



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 and results of operations of Theratechnologies Inc., on a consolidated basis, for the twelve-month periods ended November 30, 2011, or Fiscal 2011, and 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", "us", "our" or similar terms refer to Theratechnologies Inc. and its subsidiaries on a consolidated basis. This MD&A is dated February 7, 2012 and should be read in conjunction with the audited consolidated financial statements and the notes thereto. Unless specified otherwise, all amounts are in Canadian dollars.

In this MD&A, the use of *EGRIFTA*[™] 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*[™] is the trade name used in the United States for tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA*[™] is our trademark.

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 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.

Forward-Looking Information

This MD&A contains certain statements that are considered "forward-looking information" within the meaning of applicable securities legislation, which statements may contain words such as "will", "may", "could", "should", "outlook", "believe", "plan", "envisage", "anticipate", "expect" and "estimate", or the negatives of these terms, or variations of them. This forward-looking information includes, but is not limited to, information regarding the regulatory approval of tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in various territories outside of the United States, the maximization of the commercial value of *EGRIFTA*[™], the value of the decrease in our payroll expenses for fiscal 2012, and our ability to discover and develop new growth hormone releasing factor peptides, or GRF peptides.

Forward-looking information is based upon a number of assumptions and is subject to a number of risks and uncertainties, many of which are beyond our control that could cause actual results to differ materially from those that are disclosed in or implied by such forward-looking information. These assumptions made in preparing the forward-looking information include, but are not limited to, the assumption that tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy will receive approvals in various territories outside the United States, that no additional clinical studies will be required to obtain these regulatory approvals, that *EGRIFTA*[™] will be accepted by the marketplace in these territories and will be on the list of reimbursed drugs by third-party payers in these territories, that the relationship with our commercial partners and third-party suppliers will be conflict-free and that such third-party suppliers will have enough capacity to manufacture and supply *EGRIFTA*[™] to meet demand and on a timely basis, that we will have the capacity to discover and develop new GRF peptides, that the prescription base in the United States for *EGRIFTA*[™] will continue to grow, that our estimates of cost savings related to payroll reductions are accurate, and that our old inventory of stock will soon be depleted. These risks and uncertainties include, but are not limited to, the risk that tesamorelin is not approved in all or some of the territories where our commercial partners will file marketing applications, that revenues and royalties generated from sales of *EGRIFTA*[™] are lower than

anticipated, that conflicts occur with our commercial partners jeopardizing the commercialization of *EGRIFTA*[™], that the supply of *EGRIFTA*[™] to our commercial partners is delayed or suspended as a result of problems with our third-party suppliers, that *EGRIFTA*[™] is withdrawn from the market as a result of defects or recalls, that our intellectual property is not adequately protected, that even if approved, *EGRIFTA*[™] is not accepted in the marketplace or is not on the list of reimbursed drugs by third-party payers, that the cost savings anticipated following our restructuring do not materialize, and that we are unable to discover and develop new GRF peptides.

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 information. Forward-looking information reflects current expectations regarding future events and speaks only as of the date of this MD&A and represents 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 specialty pharmaceutical company that discovers and develops innovative therapeutic peptide products, with an emphasis on 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. EMD Serono launched *EGRIFTA*[™] on January 10, 2011.

2011 Business Plan

We achieved measurable progress on all three of our principal business plan objectives in 2011. They were:

- to maximize the global commercial value of *EGRIFTA*[™] by working closely with our commercial partners;
- to launch a Phase 2 clinical program evaluating tesamorelin for the treatment of muscle wasting associated with chronic obstructive pulmonary disease, or COPD; and
- to solidify our position as a leader in the field of novel GRF products by discovering and developing new GRF peptides.

In light of the changing nature of our business following the FDA approval of *EGRIFTA*[™], we also undertook a re-evaluation of our research and development, or R&D, business model in the first half of the year. Following this review, on June 2, 2011, we announced a restructuring aimed at relying more on external partners in both the private and public sectors to bring our R&D projects forward. The restructuring increased our flexibility in pursuing R&D objectives and led to a workforce reduction affecting 24 of our 95 employees.

Maximization of the Global Commercial Value of *EGRIFTA*[™]

During the first quarter of 2011, we concluded two distribution and licensing agreements for tesamorelin outside of the United States. We signed a distribution and licensing agreement with an affiliate of sanofi-aventis, or Sanofi, in December 2010, granting them exclusive commercialization rights to tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Latin America, Africa and the Middle East. Sanofi subsequently filed for regulatory approvals of tesamorelin for the treatment of excess abdominal fat in HIV-infected patients in Israel

on July 5, 2011, in Brazil on August 31, 2011, in Argentina on September 1, 2011, and in Mexico on October 19, 2011.

The second agreement was signed in February 2011 with Ferrer Internacional S.A., or Ferrer, granting them exclusive commercialization rights to tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries. On June 6, 2011, Ferrer filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, for tesamorelin proposed for the treatment of excess abdominal fat in adult HIV-infected patients with lipodystrophy. The MAA was accepted for review by the EMA on June 27, 2011. If approved, tesamorelin will receive marketing authorization for the 27 European Union member countries as well as for Iceland, Liechtenstein and Norway.

On June 20, 2011, we announced the filing of a New Drug Submission, or NDS, with the Therapeutic Products Directorate of Health Canada for *EGRIFTA*TM (tesamorelin for injection). The NDS was accepted for review on July 16, 2011.

Phase 2 Clinical Program in COPD

On February 22, 2011, we announced a new clinical program, and launched same on September 6, 2011, evaluating tesamorelin in COPD, a seriously debilitating condition suffered by an estimated 3.1 million patients in North America, Western Europe and Japan. The multi-center Phase 2 study was to evaluate two different doses using a new formulation of tesamorelin in approximately 200 patients.

New GRF Peptides

In 2011, our discovery team synthesized approximately 250 GRF peptides in order to find successors to tesamorelin with improved properties. On October 6, 2011, we announced the discovery of a new GRF peptide, which may prove to be suitable for the treatment of a broader range of medical indications, using methods of administration that are more patient-friendly than tesamorelin. Feasibility studies to explore this new GRF's potential are ongoing.

Review of Strategy in Light of Unfavorable Market Conditions (Subsequent Event)

As part of our planning and budget process, at year-end we reviewed our plans for 2012 in the context of current market conditions. The company continued to enjoy a strong financial position; and sales of *EGRIFTA*TM in the U.S. market were growing steadily and on track to reach our year-end target of 3,000 – 3,500 new prescriptions. However, the state of the economy was far from certain. In the latter half of the year, financial markets became increasingly volatile and the stock prices of small-cap biotechnology companies, particularly those with recent product launches like Theratechnologies, were hit hard.

On December 6, 2011, the Board of Directors met to consider the available options and decided that the best course of action was to restructure the business and concentrate the Company's efforts on *EGRIFTA*TM and on developing the new GRF peptide while accelerating the path to profitability. The following day, we announced that we were discontinuing our clinical program in COPD and significantly downsizing our business. The Board also adopted a plan aimed at lowering its own costs by 50%. The overall objective of the restructuring is to achieve positive earnings before interest, taxes, depreciation and amortization, or EBITDA, by 2013. The announced initiatives, which are expected to yield significant operating cost savings in future years, will trigger certain charges in 2012. See "Subsequent Events" below.

Financial Position

On February 22, 2011, we filed a preliminary prospectus aimed at raising equity and concurrently listing our common shares on the NASDAQ stock exchange in the United States. The offering was subsequently withdrawn because the offering price proved to be more dilutive than we were prepared to accept at the time. However, we did proceed with the NASDAQ listing and our stock began trading on June 16, 2011 under the symbol "THER".

We completed Fiscal 2011 with a strong liquidity position of \$37,133,000, consisting of \$36,787,000 of cash and bonds and \$346,000 of tax credits and grants receivable. Our funds are invested in liquid, low-risk instruments as described under "Liquidity and Capital Resources".

Outlook for 2012

Moving forward, our two principal operating objectives – maximizing the global commercial value of *EGRIFTA*TM and developing the new GRF peptide – are cornerstones of our plan to build value for shareholders in 2012 and beyond. Specifically, our 2012 operating goals are to:

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

Selected Annual Information

Consolidated statement of comprehensive income years ended November 30 (in thousands of Canadian dollars, except per share amounts)	2011	2010	2009
Revenue ⁽¹⁾	\$14,928	\$31,868	\$17,468
Research and development expenses, net of tax credits	\$10,992	\$14,064	\$20,810
Results from operating activities	\$(18,768)	\$6,663	\$(16,747)
Net finance income	\$966	\$2,381	\$1,591
Net (loss) profit	\$(17,730)	\$8,930	\$(15,156)
Basic and diluted (loss) earnings per share	\$(0.29)	\$0.15	\$(0.25)

Consolidated statement of financial position at November 30 (in thousands of Canadian dollars)	2011	2010	2009
Cash and current and non-current bonds	\$36,787	\$64,550	\$63,362
Tax credits and grants receivable	\$346	\$332	\$1,333
Total assets	\$52,873	\$71,651	\$69,154
Total share capital	\$280,488	\$279,398	\$279,169

**Consolidated statement of financial position
at November 30 (in thousands of Canadian
dollars)**

	2011	2010	2009
Total equity	\$36,343	\$52,656	\$43,048

⁽¹⁾ Revenue in 2009 includes a milestone payment of \$10,884,000 received from EMD Serono following the FDA's acceptance to file our New Drug Application, or NDA, for *EGRIFTA*TM. Revenue in 2010 includes a milestone payment of \$25,000,000 received from EMD Serono following marketing approval of *EGRIFTA*TM by the FDA. Revenue in 2011 includes revenue generated from the sales of *EGRIFTA*TM to EMD Serono for re-sale and royalties received from EMD Serono on U.S. sales to customers.

Operating Results

Revenue

Consolidated revenue for the year ended November 30, 2011 amounted to \$14,928,000 compared to \$31,868,000 in 2010. Revenue in 2010 included 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. Revenue in 2011 includes revenue generated from the sales of *EGRIFTA*TM to EMD Serono for re-sale and royalties received from EMD Serono on U.S. sales to customers. There were no product sales or royalties received from EMD Serono in 2010.

Under the terms of our agreement, we supply *EGRIFTA*TM to EMD Serono for resale. The revenue generated from these sales amounted to \$8,351,000 in Fiscal 2011.

Royalties on sales are paid quarterly in arrears based on the calendar year. 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 year due to an increase in the prescription base, which includes both new and repeat prescriptions.

Revenue also includes the amortization of the initial payment of \$27,097,000 received upon the closing of the agreement with EMD Serono in 2008. For the year ended November 30, 2011, an amount of \$5,134,000 was recognized as revenue related to this transaction, compared to \$6,846,000 in 2010. The lower amount for the current year reflects a change in the service period attributed to the initial payment. Prior to the second quarter of 2011, the initial payment was to be fully amortized by year-end 2012. However, the addition of some further development work has caused us to extend the service period to year-end 2013. At November 30, 2011, the remaining deferred revenue related to this transaction recorded on the consolidated statement of financial position amounted to \$8,558,000.

Cost of Sales

For the year ended November 30, 2011, the cost of sales of *EGRIFTA*TM totalled \$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 2010.

The cost of sales slightly exceeded sales revenue in 2011. *EGRIFTA*TM sales are expected to become profitable when our old inventory is depleted and when the costs associated with validating additional suppliers are behind us. Cost of sales is detailed in note 7 "Cost of sales" of our audited consolidated financial statements for the year ended November 30, 2011.

R&D Expenses

R&D expenses, net of tax credits, totalled \$10,992,000 for the year ended November 30, 2011 compared to \$14,064,000 in 2010, a decrease of 21.8%. R&D expenses incurred in 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 development of novel GRF peptides. R&D expenses also include the cost of filing an 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 2010 were mainly related to the pursuit of the regulatory approval of *EGRIFTA*[™] by the FDA. The lower R&D expenses in 2011 are due to changes in the nature of the activities undertaken, the staff reductions implemented in June, as well as lower bonus payments.

Selling and Market Development Expenses

Selling and market development expenses amounted to \$2,019,000 for the year ended November 30, 2011, compared to \$2,670,000 in 2010, a decrease of 24.4%. The decrease reflects the execution of distribution and licensing agreements with Sanofi and Ferrer in the first quarter of 2011, which transferred responsibility for all marketing expenses to these licensees, as well as lower bonus payments. Current selling and market development expenses are largely associated with the management of the agreements with our three commercial partners.

General and Administrative Expenses

General and administrative expenses amounted to \$10,823,000 in 2011 compared to \$8,002,000 in 2010. The higher expenses in 2011 include \$1,881,000 in costs associated with the planned public offering of shares, costs related to the change in leadership of the Company, and the cost of listing our shares on NASDAQ. 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. The restructuring led to a workforce reduction of 25%, affecting 24 of our 95 employees. As a result, we incurred restructuring costs of \$716,000 in the third quarter of 2011. The restructuring resulted in a reduction in payroll expenses of approximately \$1,000,000 for Fiscal 2011.

Net Financial Income

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

Finance costs for 2011 were \$636,000 compared to finance income of \$493,000 in 2010. The finance costs in 2011 include 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 translated into the functional currency of the Company at the more favorable exchange rate in effect at the year-end fiscal 2010, resulting in an exchange gain of \$511,000.

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 in 2011 compared to a net profit of \$8,930,000 or \$0.15 per share in 2010. The net profit in 2010 was principally due to milestone-payment revenue of US \$25,000,000 related to the collaboration and licensing agreement with EMD Serono.

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)

	2011				2010			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Sale of goods	\$2,670	\$1,878	\$2,005	\$1,798	-	-	-	-
Upfront and milestone payments	\$1,069	\$1,070	\$1,284	\$1,711	\$26,711	\$1,711	\$1,712	\$1,711
Royalties and license fees	\$671	\$569	\$194	\$9	\$6	\$6	\$5	\$6
Revenue	\$4,410	\$3,517	\$3,483	\$3,518	\$26,717	\$1,717	\$1,717	\$1,717
Net (loss) profit	\$(1,687)	\$(4,170)	\$(5,941)	\$(5,932)	\$21,299	\$(3,357)	\$(4,771)	\$(4,241)
Basic and diluted (loss) earnings per share	\$(0.03)	\$(0.07)	\$(0.10)	\$(0.10)	\$0.35	\$(0.06)	\$(0.08)	\$(0.07)

As described above, revenue in the fourth quarter of 2011 includes sales of *EGRIFTA*TM to EMD Serono for resale. Revenues in the second, third, and fourth quarters of 2011 also include royalties received from EMD Serono on U.S. sales of *EGRIFTA*TM from product launch to September 30, 2011. Revenue also includes the amortization of the initial payment of \$27,097,000 received upon the closing of the agreement with EMD Serono. Decreases in the amortization amounts for the current year reflect a change in the service period attributed to the initial payment.

Higher revenue in the fourth quarter of 2010 is related to the receipt of a milestone payment of \$25,000,000 from EMD Serono following the marketing approval of *EGRIFTA*TM by the FDA.

Fourth Quarter Comparison

Consolidated revenue for the three months ended November 30, 2011 amounted to \$4,410,000 compared to \$26,717,000 for the same period in 2010. Revenue in 2010 included 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. Revenue in 2011 includes revenue generated from the sales of *EGRIFTA*TM to EMD Serono for re-sale and royalties received from EMD Serono on U.S. sales to customers. There were no product sales and no royalties received from EMD Serono in 2010.

The cost of sales for the three months ended November 30, 2011 was \$2,018,000. Even though there were no *EGRIFTA*TM sales in 2010, we began production through our third-party suppliers late in the 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 \$349,000 in the comparable period of 2010.

R&D expenses, net of tax credits, totalled \$2,020,000 for the three months ended November 30, 2011 compared to \$3,172,000 for the same period in 2010, a decrease of 36.3%. R&D expenses incurred in 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 development of novel GRF peptides. R&D expenses also include 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 the prior-year period were mainly related to the pursuit of the regulatory approval of *EGRIFTA*[™] by the FDA.

General and administrative expenses amounted to \$1,789,000 in the three months ended November 30, 2011, compared to \$2,036,000 in the comparable period of 2010, reflecting variations in salaries paid and lower bonus payments.

Selling and market development expenses were \$530,000 for the three months ended November 30, 2011, compared to \$761,000 in the comparable period of 2010, a decrease of 30.4%. The decrease results primarily from the execution of distribution and licensing agreements with Sanofi and Ferrer in the first quarter of 2011, which transferred responsibility for all marketing expenses to these licensees. Selling and market development expenses continue to include activities associated with the management of the agreements with our three commercial partners.

Net financial income for the three months ended November 30, 2011 was \$285,000, compared to \$1,014,000 in 2010. The prior-year period includes an exchange gain of \$511,000 recorded upon the conversion of the \$25,000,000 EMD Serono milestone payment from U.S. dollars to Canadian dollars. In addition, interest revenues for 2011 were generally lower than 2010 due to a gradual decline in the portfolio size as investments were used to fund operations.

Consequently, we recorded a net loss of \$1,687,000, or \$0.03 per share in the three months ended November 30, 2011 compared to a net profit of \$21,299,000 or \$0.35 per share in 2010. The net profit in 2010 is principally due to the milestone payment of \$25,000,000 received from EMD Serono.

In the three months ended November 30, 2011, the use of cash in operating activities amounted to \$2,322,000 compared to cash inflows from operating activities of \$21,501,000 in 2010, reflecting the impact of the \$25,000,000 milestone payment received in the prior-year period.

Liquidity and Capital Resources

Our objective in managing capital is to ensure a sufficient liquidity position to finance our R&D activities, general and administrative expenses, working capital and capital spending.

Prior to 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 agreement with EMD Serono. 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*[™] in Fiscal 2011, we now receive additional revenues in the form of product sales and royalties.

For the year ended November 30, 2011, the use of cash in operating activities was \$27,218,000 compared to cash inflows from operating activities of \$2,900,000 in Fiscal 2010. The use of cash in 2011 reflected increases in inventory levels of \$6,415,000 and increases in trade and other receivables of \$1,623,000. The cash flow generated in Fiscal 2010 was principally due to the milestone payment of \$25,000,000 received from EMD Serono.

In Fiscal 2011, the Company received share subscriptions amounting to \$34,000 (\$15,000 in fiscal 2010) for the issuance of 7,837 common shares (2,880 in 2010) in connection with the Share Purchase Plan. In addition, 344,665 stock options were exercised in Fiscal 2011 for cash consideration of \$668,000.

As at November 30, 2011, cash and bonds amounted to \$36,787,000 and tax credits and grants receivable amounted to \$346,000, for a total liquidity position of \$37,133,000. We invest our available cash in highly liquid fixed income instruments from governmental, municipal and paragonovernmental bodies (\$34,288,000 at November 30, 2011).

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

We rent our headquarters and main office pursuant to a lease expiring in April 2021. At November 30, 2011 and 2010, the minimum payments required under the terms of the non-cancellable lease were as follows:

(in thousands of Canadian dollars)

	November 30, 2011	November 30, 2010
	\$	\$
Less than one year	136	55
Between one and three years	1,310	1,310
Four - five years	1,001	928
After five years	3,215	3,944
Total	5,662	6,237

Long-Term Procurement Agreements

As at November 30, 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, 2011, we had outstanding purchase orders under these agreements amounting to \$6,773,000 for the manufacture of *EGRIFTA*TM for delivery in the fiscal years 2012 and 2013.

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, 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:

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

We have developed a new presentation of *EGRIFTA*TM, which is more user-friendly than its current presentation. The new presentation uses the same formulation and will be available as a single unit dose (one vial containing 2 mg of tesamorelin) of sterile, lyophilized powder to be reconstituted with sterile water for injection. This new presentation complies with the first of the FDA's post-approval requirements and is required to be available by November 2013.

The long-term observational study required by the FDA is to evaluate the safety of long-term administration of *EGRIFTA*TM while the Phase 4 clinical trial is to assess whether *EGRIFTA*TM has an impact on diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat. Protocols for both studies were submitted to the FDA by EMD Serono. The protocol for the Phase 4 clinical trial has been approved and the protocol for the long-term observational study is under review by the FDA.

Contingent Liability

On July 26, 2010, we received a motion of authorization to institute a class action lawsuit, or Motion, against the Company, a director and a former executive officer. This Motion was filed in the Superior Court of Quebec, district of Montreal, or Court. The applicant is seeking to initiate a class action suit to represent the class of persons who were shareholders at May 21, 2010 and who sold their common shares of the Company on May 25 or 26, 2010. This applicant alleges that the Company did not comply with its continuous disclosure obligations as a reporting issuer by failing to disclose certain alleged adverse effects relating to the administration of *EGRIFTA*TM. The Company is of the view that the allegations contained in the Motion are entirely without merit and intends to take all appropriate actions to vigorously defend its position.

The Motion was heard by the Court in December 2011 and, as of the date of this MD&A, no judgement has been rendered by the Court.

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, 2011, with the exception of the lease of our headquarters as described above.

Subsequent Events

Restructuring

On December 7, 2011, we announced that we were discontinuing our clinical program evaluating tesamorelin in muscle wasting associated with COPD, resulting in the lay-off of 37 employees; and that we were accelerating the development of our new GRF peptide. We estimated that these initiatives would translate into cost savings of approximately \$10,000,000 in 2012.

Following the announcement, further analysis by management concluded that after the restructuring the Company will occupy approximately fifty percent of the premises it previously occupied under the lease as described in note 18 and 24 (a) of the audited consolidated financial statements. An onerous lease provision of \$4,055,000 is therefore expected to be recorded in the first quarter of 2012, which includes a provision for the future lease costs of the vacant portion of the premises, net of estimated of sublease rentals that could reasonably be obtained. The provision is based on management's best estimates of sublease rates that have yet to be negotiated, the timing of a sublease transaction, discount rates and other factors.

The following restructuring costs are expected to be recorded in the first quarter of 2012 and are subject to change as the Company finalizes its analysis:

Onerous lease provision	\$4,055,000
Employee termination benefits	\$1,325,000
Termination of the COPD Clinical Program	\$1,000,000
Other fees	\$200,000
	<hr/>
	\$6,580,000

It is expected that, except for the onerous lease provision, these restructuring costs will mainly be disbursed during the first quarter of 2012.

Stock Option Plan

Between December 1, 2011 and February 6, 2012, 72,667 options were forfeited and expired at a weighted exercise average price of \$8.92 per share. Furthermore, 104,503 stock options were exercised at a weighted exercise average price of \$1.81 per share for a cash consideration of \$189,000.

Deferred Stock Unit Plan

Between December 1, 2011 and February 6, 2012, 105,042 deferred stock units, or DSU, were granted and a related expense of \$250,000 will be recorded in the first quarter of 2012.

To protect against fluctuation in the value of the DSU's, we entered into a cash settled forward stock contract. We paid \$247,000 as advance payment on the contract. This amount corresponds to 101,822 common shares of the Company at a price of \$2.42. On December 2, 2011, the two cash settled forward stock contracts (note 16 (ii) of the consolidated financial statements) have been amended to expire in November 2012.

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.

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 (\$34,288,000 as at November 30, 2011). As at November 30, 2011, we believe we were not exposed to any significant credit risk over 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, 2011, are presented in notes 18 and 24(a) 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 on hand 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 2011, we entered into two forward foreign exchange contracts to sell, in aggregate, US\$1,307,000 for C\$1,319,000 in January 2012. The fair value of these instruments at November 30, 2011 was a liability of \$16,000. The change in fair value was recorded in finance costs in the consolidated statements of comprehensive income.

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 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, 2011:

(in thousands)

	November 30, 2011		
	\$US	EURO	GBP
Cash	2,386	–	–
Trade and other receivables	1,445	–	–
Accounts payable and accrued liabilities	(1,007)	(31)	(11)
Total exposure from above	2,824	(31)	(11)
Forward exchange contracts	(1,307)	–	–
Net exposure	1,517	(31)	(11)

The following exchange rates applied during the year ended November 30, 2011:

	November 30, 2011	
	Average rate	Reporting date rate
\$ US - C\$	0.9879	1.0203
EURO - C\$	1.3754	1.3706
GBP - C\$	1.5844	1.6009

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 increased the net (loss) profit as follows, assuming that all other variables remained constant:

(in thousands)

	November 30, 2011		
	\$US	EURO	GBP
Increase in net (loss) profit	76	(2)	(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 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, 2011, 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 \$440,000; 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, 2011 (\$3,726,000), an assumed 0.5% increase in interest rates during such period would have increased the future cash flow and the net profit by approximately \$19,000; an assumed decrease of 0.5% would have had an equal but opposite effect.

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 (level 2 inputs – 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 judgements 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 included in the following notes to the audited consolidated financial statements:

- 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.

- 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 judgement in assessing the possibility of any outflow in settlement of contingent liabilities.

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.

Upcoming changes in accounting standards:

(a) Amendments to existing standards:

Annual improvements to IFRS:

The IASB's improvements to IFRS contain seven amendments that result in accounting changes for presentation, recognition or measurement purposes. The most significant features of the IASB's annual improvements project published in May 2010 which are applicable for annual period beginning on or after January 1, 2011 with partial adoption permitted are included under the specific revisions to standards discussed below.

(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.

(iv) IAS 34:

Amendment to IAS 34, Interim Financial Reporting:

The amendments place greater emphasis on the disclosure principles for interim financial reporting involving significant events and transactions, including changes to fair value measurements and the need to update relevant information from the most recent annual report.

(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 yet applicable to the Company:

(i) IFRS 9 Financial instruments:

Effective for annual periods beginning on or after January 1, 2015, with earlier adoption permitted.

Applies to the classification and measurement of financial assets and liabilities. It is the first of three phases of a project to develop standards to replace IAS 39, *Financial Instruments*.

(ii) IFRS 10 Consolidated Financial Statements:

Effective for annual periods beginning on or after January 1, 2013, with earlier adoption permitted.

Establishes principles for the presentation and preparation of consolidated financial statements when an entity controls one or more other entities. IFRS 10 replaces the consolidation requirements in SIC-12, *Consolidation - Special Purpose Entities*, and IAS 27, *Consolidated and Separate Financial Statements*.

(iii) IFRS 13 Fair Value Measurement:

Effective for annual periods beginning on or after January 1, 2013, with earlier adoption permitted.

Provides new guidance on fair value measurement and disclosure requirements.

The Company has not yet determined the impact of these amendments to existing standards on the consolidated financial statements.

Outstanding Share Data

On February 6, 2012, the number of shares issued and outstanding was 60,969,769 while outstanding options granted under the stock option plan were 2,152,300.

Disclosure Controls and Procedures and Internal Control Over Financial Reporting

As at November 30, 2011, an evaluation of the design and operating effectiveness of our disclosure controls and procedures, as defined in Canadian securities laws and the U.S securities laws, was carried out. Based on that evaluation, the President and Chief Executive Officer and the Senior Executive Vice President and Chief Financial Officer concluded that the design and operating effectiveness of those disclosure controls and procedures were effective.

Also as at November 30, 2011, an evaluation of the design and operating effectiveness of internal controls over financial reporting, as defined in Canadian securities laws, was carried out. Based on that evaluation, the President and Chief Executive Officer and the Senior Executive Vice President and Chief Financial Officer concluded that the design and operating effectiveness of internal controls over financial reporting were effective.

These evaluations were based on the framework established in *Internal Control –Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, a recognized control model, the requirements of National Instrument 52-109 of Canadian securities laws and also, and specifically for disclosure controls and procedures, the U.S. Securities Exchange Act of 1934. A disclosure committee comprised of members of senior management assists the President and Chief Executive Officer and the Senior Executive Vice President and Chief Financial Officer in their responsibilities.

All control systems, no matter how well designed, have inherent limitations, including the possibility of human error and the circumvention or overriding of the controls or procedures. As a result, there is no certainty that our disclosure controls and procedures or internal control over financial reporting will prevent all errors or all fraud. There were no changes in our internal controls over financial reporting that occurred during the year ended November 30, 2011 that have materially affected, or are 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 depends largely on the commercialization of EGRIFTA™; the failure of EGRIFTA™ to obtain commercial acceptance would have a material adverse effect on us.

Our ability to generate revenues in the future is primarily based on the commercialization of EGRIFTA™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. In the short-term, these revenues should be primarily derived from the U.S. market alone. Although we have entered into a collaboration and licensing agreement with EMD Serono for the commercialization of EGRIFTA™ in the United States and the launch of EGRIFTA™ was made in January 2011, there can be no assurance that sales of EGRIFTA™ in the United States will

increase or remain the same. In addition, there is no assurance that *EGRIFTA*TM will be successfully commercialized in any other country. Although we are developing new GRFpeptides, these peptides are at earlier stages of development and none of them may reach the clinical trial phase, obtain regulatory approval or, even if approved, be successfully commercialized.

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

- receipt of regulatory approvals for *EGRIFTA*TM from regulatory agencies in the territories other than the United States in which we wish to expand the commercialization of tesamorelin;
- market acceptance of *EGRIFTA*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 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.

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

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

Although our collaboration and licensing agreements with EMD Serono, Sanofi and Ferrer 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 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 tesamorelin, all of which would divert our management's attention and our resources;
- our commercial partners not properly defending our intellectual property rights or using them in such a way as to expose us to potential litigation, which could, in both cases, adversely affect the value of our intellectual property rights; and

- corporate reorganizations or changes in business strategies of our commercial partners, which could adversely affect a commercial partner's willingness or ability to fulfill its obligations under its respective agreement.

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

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

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

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

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

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

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We do not

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

Our reliance on third-party manufacturers exposes us to a number of risks. We may be subject to delays in or suspension of the manufacturing of *EGRIFTA*TM 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 or insolvency; or
- fails to perform its contractual obligations under our agreement, such as failing to deliver the quantities requested on a timely basis.

Any delay in or suspension of the supply of *EGRIFTA*TM could delay or prevent the sale of *EGRIFTA*TM and, accordingly, adversely affect our revenues and results of operations. In addition, any manufacturing delay or delay in delivering *EGRIFTA*TM, or delay in entering into additional commercial agreements for the manufacture and supply of our drug substance and drug product, may result in our being in default under our collaboration agreements. If the damage to a supplier's manufacturer facility is extensive, or, for any reason, it does not operate in compliance with GMP or the third-party manufacturer is unable or refuses to perform its obligations under our agreement, we would need to find an alternative third-party manufacturer. The selection of a replacement third-party manufacturer would be time-consuming and costly since we would need to validate the manufacturing facility of such new third-party manufacturer. The validation process would include an assessment of the capacity of such third-party manufacturer to produce the quantities that we may request from time to time, the manufacturing process and its compliance with GMP. In addition, the third-party manufacturer would have to familiarize itself with our technology. Any delay in finding an alternative third-party manufacturer of tesamorelin and *EGRIFTA*TM could result in a shortage of such analogue or product, which could materially adversely affect our business and results of operations.

Even though *EGRIFTA*TM was launched in the United States, revenue that we generate from its sales may be limited.

Sales of *EGRIFTA*TM or any future products for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of such product by the medical community, including physicians, patients and health care payors. The degree of market acceptance of any of our products will depend on a number of factors, including:

- acceptance of the product by physicians and patients as safe and effective treatments and addressing a significant unmet medical need;
- product price;
- the effectiveness of the sales and marketing efforts of our commercial partners (or ours);

- storage requirements and ease of administration;
- dosing regimen;
- safety and efficacy;
- prevalence and severity of side effects;
- competitive products;
- the ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness and ability of patients to pay out-of-pocket in the absence of third-party coverage.

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

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

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

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

We are substantially dependent on revenues from EGRIFTA[™].

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

Our levels of revenues are highly dependent on obtaining patient reimbursement for EGRIFTA[™].

Market acceptance and sales of *EGRIFTA*[™] will substantially depend on the availability of reimbursement from third party payors such as governmental authorities, including U.S. Medicare and Medicaid, managed care providers, and private insurance plans and may be affected by healthcare reform measures in the United States and elsewhere. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors have been challenging the prices charged for products.

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

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

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

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

- differing regulatory requirements for drug approvals in foreign countries;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market, with low or lower prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in foreign economies and markets;
- compliance with tax, employment, immigration and labour laws for employees traveling abroad;
- foreign taxes;
- foreign exchange contracts and foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labour unrest is more common than in the United States and Canada;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

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

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

In several countries, including countries which are in Europe, Latin America, Africa, 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 case, our business, prospects and results of operations could be materially adversely affected.

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

The biopharmaceutical and pharmaceutical industries are highly competitive and we must compete with pharmaceutical companies, biotechnology companies, academic and research institutions as well as governmental agencies for the development and commercialization of products, most of which have substantially greater financial, technical and personnel resources than us. Although we believe that we have no direct competitors for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, we could face indirect competition from other companies developing and/or commercializing metabolic products and/or other products that reduce or eliminate the occurrence of lipodystrophy.

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

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

We import and export products and raw materials from and to several jurisdictions around the world. This process requires us and our commercial partners to operate in a number of jurisdictions with different customs and import/export regulations. The regulations of these countries are subject to change from time to time and we cannot predict the nature, scope or impact of these changes upon our operations. We and our commercial partners are subject to periodic reviews and audits by U.S. and foreign authorities responsible for administering these regulations. To the extent that we

or our commercial partners are unable to successfully defend against an audit or review, we may be required to pay assessments, penalties and increased duties, which may, individually or in the aggregate, negatively impact our business, operating results and financial condition.

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*TM in the United States, the FDA and regulatory agencies in other countries have the ability to limit the indicated use of a product. Also, the manufacture, marketing and sale of our products will be subject to ongoing and extensive governmental regulation in the country in which we intend to market our products. For example, although we obtained marketing approval of *EGRIFTA*TM for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the United States, the marketing of *EGRIFTA*TM 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*TM for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, namely, the development of a single vial formulation of *EGRIFTA*TM (the development of a new presentation of the same formulation), a long-term observational safety study using *EGRIFTA*TM; and a Phase 4 clinical trial. Although we have received marketing approval from the FDA of tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, there can be no guarantee that regulatory agencies in other countries will approve tesamorelin for this treatment in their respective countries.

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

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

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

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

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

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

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

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

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

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

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

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

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for *EGRIFTA*[™] and our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell *EGRIFTA*[™] or any of our other product candidates for which we intend to seek marketing approval.

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

In the United States, the 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.

More recently, in March 2010, U.S. President Obama signed into law the *Health Care Reform Law*, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the *Health Care Reform Law* revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, beginning in 2011, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. We will not know the full effects of the *Health Care Reform Law* until applicable U.S. federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the *Health Care Reform Law*, the new law appears likely to continue to apply the pressure on pharmaceutical pricing. Pressure on pharmaceutical pricing may adversely affect the amount of our royalties in the United States.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

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

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

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

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

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

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

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

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

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

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

If we are involved in patent infringement litigation, we would need to prevail in demonstrating that our products do not infringe the asserted patent claims of the relevant patent, that the patent claims are invalid or that the patent is unenforceable. If we are found to infringe a third-party patent or other intellectual property right, we could be required to enter into royalty or licensing agreements on terms and conditions that may not be favourable to us, and/or pay damages, including up to treble damages in the United 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 high profitability.

We have been reporting losses since our inception (except for the financial years ended November 30, 2010, 2001 and 2000) and, as at November 30, 2011, we had an accumulated deficit of \$252,846,000. We do not currently generate sufficient recurrent revenues to cover our overall activities.

Our profitability will depend on, among other things, our commercial partners' ability and willingness to successfully commercialize *EGRIFTA*TM and to obtain regulatory approval for the use of tesamorelin in the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Latin America, Africa and the Middle East. However, 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 jurisdiction and, accordingly, we may never sustain profitability.

We rely on third-party service providers to conduct our preclinical studies and clinical trials and the failure by any of these third parties to comply with their obligations may delay the studies which could have an adverse effect on our development programs.

We have limited human resources to conduct preclinical studies and clinical trials and must rely on third-party service providers to conduct our studies and trials and carry out certain data gathering and analyses. If our third-party service providers become unavailable for any reason, including as a result of the failure to comply with the rules and regulations governing the conduct of preclinical studies and clinical trials, operational failures such as equipment failures or unplanned facility shutdowns, or damage from any event such as fire, flood, earthquake, business restructuring or insolvency or, if they fail to perform their contractual obligations pursuant to the terms of our agreements with them, such as failing to perform the testing, compute the data or complete the reports further to the testing, we may incur delays which may be significant in connection with the planned timing of our trials and studies which could adversely affect the timing of the development program of a product candidate or the filing of an application for marketing approval in a jurisdiction where we rely on third-party service providers to make such filing. In addition, where we rely on such third-party service provider to help in answering any question raised by a regulatory agency during its review of one of our files, the unavailability of such third-party service provider may adversely affect the timing of the review of an application and could ultimately delay the approval. If the damages to any of our third-party service providers are material, or, for any reason, such providers do not operate in compliance with 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 to continue and complete the research and development of our product candidates and their commercialization.

We do not generate significant recurrent revenues and may need financing in order to fund all or part of our capital requirements to sustain our growth, to continue research and development of new product candidates, to conduct clinical programs, to develop our marketing and commercial capabilities and to meet our compliance obligations with various rules and regulations to which we are subject. In the past, we have been financed through public equity offerings in Canada and private placements of our equity securities and we may need to seek additional equity offerings to raise capital, the size of which cannot be predicted. However, the market conditions or our business performance may prevent us from having access to the public market in the future at the times or in the amounts necessary. Therefore, there can be no guarantee that we will be able to continue to raise additional equity capital by way of public or private equity offerings in the future. In such a case, we would have to use other means of financing, such as issuing debt instruments or entering into private financing or credit agreements, the terms and conditions of which may not be favourable to us. If adequate funding is not available to us, we may be required to delay, reduce, or eliminate our research and development of new product candidates, our clinical trials or our marketing and commercialization efforts to launch and distribute new products, curtail significant portions of our product development programs that are designed to identify new product candidates and sell or assign rights to our technologies, products or product candidates. In addition, the issuance and sale of substantial amounts of equity, or other securities, or the perception that such issuances and sales may occur could adversely affect the market price of our common shares.

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

Despite all reasonable efforts to ensure the safety of *EGRIFTA*[™] and our other product candidates, it is possible that we or our commercial partners will sell products which are defective, to which patients react in an unexpected manner, or which are alleged to have side effects. The manufacture and sale of such products may expose us to potential liability, and the industries in which our products are likely to be sold have been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

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

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

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

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

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

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

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

- diversion of management's attention;

- disruption to our ongoing business;
- failure to retain key acquired personnel;
- difficulties in integrating acquired operations, technologies, products or personnel;
- unanticipated expenses, events or circumstances;
- assumption of disclosed and undisclosed liabilities;
- inappropriate valuation of the acquired in-process research and development, or the entire acquired business; and
- difficulties in maintaining customer relations.

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

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

From time to time, we publicly announce the timing of certain events to occur or the attainment of certain commercial objectives. These statements are forward-looking and are based on the best estimate of management at the time relating to the occurrence of such events. However, the actual timing of such events or our ability to achieve these objectives may differ from what has been publicly disclosed. Events such as completion of a clinical program, discovery of a new product candidate, filing of an application to obtain regulatory approval, beginning of commercialization of our product, announcement of additional clinical programs for a product candidate or levels of sales of a product may vary from what is publicly disclosed. These variations may occur as a result of a series of events, including the nature of the results obtained during a clinical trial or during a research phase, problems with a supplier or a commercial partner or any other event having the effect of delaying the publicly announced timeline or reducing the publicly announced commercial objective. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of certain events having the effect of postponing such events or any variation in the occurrence of certain events having the effect of altering publicly announced commercial objectives could have an adverse material effect on our business plan, financial condition or operating results.

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

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

RISKS RELATED TO OUR COMMON SHARES

Our share price has been volatile, and an investment in our common shares could suffer a decline in value.

Since our initial public offering in Canada, our valuation and share price have had no meaningful relationship to current or historical financial results, asset values, book value or many other criteria based on conventional measures of the value of common shares. The market price of our common shares will fluctuate due to various factors including the risk factors described herein and other circumstances beyond our control.

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

Our quarterly operating results may fluctuate significantly.

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

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

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

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

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

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

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

- the sales of *EGRIFTA*[™] by our commercial partners;
- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals or allowances to commercialize product candidates;
- the timing of regulatory submissions and approvals;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize our product candidates;
- the outcome of any litigation; changes in foreign currency fluctuations;
- the timing of achievement and the receipt of milestone or royalty payments from current or future third parties;
- failure to enter into new or the expiration or termination of current agreements with third parties; and
- failure to introduce our product candidates to the market in a manner that generates anticipated revenues.

We may be adversely affected by currency fluctuations.

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

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

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

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

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

Further Information on Theratechnologies

Further information on Theratechnologies, including the Company's annual information form, is available on the SEDAR site at www.sedar.com.