experience in developing, training or managing a sales force. The development of a sales force would be costly and would be time-consuming given the limited experience we have in this area. To the extent we develop a sales force, we could be competing against companies that have more experience in managing a sales force than we have and that have access to more funds than we with which to manage a sales force. Consequently, there can be no assurance that a sales force which we develop would be efficient and would maximize the revenues derived from the sale of *EGRIFTA*™ or any future products.

We are substantially dependent on revenues from EGRIFTA™.

Our current and future revenues depend substantially upon sales of *EGRIFTA*™ by our commercial partners, EMD Serono, Sanofi, Ferrer and Actelion. Any negative developments relating to this product, such as safety or efficacy issues, the introduction or greater acceptance of competing products, including those marketed and sold by our commercial partners, or adverse regulatory or legislative developments, would have a material adverse effect on our business, prospects and results of operations. Although we continue to develop additional product candidates for commercialization, we expect to be substantially dependent on sales from *EGRIFTA*™ for the foreseeable future. A decline in sales from this product and the non-approval of this product by regulatory agencies outside of the United States would have 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*™ will 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. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, 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 have attempted 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.

Under our agreements with our commercial partners, they are responsible for seeking reimbursement of *EGRIFTA*™ in their respective territories and as a result we have no control over whether or what level of reimbursement is achieved.

We cannot be sure that reimbursement by insurers, government or other third parties will be available for *EGRIFTA*™ and, if reimbursement is available, the level of reimbursement provided to patients. Reimbursement may impact the demand for, or the price of, *EGRIFTA*™ and our future products for which we obtain marketing approval. If reimbursement is not available or is available only in limited amount, our commercial partners may not be able to successfully commercialize *EGRIFTA*™ or our future products and it will have a material adverse effect on our revenues and royalties, business and prospects.

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

International business relationships in the United States, Europe, Latin America, Africa, the Middle East and elsewhere subject us to additional risks, including:

- differing regulatory requirements for drug approvals in foreign countries;
- potentially reduced protection for intellectual property rights;
- 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.

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

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In several countries, including countries which are in Europe, Latin America, Africa, the Middle East and Canada, the pricing of prescription drugs may be subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time and delay the marketing of a product. To obtain reimbursement or pricing approval in some countries, a clinical trial that compares the cost-effectiveness of a product candidate to other available therapies may be required. If reimbursement of our product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our commercial partners may not be willing to devote resources to market and commercialize *EGRIFTA*™ or may decide to cease marketing such product. In such case, our business, prospects and results of operations could be materially adversely affected.

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

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. Although we believe that we have no direct competitors for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, we could face indirect competition from other companies developing and/or commercializing metabolic products and/or other products that reduce or eliminate the occurrence of lipodystrophy.

In the other clinical programs that we are currently evaluating for development, there may exist companies that are at a more advanced stage of developing a product to treat the diseases for which we are evaluating clinical programs. Some of these competitors could have access to capital resources, research and development personnel and facilities that are superior to ours. In addition, some of these competitors could be more experienced than we are in the development and commercialization of medical products and already have a sales force in place to launch new products. Consequently, they may be able to develop alternative forms of medical treatment which could compete with our products and which could be commercialized more rapidly and effectively than our products.

If we fail to comply with government regulations regarding the import and export of products and raw materials, we could be subject to fines, sanctions and penalties that could adversely affect our ability to operate our business.

We import and export products and raw materials from and to several jurisdictions around the world. This process requires us and our commercial partners to operate in a number of jurisdictions with different customs and import/export regulations. The regulations of these countries are subject to change from time to time and we cannot predict the nature, scope or impact of these changes upon our operations. We and our commercial partners are subject to periodic reviews and audits by U.S. and foreign authorities responsible for administering these regulations. To the extent that we or our commercial partners are unable to successfully defend against an audit or review, we may be required to pay assessments, penalties and increased duties, which may, individually or in the aggregate, negatively impact our business, operating results and financial condition.

3.2 RISKS RELATED TO THE REGULATORY REVIEW PROCESS

Even after regulatory approval has been obtained regulatory agencies may impose limitations on the indicated uses for which our products may be marketed, subsequently withdraw approval or take other actions against us that would be adverse to our business.

Even though we have obtained marketing approval of *EGRIFTA*™ in the United States, the FDA and regulatory agencies in other countries have the ability to limit the indicated use of a product. Also, the manufacture, marketing and sale of our products will be subject to ongoing and extensive governmental regulation in the country in which we intend to market our products. For example, although we obtained marketing approval of *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the United States, the marketing of *EGRIFTA*™ will be subject to extensive regulatory requirements administered by the FDA, such as adverse event reporting and compliance with marketing and promotional requirements. The FDA has also requested that we comply with certain post-approval requirements in connection with the approval of *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, namely, the development of a single vial formulation of *EGRIFTA*™ (the development of a new presentation of the

same formulation), a long-term observational safety study using *EGRIFTA™*; and a Phase 4 clinical trial. Although we have received marketing approval from the FDA of tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, there can be no guarantee that regulatory agencies in other countries will approve tesamorelin for this treatment in their respective countries.

Our third party manufacturing facilities for *EGRIFTA™* will also be subject to continuous reviews and periodic inspections and approval of manufacturing modifications by regulatory agencies, including the FDA. The facilities must comply with GMP regulations. The failure to comply with FDA requirements (and those of other regulatory agencies) can result in a series of administrative or judicial sanctions or other setbacks, including:

- restrictions on the use of the product, manufacturers or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import or export bans or restrictions;
- product recalls and related publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new product candidates or supplements to approved applications.

Addressing any of the foregoing or any additional requirements of the FDA or other regulatory authorities may require significant resources and could impair our ability to successfully commercialize our products.

To date, we do not have the required regulatory approvals to commercialize EGRIFTA™ outside of the United States and cannot guarantee that we will obtain such regulatory approvals or that any of our product candidates will be approved for commercialization in any country, including the United States.

The commercialization of *EGRIFTA™* outside of the United States and our future products first requires the approval of the regulatory agencies in each of the jurisdictions where we intend to sell such products. In order to obtain the required approvals, we must demonstrate, following preclinical and clinical studies, the safety, efficacy and quality of a product.

The rules and regulations relating to the approval of a new drug are complex and stringent. Although we have received marketing approval in the United States from the FDA for *EGRIFTA™*, there can be no guarantee that regulatory agencies in other territories will approve *EGRIFTA™* in their respective countries.

All of our product candidates are subject to preclinical and clinical studies. If the results of such studies are not positive, we may not be in a position to make any filing to obtain the regulatory approval for the product candidate or, even where a product candidate has been filed for approval, we may have to conduct additional clinical trials or testing on such product candidate in an effort to obtain results that further support the safety and efficacy of such product candidate. Such studies are often costly and may also delay a filing or, where additional studies or testing are required after a filing has been made, the approval of a product candidate.

While an application for a new drug is under review by a regulatory agency, it is standard for such regulatory agency to ask questions regarding the application that was submitted. If these questions are not answered quickly and in a satisfactory manner, the marketing approval of the product candidate subject to the review and its commercialization could be delayed or, if the questions are not answered in a satisfactory manner, denied. If *EGRIFTA*™ is not approved by the appropriate regulatory agencies for commercialization outside of the United States, our capacity to generate revenues in the long-term will be impaired and this will have an adverse effect on our financial condition and our operating results.

Obtaining regulatory approval is subject to the discretion of regulatory agencies in each relevant jurisdiction. Therefore, even if we obtain regulatory approval from one agency, or succeed in filing the equivalent of an NDA, in other countries, or have obtained positive results relating to the safety and efficacy of a product candidate, a regulatory agency may not accept the filing or the results contained therein as being conclusive evidence of the safety and efficacy of a product candidate in order to allow us to sell the product candidate in its country. A regulatory agency may require that additional tests on the safety and efficacy of a product candidate be conducted prior to granting approval of such product candidate. These additional tests may delay the approval of such product candidate, can have a material adverse effect on our financial condition and results of operations based on the type of additional tests to be conducted and may not necessarily lead to the approval of the product candidate.

We have only obtained FDA approval for EGRIFTA™ and we must complete several preclinical studies and clinical trials for our other product candidates which may not yield positive results and, consequently, could prevent us from obtaining regulatory approval.

Obtaining FDA approval for the commercialization of drug products requires a demonstration through preclinical studies and clinical trials that the drug is safe and effective. All other product candidates are either at the discovery or pre-clinical stage.

If any of our preclinical studies or clinical trials fail to show positive efficacy data or result in adverse patient reactions, we may be required to perform additional preclinical studies or clinical trials, to extend the term of our studies and trials, to increase the number of patients enrolled in a given trial or to undertake ancillary testing. Any of these events could cause an increase in the cost of product development, delay filing of an application for marketing approval or result in the termination of a study or trial and, accordingly, could cause us to cease the development of a product candidate. In addition, the future growth of our business could be negatively impacted since there can be no guarantee that we will be able to develop new compounds, license or purchase compounds or product candidates that will result in marketed products.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or

delay marketing approval for *EGRIFTA*™ and our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell *EGRIFTA*™ or any of our other product candidates for which we intend to seek marketing approval.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the MMA changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and sales price that we receive for *EGRIFTA*™ or any other approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

More recently, in March 2010, U.S. President Obama signed into law 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 to states. Further, beginning in 2011, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. We will not know the full effects of the *Health Care Reform Law* until applicable U.S. federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the *Health Care Reform Law*, the new law appears likely to continue to apply the pressure on pharmaceutical pricing. Pressure on pharmaceutical pricing may adversely affect the amount of our royalties in the United States.

3.3 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 or are effectively maintained as trade secrets. We try to protect our intellectual property position by, among other things, filing patent applications related to our proprietary technologies, inventions and improvements that are important to the development of our business.

Because the patent position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope, validity, and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. 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 product candidates, 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. Any such litigation could also divert our research, technical and management personnel from their normal responsibilities.

Our ability to defend ourselves against infringement by third parties of our intellectual property in the United States with respect to tesamorelin for the treatment of HIV-related lipodystrophy depends, in part, on our commercial partner's decision to bring an action against such third party. Under the terms and conditions of our collaboration and licensing agreement with EMD Serono, EMD Serono has the first right to bring an action against a third party for infringing our patent rights with respect to tesamorelin for the treatment of HIV-related lipodystrophy. Any delay in pursuing such action or in advising us that it does not intend to pursue the matter could decrease sales, if any, of tesamorelin for the treatment of HIV-related lipodystrophy and adversely affect our revenues.

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 our product candidates, and more particularly tesamorelin, 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.

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 favourable to us, and/or pay damages, including up to treble damages in the United Sates (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 nonexclusive, 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. We are aware of third-party patents for the reduction of accumulation of fat tissue in HIV patients and, if a patent infringement suit was brought against us, we believe that we should not be found to infringe any valid claims of these patents. 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.

3.4 OTHER RISKS RELATED TO OUR BUSINESS

We have a history of net losses and we may never achieve high profitability.

We have been reporting losses since our inception (except for the financial years ended November 30, 2010, 2001 and 2000) and, as at November 30, 2011, we had an accumulated deficit of $252,846,000.

Our profitability will depend on, among other things, our commercial partners' ability and willingness to successfully commercialize *EGRIFTA*™ and to obtain regulatory approval for the use of tesamorelin in the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Latin America, Africa, the Middle East and Canada. However, there is no guarantee that our commercial partners will succeed in commercializing *EGRIFTA*™ or that *EGRIFTA*™ and our product candidates will ever receive approval for commercialization in any jurisdiction and, accordingly, we may never sustain profitability.

We rely on third-party service providers to conduct our preclinical studies and clinical trials and 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 development programs.

We have limited human resources to conduct preclinical studies and clinical trials and must rely on third-party service providers to conduct our studies and trials and carry out certain data gathering and analyses. 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 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 the planned timing of our trials and studies which could adversely affect the timing of the development program of a product candidate or the filing of an application for 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 question raised by a regulatory agency during its review of one of our files, 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 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 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 any new drug application with regulatory agencies for the purposes of obtaining regulatory approval to commercialize our product candidates. Furthermore, such delays could increase our expenditures to develop a product candidate and materially adversely affect our 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 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 product candidates, the filing of an NDA, or its equivalent, with regulatory agencies and the commercialization of such product candidates.

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 to continue and complete the research and development of our product candidates and their commercialization.

We do not generate significant recurrent revenues and may need financing in order to fund all or part of our capital requirements to sustain our growth, to continue research and development of new product candidates, 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. In the past, we have been financed through public equity offerings in Canada and private placements of our equity securities and we may need to seek additional equity offerings to raise capital, the size of which cannot be predicted. 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 favourable to us. If adequate funding is not available to us, we may be required to delay, reduce, or eliminate our research and development of new product candidates, our clinical trials or our marketing and commercialization efforts to launch and distribute new products, curtail significant portions of our product development programs that are designed to identify new product candidates and sell or assign rights to our technologies, products or product candidates. 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.

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 manufacture and sale of such products may expose us to potential liability, and the industries in which our products are likely to be sold have 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 results of operations.

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 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.

The development and commercialization of our drugs could expose us to liability claims which could exceed our insurance coverage.

A risk of product liability claims is inherent in the development and commercialization of human therapeutic products. Product liability insurance is very expensive and offers limited protection. A product liability claim against us could potentially be greater than the available coverage and, therefore, have a material adverse effect upon us and our financial condition. Furthermore, a product liability claim could tarnish our reputation, whether or not such claims are covered by insurance or are with or without merit.

We depend on our key personnel to research, develop and bring new products to the market and the loss of key personnel or the inability to attract highly qualified individuals could have a material adverse effect on our business and growth potential.

The operation of our business requires qualified scientific and management personnel. The loss of scientific personnel or members of management could have a material adverse effect on our business. In addition, our growth is and will continue to be dependent, in part, on our ability to hire and retain the employment of qualified personnel. There can be no guarantee that we will be able to continue to retain our current employees or will be able to attract qualified personnel to achieve our business plan.

We may be unable to identify and complete in-licensing or acquisitions. In-licensing or acquisitions could divert management's attention and financial resources, may negatively affect our operating results and could cause significant dilution to our shareholders.

In the future, we may engage in selective in-licensing or acquisitions of products or businesses. There is a risk that we will not be able to identify suitable in-licensing or acquisition candidates available for sale at reasonable prices, complete any in-licensing or acquisition, or successfully integrate any in-licensed or acquired product or business into our operations. We are likely to face competition for in-licensing or acquisition candidates from other parties including those that have substantially greater available resources. In-licensing or acquisitions may involve a number of other risks, including:

- diversion of management's attention;
- disruption to our ongoing business;
- failure to retain key acquired personnel;
- difficulties in integrating acquired operations, technologies, products or personnel;
- unanticipated expenses, events or circumstances;

- assumption of disclosed and undisclosed liabilities;
- inappropriate valuation of the acquired in-process research and development, or the entire acquired business; and
- difficulties in maintaining customer relations.

If we do not successfully address these risks or any other problems encountered in connection with an acquisition, the acquisition could have a material adverse effect on our business, results of operations and financial condition. Inherited liabilities of or other issues with an acquired business could have a material adverse effect on our performance or our business as a whole. In addition, if we proceed with an acquisition, our available cash may be used to complete the transaction, diminishing our liquidity and capital resources, or shares may be issued which could cause significant dilution to our existing shareholders.

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 our product, announcement of additional clinical programs for a product candidate or levels of sales of a product 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 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 an adverse material effect on our business plan, financial condition or operating results.

The outcome of scientific research is uncertain and our failure to discover new compounds could slow down the growth of our portfolio of products.

We conduct research activities in order to increase our portfolio of product candidates. The outcome of scientific research is uncertain and may prove unsuccessful and, therefore, may not lead to the discovery of new molecules and progression of existing compounds to an advanced development stage. Our inability to develop new compounds or to further develop the existing ones could slow down the growth of our portfolio of products.

3.5 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 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. The market price of our common shares will fluctuate due to various factors including the risk factors described herein and other circumstances beyond our control.

In the past, when the market price of a stock has been volatile, shareholders have often instituted securities class action litigation against that company. If any of our shareholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of revenues and royalties received related to *EGRIFTA*™;
- variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- the achievement and timing of milestone payments under our existing strategic partnership agreements.

If our quarterly operating results fall below the expectations of investors or securities analysts, 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, your ability to achieve a return on your 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 do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. 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 revenues and expenses may fluctuate significantly and any failure to meet financial expectations 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 sales of *EGRIFTA*™ by our commercial partners;

- 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; changes in foreign currency fluctuations;
- the timing of achievement and the receipt of milestone or royalty payments from current or future third parties;
- failure to enter into new or the expiration or termination of current agreements with third parties; and
- failure to introduce our product candidates to the market in a manner that generates anticipated revenues.

We may be adversely affected by currency fluctuations.

A substantial portion of our revenue is earned in U.S. dollars, but a substantial portion of our operating expenses are incurred in Canadian dollars. Fluctuations in the exchange rate between the U.S. dollar and other currencies, such as the Canadian dollar, may have a material adverse effect on our business, financial condition and operating results. We engage occasionally in limited transactional hedging schemes and we also mitigate the risk of currency fluctuations by actively monitoring and managing our foreign currency holdings relative to our foreign currency expenses.

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

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

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

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

ITEM 4 DIRECTORS AND EXECUTIVE OFFICERS

4.1 DIRECTORS

The following table lists the names of our directors, their province or state and country of residence, their principal occupation, their position or office held (if any), the year in which each of them first became a director and the number of common shares and deferred share units each of them beneficially owned, directly or indirectly, or over which they exercised control or direction as of February 27, 2012. Each elected director remains in office until the next annual meeting of shareholders, unless he resigns or his position becomes vacant following his death, destitution or for any other reason before the next annual meeting of shareholders.

DIRECTORS

Name and Place of Residence	Principal Occupation	Director Since	Number of Common Shares	Number of Deferred Share Units
Paul Pommier[1] [2] [3] [4] Québec, Canada	Chairman of the Board	1997	220,100	20,998
John-Michel T. Huss Québec, Canada	President and Chief Executive Officer of the Company	2010	14,000	149,290[5]
Gilles Cloutier[3] [4] North Carolina, United States	Corporate Director	2003	71,000	3,000
Robert G. Goyer[3] Québec, Canada	Emeritus Professor Faculty of Pharmacy Université de Montreal	2005	10,000	5,250
Gérald A. Lacoste[1] [3] [4] Québec, Canada	Corporate Director	2006	11,000	5,250
Bernard Reculeau[2] Paris, France	Corporate Director	2005	18,100	3,000
Jean-Denis Talon[1] [2] [4] Québec, Canada	Corporate Director	2001	70,000	3,000
Luc Tanguay Québec, Canada	Senior Executive Vice President and Chief Financial Officer of the Company	1993	83,000	27,572

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee
(4) Member of the Strategic Review Committee
(5) Mr. Huss' DSU are not redeemable before the third anniversary date of their dates of grant.

Biographical Notes of the Directors

Paul Pommier, MBA. *Chairman of the Board*. 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.

John-Michel T. Huss, MBA. *President & Chief Executive Officer.* John-Michel T. Huss brings more than 20 years of global experience in the pharmaceutical industry to Theratechnologies. He began his career at Merck & Co., occupying various sales and marketing positions in the United States and in Europe. In 1996, he accepted an International Product Manager position at the headquarters of F. Hoffman-La Roche, in Basel, Switzerland. Mr. Huss joined Sanofi-Synthelabo GmbH in 1999, where he held positions in Germany and in Canada. He was appointed General Manager of the Swiss subsidiary at Sanofi in 2007 (Sanofi-Synthelabo merged with Aventis in 2004), and in 2009 was promoted to the position of Chief of Staff, Office of the CEO, in Paris. In 2011, Mr. Huss joined the board of BioQuébec and the board of Rx&D in Canada.

Gilles Cloutier, Ph.D. *Corporate Director*. Dr. Gilles Cloutier has over 30 years of experience in the pharmaceutical industry including five years with contract research organizations, providing strategic support to biotechnology and pharmaceutical companies. Dr. Cloutier has also held key positions with large North-American pharmaceutical companies, where he developed expertise in the field of clinical research. His experience includes the development and approval of several drugs in Canada, the United States and Europe. Dr. Cloutier sits on our board of directors and is also Chairman of the Fondation André Delambre for amyotrophic lateral sclerosis (ALS).

Robert G. Goyer, Ph.D. *Emeritus professor, Faculty of Pharmacy of the Université de Montréal*. Dr. Goyer has more than 40 years of experience in the pharmaceutical field. Dr. Goyer is the former President of Jouveinal Canada and is also a former dean of the Faculty of Pharmacy of Université de Montréal. Recognized for his broad expertise in drug development, he has served on the boards of several companies and governmental organizations. He was notably Chairman of the Advisory Committee on drug approval procedures of Health Canada's Therapeutic Products Directorate and a member of the board of directors of the Régie de l'assurance maladie du Québec. He was Chairman of the Conseil du médicament du Québec from 2003 to 2005.

Gérald A. Lacoste, Q.C. *Corporate Director.* Gérald A. Lacoste is a 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 CEO of the Montreal Stock 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, actively involved in the biotechnology industry, and is a member of the North American Free Trade Agreement (NAFTA) arbitration panel.

Bernard Reculeau. *Corporate Director*. Mr. Bernard Reculeau brings over 25 years of pharmaceutical industry experience to Theratechnologies. From September 2006 to December 2009, he was the President of CIS Bio International, a French company specializing in nuclear medicine and biomedical technologies. Prior to joining CIS Bio International, Mr. Reculeau was Senior Vice President Pharmaceutical Operations of Sanofi for the InterContinental Region. In his previous functions, he was responsible for product development and commercialization in numerous countries around the world. Mr. Reculeau has close to 25 years in pharmaceutical operations, notably in France where he ran the pharmaceutical operations for Rhône-Poulenc and Rhône-Poulenc Rorer as well as in other countries in the European Union. Mr. Reculeau retired in early 2010.

Jean-Denis Talon. *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 former President of the Financial Affairs Committee at the Insurance Bureau of Canada.

Luc Tanguay, M.Sc., CFA. *Senior Executive Vice President and Chief Financial Officer of the Company.* Mr. Luc Tanguay has been active in the biotechnology industry for over 15 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.

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, 2011, 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 Chairman 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 has been 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 the issuer's financial statements.

External Auditors Service Fees

	Financial Year Ended November 30, 2011	Financial Year Ended November 30, 2010
Audit Fees [1]	$ 495,000	$ 122,000
Audit-Related Fees [2]	$ 15,250	$ 158,025
Tax Fees [3]	$ 35,285	$ 56,600
All Other Fees	—	—

[1] Audit fees include fees of $355,000 for audit services performed in connection with our intended public offering and our subsequent listing on NASDAQ.

[2] Audit-related fees relate to services rendered in connection with the conversion of our annual financial statements from Canadian Generally Accepted Accounting Principles into IFRS.

[3] Tax fees relate to services rendered in connection with the preparation of corporate tax returns and general tax advice.

4.3 EXECUTIVE OFFICERS

The following table lists the names of all executive officers, their province or state and country of residence, their office and the number of common shares and deferred share units beneficially owned, directly or indirectly, by each of them or over which they exercised control or direction as at February 27, 2012.

EXECUTIVE OFFICERS

Name and Place of Residence	Office	Number of Common Shares of the Company over which Control or Direction is Exercised	Number of Deferred Share Units
Paul Pommier Québec, Canada	Chairman of the Board	220,100	20,998
John-Michel T. Huss Québec, Canada	President and Chief Executive Officer	14,000	149,290
Luc Tanguay Québec, Canada	Senior Executive Vice President and Chief Financial Officer	83,000	27,572
Marie-Noël Colussi Québec, Canada	Vice President, Finance	10,075	3,182
Jocelyn Lafond Québec, Canada	Vice President, Legal Affairs, and Corporate Secretary	—	5,000
Julie Mac Allister[1] Québec, Canada	Vice President, Human Resources	—	—
Christian Marsolais Québec, Canada	Vice President, Scientific Affairs and Alliances	8,597	6,312
Pierre Perazzelli Québec, Canada	Vice President, Pharmaceutical Development	—	4,061
Krishna Peri Québec, Canada	Vice President, Research	40,000	—

[1] Ms. Mac Allister will be leaving the Company on June 1, 2012.

Biographical Notes of the Executive Officers

For the biographical notes of Paul Pommier, John-Michel T. Huss and Luc Tanguay, please refer to ITEM 4 of this AIF.

Marie-Noël Colussi, CA. *Vice President, Finance*. Ms. Marie-Noël Colussi is a graduate of *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 March 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.

Jocelyn Lafond, LL.B., LL.M. *Vice President, Legal Affairs, and Corporate Secretary*. Mr. Lafond has over 15 years of experience in the fields of corporate and securities law. Mr. Lafond holds a law degree from *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.

Julie Mac Allister, M.B.A. *Vice President, Human Resources.* Ms. Julie Mac Allister joined us in 2011 and has over 18 years of experience in human resources and organizational behavior. She holds an M.B.A. from the *Université de Sherbrooke*. Prior to joining us, Ms. Mac Allister held various senior positions in human resources in large public and private companies. She spent her last eight (8) years as a senior member of the human resources group at Sanofi in Canada.

Christian Marsolais, Ph.D. *Vice President, Scientific Affairs and Alliances*. 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*.

Pierre Perazzelli, B. Sc. *Vice President, Pharmaceutical Development*. A graduate of *Université Laval*, Mr. Perazzelli has been working in the pharmaceutical manufacturing industry for over 20 years. Throughout his career, he has held various positions in large pharmaceutical companies, including Bristol Myers Squibb and Abbott Laboratories, Ltd. He was Director of the LAB Laboratory, a research centre specializing in pharmaceutical formulation. He is also experienced in the production of generic drugs. Mr. Perazzelli joined us in May 2000.

Krishna Peri, Ph.D. *Vice President, Research*. Co-inventor of the ExoPep™ technology and a founder of Pharma-G, Dr. Krishna Peri holds a Ph.D. in biochemistry from the University of Saskatchewan, Canada. He pursued post-doctoral research in cancer as an NCI fellow at McGill University and at Ste. Justine Hospital Research Center. After our acquisition of Pharma-G in 2000, he served as director of discovery research, and was subsequently appointed Vice-President, Research, in June 2004.

4.4 DECLARATION OF THE DIRECTORS' AND OFFICERS' ANTECEDENTS

Except as described below, to our knowledge, no director or executive officer (a) is, as at the date of this Annual Information Form, or has been within the ten years before the date of this Annual Information Form, a director or executive officer of any company (including us) 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 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 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 years before the date of this Annual Information Form, 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.

Jean-Denis 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 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.

Luc 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). 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, TSX determined 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 TSX. The common shares will remain suspended from trading.

4.5 SECURITIES HELD BY THE DIRECTORS AND EXECUTIVE OFFICERS

As at February 27, 2012, the total number of common shares (the only securities carrying a voting right) held by our directors and executive officers amounted to 555,872, which represented 0.91% 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.

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 and Denver 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 27, 2012	$2.72	$2.16	1,177,266
January 2012	$2.79	$2.25	1,275,472
December 2011	$2.79	$1.82	2,625,873
November 2011	$3.06	$2.09	1,184,234
October 2011	$3.36	$2.86	1,051,958
September 2011	$4.03	$3.06	1,157,549
August 2011	$4.16	$3.09	1,289,426
July 2011	$4.63	$3.85	1,571,640
June 2011	$4.71	$4.11	1,781,912
May 2011	$5.17	$4.14	3,372,734
April 2011	$4.86	$4.25	1,896,314
March 2011	$5.06	$4.48	4,204,004
February 2011	$5.98	$4.65	5,746,987
January 2011	$5.96	$5.36	3,318,718
December 2010	$5.87	$5.18	4,038,571

7.2 PRIOR SALES

The following table summarizes the distribution of securities other than our common shares that we issued during the most recently completed financial year, identifying the type of security, the price per security, the number of securities issued, and the date on which the securities were issued.

Date	Type of Security	Price per Security	Number of Securities
December 1, 2010	Options	$ 5.65	250,000
December 15, 2010	Deferred Share Units[1]	$ 5.41	99,912[2]
February 9, 2011	Deferred Share Units[1]	$ 5.55	45,748

(1) Under our Deferred Share Unit Plan, except as described in Note 2, the units are redeemable for cash and may only be redeemed when a holder leaves his position.

(2) Out of this number, 44,248 units may not be redeemed before December 15, 2013.

ITEM 8 LEGAL PROCEEDINGS

On July 26, 2010, we received a motion for authorization to institute a class action lawsuit against us, our chairman and our former chief executive officer. This motion was filed in the Superior Court of Québec, district of Montreal. The applicant is seeking to initiate a class action suit and to certify and represent a class of persons who were shareholders at May 21, 2010 and who sold their common shares on May 25 or 26, 2010. This applicant alleges that we did not comply with our continuous disclosure obligations as a reporting issuer by failing to disclose certain alleged adverse effects relating to the administration of *EGRIFTA*™.

On February 24, 2012, the Superior Court of Québec delivered its judgement granting the applicant the authorization to institute a class action lawsuit against us, our chairman and our former chief executive officer. Despite the granting of this motion in favor of the applicant, we are of the view that the allegations contained therein are entirely without merit and we intend to take all appropriate actions to vigorously defend our position.

We have subscribed for insurance covering our potential liability and the potential liability of our directors and officers in the performance of all their duties for us subject to a $200,000 deductible and standard terms, conditions and exclusions.

We are not otherwise currently subject to any material legal proceedings.

ITEM 9 MATERIAL CONTRACTS

Licensing Agreements. We have executed commercialization agreements with third parties for the exclusive distribution rights to *EGRIFTA*™ for the reduction of excess abdominal fact in HIV-infected patients with lipodystrophy for (i) the United States; (ii) Latin America, Africa, the Middle East; (iii) Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries; and (iv) Canada. For a description of these agreements, see Item 2.5.

Supply Agreements. We have executed five supply agreements with Bachem, Draxis, Becton Dickinson, Hospira and ABAR. For a description of these agreements, see Item 2.7.

Shareholder Rights Plan Agreement. On February 10, 2010, we entered into a shareholder rights plan agreement, or Rights Plan. The Rights Plan entitles a holder of rights (other than the Acquiring Person, as defined below, or any affiliate or associate of an Acquiring Person or any person acting jointly or in concert with an Acquiring Person or any affiliate or associate of an Acquiring Person) to purchase to our common shares at a discount of 50% to the market price upon a person becoming an "Acquiring Person", subject to certain exceptions and the terms and conditions set out in the Rights Plan. An "Acquiring Person" is defined in the Rights Plan as a beneficial owner of 20% or more of our common shares. The Rights Plan will expire at the close of our annual meeting of shareholders in 2013.

In order to implement the Rights Plan, we issued one right in respect of each common share outstanding as of 6:00 p.m. (Montreal time) on February 9, 2010, the "Effective Date". One right will also be issued and attached to each subsequently issued common share. The rights will separate and trade separately from the common shares to which they are attached and will become exercisable after the "Separation Time", as defined below:

The "Separation time" is the close of business on the tenth business day following the earliest of:

(a) the date of the first public announcement made by us or an Acquiring Person that a person has become an Acquiring Person;

(b) the date of the commencement of, or first public announcement of the intent of any Person to commence, a take-over bid (other than a Permitted Bid (as defined in the Rights Plan) or a Competing Permitted Bid (as defined in the Rights Plan)) by any person for our common shares;

(c) the date upon which a Permitted Bid or Competing Permitted Bid ceases to be such; or

(d) such later date as may be determined by the board of directors.

After the time at which a person becomes an Acquiring Person, and subject to the terms and conditions set out in the shareholder rights plan agreement, each right would, upon exercise, entitle a rights holder, other than the Acquiring Person and related persons, to purchase common shares at a 50% discount to the market price at the time.

Under the Rights Plan, a "Permitted Bid" is a bid made to all holders of the common shares and which is open for acceptance for not less than 60 days. If at the end of 60 days at least 50% of the outstanding common shares, other than those owned by the offeror and certain related parties, have been tendered, the offeror may take up and pay for the common shares but must extend the bid for a further 10 days to allow other shareholders to tender.

Lease Agreement. In October 2009, we entered into a new lease agreement with *Société de portefeuille immobilier GE Q-Tech inc*. for the renewal of our lease for our offices and laboratories located in Montréal, Québec. The new lease became effective on May 1, 2010 and will expire on April 30, 2021. Under the terms of this new lease agreement, we have two five year renewal options. If exercised, the first renewal option will start on May 1, 2021 and expire on April 30, 2026 and the second renewal option, if exercised, will start on May 1, 2026 and expire on April 30, 2031.

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, 2011.

Additional information regarding our Company is available on SEDAR at www.sedar.com and on the Securities and Exchange Commission's website at www.sec.gov, or upon request addressed to Jocelyn Lafond, Corporate Secretary, at 2310 Alfred Nobel Boulevard, Montreal, Québec, Canada H4S 2B4. 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 and certify the accurate presentation of the Company's financial statements; at the same time evaluating the internal control process to determine the nature, extent and chronology of the auditing procedures used. 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, 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 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:

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

   b. all material alternative treatments of financial information within generally accepted accounting principles that have been discussed with management, including the ramifications of the use of such alternate treatments and disclosures and the treatment preferred by the external auditor.

B. Supervision of the Company's Internal Control Systems

1. Review and discuss with management and with the external auditor present reports 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 the external auditors' report to the audit committees on the planning of external auditing;

      • obtain the external auditors' report to the audit committees on the auditing results;

      • 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 statement i) describing all relationships between the external auditor and the Company; ii) assuring that lead audit partner rotation is carried out, as required by law; and iii) describing any other relationship that may adversely 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 and February 8, 2006 Board meetings.

CERTIFICATION PURSUANT TO
RULE 13a-14(a)

I, John-Michel T. Huss, certify that:

1. I have reviewed this annual report on Form 40-F of Theratechnologies Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;
4. The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have:
    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    (b) **[Intentionally omitted pursuant to Rule 13A-14(a)] ;**
    (c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    (d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and
5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and
    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: February 28, 2012

/s/ John-Michel T. Huss
John-Michel T. Huss
President and Chief Executive Officer

CERTIFICATION PURSUANT TO
RULE 13a-14(a)

I, Luc Tanguay, certify that:

1. I have reviewed this annual report on Form 40-F of Theratechnologies Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;
4. The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) **[Intentionally omitted pursuant to Rule 13A-14(a)]** ;
   (c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and
5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: February 28, 2012

/s/ Luc Tanguay
Luc Tanguay
Senior Executive Vice President and Chief Financial Officer

C E R T I F I C A T I O N PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES–OXLEY ACT OF 2002

In connection with the Annual Report on Form 40-F of Theratechnologies Inc. (the "Company") for the fiscal year ended November 30, 2011, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John-Michel T. Huss, President and Chief Executive Officer of the Company certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2012

/s/ John-Michel T. Huss
Name: John-Michel T. Huss
Title: President and Chief Executive Officer

C E R T I F I C A T I O N PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES–OXLEY ACT OF 2002

In connection with the Annual Report on Form 40-F of Theratechnologies Inc. (the "Company") for the fiscal year ended November 30, 2011, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Luc Tanguay, Senior Executive Vice President and Chief Financial Officer of the Company certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2012

/s/ Luc Tanguay
Name: Luc Tanguay
Title: Senior Executive Vice President and Chief Financial Officer

FORM 52-109F1
CERTIFICATION OF ANNUAL FILINGS
FULL CERTIFICATE

I, John-Michel T. Huss, President and Chief Executive Officer of Theratechnologies Inc., certify the following:

1. ***Review***: I have reviewed the AIF, if any, annual financial statements and annual MD&A, including, for greater certainty, all documents and information that are incorporated by reference in the AIF (together, the "annual filings") of Theratechnologies Inc. (the "issuer") for the financial year ended November 30, 2011.

2. ***No misrepresentations***: Based on my knowledge, having exercised reasonable diligence, the annual filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, for the period covered by the annual filings.

3. ***Fair presentation***: Based on my knowledge, having exercised reasonable diligence, the annual financial statements together with the other financial information included in the annual filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date of and for the periods presented in the annual filings.

4. ***Responsibility***: The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures ("DC&P") and internal control over financial reporting ("ICFR"), as those terms are defined in Regulation 52-109 respecting Certification of Disclosure in Issuers' Annual and Interim Filings, for the issuer.

5. ***Design***: Subject to the limitations, if any, described in paragraphs 5.2 and 5.3, the issuer's other certifying officers(s) and I have, as at the financial year end

   (a) designed DC&P, or caused it to be designed under our supervision, to provide reasonable assurance that

      (i) material information relating to the issuer is made known to us by others, particularly during the period in which the annual filings are being prepared; and

      (ii) information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and

   (b) designed ICFR, or caused it to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP.

5.1 ***Control framework***: The control framework the issuer's other certifying officer(s) and I used to design the issuer's ICFR is the Internal Control over Financial Reporting – Guidance for Smaller Public Companies (COSO).

5.2 N/A

5.3 N/A

6. ***Evaluation***: The issuer's other certifying officer(s) and I have

   (a) evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer's DC&P at the financial year end and the issuer has disclosed in its annual MD&A our conclusions about the effectiveness of DC&P at the financial year end based on that evaluation; and

   (b) evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer's ICFR at the financial year end and the issuer has disclosed in its annual MD&A

      (i) our conclusions about the effectiveness of ICFR at the financial year end based on that evaluation; and

      (ii) N/A.

7. ***Reporting changes in ICFR***: The issuer has disclosed in its annual MD&A any change in the issuer's ICFR that occurred during the period beginning on September 1, 2011 and ended on November 30, 2011 that has materially affected, or is reasonably likely to materially affect, the issuer's ICFR.

8. ***Reporting to the issuer's auditors and board of directors or audit committee***: The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of ICFR, to the issuer's auditors, and the board of directors or the audit committee of the board of directors any fraud that involves management or other employees who have a significant role in the issuer's ICFR.

Date: February 28, 2012

/s/ John-Michel T. Huss

John-Michel T. Huss
President and Chief Executive Officer

FORM 52-109F1
CERTIFICATION OF ANNUAL FILINGS
FULL CERTIFICATE

I, Luc Tanguay, Senior Executive Vice President and Chief Financial Officer of Theratechnologies Inc., certify the following:

1. ***Review***: I have reviewed the AIF, if any, annual financial statements and annual MD&A, including, for greater certainty, all documents and information that are incorporated by reference in the AIF (together, the "annual filings") of Theratechnologies Inc. (the "issuer") for the financial year ended November 30, 2011.

2. ***No misrepresentations***: Based on my knowledge, having exercised reasonable diligence, the annual filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, for the period covered by the annual filings.

3. ***Fair presentation***: Based on my knowledge, having exercised reasonable diligence, the annual financial statements together with the other financial information included in the annual filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date of and for the periods presented in the annual filings.

4. ***Responsibility***: The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures ("DC&P") and internal control over financial reporting ("ICFR"), as those terms are defined in Regulation 52-109 respecting Certification of Disclosure in Issuers' Annual and Interim Filings, for the issuer.

5. ***Design***: Subject to the limitations, if any, described in paragraphs 5.2 and 5.3, the issuer's other certifying officers(s) and I have, as at the financial year end

   (a) designed DC&P, or caused it to be designed under our supervision, to provide reasonable assurance that

      (i) material information relating to the issuer is made known to us by others, particularly during the period in which the annual filings are being prepared; and

      (ii) information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and

   (b) designed ICFR, or caused it to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP.

5.1 ***Control framework***: The control framework the issuer's other certifying officer(s) and I used to design the issuer's ICFR is the Internal Control over Financial Reporting – Guidance for Smaller Public Companies (COSO).

5.2 N/A

5.3 N/A

6. ***Evaluation***: The issuer's other certifying officer(s) and I have

   (a) evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer's DC&P at the financial year end and the issuer has disclosed in its annual MD&A our conclusions about the effectiveness of DC&P at the financial year end based on that evaluation; and

   (b) evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer's ICFR at the financial year end and the issuer has disclosed in its annual MD&A

      (i) our conclusions about the effectiveness of ICFR at the financial year end based on that evaluation; and

      (ii) N/A.

7. ***Reporting changes in ICFR***: The issuer has disclosed in its annual MD&A any change in the issuer's ICFR that occurred during the period beginning on September 1, 2011 and ended on November 30, 2011 that has materially affected, or is reasonably likely to materially affect, the issuer's ICFR.

8. ***Reporting to the issuer's auditors and board of directors or audit committee***: The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of ICFR, to the issuer's auditors, and the board of directors or the audit committee of the board of directors any fraud that involves management or other employees who have a significant role in the issuer's ICFR.

Date: February 28, 2012

/s/ Luc Tanguay

Luc Tanguay
Senior Executive Vice President and Chief Financial Officer