



MANAGEMENT'S DISCUSSION AND ANALYSIS

The following Management's Discussion and Analysis, or MD&A, provides Management's point of view on the financial position of Theratechnologies Inc., on a consolidated basis, as at November 30, 2012 and November 30, 2011. It also provides a review of our performance by comparing the Company's results of operations, on a consolidated basis, for the twelve-month period ended November 30, 2012, or Fiscal 2012, with the twelve-month period ending November 30, 2011, or Fiscal 2011, and for Fiscal 2011 with the twelve-month period ended November 30, 2010, or Fiscal 2010. Unless otherwise indicated or unless the context requires otherwise, all references in this MD&A to "Theratechnologies", the "Company", the "Corporation", "we", "our", "us" or similar terms refer to Theratechnologies Inc. and its subsidiaries on a consolidated basis. This MD&A is dated February 26, 2013 and should be read in conjunction with the audited consolidated financial statements and the notes thereto. All monetary amounts set forth in this MD&A 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.

Except as otherwise indicated, the financial information contained in this MD&A and in our audited consolidated financial statements has been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. The audited consolidated financial statements and MD&A have been reviewed by our Audit Committee and approved by our Board of Directors.

In this MD&A, the use of *EGRIFTA*TM refers to tesamorelin for the reduction of excess abdominal in HIV-infected patients with lipodystrophy regardless of the trade name used for such product in any particular territory. *EGRIFTA*TM 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*TM is our trademark. Tesamorelin refers to the use of tesamorelin for the potential treatment of other diseases.

Forward-Looking Information

This MD&A contains forward-looking statements and forward-looking information, or, collectively, forward-looking statements, 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. You can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "outlook", "believe", "plan", "envisage", "anticipate", "expect" and "estimate", or the negatives of these terms, or variations of them. The forward-looking statements contained in this MD&A include, but are not limited to, statements regarding the regulatory approval of *EGRIFTA*TM in various territories outside of the United States, the capacity of our commercial partner in the United States to continue the commercialization of *EGRIFTA*TM in that country, the capacity of our commercial partners outside of the United States to commercialize *EGRIFTA*TM in their respective territories, our capacity to become cash neutral and to tightly control our expenses and our capacity to re-file a marketing authorization application in Europe or in certain European countries for *EGRIFTA*TM.

Forward-looking statements are based upon a number of assumptions and include, but are not limited to, the following: *EGRIFTA*TM will receive approvals in various territories outside the United States, no additional clinical studies will be required by regulatory authorities outside of the United States to obtain these regulatory approvals, *EGRIFTA*TM will be accepted by the marketplace in territories outside of the United States and will be on the list of reimbursed drugs by third-party payors in these territories, the relationships with our commercial partners and third-party suppliers will be conflict-free, such third-party suppliers will have enough capacity to manufacture and supply *EGRIFTA*TM to meet demand and on a timely basis, the prescription base in the United States for

EGRIFTA[™] will continue to grow and no unexpected events resulting in unplanned material expenses will occur.

Forward-looking statements are subject to a variety of risks and uncertainties, many of which are beyond our control that could cause our actual results to differ materially from those that are disclosed in or implied by the forward-looking statements contained in this MD&A. These risks and uncertainties include, but are not limited to, the following: the risk that *EGRIFTA*[™] is not approved in all or some of the territories where our commercial partners have filed and intend to file marketing authorization applications, the risk that the royalties generated from sales of *EGRIFTA*[™] in the United States do not increase or that they decrease, the risk that conflicts occur with our commercial partners jeopardizing the commercialization of *EGRIFTA*[™], the risk that the supply of *EGRIFTA*[™] to our commercial partners is delayed or suspended as a result of problems with our third-party suppliers, the risk that *EGRIFTA*[™] is withdrawn from the market as a result of defects or recalls, the risk that our intellectual property is not adequately protected, the risk that even if approved in territories outside of the United States, *EGRIFTA*[™] is not accepted in these marketplaces or is not on the list of reimbursed drugs by third-party payors and the risk that unexpected events occur resulting in unplanned material expenses.

We refer potential investors to the "Risks and Uncertainties" section of this MD&A. The reader is cautioned to consider these and other risks and uncertainties carefully and not to put undue reliance on forward-looking statements. Forward-looking statements reflect current expectations regarding future events and speak only as of the date of this MD&A and represent our expectations as of that date.

We undertake no obligation to update or revise the information contained in this MD&A, whether as a result of new information, future events or circumstances or otherwise, except as may be required by applicable law.

Business Overview

We are a biopharmaceutical company that specializes in innovative therapeutic peptide products, with an emphasis on growth hormone releasing factor, or GRF, peptides.

Our first product, *EGRIFTA*[™] (tesamorelin for injection), was approved by the United States Food and Drug Administration, or FDA, in November 2010 and is, to date, the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA*[™] is currently marketed in the United States by EMD Serono, Inc., or EMD Serono, pursuant to a collaboration and licensing agreement executed in October 2008, as amended in April 2012, or the EMD Serono Agreement. EMD Serono launched *EGRIFTA*[™] on January 10, 2011.

In order to expand the commercial distribution of *EGRIFTA*[™], we have also granted exclusive commercialization rights to *EGRIFTA*[™] in other territories as follows;

- in December 2010 to an affiliate of sanofi, or sanofi, for Latin America, Africa and the Middle East;
- in February 2011 to Ferrer Internacional S.A., or Ferrer, for Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries; and
- in February 2012 to Actelion Pharmaceuticals Canada Inc., or Actelion, for Canada.

In each case, we are responsible for the manufacture of *EGRIFTA*[™] and its supply to EMD Serono, sanofi, Ferrer and Actelion.

Business Plan

The two principal operating objectives that we established for ourselves at the outset of Fiscal 2012 were to maximize the global commercial value of *EGRIFTA*[™] and advance the development of TH1173, our second-generation GRF peptide.

Specifically, our Fiscal 2012 operating goals were to:

- assist our commercial partners in obtaining additional regulatory approvals for *EGRIFTA*[™] quickly and in as many markets as possible; and
- initiate feasibility studies testing new methods of administration for the TH1173 and undertake pre-clinical testing of the compound in anticipation of launching a Phase 1 clinical trial in the second half of 2013.

Progress was made throughout the year towards achieving both goals; however, the results with respect to obtaining regulatory approvals for *EGRIFTA*[™], and the related revenue growth, were adversely affected by setbacks and delays. Most notable among these was Ferrer's withdrawal of its Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in June 2012.

On October 11, 2012, the Company announced that the President and Chief Executive Officer had been relieved of his duties and was leaving the Company. The Board of Directors selected the Senior Executive Vice President and Chief Financial Officer to fulfill the responsibilities of President and Chief Executive Officer. On October 30, 2012, we announced revisions to our business plan and a related restructuring. The principal thrust of the revised plan is to become cash neutral as soon as possible by focusing almost all of our efforts and resources on maximizing revenues from *EGRIFTA*[™], while continuing to tightly manage expenses. Completing the ongoing preclinical studies for TH1173 was retained as an objective for 2012 but the launch of the Phase 1 clinical program was put on hold, until we have sufficient funds to invest in the project. In addition, all significant long-term research and development activities with respect to our other product candidates and discovery of new peptides were suspended.

With the restructuring behind us, we enter the 2013 fiscal year highly focused on our business plan objectives; and, we are well-financed with \$20,924,000 in liquidities (cash, bonds, and tax credits and grants receivable) as at November 30, 2012 and an expected cash burn rate that is lower than in prior years. In keeping with the overriding strategy of becoming cash neutral by focusing on *EGRIFTA*[™], our principal objectives for fiscal 2013 are as follows:

- continue to actively support EMD Serono's efforts to develop the market for *EGRIFTA*[™] in the United States, through financing the post-approval commitments made to the FDA and also by lifecycle management initiatives such as formulation improvements;
- continue to support the efforts of sanofi to obtain regulatory approvals in Latin America;
- re-file for marketing approval in Europe, on the condition that, in our judgment, there is a reasonable likelihood of success;
- continue to pursue regulatory approval in Canada; and
- tightly control expenses.

In the mid-term, we intend to continue exploring the possibility of partnering *EGRIFTA*[™] for commercialization in new territories, and identifying diseases for which tesamorelin could be indicated as a treatment and further develop our lifecycle management program for *EGRIFTA*[™], which includes developing new formulations and presentations. We will also be exploring partnership and licensing activities with respect to TH1173 in certain territories.

In the longer term, we intend to resume our research and development programs on our product candidates, including TH1173, and develop new GRF peptides that could have routes of administration other than injection.

The paragraphs that follow provide more background information and details on the various aspects of our business including the progress made in Fiscal 2012 and plans for fiscal 2013.

Commercial and Regulatory Activities

United States

EMD Serono began selling *EGRIFTA*[™] in the United States in January 2011 and we receive royalties on their sales. While the EMD Serono sales figures for *EGRIFTA*[™] are not publicly available, the year-over-year, quarterly royalties earned on those sales have grown since the product launch. A second indicator of underlying sales trends is IMS, a third-party supplier of prescription information to the pharmaceutical industry. IMS data is not always an accurate measure of sales in the short term, particularly for products like *EGRIFTA*[™] with relatively low sales volumes and only a limited number of dispensing pharmacies. However, IMS data does provide insight into sales trends over time and, according to the data, total *EGRIFTA*[™] prescriptions for calendar year 2012 were 65% higher than in calendar year 2011.

Our 2012 regulatory activities in the United States were largely focused on optimizing the lifecycle of *EGRIFTA*[™] and supporting the efforts of EMD Serono to expand the patient base. This included completing the development of a new, single-vial, presentation of *EGRIFTA*[™]. Shipments of the new presentation began in September 2012 and it was launched by EMD Serono in October 2012. In January 2013, EMD Serono received FDA approval for a revision to the *EGRIFTA*[™] prescribing information to include storage conditions at or below 25°C, or room-temperature storage, for a 12-week period after dispensing to patients. Previously, *EGRIFTA*[™] required refrigeration as it could only be stored between 2°C and 8°C (36°F and 46°F).

Latin America, Africa and the Middle East

Pursuant to our distribution and licensing agreement with sanofi, or Sanofi Agreement, marketing authorization applications were filed in Israel, Brazil, Argentina, Mexico, Colombia and Venezuela. Throughout 2012, we provided support to sanofi, as needed, to meet the needs of the regulators in these countries.

In June 2012, we were informed by sanofi that as part of the manufacturing assessment for the application in Brazil, the Brazilian National Health Surveillance Agency, or ANVISA, had audited the Montreal-based third-party manufacturing site for *EGRIFTA*[™] and identified technical deficiencies. We subsequently met with the manufacturer and identified a series of corrective measures to address ANVISA's concerns. All of the corrective measures proposed by ANVISA have been agreed to by the manufacturer and most of them have now been implemented. The final step in the manufacturing assessment is a conformational audit by ANVISA which is expected to occur in 2013 and the corrective measures will have been completed by the time of such audit. The evaluation of the Brazilian marketing application for *EGRIFTA*[™] is ongoing. It is a separate process, conducted in parallel with the manufacturing assessment.

In Argentina, we were informed by sanofi that the marketing authorization application filed in September 2011 needs to be amended as a result of the new presentation of *EGRIFTA*[™] launched in the United States in October 2012 and, accordingly, the file will be resubmitted. We are supporting sanofi with corrective measures and we expect sanofi to resubmit the file in the third quarter of 2013, after which the review process will begin anew.

We have also been advised by sanofi that the filing in Venezuela made in June 2012 was deemed by local authorities to be incomplete for technical reasons. We have since supported sanofi with corrective measures; and we expect sanofi to resubmit the file in the first half of 2013, after which the review process will begin anew.

The regulatory review processes for marketing authorization applications in Israel, Mexico and Colombia are ongoing.

Europe

Ferrer filed a MAA with the EMA in June 2011. On June 22, 2012, we announced that Ferrer was withdrawing the MAA following an oral explanation with the EMA's Committee for Medicinal Products for Human Use, or CHMP, which did not allow for the CHMP to conclude on a positive risk/benefit balance. Concerns were raised by the CHMP regarding the increase level of IGF-1 and the related potential safety concerns over the long-term use of *EGRIFTA*TM. The CHMP also raised concerns about the lack of data on the correlation between the effect of reducing VAT and cardiovascular diseases.

In keeping with the decision made in October 2012 to focus substantially all of our efforts on *EGRIFTA*TM, we are currently discussing the terms of our distribution and licensing agreement with Ferrer, or Ferrer Agreement. In the course of such discussions, Ferrer has indicated that we could be responsible for re-filing a MAA in European countries if we decide to do so. Our objective is to re-file in Europe, or in certain European countries, before the end of 2013 and we are currently working with key physicians, patient groups, regulatory consultants and certain regulators to achieve that goal. We will only proceed with an application if we determine that there is a reasonable likelihood of success, based on the *EGRIFTA*TM data that is currently available.

Canada

We filed a New Drug Submission, or NDS, for *EGRIFTA*TM with Health Canada's Therapeutic Products Directorate, or TPD, in June 2011; and, in February 2012, we entered into a supply, distribution and licensing agreement with Actelion, or Actelion Agreement.

TPD issued a notice of non-compliance, or NON, in relation to the NDS in June 2012. The NON contained questions regarding long-term safety, the appropriate patient population and the proposed indication. We were granted 90 days to respond to the questions and did so within the time delay. TPD then confirmed that the screening of the NDS was complete, which allowed the regulatory review to proceed. The process is ongoing and a decision from TPD is expected in the second quarter of fiscal 2013.

Research and Development Activities

*EGRIFTA*TM

Research and development, or R&D, activities in Fiscal 2012 included work on the three post-approval commitments made to the FDA in relation to the marketing approval granted to *EGRIFTA*TM. The first of these was the development of a single-vial presentation of *EGRIFTA*TM, which was completed. The first shipment of the new presentation to EMD Serono occurred in September 2012 and the new presentation was launched by EMD Serono in October 2012. Preparations for the Phase 4 clinical trial to assess whether *EGRIFTA*TM has an impact on diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat were completed in Fiscal 2012 and patient recruitment is now underway. The long-term observational safety study using *EGRIFTA*TM is in the early stages with EMD Serono now recruiting clinical sites.

Other R&D projects involving *EGRIFTA*TM are aimed at product improvements such as new, lower-volume formulations and the previously described Supplemental New Drug Application, or sNDA, providing for room-temperature storage of *EGRIFTA*TM, which was filed by EMD Serono and approved by the FDA in January 2013.

TH1173

In October 2011, we announced the discovery of TH1173, a second-generation GRF peptide. In May 2012, we initiated a preclinical safety program for TH1173, including the seven-day and 28-day toxicology studies required for human testing. The results of the preclinical program were positive

and we are now in a position to proceed with Phase 1 clinical testing at the appropriate time. In January 2013, the United States Patent and Trademark Office, or USPTO, issued a composition of matter patent for TH1173, providing scheduled protection until 2032.

Other Developments

On August 7, 2012, we received notification from NASDAQ that, for 30 consecutive business days, the bid price of our common shares had closed below \$1.00 per share, the minimum closing bid price required by the exchange's continued listing requirements. On January 14, 2013, we announced our intention to voluntarily delist our common shares from the NASDAQ Global Market and the delisting took effect on February 5, 2013. Our common shares continue to trade on the Toronto Stock Exchange under the symbol "TH".

A motion to authorize the institution of a class action was originally filed in July 2010 in the Superior Court of Québec, District of Montreal, entitled 121851 Canada Inc. v. Theratechnologies Inc. et al., Number 500-06-000515-102. The complaint alleged that we, a director and a former executive officer violated the secondary market liability provisions of the *Securities Act* (Québec) by failing to disclose a material change relating to the administration of *EGRIFTA*TM. The plaintiff sought damages on behalf of a class of persons who were shareholders at May 21, 2010 and who sold their common shares on May 25 or 26, 2010. On February 24, 2012, the Superior Court of Québec authorized 121851 Canada Inc. to institute a class action against us, a director and a former executive officer. On March 20, 2012, we filed a motion seeking permission to appeal this judgement with the Court of Appeal of Québec, District of Montreal, Number 500-09-022519-128, and the hearing took place on January 24, 2013. No judgement has been rendered yet following the January 24, 2013 hearing.

Selected Annual Information

Consolidated statement of comprehensive income years ended November 30 (in thousands of Canadian dollars, except per share amounts)	2012	2011	2010
Revenue	\$13,567	\$14,928	\$31,868
Research and development expenses, net of tax credits	\$6,341	\$10,992	\$14,064
Restructuring costs	\$10,702	\$716	-
Results from operating activities	\$(14,846)	\$(18,768)	\$6,663
Net finance income	\$911	\$966	\$2,381
Net (loss) profit	\$(13,940)	\$(17,730)	\$8,930
Basic and diluted (loss) earnings per share	\$(0.23)	\$(0.29)	\$0.15

Consolidated statement of financial position at November 30 (in thousands of Canadian dollars)	2012	2011	2010
Cash and current and non-current bonds	\$20,503	\$36,787	\$64,550
Tax credits and grants receivable	\$421	\$346	\$332
Total assets	\$36,332	\$52,873	\$71,651
Total share capital	\$280,872	\$280,488	\$279,398
Total equity	\$22,670	\$36,343	\$52,656

**Operating Results - twelve months ended November 30, 2012 compared to twelve months
ended November 30, 2011**

Revenue

Our revenues are mainly sales of *EGRIFTA*TM to EMD Serono for re-sale, royalties received from EMD Serono on U.S. sales to customers, and research services, which include milestone payments and the amortization of the initial payment received upon the closing of the agreement with EMD Serono. Consolidated revenue for the twelve months ended November 30, 2012 amounted to \$13,567,000 compared to \$14,928,000 in Fiscal 2011.

(in thousands of Canadian dollars)	2012	2011
Sale of goods	\$5,235	\$8,351
Upfront and milestone payments	\$4,077	\$5,134
Royalties and license fees	\$4,255	\$1,443
Revenue	\$13,567	\$14,928

Revenue generated from sale of goods amounted to \$5,235,000 in the twelve-month period ended November 30, 2012 compared to \$8,351,000 in Fiscal 2011. *EGRIFTA*TM was first offered for sale to the public in January 2011 and our sales in Fiscal 2011 reflect the buildup of stocks needed by EMD Serono for the product launch in the U.S. market. Revenues from sale of goods in Fiscal 2012 were more closely tied to actual sales to patients. Future sales of goods should also track patient sales but they can also vary significantly in the short term as a function of EMD Serono's procurement policies.

Royalties, which are almost entirely derived from the sales of *EGRIFTA*TM, were \$4,255,000 in Fiscal 2012 compared to \$1,443,000 in Fiscal 2011. Most of the increase is due to growth in *EGRIFTA*TM sales, which were up significantly in Fiscal 2012 compared to Fiscal 2011. In addition, the royalties reported in Fiscal 2012 include an amount of \$699,000 based on management's

estimate of the royalties earned on *EGRIFTA*[™] sales in October 2012 and November 2012, for which the comparable amounts from last year were only recorded in the first quarter of Fiscal 2012. Revenue also includes the amortization of the initial payment of \$27,097,000 received upon the closing of the EMD Serono Agreement. For the twelve-month period ended November 30, 2012, \$4,077,000 was recognized as revenue related to the initial payment, compared to \$5,134,000 in Fiscal 2011. The amortization amount in Fiscal 2012 reflects an extension made to the service period attributed to the initial payment in order to allow sufficient time for work that has yet to be completed. At November 30, 2012, the remaining deferred revenue related to this transaction recorded on the consolidated statement of financial position amounted to \$4,481,000.

Cost of Sales

For the twelve months ended November 30, 2012, the cost of sales of *EGRIFTA*[™] amounted to \$5,056,000 compared to \$9,146,000 in Fiscal 2011, largely as a result of the lower sale of goods in Fiscal 2012 as described above. The cost of sales exceeded sale of goods revenue in 2011, reflecting the depletion of higher-cost inventory produced at an earlier date and expenses associated with validating additional suppliers for *EGRIFTA*[™]. Cost of sales is detailed in note 7 "Cost of sales" of our audited consolidated financial statements for the years ended November 30, 2012, 2011 and 2010.

R&D Expenses

R&D expenses, net of tax credits, amounted to \$6,341,000 in the twelve months ended November 30, 2012 compared to \$10,992,000 in Fiscal 2011. The significant reduction in R&D expenses is largely due to the adoption of a more focused business plan and the related restructuring initiatives. R&D expenses in 2012 were associated with pursuing the development of TH1173 and a new formulation of *EGRIFTA*[™], the two Phase 4 clinical trials, and helping our commercial partners to pursue regulatory approvals in their respective jurisdictions.

R&D expenses in Fiscal 2011 were related to the Phase 2 clinical trial evaluating tesamorelin in muscle wasting associated with COPD, to the work on a new formulation and a new presentation of *EGRIFTA*[™] and to the discovery and development of novel GRF peptides, including TH1173. R&D expenses in Fiscal 2011 also included the cost of filing the NDS in Canada, all regulatory and clinical activities to support our three commercial partners, and follow-up on post-approval commitments made to the FDA.

Selling and Market Development Expenses

Selling and market development expenses amounted to \$852,000 for the twelve months ended November 30, 2012, compared to \$2,019,000 in Fiscal 2011, reflecting cost savings from restructuring initiatives in Fiscal 2012. With *EGRIFTA*[™] licensing agreements now in place in major markets, the ongoing selling and market development expenses are reduced to the costs of managing relationships with our commercial partners and certain selling expenses such as insurance coverage for inventories.

General and Administrative Expenses

General and administrative expenses amounted to \$5,462,000 in the twelve months ended November 30, 2012 compared to \$10,823,000 in Fiscal 2011. The expenses in 2012 were considerably lower as a result of restructurings, the departure of the former President and Chief Executive Officer and the suspension of executive bonuses. In addition, the relatively high expenses in 2011 included the costs associated with the planned public offering of our common shares, the cost of listing our common shares on NASDAQ, as well as costs related to the change in leadership of the Company in that year.

Restructuring Costs

Restructuring costs amounted to \$10,702,000 in the twelve months ended November 30, 2012 compared to \$716,000 in Fiscal 2011. Early in Fiscal 2012, we took steps to narrow the focus of our business by concentrating our efforts on *EGRIFTA*TM and on developing TH1173. The related restructuring costs were \$6,176,000, which were mainly incurred in the first quarter. We announced further revisions to our business plan and related restructuring activities aimed at accelerating the process of becoming cash neutral in October 2012. The second restructuring resulted in fourth-quarter costs of \$4,526,000.

In Fiscal 2011, a restructuring was undertaken in June, following a re-evaluation of our R&D business model. The objective was to rely more on external partners in both the private and public sectors in order to bring our R&D projects forward. As a result, we incurred restructuring costs of \$716,000 in the third quarter.

Restructuring costs, which include provisions and write-downs, are described in more detail in note 20 (b) "Restructuring costs" of our audited consolidated financial statements for the years ended November 30, 2012, 2011 and 2010.

Net Financial Income

Finance income for the twelve months ended November 30, 2012 was \$890,000 compared to \$1,602,000 in Fiscal 2011. Interest revenue has trended lower due to a gradual decline in the portfolio size as investments were liquidated to fund operations.

Finance costs for the twelve months ended November 30, 2012 were actually a gain of \$21,000 as a result of favorable foreign exchange fluctuations. The finance costs of \$636,000 in Fiscal 2011 included a foreign exchange loss incurred in the first quarter, upon receipt and translation to Canadian dollars of a US\$25,000,000 milestone payment from EMD Serono. The milestone payment had originally been recognized as revenue and translated into Canadian dollars at the more favorable exchange rate in effect at the end of Fiscal 2010, resulting in an exchange gain of \$511,000 in that period.

Net Loss

Taking into account the revenue and expense variations described above, we recorded a net loss of \$13,940,000 or \$0.23 per share (including restructuring costs of \$10,702,000) in the twelve months ended November 30, 2012 compared to a net loss of \$17,730,000 or \$0.29 per share (including restructuring costs of \$716,000) in Fiscal 2011.

Fourth Quarter Comparison

Consolidated revenue for the three months ended November 30, 2012 amounted to \$3,899,000 compared to \$4,410,000 for the same period in 2011.

(in thousands of Canadian dollars)	2012	2011
Sale of goods	\$1,375	\$2,670
Upfront and milestone payments	\$868	\$1,069
Royalties and license fees	\$1,656	\$671

(in thousands of Canadian dollars)	2012	2011
Revenue	\$3,899	\$4,410

Revenue generated from the sale of goods for the three months ended November 30, 2012 was \$1,375,000 compared to \$2,670,000 in the comparable period in Fiscal 2011. The decline reflects the procurement policies of EMD Serono. In fact, royalty revenues demonstrate that sales by EMD Serono to end-users in the fourth quarter of Fiscal 2012 were higher than those of the comparable quarter in Fiscal 2011.

Royalties were \$1,656,000 in the three months ended November 30, 2012, compared to \$671,000 in the comparable period of Fiscal 2011. The increase is due, in part, to growth in year-over-year *EGRIFTA*TM sales. In addition, the royalties reported in Fiscal 2012 include an amount of \$699,000 based on management's estimate of the royalties earned on *EGRIFTA*TM sales in October 2012 and November 2012, for which the comparable amounts from last year were only recorded in the first quarter of Fiscal 2012.

Revenue related to the amortization of the initial payment received upon the closing of the EMD Serono Agreement was \$868,000 for the three-month period ended November 30, 2012, compared to \$1,069,000 in the comparable period of Fiscal 2011. The amortization amount in Fiscal 2012 reflects an extension made to the service period attributed to the initial payment in order to allow sufficient time for work that has yet to be completed.

Reflecting the decrease in sale of goods described above, the cost of sales for the three months ended November 30, 2012 was \$1,323,000 compared to \$2,018,000. The decrease in sales also resulted in higher absorption rates for fixed manufacturing costs resulting in a lower gross margin in the fourth quarter of Fiscal 2012.

R&D expenses, net of tax credits, amounted to \$1,894,000 in the three months ended November 30, 2012 compared to \$2,020,000 in the comparable period of Fiscal 2011. R&D expenses in 2012 were associated with pursuing the development of TH1173 and a new formulation of *EGRIFTA*TM, the two Phase 4 clinical trials, and helping our commercial partners to pursue regulatory approvals in their respective jurisdictions. R&D activities in 2011 included the discontinued Phase 2 clinical trial evaluating tesamorelin in muscle wasting associated with COPD, work on a new formulation and a new presentation of *EGRIFTA*TM, the development of novel GRF peptides including TH1173, as well as regulatory and clinical activities to support our commercial partners and to meet post-approval commitments made to the FDA.

Selling and market development expenses amounted to \$116,000 for the three months ended November 30, 2012, compared to \$530,000 for the comparable period of Fiscal 2011, reflecting cost savings from restructuring initiatives in Fiscal 2012. With *EGRIFTA*TM licensing agreements now in place in major markets, the ongoing selling and market development expenses are reduced to the costs of managing relationships with our commercial partners and certain selling expenses such as insurance coverage for inventories.

General and administrative expenses amounted to \$556,000 in the three months ended November 30, 2012 compared to \$1,789,000 in the comparable period of Fiscal 2011. The expenses in 2012 were considerably lower as a result of restructuring activities, the departure of the former President and Chief Executive Officer, and the suspension of executive bonuses.

The restructuring costs in the three months ended November 30, 2012 of \$4,526,000 resulted from the previously described revisions to our business plan aimed at becoming cash neutral as soon as possible.

Net financial income for the three months ended November 30, 2012 was \$166,000 compared to \$285,000 in the comparable period of Fiscal 2011. The decline in 2012 is principally due to lower interest revenues related to a gradual decline in the portfolio size as investments were liquidated to fund operations.

Taking into account the revenue and expense variations described above, we recorded a net loss of \$4,341,000 or \$0.07 per share (including restructuring costs of \$4,526,000) in the three months ended November 30, 2012 compared to a net loss of \$1,687,000 or \$0.03 per share in the comparable period of Fiscal 2011.

In the three months ended November 30, 2012, the use of cash in operating activities amounted to \$3,756,000 compared to \$2,322,000 in the comparable period of Fiscal 2011.

Operating Results - twelve months ended November 30, 2011 compared to twelve months ended November 30, 2010

Revenue

Our revenues are mainly sales of *EGRIFTA*TM to EMD Serono for re-sale, royalties received from EMD Serono on U.S. sales to customers, and research services, which include milestone payments and the amortization of the initial payment received upon the closing of the EMD Serono Agreement. Consolidated revenue for the twelve months ended November 30, 2011 amounted to \$14,928,000 compared to \$31,868,000 in Fiscal 2010.

(in thousands of Canadian dollars)	2011	2010
Sale of goods	\$8,351	\$ -
Upfront and milestone payments	\$5,134	\$31,846
Royalties and license fees	\$1,443	\$22
Revenue	\$14,928	\$31,868

Revenue generated from sale of goods amounted to \$8,351,000 in the twelve-month period ended November 30, 2011. There were no product sales in Fiscal 2010 because *EGRIFTA*TM was first offered for sale by EMD Serono in January 2011.

Royalties reported in Fiscal 2011 were based on royalty payments received rather than on royalties earned. In Fiscal 2011, we received royalty and license fees revenue of \$1,423,000 for the selling period from January 1, 2011 to September 30, 2011. Royalty revenue grew throughout the selling period due to an increase in the prescription base, which includes both new and repeat prescriptions. There were no royalties received in Fiscal 2010 because *EGRIFTA*TM was first offered for sale by EMD Serono in January 2011.

Revenue also includes the amortization of the initial payment of \$27,097,000 received upon the closing of the EMD Serono Agreement in 2008. For the twelve months ended November 30, 2011, an amount of \$5,134,000 was recognized as revenue related to this transaction, compared to \$6,846,000 in Fiscal 2010. The amortization amount in Fiscal 2011 reflects an extension made to the service period attributed to the initial payment in order to allow sufficient time for work that has yet to be completed. Revenue in Fiscal 2010 includes a milestone payment of \$25,000,000

received from EMD Serono on November 30, 2010 associated with the satisfaction of the condition of approval of *EGRIFTA*TM by the FDA.

Cost of Sales

For the twelve months ended November 30, 2011, the cost of sales of *EGRIFTA*TM totaled \$9,146,000. There were no *EGRIFTA*TM sales in Fiscal 2010; however, we began production through our third-party suppliers late in that year in anticipation of the *EGRIFTA*TM launch in the United States. Costs related to this activity and other unallocated costs related to the start-up of the manufacturing process amounted to \$469,000 in Fiscal 2010.

The cost of sales exceeded sale of goods revenue in Fiscal 2011, reflecting the depletion of higher-cost inventory produced at an earlier date and expenses associated with validating additional suppliers for *EGRIFTA*TM. Cost of sales is detailed in note 7 "Cost of sales" of our audited consolidated financial statements for the years ended November 30, 2012, 2011 and 2010.

R&D Expenses

R&D expenses, net of tax credits, totaled \$10,992,000 for the twelve months ended November 30, 2011 compared to \$14,064,000 in Fiscal 2010. The lower R&D expenses in Fiscal 2011 are due to changes in the nature of the activities undertaken, to staff reductions implemented as part of a restructuring in June 2011, as well as lower bonus payments.

R&D expenses in Fiscal 2011 were related to the Phase 2 clinical trial evaluating tesamorelin in muscle wasting associated with COPD, to the work on a new formulation and a new presentation of *EGRIFTA*TM and to the discovery and development of novel GRF peptides, including TH1173. R&D expenses in Fiscal 2011 also include the cost of filing a NDS in Canada, all regulatory and clinical activities to support our three commercial partners, and follow-up on post-approval commitments made to the FDA. R&D expenses incurred in Fiscal 2010 were mainly related to the pursuit of the regulatory approval of *EGRIFTA*TM by the FDA.

Selling and Market Development Expenses

Selling and market development expenses amounted to \$2,019,000 for the twelve months ended November 30, 2011, compared to \$2,670,000 in Fiscal 2010. The decrease reflects the execution of the Sanofi Agreement and the Ferrer Agreement in the first quarter of Fiscal 2011, which transferred responsibility for all marketing expenses to these licensees, as well as lower bonus payments. In Fiscal 2011, selling and market development expenses were largely associated with the management of the agreements with the three commercial partners.

General and Administrative Expenses

General and administrative expenses amounted to \$10,823,000 in the twelve months ended November 30, 2011 compared to \$8,002,000 in Fiscal 2010. The higher expenses in Fiscal 2011 included the costs associated with the planned public offering of our common shares, the cost of listing our common shares on NASDAQ, as well as costs related to the change in leadership of the Company in that year. These increased expenses were partially offset by staff reductions and lower bonus payments.

Restructuring Costs

Following a re-evaluation of our R&D business model, we announced a restructuring on June 2, 2011, aimed at relying more on external partners in both the private and public sectors in order to bring our R&D projects forward. As a result, we incurred restructuring costs of \$716,000 in the third quarter of Fiscal 2011.

Net Financial Income

Finance income for the twelve months ended November 30, 2011 was \$1,602,000 compared to \$1,888,000 in Fiscal 2010. Interest revenues for Fiscal 2011 were generally lower than Fiscal 2010 due to a gradual decline in the portfolio size as investments were liquidated to fund operations.

Finance costs for Fiscal 2011 were \$636,000 compared to finance income of \$493,000 in Fiscal 2010. The finance costs in Fiscal 2011 included a foreign exchange loss incurred in the first quarter, upon receipt and translation to Canadian dollars of a US\$25,000,000 milestone payment from EMD Serono. The milestone payment had originally been recognized as revenue and translated into Canadian dollars at the more favorable exchange rate in effect at the end of Fiscal 2010, resulting in an exchange gain of \$511,000 in that period.

Net Results

Taking into account the revenue and expenses described above, we recorded a net loss of \$17,730,000 or \$0.29 per share (including restructuring costs of \$716,000) in Fiscal 2011 compared to a net profit of \$8,930,000 or \$0.15 per share in Fiscal 2010. The net profit in Fiscal 2010 was principally due to milestone-payment revenue of US \$25,000,000 related to the EMD Serono Agreement.

Quarterly Financial Information

The following table is a summary of our unaudited consolidated operating results presented in accordance with IFRS for the last eight quarters.

(In thousands of dollars, except per share amounts)

	2012				2011			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Sale of goods	\$1,375	\$1,725	\$856	\$1,279	\$2,670	\$1,878	\$2,005	\$1,798
Upfront and milestone payments	\$868	\$1,070	\$1,069	\$1,070	\$1,069	\$1,070	\$1,284	\$1,711
Royalties and license fees	\$1,656	\$1,027	\$731	\$841	\$671	\$569	\$194	\$9
	\$3,899	\$3,822	\$2,656	\$3,190	\$4,410	\$3,517	\$3,483	\$3,518
Net loss	\$(4,341)	\$(698)	\$(1,417)	\$(7,484)	\$(1,687)	\$(4,170)	\$(5,941)	\$(5,932)
Basic and diluted loss per share	\$(0.07)	\$(0.01)	\$(0.02)	\$(0.12)	\$(0.03)	\$(0.07)	\$(0.10)	\$(0.10)

*EGRIFTA*TM was first offered for sale to the public in January 2011 and our quarterly sales of goods in Fiscal 2011 reflect the buildup of stocks needed by EMD Serono for the product launch. Revenues from sale of goods in Fiscal 2012 were more closely tied to actual sales to patients but they can also vary significantly in the short term due to EMD Serono procurement policies, as occurred in the fourth quarter of 2012.

Royalties and license fees in the fourth quarter of Fiscal 2012 include an amount of \$699,000 based on management's estimate of the royalties earned on *EGRIFTA*TM sales in October 2012 and

November 2012, for which the comparable amounts from last year were only recorded in the first quarter of Fiscal 2012.

The net losses reported in the first and fourth quarters of Fiscal 2012 and the third quarter of Fiscal 2011; include restructuring costs of \$6,176,000, \$4,526,000 and \$716,000, respectively.

Liquidity and Capital Resources

Our objective in managing capital is to ensure a sufficient liquidity position to finance our business activities. Prior to Fiscal 2011, we funded our activities by relying primarily on public offerings of common shares in Canada and private placements of our common shares as well as on up-front payments and milestone payments primarily associated with the EMD Serono Agreement. When possible, we try to optimize our liquidity position using non-dilutive sources, including investment tax credits, grants and interest income. With the market launch of *EGRIFTA*TM in Fiscal 2011, we now receive additional revenues in the form of product sales and royalties. We believe the Company has sufficient cash and bonds on hand at November 30, 2012 to carry out our planned activities and meet our liabilities as they come due for the next 12 months.

For the twelve months ended November 30, 2012, the use of cash in operating activities was \$15,634,000 (including \$4,325,000, representing the cash portion of restructuring costs) compared to \$27,218,000 (including \$664,000, representing the cash portion of restructuring costs) in Fiscal 2011.

The large decrease in the use of cash in Fiscal 2012 reflects the reduction in the net loss from \$17,730,000 in Fiscal 2011 to \$13,940,000 in Fiscal 2012. Furthermore, the nature of the net loss in Fiscal 2012 had a positive effect on working capital because it included substantial restructuring provisions for which cash was not disbursed in the period. Provisions increased by \$5,574,000 in Fiscal 2012 compared to \$52,000 in Fiscal 2011. Inventory increased by \$2,864,000 in Fiscal 2012 compared to an increase of \$6,415,000 in Fiscal 2011. Following a buildup of inventory in Fiscal 2011 and the first six months of Fiscal 2012 related to the market launch of *EGRIFTA*TM, inventory levels stabilized and started to decrease. Largely as a result of the restructuring provisions and the stabilization of inventory levels, changes in operating assets and liabilities generated \$1,427,000 of cash in Fiscal 2012, compared to \$6,477,000 of cash used in Fiscal 2011.

The Company's share purchase plan, or Plan, was discontinued in March 2012 and no common share subscriptions were received in connection with the Plan in Fiscal 2012 (7,837 common shares for \$34,000 in Fiscal 2011). In addition, 145,337 stock options were exercised in Fiscal 2012 for cash consideration of \$243,000 (344,665 stock options for \$668,000 in Fiscal 2011).

As at November 30, 2012, cash and bonds amounted to \$20,503,000 and tax credits and grants receivable amounted to \$421,000 for a total liquidity position of \$20,924,000. We invest our available cash in highly liquid fixed income instruments from governmental, municipal and paragonovernmental bodies (\$18,991,000 November 30, 2012).

Apart from our \$3,800,000 of unused credit facilities, we do not have any additional arrangements for external debt financings. We may seek additional capital through the incurrence of debt, the issuance of equity or other financing alternatives.

Contractual Obligations

Commitments

The following table lists as at November 30, 2012 information with respect to the Company's known contractual obligations.

(In thousands of Canadian dollars)

Contractual Obligations	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
Long Term Debt Obligations	--	--	--	--	--
Capital Lease Obligations	--	--	--	--	--
Operating Lease Obligations	\$5,526,000	\$655,000	\$928,000	\$1,456,000	\$2,487,000
Purchase Obligations	--	--	--	--	--
Other Long-Term Liabilities	--	--	-	--	--
Total	\$5,526,000	\$655,000	\$928,000	\$1,456,000	\$2,487,000

Long-Term Procurement Agreements

In 2011, we had entered into long-term procurement agreements with third-party suppliers in connection with the commercialization of *EGRIFTA*TM. As at November 30, 2012, we had outstanding purchase orders and minimum payments required under these agreements amounting to \$2,724,000 for the manufacture of *EGRIFTA*TM for delivery in fiscal 2013 and 2014 (\$1,893,000 and \$831,000 respectively).

Credit Facilities

We have a \$1,800,000 revolving credit facility, bearing interest at prime plus 0.5%. Under the terms of the revolving credit facility, the market value of investments held must always be equivalent to 150% of amounts drawn under the facility. If the market value falls below \$7,000,000, we will provide the bank with a first ranking movable hypothec (security interest) of \$1,850,000 on securities judged satisfactory by the bank.

We also have a \$2,000,000 line of net risk for derivative instruments.

As at November 30, 2012 and 2011, we did not have any borrowings outstanding under these credit facilities.

Post-Approval Commitments

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

- to develop a single vial formulation of *EGRIFTA*TM (the development of a new presentation of the same formulation);
- to conduct a long-term observational safety study using *EGRIFTA*TM; and
- to conduct a Phase 4 clinical trial using *EGRIFTA*TM.

We have developed a new presentation of *EGRIFTA*TM which complies with the first of the FDA's post-approval requirements and it was launched by EMD Serono in October 2012.

The long-term observational safety study is to evaluate the safety of long-term administration of *EGRIFTA*TM and is currently recruiting clinical sites. We have agreed to share the cost of this study equally with EMD Serono and estimate that our share of the cost could amount to an average of \$1,300,000 per year, over a fifteen-year period.

The Phase 4 clinical 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. EMD Serono is responsible for executing the trial and is to be reimbursed by the Company for the direct costs involved. EMD Serono has now started recruiting patients. The FDA-approved protocol for the trial calls for patients to inject themselves daily with either *EGRIFTA*[™] or placebo over a three-year treatment period. While the Company is committed to supporting the trial, management believes that the protocol conditions will be difficult to meet. We estimate that the trial, if completed, could cost approximately \$20,000,000 over a four- to five-year period.

Contingent Liability

A motion to authorize the institution of a class action was originally filed in July 2010 in the Superior Court of Québec, District of Montreal, entitled 121851 Canada Inc. v. Theratechnologies Inc. et al., Number 500-06-000515-102. The complaint alleged that we, a director and a former executive officer violated the secondary market liability provisions of the *Securities Act* (Québec) by failing to disclose a material change relating to the administration of *EGRIFTA*[™]. The plaintiff sought damages on behalf of a class of persons who were shareholders at May 21, 2010 and who sold their common shares on May 25 or 26, 2010. On February 24, 2012, the Superior Court of Québec authorized 121851 Canada Inc. to institute a class action against us, a director and a former executive officer. On March 20, 2012, we filed a motion seeking permission to appeal this judgement with the Court of Appeal of Québec, District of Montreal, Number 500-09-022519-128, and the hearing took place on January 24, 2013. No judgement has been rendered yet following the January 24, 2013 hearing.

The Company has subscribed to insurance covering its potential liability and the potential liability of its directors and officers in the performance of all their duties for the Company subject to a \$200,000 deductible.

Off-Balance Sheet Arrangements

We were not involved in any off-balance sheet arrangements for the year ended November 30, 2012, with the exception of the lease of our headquarters as described above.

Subsequent Events

Inventories

During the conversion of materials to finished goods in January 2013, a loss of \$192,000 of materials was incurred. The Company is analyzing the responsibility in regards of this event.

Stock Option Plan

Between December 1, 2012 and February 25, 2013, 233,500 options were forfeited and expired at a weighted exercise average price of \$5.37 per share. On December 20, 2012, we granted 830,000 options as an employee retention measure. The new options, which have an exercise price of \$0.38, become vested in 2015.

Deferred Stock Unit Plan

Between December 1, 2012 and February 25, 2013, 100,747 deferred stock units, or DSU, were granted to certain members of the Board of Directors who elected to be compensated by DSU in lieu of cash pursuant to our deferred stock unit plan, or DSU Plan. A related expense of \$34,000 will be recorded in the first quarter of 2013.

In December 2012, the two cash settled forward stock contracts (note 16 (ii) of the consolidated financial statements) were amended to expire in December 2013. To protect against fluctuation in the value of the DSU, we entered into another cash settled forward stock contract. In January 2013, we paid \$50,000 as advance payment on the contract. This amount corresponds to 100,747 common shares of the Company at a price of \$0.50.

Financial Risk Management

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

Credit Risk

The Company's exposure to credit risk currently relates to accounts receivable from only one customer (see note 5 (a) of the audited consolidated financial statements) and derivative financial assets which it manages by dealing with highly-rated Canadian financial institutions. Credit risk is the risk of a loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations. We regularly monitor credit risk exposure and take steps to mitigate the likelihood of this exposure resulting in losses.

Included in the consolidated statement of financial position are trade receivables of \$1,045,000 (2011 - \$1,364,000), all of which were aged under 60 days. There was nil recorded as bad debt expense for the year ended November 30, 2012 (November 30, 2011 - nil). Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds. We invest our available cash in highly liquid fixed income instruments from governmental, paragonovernmental and municipal bodies (\$18,991,000 as at November 30, 2012; \$34,288,000 as at November 30, 2011). As at November 30, 2012, we believe we were not exposed to any significant credit risk for the carrying amount of the bonds.

Liquidity Risk

Liquidity risk is the risk that we will not be able to meet our financial obligations as they become due. We manage liquidity risk through the management of our capital structure, as outlined under "Liquidity and Capital Resources". We also manage liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors and/or the Audit Committee reviews and approves our operating and capital budgets, as well as any material transactions out of the ordinary course of business.

We have adopted an investment policy in respect of the safety and preservation of capital to ensure that our liquidity needs are met. The instruments are selected with regard to the expected timing of expenditures and prevailing interest rates.

The required payments on the contractual maturities of financial liabilities, as well as the payments required under the terms of the operating lease, as at November 30, 2012, are presented in notes 18 and 24(b) of the audited consolidated financial statements.

Currency Risk

We are exposed to financial risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. Currency risk is limited to the portion of our business transactions denominated in currencies other than the Canadian dollar, primarily revenues from milestone payments, sale of goods and expenses incurred in U.S. dollars, euros and pounds sterling, or GBP.

We manage currency risk by maintaining cash in U.S. dollars and by entering into foreign exchange contracts to support U.S. forecasted outflows over a 12-month period. We do not currently view our exposure to the euro and GBP as a significant foreign exchange risk due to the limited volume of transactions conducted by the Company in these currencies.

In November 2012, we entered into two forward foreign exchange contracts to sell, in aggregate, US\$390,000 for C\$387,000 in December 2012 and January 2013. The fair value of these instruments at November 30, 2012 was nil.

Exchange rate fluctuations for foreign currency transactions can cause cash flow as well as amounts recorded in consolidated statement of comprehensive income to vary from period to period and not necessarily correspond to those forecasted in operating budgets and projections. Additional earnings variability arises from the translation of monetary assets and liabilities denominated in currencies other than the Canadian dollar at the rates of exchange at each consolidated statement of financial position date, the impact of which is reported as foreign exchange gain or loss in the consolidated statement of comprehensive (loss) income. Given our policy on the management of our U.S. foreign currency risk, we do not believe a sudden change in foreign exchange rates would impair or enhance our ability to pay our U.S. dollar denominated obligations.

The following table presents the significant items in foreign currencies exposed to currency risk as at November 30, 2012:

(In thousands)

	November 30, 2012		
	\$US	EURO	GBP
Cash	514	-	-
Trade and other receivables	1,048	-	-
Accounts payable and accrued liabilities	(657)	(17)	(15)
Total exposure from above	905	(17)	(15)
Forward exchange contracts	(390)	-	-
Net exposure	515	(17)	(15)

The following exchange rates applied during the year ended November 30, 2012:

	November 30, 2012	
	Average rate	Reporting date rate
\$ US - C\$	1.0023	0.9936
EURO - C\$	1.2886	1.2923
GBP - C\$	1.5838	1.5919

Based on the Company's foreign currency exposures noted above, varying the above foreign exchange rates to reflect a 5% strengthening of the Canadian dollar would have a positive or (negative) impact on the net profit or (loss) as follows, assuming that all other variables remained constant:

(In thousands)

	November 30, 2012		
	\$US	EURO	GBP
Positive or (negative) impact	(26)	1	1

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

Interest Rate Risk

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

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

Based on the value of our short and long-term bonds at November 30, 2012, an assumed 0.5% decrease in market interest rates would have increased the fair value of these bonds and the accumulated other comprehensive income by approximately \$258,000; an assumed increase in interest rate of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

Cash bears interest at a variable rate. Trade and other receivables, accounts payable and accrued liabilities bear no interest.

Based on the average value of variable interest-bearing cash during the year ended November 30, 2012 (\$1,043,000), an assumed 0.5% increase in interest rates during such period would have increased the future cash flow and the net profit by approximately \$5,000; an assumed decrease of 0.5% would have had an equal but opposite effect.

Fair Values of Financial Instruments

We have determined that the carrying values of our short-term financial assets and liabilities, including cash, trade and other receivables as well as accounts payable and accrued liabilities, approximate their fair value because of the relatively short period to maturity of the instruments.

Bonds, derivative financial assets and liabilities, and liability related to the DSU Plan are stated at estimated fair value, determined by inputs that are primarily based on broker quotes at the reporting date and the quoted market value of the shares of the Company for the liability related to the DSU (see note 23 of the audited consolidated financial statements – Determination of fair values).

Critical Accounting Estimates

Use of Estimates and the Exercise of Judgment

The preparation of our audited consolidated financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

Information about critical judgments in applying accounting policies and assumption and estimation uncertainties that have the most significant effect on the amounts recognized in the consolidated financial statements is as follows:

- Revenue and deferred revenue:

Revenue recognition is subject to critical judgements, particularly in collaboration agreements that include multiple deliverables, as judgement is required in allocating revenue to each component, including upfront payments, milestone payments, research services, royalties and license fees and sale of goods.

Management uses judgement in estimating the amount of royalties earned. The amount earned is calculated as a percentage of net sales of its products realized by the Company's licensees. Net sales are provided by licensees or estimated by management using estimates of revenues from product sales of the licensees less estimates for discounts, rebates, chargebacks and allowances.

- Stock option plan:

There is estimation uncertainty with respect to selecting inputs to Black-Scholes model used to determine the fair value of the stock options.

- Income taxes:

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income. The generation of future taxable income is dependent on the successful commercialization of the Company's products and technologies.

- Contingent liability:

Management uses judgment in assessing the possibility of any outflow in settlement of contingent liabilities.

- Onerous contracts:

There is estimation uncertainty with respect to selecting inputs to the discounted cash flows used to determine the amount of the onerous contracts.

Other areas of judgement and uncertainty relate to the estimation of accruals for clinical trial expenses, the recoverability of inventories, the measurement of the amount and assessment of the recoverability of tax credits and grants receivable and capitalization of development expenditures.

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

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

Recent changes in accounting standards:

- (a) Amendments to existing standards that were adopted in Fiscal 2012:

Annual improvements to IFRS:

The IASB's improvements to IFRS contain amendments that were applicable for the annual period beginning on December 1, 2011 as follows:

- (i) IFRS 7:

Amendment to IFRS 7, Financial Instruments: Disclosures:

Multiple clarifications related to the disclosure of financial instruments and in particular in regards to transfers of financial assets.

- (ii) IAS 1:

Amendment to IAS 1, Presentation of Financial Statements:

Entities may present the analysis of the components of other comprehensive income either in the statement of changes in equity or within the notes to the financial statements.

- (iii) IAS 24:

Amendment to IAS 24, Related Party Disclosures:

There are limited differences in the definition of what constitutes a related party; however, the amendment requires more detailed disclosures regarding commitments.

- (b) New or revised standards and interpretations issued but not yet adopted:

In addition, the following new or revised standards and interpretations have been issued but are not effective for the Company:

- (i) IFRS 9 *Financial Instruments*

In November 2009, the IASB issued IFRS 9 *Financial Instruments* (IFRS 9 (2009)), and in October 2010, the IASB published amendments to IFRS 9 (IFRS 9 (2010)).

IFRS 9 (2009) replaces the guidance in IAS 39 *Financial Instruments: Recognition and Measurement*, on the classification and measurement of financial assets. The Standard eliminates the existing IAS 39 categories of held to maturity, available-for-sale and loans and receivable.

Financial assets will be classified into one of two categories on initial recognition:

- financial assets measured at amortized cost; or
- financial assets measured at fair value.

Gains and losses on remeasurement of financial assets measured at fair value will be recognized in profit or loss, except that for an investment in an equity instrument which is not held-for-trading, IFRS 9 provides, on initial recognition, an irrevocable election to present all fair value changes from the investment in other comprehensive income (OCI). The election is available on an individual share-by-share basis. Amounts presented in OCI will not be reclassified to profit or loss at a later date.

IFRS 9 (2010) added guidance to IFRS 9 (2009) on the classification and measurement of financial liabilities, and this guidance is consistent with the guidance in IAS 39 except as described below.

Under IFRS 9 (2010), for financial liabilities measured at fair value under the fair value option, changes in fair value attributable to changes in credit risk will be recognized in OCI, with the remainder of the change recognized in profit or loss. However, if this requirement creates or enlarges an accounting mismatch in profit or loss, the entire change in fair value will be recognized in profit or loss. Amounts presented in OCI will not be reclassified to profit or loss at a later date.

IFRS 9 (2010) supersedes IFRS 9 (2009) and is effective for annual periods beginning on or after January 1, 2015, with early adoption permitted. The Company intends to adopt IFRS 9 (2010) in its financial statements for the annual period beginning on December 1, 2015. The extent of the impact of adoption of IFRS 9 (2010) has not yet been determined.

(ii) IFRS 10 *Consolidated Financial Statements*

In May 2011, the IASB issued IFRS 10 *Consolidated Financial Statements*, which is effective for annual periods beginning on or after January 1, 2013, with early adoption permitted.

IFRS 10 replaces the guidance in IAS 27 *Consolidated and Separate Financial Statements* and SIC-12 *Consolidation – Special Purpose Entities (“SPE”)*. IAS 27 (2008) survives as IAS 27 (2011) *Separate Financial Statements*, only to carry forward the existing accounting requirements for separate financial statements.

IFRS 10 provides a single model to be applied in the control analysis for all investees, including entities that currently are SPEs in the scope of SIC-12. In addition, the consolidation procedures are carried forward substantially unmodified from IAS 27 (2008).

The amendments issued in June 2012 simplify the process of adopting IFRS 10 and provide additional relief from certain disclosures.

The Company intends to adopt IFRS 10, including the amendments issued in June 2012, in its financial statements for the annual period beginning on December 1, 2013. The extent of the impact of adoption of IFRS 10 has not yet been determined.

(iii) IFRS 13 *Fair Value Measurement*

In May 2011, the IASB published IFRS 13 *Fair Value Measurement*, which is effective prospectively for annual periods beginning on or after January 1, 2013. The disclosure requirements of IFRS 13 need not be applied in comparative information for periods before initial application.

IFRS 13 replaces the fair value measurement guidance contained in individual IFRSs with a single source of fair value measurement guidance. It defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, i.e. an exit price. The standard also establishes a framework for measuring fair value and sets out disclosure requirements for fair value measurements to provide information that enables financial statement users to assess the methods and inputs used to develop fair value measurements and, for recurring fair value measurements that use significant unobservable inputs (Level 3), the effect of the measurements on profit or loss or other comprehensive income.

IFRS 13 explains ‘how’ to measure fair value when it is required or permitted by other IFRSs. IFRS 13 does not introduce new requirements to measure assets or liabilities at fair value, nor does it eliminate the practicability exceptions to fair value measurements that currently exist in certain standards.

The Company intends to adopt IFRS 13 prospectively in its financial statements for the annual period beginning on December 1, 2013. The extent of the impact of adoption of IFRS 13 has not yet been determined.

(iv) Amendments to IAS 1 *Presentation of Financial Statements*

In June 2011, the IASB published amendments to IAS 1 *Presentation of Financial Statements: Presentation of Items of Other Comprehensive Income*, which are effective for annual periods beginning on or after July 1, 2012 and are to be applied retrospectively. Early adoption is permitted.

The amendments require that an entity present separately the items of OCI that may be reclassified to profit or loss in the future from those that would never be reclassified to profit or loss. Consequently an entity that presents items of OCI before related tax effects will also have to allocate the aggregated tax amount between these categories.

The existing option to present the profit or loss and other comprehensive income in two statements has remained unchanged.

The Company intends to adopt the amendments in its financial statements for the annual period beginning on December 1, 2012. As the amendments only require changes in the presentation of items in other comprehensive income, the Company does not expect the amendments to IAS 1 to have a material impact on the financial statements.

(v) Amendments to IAS 19 *Employee Benefits*

In June 2011, the IASB published an amended version of IAS 19 *Employee Benefits*. Adoption of the amendment is required for annual periods beginning on or after January 1, 2013, with early adoption permitted.

The amendments impact termination benefits, which would now be recognized at the earlier of when the entity recognizes costs for a restructuring within the scope of IAS 37 *Provisions*, and when the entity can no longer withdraw the offer of the termination benefits.

The Company intends to adopt the amendments in its financial statements for the annual period beginning on December 1, 2013. The extent of the impact of adoption of the amendments has not yet been determined.

Outstanding Share Data

On February 25, 2013, the number of common shares issued and outstanding was 61,010,603 while outstanding options granted under our stock option plan were 2,022,798.

Disclosure Controls and Procedures and Internal Control Over Financial Reporting

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under Canadian and American laws is recorded, processed, summarized and reported within the time periods specified under Canadian and SEC's rules and forms, and that such information is accumulated and communicated to our President and Chief Executive Officer and Vice President, Finance, to allow timely decisions regarding required disclosure. Our management, including our President and Chief Executive Officer and Vice President, Finance, conducted an evaluation of our disclosure controls and procedures, as defined under National Instrument 52-109 – Certification of Disclosure in Issuer's Annual and Interim Filings and under Exchange Act Rule 13a-15(e), as of the end of the period covered by this MD&A. Based upon that evaluation, our President and Chief Executive Officer and Vice President, Finance, have concluded that, as of November 30, 2012, our disclosure controls and procedures, as defined under National Instrument 52-109 – Certification of Disclosure in Issuer's Annual and Interim Filings and under Exchange Act Rule 13a-15(e), were effective to ensure that information we are required to disclose in reports that we file or submit under Canadian and American laws is communicated to

management, including our President and Chief Executive Officer and Vice President, Finance, as appropriate, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified under Canadian and SEC's rules and forms.

Management's Annual Report on Internal Control over Financial Reporting

Our management, including our President and Chief Executive Officer and Vice President, Finance, is responsible for establishing and maintaining adequate internal control over financial reporting, as defined under National Instrument 52-109 – Certification of Disclosure in Issuer's Annual and Interim Filings and under Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS. Internal controls over financial reporting include those policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets, (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

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

Our management assessed the effectiveness of our internal controls over financial reporting as of the end of the period covered by this Annual Report based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included an evaluation of the design of our internal controls over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on that assessment, our management concluded that as of November 30, 2012, our internal controls over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There was no change in our internal controls over financial reporting that occurred during the period covered by this MD&A that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Risks and Uncertainties

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.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCT AND PRODUCT CANDIDATES

Our commercial success and revenue growth depend largely on the commercialization of EGRIFTA™ in the United States and in other territories; the failure of EGRIFTA™ to obtain commercial acceptance in other important territories would have a material adverse effect on us.

Our ability to generate revenue is currently solely based on the commercialization of EGRIFTA™ in the United States. Our revenues are mainly derived from sales of EGRIFTA™ to EMD Serono, Inc., or EMD Serono, for re-sale, royalties received from EMD Serono on U.S. sales of EGRIFTA™ to customers, milestone payments from our collaboration and licensing agreement entered into on October 28, 2008, as amended on April 9, 2012, with EMD Serono, or the EMD Serono Agreement, and the amortization of the initial payment received upon the closing of the EMD Serono Agreement. Since the launch of EGRIFTA™ in the United States in January 2011, the year-over-year, quarterly royalties have grown. There can be no assurance that sales of EGRIFTA™ by EMD Serono to customers will continue to increase or remain the same. If sales of EGRIFTA™ to customers decrease, our royalties could be materially adversely affected which, in turn, could materially adversely affect our financial condition and operating results. In addition, if sales of EGRIFTA™ to customers do not increase, we may never receive the milestone payments negotiated with EMD Serono under the EMD Serono Agreement.

Our ability to grow our revenues from sales of EGRIFTA™ will be limited if our commercial partners do not obtain approval, or experience significant delays in their efforts to obtain approval, to market EGRIFTA™ in countries outside of the United States.

In order for EGRIFTA™ to be commercialized outside of the United States, it is necessary to obtain regulatory approval from the appropriate regulatory authorities. The regulatory authority of each country has its own rules and regulations and the requirements and timing for regulatory approval vary widely from country to country and may, in some cases, be different than or more rigorous than requirements in the United States. The marketing authorization applications filed by our commercial partners seeking approval of EGRIFTA™ is supported by data from clinical trials we conducted to support our new drug application, or NDA, with the United States Food and Drug Administration, or FDA. There is no assurance that these marketing authorization applications supported by the data used to obtain approval of EGRIFTA™ in the United States will meet the requirements of various regulatory agencies outside of the United States to approve EGRIFTA™.

Our commercial partner in Africa, Latin America and the Middle East, sanofi, has filed marketing authorization applications for EGRIFTA™ in Argentina, Brazil, Columbia, Israel, Mexico and Venezuela. There is no assurance that EGRIFTA™ will be approved in those countries. If we do not obtain approval of EGRIFTA™ in major Latin American countries, our potential revenue growth could be materially adversely affected. Furthermore, sanofi could decide not to file any application in certain countries if they deem that the potential market is too small.

In Canada, the non-approval of the new drug submission, or NDS, filed with Health Canada's Therapeutic Products Directorate, or TPD, for EGRIFTA™ would have adverse consequences on the potential approval of EGRIFTA™ in certain other countries of the world, including Bahrain, Kuwait, Oman, Qatar, Russia, Moldova, Ukraine, Republic of Belarus, Turkmenistan and Tajikistan. In those countries, regulatory agencies require that a certificate of pharmaceutical product, or CPP, from the country of origin of a product for which authorization is sought be filed with the application to begin the review process. If TPD does not approve our NDS for tesamorelin, no Canadian CPP will be issued and our commercial partners will be unable to file a marketing authorization application in countries requiring a Canadian CPP to begin the regulatory review process. In such instances, our capacity to grow our revenues could be adversely affected.

In Europe, we are developing an approach to re-file a marketing authorization application, or MAA, using our currently available data on EGRIFTA™. However, we will not proceed with a re-filing if the likelihood of success of being approved is not reasonable. Even if we decide to re-file a MAA in Europe, such re-filing could be made in certain European countries only and not in the 27 countries

covered by the initial filing made by Ferrer Internacional S.A., or Ferrer. There is no assurance that we will be able to re-file a MAA for *EGRIFTA*TM in Europe or in certain European countries and our failure to re-file or, even if re-filed, to obtain approval of *EGRIFTA*TM in Europe or in certain European countries could have a material adverse effect on our revenue growth, operating results and business prospects.

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

The overall commercialization success of *EGRIFTA*TM will depend on several factors, including:

- receipt of regulatory approvals for *EGRIFTA*TM from regulatory agencies in the territories other than the United States in which we wish to expand the commercialization of tesarorelin;
- market acceptance of *EGRIFTA*TM 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, and their local agents in certain countries, to commercialize *EGRIFTA*TM in their respective territories;
- maintaining manufacturing and supply agreements to ensure the availability of commercial quantities of *EGRIFTA*TM through validated processes;
- the number of competitors in our market; and
- protecting and enforcing our intellectual property and avoiding patent infringement claims.

A decrease in sales of *EGRIFTA*TM in the United States and the non-approval of *EGRIFTA*TM in major Latin American countries, would decrease our capacity to grow revenues and would have a material adverse effect on our financial condition and operating results.

We are substantially dependent on revenues from EGRIFTATM.

Our current and future revenues depend substantially upon sales of *EGRIFTA*TM by our commercial partners, EMD Serono, sanofi, Ferrer and Actelion Pharmaceuticals Canada Inc., or 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 operating results. We expect to be substantially dependent on sales from *EGRIFTA*TM 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.

We have suspended all significant research and development activities related to our product candidates, including TH1173, and the discovery of new peptides until we have sufficient funds to invest in our research and development programs. We may never be able to resume our research and development activities for our product candidates and in connection with the discovery of new peptides. Our incapacity to resume these activities could materially adversely affect our long-term growth and could cause us to rely solely on EGRIFTATM as a revenue-generating asset.

Our portfolio of product candidates is very limited and these product candidates are at early stages of development, except tesamorelin which has been approved for commercialization in the United States. As a result of our revised business plan, we put on hold the launch of the Phase I clinical program for TH1173 and suspended all significant long-term research and development activities on our product candidates and the discovery of new peptides until we have sufficient funds to resume these activities. There is no assurance that we will have sufficient funds to resume these activities and our long-term growth could be materially adversely affected.

Currently, we are relying on *EGRIFTA*[™] only to generate revenue and grow our business. If sales of *EGRIFTA*[™] in the United States decrease or remain the same, or if *EGRIFTA*[™] is withdrawn from the market or is not approved for commercialization in other countries, or if approved, is not successfully commercialized in other countries, we will be unable to grow our business and resume our research and development activities. In addition, even if our financial resources allow us to continue the research and development of our product candidates, there can be no assurance that these product candidates will reach the clinical trial phase, obtain positive results in clinical trials, obtain regulatory approval or, if approved, be successfully commercialized.

Significant safety or drug interaction problems could arise with respect to EGRIFTA[™], which could result in restrictions in EGRIFTA[™]'s label, product recalls, withdrawal of EGRIFTA[™] from the market or cause us to alter or terminate future development programs using tesamorelin or other GRF peptides, all of which could materially adversely impact our business and its future business prospects.

New safety or drug interaction issues may arise as *EGRIFTA*[™] is used over longer periods of time by a wider group of patients some of whom may be taking numerous other medicines or by patients with additional underlying health problems. Significant safety or drug interaction problems could arise with respect to *EGRIFTA*[™], including an increase in the severity or frequency of known problems or the discovery of previously unknown problems, and may result in a variety of adverse regulatory actions. Under U.S. laws, the FDA has broad authority to force drug manufacturers to take any number of actions if safety or drug interaction problems arise, including, but not limited to: (i) requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandating labeling changes to a product based on new safety information; or (iii) requiring manufacturers to implement a Risk Evaluation Mitigation Strategy where necessary to assure safe use of the drug. Similar laws and regulations exist in countries outside of the United States. In addition, previously unknown safety or drug interaction problems could result in product recalls, restrictions on the product's permissible uses, or withdrawal of the product from the United States market and/or a rejection of the pending marketing authorization applications in other markets.

In addition, if we conduct and complete other clinical trials with tesamorelin, new safety issues may be identified which could negatively impact our ability to successfully complete these studies, the use and/or regulatory status of tesamorelin in other indications and the prospects for approval of future supplemental New Drug Applications, or sNDAs, regardless of the underlying cause. New safety or drug interaction issues may require us to, among other things, provide additional warnings and/or restrictions on the *EGRIFTA*[™]'s label, including a boxed warning in the United States or similar warnings outside of the United States, directly alert healthcare providers of new safety information, narrow the current approved indication for *EGRIFTA*[™], alter or terminate future planned trials for additional uses of tesamorelin, any of which could have a material effect on potential sales of *EGRIFTA*[™].

We are 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*TM in their respective territories, our dependence on these partners to commercialize *EGRIFTA*TM is subject to a number of risks, including:

- our limited control of the amount and timing of resources that our commercial partners, and their local agents in certain countries, will be devoting to the commercialization, marketing and distribution of tesamorelin, including obtaining patient reimbursement for *EGRIFTA*TM, 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 *EGRIFTA*TM, 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*TM, for which we rely on third parties. The EMD Serono Agreement can also be terminated by EMD Serono at their convenience on 180 days notice. Such a termination could have an adverse effect on our revenues related to the commercialization of *EGRIFTA*TM 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*TM in HIV-associated lipodystrophy. In the event of a termination of the EMD Serono Agreement, EMD Serono could assert that such patent would be infringed by our continued sale of *EGRIFTA*TM 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*TM in the United States, all of which could have a material adverse effect on our operating results, cash flows and financial condition.

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

We are responsible for reporting to our commercial partners all adverse events derived from the use of EGRIFTATM 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 them. 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 result in 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 EGRIFTA™, 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 and for EGRIFTA™ for commercial sales, we are currently using, and relying on, single suppliers and single manufacturers for raw materials and the final drug substance. Although potential alternative suppliers and manufacturers have been identified, we have not entered into any agreements with them and qualified these vendors to date and no assurance can be given that such suppliers will be qualified in the future or receive necessary regulatory approvals.

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 good manufacturing practice, or 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, labour disputes or insolvency; or
- fails to perform its contractual obligations under our agreement, such as failing to deliver the quantities requested on a timely basis or not meeting product specifications.

We are aware that our third-party manufacturer of EGRIFTA™ for commercial sales located in Kirkland, Province of Québec, Canada, received a warning letter from the FDA, or Warning Letter, for its failure to comply with the GMP regulation. The Warning Letter was issued further to an inspection made by the FDA in early 2012 and after review by the FDA of response letters submitted by such third-party to the FDA to propose corrective measures to issues raised during such inspection. This third-party manufacturer has fifteen (15) business days to respond to the FDA to explain the corrective measures it has taken or intends to take to correct its deficiencies. The Warning Letter states that until all corrective measures have been completed and the FDA has confirmed the corrections and the third-party manufacturer's compliance with GMP, the FDA may withhold approval of any new applications or supplements listing such third-party manufacturer as a drug manufacturer. In addition, the Warning Letter states that the failure by this third-party

manufacturer to implement satisfactory corrective measures may result in the FDA refusing admission of articles manufactured at such third-party manufacturer's Kirkland site into the United States. If our third-party manufacturer is unable to adequately respond to FDA's Warning Letter, there could be a delay in or suspension of the supply of *EGRIFTA*[™].

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 operating results. In addition, any manufacturing delay or delay in delivering *EGRIFTA*[™] caused by quality control problem could result in product defects, recall or withdrawal of products previously shipped for commercial sales or inventory write-offs. Any delay in entering into additional commercial agreements for the manufacture and supply of our drug substance and drug product, could result in our being in default under our collaboration agreements with our commercial partners. 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 peptide 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 for 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 for medications 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 and resume our research and development activities with respect to our product candidates.

We have no internal sales, marketing or distribution capabilities so we must rely on our distribution and licensing 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 based on tesamorelin.

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 no marketing capabilities and we have no 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 lack of 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 us 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. In addition, if we decide not to develop our own sales force and to rely on a third-party sales force, there is no assurance that we will find such third party and, to the extent we find such third party, are able to enter into an agreement upon commercially reasonable terms.

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. Third-party payors decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors are attempting to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors have been challenging the prices charged for products. Third-party payors may decrease the level of reimbursement of a product or cease such reimbursement and the occurrence of any of these events could materially adversely affect the sales of *EGRIFTA*[™].

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 may 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 based on tesamorelin 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, operating results and financial condition.

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

In several countries, including Canada and countries which are in Europe, Latin America, Africa and the Middle East, 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 cases, our business, prospects and operating results 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 excess abdominal fat.

If we fail to comply with our contractual obligations, undertakings and covenants under our agreements with our commercial partners and third-party service providers, we may be exposed to claims for damages and/or termination of these agreements, all of which could materially adversely affect the commercialization of EGRIFTA™, our capacity to generate revenues and management's attention to the development of our business.

We rely on our commercial partners, EMD Serono, sanofi, Ferrer and Actelion to commercialize and to obtain and maintain regulatory approvals of EGRIFTA™ in the United States, Europe, Latin America, Africa, the Middle-East and Canada under our distribution and licensing agreements with each of them. We also rely on third-party service providers to manufacture EGRIFTA™ for commercialization and tesamorelin for our clinical trials. Under those agreements, we have assumed certain obligations, undertakings and covenants which, if breached by us and not remedied within the agreed upon periods, could expose us to claims for damages and/or termination of these agreements. If we are unable to meet our obligations under any of our agreements with our commercial partners and third-party service providers, this could materially adversely affect our capacity to generate revenues, our operating results and financial condition as well as divert management's attention from the conduct of our business plan.

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 unfavorable audit or review, we may be required to pay assessments, penalties and increased duties, which may, individually or in the aggregate, adversely affect our business, operating results and financial condition.

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 countries in which we intend to market our products. For example, although we obtained marketing approval of EGRIFTA™ 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*[™], 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 of *EGRIFTA*[™] in the United States, there is no assurance that regulatory agencies in other countries will approve *EGRIFTA*[™]. Regulatory agencies in these other countries could approve *EGRIFTA*[™] subject to additional post-approval requirements. If such is the case, we may incur unforeseen expenses to meet these post-approval requirements and such expenses could have a material adverse effect on our liquidities and financial condition.

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 *EGRIFTA*[™], new product candidates or supplements to approved applications.

Addressing any of the foregoing or any additional requirements of the FDA or other regulatory agencies 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 of 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 obtained marketing approval of *EGRIFTA*[™] in the United States, there is no assurance that regulatory agencies in other territories will approve *EGRIFTA*[™].

All of our product candidates are subject to preclinical and clinical studies. If the results of such studies are not positive, we will not be in a position to make any filing seeking the regulatory approval for our product candidates 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 customary for such regulatory agency as part of its review process to ask questions regarding the application that was filed, including questions regarding the manufacturing of the product, its safety and efficacy. If these questions are not answered quickly and in a satisfactory manner, the marketing approval of the product 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 could materially adversely affect 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, and depending on the type of additional tests, can have a material adverse effect on our financial condition and operating results 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 additional regulatory approvals.

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 of our other product candidates are either at the discovery or pre-clinical stage, except TH1173 which is ready to enter into Phase 1 clinical trial.

If any of our future preclinical studies or clinical trials fail to show positive efficacy data or result in adverse patient reactions, we could 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 seeking 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 would be able to develop new compounds, license or purchase compounds or product candidates that would 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 may also affect the prices we can obtain.

In the United States and other 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 *Medicare Prescription Drug, Improvement and Modernization Act of 2003*, or 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.

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.

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 United States Patent and Trademark Office, or 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. In addition, we have applied to the USPTO to obtain 1,827 days of patent term extension for U.S. patent No. 5,861,379. There is no assurance that the USPTO will issue a decision granting us the extension period sought or accept our application.

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 reducing excess abdominal fat in HIV-infected patients with lipodystrophy depends, in part, on our commercial partner's decision to bring an action against such third party. Under the terms and conditions of the EMD Serono Agreement, 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 reducing excess abdominal fat in HIV-infected patients with 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

reducing excess abdominal fat in HIV-infected patients with 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 States (for example, if found liable of wilful infringement) and/or cease the development and commercialization of our product candidates. Even if we were able to obtain a license, the rights may be 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.

OTHER RISKS RELATED TO OUR BUSINESS

We have a history of net losses and we may never achieve consistent 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, 2012, we had an accumulated deficit of \$266,786,000.

Our profitability will depend on, among other things, our commercial partners' ability and willingness to successfully commercialize *EGRIFTA*TM and to obtain regulatory approvals of *EGRIFTA*TM in certain countries of Latin America and Canada. Our profitability will also depend on our capacity to obtain approval of *EGRIFTA*TM in Europe or in some European countries. There is no guarantee that our commercial partners will succeed in commercializing *EGRIFTA*TM or that *EGRIFTA*TM and our product candidates will ever receive approval for commercialization in any jurisdictions. In addition, if revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, operating results and financial condition could be materially adversely affected and we may never sustain profitability.

We intend to rely on third-party service providers to conduct our preclinical studies and clinical trials if the research and development activities related to our product candidates are resumed 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 research and development programs.

We have limited human resources to conduct preclinical studies and clinical trials particularly in light of our recent restructurings and will have to rely on third-party service providers if the research and development activities related to our product candidates are resumed 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, labour dispute or insolvency or, if they fail to perform their contractual obligations pursuant to the terms of our agreements with them, such as failing to perform the testing, compute the data or complete the reports further to the testing, we may incur delays which may be significant in connection with 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 seeking marketing approval in a jurisdiction where we rely on third-party service providers to make such filing. In addition, where we rely on such third-party service provider to help in answering any 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 good laboratory practice, or 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 resuming the research and development programs of our product candidates and their commercialization.

We do not presently generate significant recurrent revenues and may need financing in order to fund all or part of our capital requirements to sustain our growth, to resume research and development of new and current 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, as well as through tax credits. Since the launch of *EGRIFTA*[™], we have also been financing our activities through upfront payments, milestone payments and royalties received from EMD Serono. We may need to undertake 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 favorable to us. If adequate funding is not available to us, we may be required to delay, reduce, or 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 development, manufacture and sale of such products may expose us to potential liability, and the pharmaceutical industry has been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and operating results. A product liability claim could also tarnish our reputation, whether or not such claims are with or without merit.

If a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim and, if the claim is successful, damage awards may be substantial and/or may not be covered, in whole or in part, by our insurance. We may not have sufficient capital resources to pay a judgment, in which case our creditors could levy against our assets. We may also be obligated to indemnify our commercial partners and 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.

An adverse determination, if any, in the securities class action lawsuit currently pending against us, or any other future lawsuits in which we are a defendant, could have a material adverse effect on us.

A motion to authorize the institution of a class action was originally filed in July 2010 in the Superior Court of Québec, District of Montreal, entitled 121851 Canada Inc. v. Theratechnologies Inc. et al., Number 500-06-000-515-102. The complaint alleged that we, a director and a former executive officer violated the secondary market liability provisions of the *Securities Act* (Québec) by failing to disclose a material change relating to the administration of *EGRIFTA*TM. The plaintiff sought damages on behalf of a class of persons who were shareholders at May 21, 2010 and who sold their common shares on May 25 or 26, 2010. On February 24, 2012, the Superior Court of Québec authorized 121851 Canada Inc. to institute a class action against us, a director and a former executive officer. On March 20, 2012, we filed a motion seeking permission to appeal this judgment with the Court of Appeal of Québec, District of Montreal, Number 500-09-022519-128, and the hearing took place on January 24, 2013. No judgment has been rendered yet following the January 24, 2013 hearing. Whether or not the plaintiff's claims are successful, this type of litigation is often expensive and diverts management's attention and resources, which could adversely affect the operation of our business.

We may also be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition. We maintain liability insurance, however, if any costs or expenses associated with this or any other litigation exceed our insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial and could have a material adverse effect on our available funds and operating results.

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

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our key employees and on our ability to be able to attract, retain and motivate qualified manufacturing, managerial and scientific personnel. We have entered into employment agreements with our executive officers and granted options to all of our executive officers and employees as a retention mechanism, but such agreements and options do not guarantee that our executive officers and employees will remain employed by us for any significant

period of time, or at all. In addition, we have a limited workforce to pursue our business plan and the loss of any of our key employees could materially adversely affect our business. If we lose the services of our key employees for any reason and are unable to attract qualified personnel to replace the services of these key employees, our capacity to pursue our business plan could be materially adversely affected.

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

We may 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, operating results 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, change in the procurement policy of a commercial partner or any other event having the effect of delaying the publicly announced timeline or reducing the publicly announced commercial objective. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of certain events having the effect of postponing such events or any variation in the occurrence of certain events having the effect of altering publicly announced commercial objectives could have an adverse material effect on our business plan, financial condition or operating results.

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

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

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

We have suspended all significant research and development activities relating to the discovery of new peptides. However, if we resume such activity, the outcome of scientific research is uncertain and may prove unsuccessful and, therefore, may not lead to the discovery of new peptides and progression of these peptides to an advanced development stage. Our inability to develop new peptides or to further develop our product candidates could slow down the growth of our portfolio of products.

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. In the past, the market price of our common shares has fluctuated and will continue to fluctuate due to various factors including the risk factors described herein and other circumstances beyond our control. An investment in our common shares could decline in value or fluctuate significantly.

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*TM;
- variations in the level of expenses related to the conduct of our business;
- 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, the ability of investors to achieve a return on their investment will depend on appreciation in the price of our common shares.

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

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

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

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

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

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.

Further Information on Theratechnologies

Further information on Theratechnologies, including our Annual Report on Form 20-F, is available on the SEDAR website at www.sedar.com.