MANAGEMENT'S DISCUSSION AND ANALYSIS

The following Management's Discussion and Analysis, or MD&A, provides Management's point of view on the financial position of Theratechnologies Inc., on a consolidated basis, as at November 30, 2015. It also provides a review of our performance by comparing the Company's results of operations, on a consolidated basis, for the twelve-month period ended November 30, 2015, or Fiscal 2015, with the twelve-month period ended November 30 2014, or Fiscal 2014. Unless otherwise indicated or unless the context requires otherwise, all references in this MD&A to "Theratechnologies", the "Company", the "Corporation", "we", "our", "us" or similar terms refer to Theratechnologies Inc. and its subsidiaries on a consolidated basis. This MD&A is dated February 24, 2016 and should be read in conjunction with the audited consolidated financial statements and the notes thereto.

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

Effective December 1, 2014, the Company changed its functional currency to the United States dollar, or USD, from the Canadian dollar, or CAD. This is the result of the Company's increased exposure to the USD through increased operational activity and sales in the United States. In accordance with IFRS, the Company translated all amounts for the December 1, 2014 consolidated statement of financial position into the new functional currency using the exchange rate in effect at the date of the change. However, since the Company believes that CAD currency is more useful to users of these documents, except where otherwise indicated, all monetary amounts set forth in this MD&A and the consolidated financial statements and the notes thereto are expressed in CAD for reporting purposes. The exchange difference resulting from the translation to CAD for reporting purposes is included in accumulated other comprehensive income. References to $ and C$ are to CAD and references to US$ are to USD.

In this MD&A, the use of *EGRIFTA*® refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy regardless of the trade name used for such product in any particular territory. Tesamorelin refers to the use of tesamorelin for the potential treatment of other diseases. *EGRIFTA*® is our registered trademark in the United States and Canada and it is used in those countries to commercialize tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Forward-Looking Information

This MD&A contains forward-looking statements and forward-looking information, or, collectively, forward-looking statements, within the meaning of applicable securities laws, that are based on our management's beliefs and assumptions and on information currently available to our management. You can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "outlook", "believe", "plan", "envisage", "anticipate", "expect" and "estimate", or the negatives of these terms, or variations of them. The forward-looking statements contained in this MD&A include, but are not limited to, statements regarding our anticipated revenue and Adjusted EBITDA for the Fiscal year 2016, the results from our programs and promotional campaigns in the United States, the growth regarding our patient base in the United States, the finding of commercial partners and the entering into agreements with such commercial partners to distribute *EGRIFTA*® in certain selected territories and the search for product acquisition and in-licensing opportunities.

Forward-looking statements are based upon a number of assumptions and include, but are not limited to, the following: our recently launched promotional activities and increased presence within the medical and scientific communities will increase our patient base in the United States and continue to grow *EGRIFTA*® sales and Adjusted EBITDA in Fiscal 2016; we have built an efficient commercial platform in the United

States, which will enable operating margins to increase at a greater rate than our net sales improvement; a USD/CAD exchange rate of 1.38 will apply in Fiscal 2016; the relationships with our commercial partners and third-party suppliers will be conflict-free, the United States Food and Drug Administration will not issue any order or decision having the effect of suspending the commercialization of *EGRIFTA*® in the United States; and we will have continuous supply of *EGRIFTA*®.

Forward-looking statements are subject to a variety of risks and uncertainties, many of which are beyond our control that could cause our actual results to differ materially from those that are disclosed in or implied by the forward-looking statements contained in this MD&A. We refer potential investors to the "Risks and Uncertainties" section of this MD&A. The reader is cautioned to consider these and other risks and uncertainties carefully and not to put undue reliance on forward-looking statements. Forward-looking statements reflect current expectations regarding future events and speak only as of the date of this MD&A and represent our expectations as of that date.

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

Business Overview

We are a specialty pharmaceutical company addressing unmet medical needs in metabolic disorders to promote healthy ageing and an improved quality of life.

Our first product**,** *EGRIFTA*® (tesamorelin for injection), was approved by the United States Food and Drug Administration, or FDA, in November 2010 and by Health Canada in March 2015, and is, to date, the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

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

With the EMD Serono Termination Agreement in effect, the primary focus of our 2015 business plan was to successfully commercialize *EGRIFTA*® in the United States in order to build a profitable base of operations for the Company. This important objective was achieved. In our first full year of marketing *EGRIFTA*®, revenues exceeded $30 million with the Company turning profitable and cash flow positive in the second quarter. All of our other 2015 key business plan objectives were also achieved. These included: launching *EGRIFTA*® in the Canadian market, securing a commercial partner to distribute *EGRIFTA*® in Europe, and receiving a regulatory decision concerning the approval of *EGRIFTA*® in Mexico. These achievements and other important business developments in 2015 are described more fully below.

United States Market
After re-acquiring the rights to *EGRIFTA*® from EMD Serono in May 2014, we relaunched the product in the fourth quarter of Fiscal 2014. Net *EGRIFTA*® sales grew significantly in Fiscal 2015 to reach $29.8 million by year-end. The early sales success, which was principally due to a high recapture rate of previous patients and broad acceptance by third-party payors, resulted in the Company becoming profitable and cash flow positive in the second quarter. Net profit for Fiscal 2015 was $1.6 million and adjusted earnings before interest, taxes, depreciation and amortization (Adjusted EBITDA) amounted to $6.4 million. See “Non-IFRS Financial Measures” below.

We estimate that our current customer base is largely composed of patients who were already being treated when we reacquired the *EGRIFTA*® rights in 2014. As such, we believe that there is still a large population of HIV-infected patients with lipodystrophy in the United States that is not currently being

treated. Over the past 15 months, we have carefully invested our limited resources to assemble a knowledgeable sales team and build infrastructure that includes a call center, a managed market group (reimbursement services), and a group dedicated to medical science liaison (medical and scientific information for clinicians). All of these initiatives are solely devoted to *EGRIFTA*®. Working from this base, and a much strengthened financial position, we are now expanding these programs and investing further in medical education programs, involving opinion-leading physicians and nurses who work with the HIV-infected population, as well as promotional campaigns aimed at increasing awareness of *EGRIFTA*® and its therapeutic benefits within the HIV community. We expect to see positive results from all of these initiatives in 2016.

Other Markets
Following receipt of the necessary approvals from Health Canada in March 2015, we began the Canadian distribution of *EGRIFTA*® on June 23, 2015. Our initial activities were focused on reimbursement by private drug plans and working with patient groups and key opinion leaders in the medical community to develop awareness of the disease and the availability of *EGRIFTA*® for its treatment. More recently, we turned our attention to seeking approval from the provincial government drug plans.

On February 27, 2015, we announced an agreement with AOP Orphan Pharmaceuticals AG, or AOP, for the distribution and commercialization of *EGRIFTA*® in certain European countries, or the AOP Agreement. Based in Vienna, Austria, AOP is a privately-owned pharmaceutical company that specializes in rare diseases. AOP is responsible for all regulatory activities to obtain marketing authorizations for *EGRIFTA*® on a country-by-country basis in its territory. In the meantime, they are distributing *EGRIFTA*® on a limited basis in certain European countries through Named Patient Sales Programs.

In Latin America, Africa and the Middle East, our commercial partner is sanofi, pursuant to a distribution and licensing agreement dated December 6, 2010, or the Sanofi Agreement. On July 14, 2015, we announced that the Mexican health agency, COFEPRIS, has approved the 2 mg/vial presentation of *EGRIFTA*®*.* In order to launch *EGRIFTA*® in Mexico, sanofi is now seeking approval for the 1 mg/vial presentation, the format that we are now supplying in other territories. The necessary filing has now been made by sanofi and the review process by COFEPRIS is ongoing.

In Israel, sanofi decided not to appeal an earlier decision by the Minister of Health to cancel the approval for registration of *EGRIFTA*®. As a result, the marketing authorization application has been abandoned by sanofi in this territory.

On August 31, 2015, we announced an agreement with BL&H Co., Ltd, or BL&H, for the distribution and commercialization of *EGRIFTA*® in South Korea, the BL&H Agreement. Based in Seoul, BL&H is a leading distributor of pharmaceuticals and hospital-based products and services. The BL&H agreement represents a step forward in our efforts to realize the full therapeutic and commercial potential of *EGRIFTA*® in selected territories.

Other Developments
On February 3, 2015 we announced the filing of a Form 15 with the Securities and Exchange Commission, or SEC, to suspend our reporting obligations in the United States. Our common shares continue to trade on the Toronto Stock Exchange (TSX: TH) and we continue to file our periodic reports under Canadian securities regulation with the applicable Canadian securities regulators.

On February 17, 2015, we restructured the amount and payment terms of the initial US $4,000,000 due to EMD Serono on May 1, 2015 as part of the long-term obligation created in connection with the EMD Serono Termination Agreement when we reacquired the rights to *EGRIFTA*®. Under the restructured terms, the first payment totaled US $4,167,808 and was paid in three unequal installments as follows: US $500,000 on May 1, 2015; US $1,550,548 on August 31, 2015; and US $2,117,260 on November 30, 2015. The four remaining annual payments of US $4,000,000 are unchanged and are due on May 1 of each year, beginning on May 1, 2016 (see “Contractual Obligations – EMD Serono Termination Agreement” below and Note 18 of our consolidated financial statements).

On April 17, 2015, we announced that the Supreme Court of Canada granted our appeal and dismissed 121851 Canada Inc.'s motion for leave to commence an action against the Company, a director, and a former president and chief executive officer. On May 15, 2015, we announced that the Superior Court of Quebec had authorized the discontinuation of all the related class action proceedings, which occurred on May 19, 2015. There is no longer any threat of litigation in this matter.

On August 6, 2015, we announced the closing of a public offering for gross proceeds of $11,040,000. Approximately 50% of the net proceeds of the offering are expected to be used to accelerate US commercialization activities for *EGRIFTA*® with the balance being applied to the working capital that will be needed to support the anticipated growth in *EGRIFTA*® sales.

To further support our future growth, in November 2015, we established a $2,000,000 revolving credit facility, secured by stocks and accounts receivable.

Outlook

Looking ahead, in 2016 we will continue to focus on increasing sales of *EGRIFTA*® in the U.S. market. An important strategy in support of this goal is a commitment to growing our patient base by elevating the importance of treating excess abdominal fat in HIV-infected patients with lipodystrophy in the minds of patients, health care providers and third-party payors. We are investing more in medical education programs involving opinion-leading physicians and nurses who work with the HIV-infected population. And, we have developed a promotional campaign in support of our message, which was deployed in the fourth quarter of Fiscal 2015 and will continue throughout 2016. A significant portion of the funds raised through a public offering in August 2015 will be devoted to building the market for *EGRIFTA*® in the United States.

In addition to growing our U.S. business, the 2016 business plan objectives include; establishing the market for *EGRIFTA*® in Canada; supporting our three existing commercial partners in their efforts to obtain marketing approvals in Latin America, Europe and South Korea; and securing additional commercial partners for other selected territories. We also intend to look for product acquisitions and in-licensing opportunities, but in a very disciplined manner. We will only consider products that could benefit from our current infrastructure and address a population of patients similar to that of *EGRIFTA*®.

Guidance

We believe that our recently launched promotional activities and increased presence within the medical and scientific communities will continue to drive *EGRIFTA*® sales in Fiscal 2016. For the twelve months ending November 30, 2016, we anticipate that net sales will be in the range of $46,000,000 to $49,000,000.

We also believe that we have built an efficient commercial platform in the United States, which should enable operating margins to increase at a greater rate than our net sales improvement; and, based on the same method of calculation used in Fiscal 2015, we anticipate that Adjusted EBITDA in Fiscal 2016 will be in the range of $10,000,000 to $12,000,000. See "Non-IFRS Financial Measures" below.

We have used a USD/CAD exchange rate of 1.38 to establish all of these estimates.

Selected Annual Information

Years ended November 30 (in thousands of Canadian dollars, except per share amounts)	2015	2014	2013
Revenue	**$30,055**	**$6,732**	**$7,553**
Selling and market development expenses	**$12,926**	**$6,963**	**$250**
Restructuring costs	**--**	**--**	**$(3,111)**
Adjusted EBITDA[1]	**$6,439**	**$(10,575)**	**$(3,170)**
Net profit (loss)	**$1,571**	**$(10,541)**	**$(4,055)**
Earnings (loss) per share:			
Basic	**$0.03**	**$(0.17)**	**$(0.07)**
Diluted	**$0.02**	**$(0.17)**	**$(0.07)**
Total assets	**$50,083**	**$32,654**	**$24,844**
Long-term obligation (including current portion)	**$16,896**	**$17,152**	**--**

1. See “Non-IFRS Financial Measures” below.

The significant increase in revenue in 2015 is the result of changes in our business model after the EMD Serono Termination Agreement took effect in May 2014, with 2015 being the first full year of our selling *EGRIFTA*® for our own account in the United States market. The variation in revenue between 2014 and 2013 is attributable to the business model changes as well as a prolonged product shortage experienced in 2014.

The year-over-year increases in selling and market development expenses are reflective of changes in our business model following the EMD Serono Termination Agreement taking effect in 2014.

The significant improvement in Adjusted EBITDA is principally due to our strategy of reacquiring the US commercialization rights for *EGRIFTA*® in May 2014 and successfully implementing various business plan initiatives since that time. See “Non-IFRS Financial Measures” below.

The net profit in 2015 is attributable to the successful execution of our business plan based on our new business model. The net loss in 2014 was impacted by significantly higher selling and market development expenses as well as the prolonged product shortage referred to above, partially offset by an

increase in net finance income resulting from a Federal investment tax credit refund. The net loss in 2013 benefitted from a partial recovery of prior-year restructuring costs in the amount of $3,111,000.

The increase in total assets in 2015 is due to improved operating results, the additional funds raised through the public offering in August 2015 and the effect of changes in exchange rates. The increase in total assets in 2014 is due to the intangible asset value established for the *EGRIFTA*® commercialization rights acquired in 2014, partially offset by cash flows used in operations.

The long-term obligation is in relation to the early termination fee included in the EMD Serono Termination Agreement (see "Contractual Obligations – EMD Serono Termination Agreement" below). The long-term obligation is payable in the functional currency (USD) and when translated into CAD, the outstanding balance decreased less than the amount of the payments made during the year due to the effects of changes in exchange rates. The exchange difference resulting from the translation into CAD was included in accumulated other comprehensive income and therefore had no impact on net profit in Fiscal 2015.

Operating Results - twelve months ended November 30, 2015 compared to twelve months ended November 30, 2014

Revenue

Prior to the closing of the EMD Serono Termination Agreement on May 1, 2014, our revenues were mainly composed of net sales of *EGRIFTA*® to EMD Serono for re-sale, royalties received from EMD Serono on U.S. sales to customers, and research services, which included milestone payments and the amortization of the initial payment received from EMD Serono. After May 1, 2014, our revenues were essentially net sales of *EGRIFTA*® for our own account to our exclusive distributor, RxCrossroads, which were nil from May 1 to August 31, 2014 due to a prolonged product shortage. Consolidated revenue for the twelve months ended November 30, 2015 was $30,055,000, compared to $6,732,000 in Fiscal 2014.

(in thousands of Canadian dollars)	**2015**	**2014**
Net sales	$29,839	$3,332
Upfront payments and initial technology access fees	$200	$2,770
Royalties and license fees	$16	$630
Revenue	**$30,055**	**$6,732**

Revenue generated from net sales increased significantly in 2015, due to the first full year of selling *EGRIFTA*® for our own account in the United States. The principal factors contributing to the net sales increase were: the different price structure associated with selling *EGRIFTA*® for our own account compared to selling to EMD Serono for re-sale; success in growing the patient base over the course of the year; and the positive effect of changes in exchange rates.

Revenue generated from net sales in Fiscal 2014 was adversely affected by a prolonged product shortage and included $2,657,000 of sales for our own account (all of which occurred in the fourth quarter) and $675,000 of sales to EMD Serono.

An upfront payment of $200,000 was received in 2015 in connection with the AOP Agreement. With the closing of the EMD Serono Termination Agreement on May 1, 2014, all of the unamortized balance of the initial payment received under the terms of the EMD Serono Agreement was recognized as revenue in the second quarter of that year.

Royalties in Fiscal 2014 were $630,000, principally attributable to sales of *EGRIFTA*® by EMD Serono prior to May 1, 2014.

Cost of Sales

For the twelve months ended November 30, 2015, the cost of sales was $4,024,000 compared to $2,455,000 in Fiscal 2014. In Fiscal 2015, the cost of sales included $338,000 of unallocated production costs, of which $229,000 was inventory write-downs related to the conversion of raw materials to finished goods and the expiration of goods. In Fiscal 2014, the cost of sales included unallocated production costs of $1,464,000, which were largely inventory write-downs of $1,071,000, as well as unabsorbed fixed costs and costs associated with changing over from the 2 mg/vial to the 1 mg/vial presentation of *EGRIFTA*®.

R&D Expenses

R&D expenses, net of tax credits, amounted to $4,905,000 in the twelve months ended November 30, 2015 compared to $5,617,000 in Fiscal 2014. Approximately half of our Fiscal 2015 R&D expenses were costs associated with our two Phase 4 clinical trials. A second major component results from regaining the US commercialization rights to *EGRIFTA*®, whereby we now have full responsibility for additional R&D functions, notably medical affairs (which includes medical education programs involving opinion-leading physicians and nurses who work with the HIV-infected population to build scientific awareness about *EGRIFTA*® and its therapeutic benefits) as well as regulatory affairs and quality assurance. Essentially all of the remaining difference between R&D expenses in Fiscal 2015 and Fiscal 2014 is attributable to these activities.

The first of the two Phase 4 clinical trials is a long-term observational safety study, or Observational Study, and the second trial is to assess whether *EGRIFTA*® increases the incidence or progression of diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat, or Retinopathy Study. Prior to May 1, 2014, we were responsible for only 50% of the cost of the Observational Study. With the closing of the EMD Serono Termination Agreement, we are now responsible for all of the costs associated with both studies. These costs amounted to $2,771,000 in Fiscal 2015 compared to $3,704,000 in the prior year.

Selling and Market Development Expenses

Selling and market development expenses amounted to $12,926,000 for the twelve months ended November 30, 2015, our first full year of selling *EGRIFTA*® for our own account in the United States, compared to $6,963,000, and a partial year of selling for our own account, in Fiscal 2014. Selling and Market Development Expenses now include the costs associated with maintaining our sales team as well as the various elements of our marketing program such as the marketing group itself, our call center, reimbursement services, and the recently launched promotional campaigns aimed at increasing awareness of *EGRIFTA*® and its therapeutic benefits within the HIV community.

Finally, selling and market development expenses include the amortization of the intangible asset value established for the *EGRIFTA*® commercialization rights. This amortization expense amounted to $1,905,000 in Fiscal 2015 compared to $1,009,000 in Fiscal 2014.

General and Administrative Expenses

General and administrative expenses amounted to $4,055,000 in the twelve months ended November 30, 2015, slightly lower than the $4,566,000 in Fiscal 2014 due to lower professional fees.

Finance Income

Finance income for the twelve months ended November 30, 2015 was $289,000 compared to $329,000 in Fiscal 2014. Lower interest income and a smaller gain on disposal of available-for-sale financial assets in Fiscal 2015, were largely offset by a gain of $188,000 on the renegotiation of the long-term obligation.

Finance Costs

Finance costs for the twelve months ended November 30, 2015 were $2,294,000 compared to $2,080,000 in Fiscal 2014. Finance costs in Fiscal 2015 included $2,500,000 of accretion expense on the long-term obligation compared to $1,203,000 in Fiscal 2014. Finance costs in Fiscal 2014 also included an unrealized foreign currency loss on the long-term obligation of $714,000. With the adoption of the USD as the company's functional currency effective December 1, 2014, any exchange difference resulting from the translation into CAD was included in accumulated other comprehensive income and therefore had no impact on net profit in Fiscal 2015.

Federal Investment Tax Credits

In Fiscal 2014, the Company settled a dispute with the Canada Revenue Agency in relation to an investment tax credit refund claim for the 1994 and 1995 taxation years, resulting in a refund of $4,110,000 ($1,650,000 of investment tax credit refund and $2,520,000 of interest less associated fees).

Adjusted EBITDA

Adjusted EBITDA was $6,439,000 in the twelve months ended November 30, 2015 compared to $(10,575,000) in Fiscal 2014. The significant improvement in Adjusted EBITDA is principally due to our strategy of reacquiring the US commercialization rights to *EGRIFTA*® in May 2014 and successfully implementing strategic business plan initiatives since that time. See "Non-IFRS Financial Measures" below.

Net Profit (Loss)

Taking into account the revenue and expense variations described above, we recorded a net profit of $1,571,000 or $0.03 per share ($0.02 per share on a diluted basis) in the twelve months ended November 30, 2015 compared to a net loss of $(10,541,000) or $(0.17) per share in Fiscal 2014.

Fourth Quarter Comparison

Consolidated revenue for the three months ended November 30, 2015 amounted to $9,011,000 compared to $2,663,000 for the comparable period of 2014.

(in thousands of Canadian dollars)	**2015**	**2014**
Net sales	$9,007	$2,657
Upfront payments and initial technology access fees	--	--
Royalties and license fees	$4	$6
Revenue	**$9,011**	**$2,663**

Revenue generated from net sales for the three months ended November 30, 2015 was $9,007,000 compared to $2,657,000 in the comparable period of Fiscal 2014, reflecting our success in growing the patient base over the course of the year, and the positive effect of changes in exchange rates.

The cost of sales for the three months ended November 30, 2015 was $1,161,000 compared to $604,000 in the comparable period of Fiscal 2014.

R&D expenses, net of tax credits, amounted to $926,000 in the three months ended November 30, 2015 compared to $1,164,000 in the comparable period of Fiscal 2014. Our costs associated with the two Phase 4 clinical trials (the Observational Study and the Retinopathy Study) amounted to $265,000 in the three months ended November 30, 2015, compared to $790,000 in the comparable period of Fiscal 2014. Increased activity in medical affairs, regulatory affairs and quality assurance, as well as expenditures on development of our new 2 mg/vial presentation of *EGRIFTA*®, make up essentially all of the remaining difference in R&D expenses between the fourth quarters of Fiscal 2015 and Fiscal 2014.

Selling and market development expenses amounted to $4,348,000 for the three months ended November 30, 2015, compared to $1,716,000 for the comparable period of Fiscal 2014. The significant increase in expenses is due to higher costs associated with growing and maintaining our sales force as well as various marketing services and initiatives, including the recently launched marketing campaign aimed at increasing our US patient base. In addition, selling and market development expenses now include the amortization of the intangible asset value established for the *EGRIFTA*® commercialization rights. This amortization expense amounted to $499,000 in the three months ended November 30, 2015 compared to $433,000 in the comparable period of Fiscal 2014.

General and administrative expenses amounted to $1,157,000 in the three months ended November 30, 2015 compared to $1,312,000 in the comparable period of Fiscal 2014.

The profit from operating activities for the three months ended November 30, 2015 was $1,419,000 compared to a loss from operating activities of $(2,133,000) in the comparable period of Fiscal 2014.

Finance income for the three months ended November 30, 2015 was $27,000 compared to $35,000 in the comparable period of Fiscal 2014. Interest revenue has decreased due to a gradual decline in the portfolio size as investments were liquidated to fund operations.

Finance costs for the three months ended November 30, 2015 were $399,000 compared to $1,519,000 in the comparable period of Fiscal 2014. Finance costs in Fiscal 2015 included $637,000 of accretion expense on the long-term obligation partially offset by a gain of $345,000 on change of fair value of the warrant liability. Finance costs in Fiscal 2014 included $525,000 of accretion expense on the long-term obligation as well as an unrealized foreign currency loss of $835,000 on the long-term obligation.

Net financial income for the three months ended November 30, 2015 was a loss of $372,000 compared to a loss of $1,484,000 in the comparable period of Fiscal 2014.

Adjusted EBITDA was $2,185,000 in the three months ended November 30, 2015 compared to $(1,505,000) in the comparable period of Fiscal 2014. The significant improvement in Adjusted EBITDA is principally due to our strategy of reacquiring the US commercialization rights to *EGRIFTA*® in May 2014 and successfully implementing strategic business plan initiatives since that time. See “Non-IFRS Financial Measures” below.

Taking into account the revenue and expense variations described above, we recorded a net profit of $488,000 or $0.01 per share in the three months ended November 30, 2015 compared to a net loss of $(3,620,000), or $(0.06) per share, in the comparable period of Fiscal 2014.

In the three months ended November 30, 2015, operating activities generated $3,233,000 of cash, compared to a use of cash of $2,416,000 in the comparable period of Fiscal 2014. The principal factors contributing to the improved cash flow in 2015 were the profitable operations and changes in operating assets and liabilities.

Quarterly Financial Information

The following table is a summary of our unaudited consolidated operating results for the last eight quarters.

(In thousands of dollars, except per share amounts)

	2015				2014			
	Q4	**Q3**	**Q2**	**Q1**	Q4	Q3	Q2	Q1
Net sales	**$9,007**	**$9,189**	**$7,076**	**$4,567**	$2,657	$--	$--	$675
Upfront payments and initial technology access fees	**$--**	**$--**	**$200**	**$--**	$--	$--	$2,450	$320
Royalties and license fees	**$4**	**$4**	**$4**	**$4**	$6	$4	$(57)	$677
Revenue	**$9,011**	**$9,193**	**$7,280**	**$4,571**	$2,663	$4	$2,393	$1,672
Net profit (loss)	**$488**	**$1,179**	**$818**	**$(914)**	$(3,620)	$(4,394)	$1,007	$(3,534)
Basic and diluted earnings (loss) per share	**$0.01**	**$0.02**	**$0.01**	**$(0.01)**	$(0.06)	$(0.07)	$0.02	$(0.06)

With the closing of the EMD Serono Termination Agreement on May 1, 2014, the US commercialization rights for *EGRIFTA*® reverted to us. Net sales prior to that represented sales to EMD Serono for re-sale.

Net sales in the fourth quarter of 2015 declined slightly from the third quarter due to inventory adjustments in the supply chain and flat patient prescription refills, which were largely offset by a reversal of provisions for chargebacks, rebates and returns.

Net sales in the second and third quarters of 2014 were nil due to a prolonged product shortage, which also had a negative impact on *EGRIFTA*® royalties in the second quarter of that year.

An upfront payment of $200,000 was received in the second quarter of 2015 in connection with the execution of the AOP Agreement. With the closing of the EMD Serono Termination Agreement on May 1, 2014, all of the unamortized balance of the initial payment was recognized as revenue in the second quarter of 2014.

The decline in net profit in the fourth quarter of 2015 was essentially due to a planned increase in our investment in selling and market development activities. This followed the completion of the public offering in the third quarter, which was undertaken, in large part, to finance this increased investment.

The net profit reported in the second quarter of 2014 took into account $4,110,000 received in settlement of a dispute over an investment tax credit refund claim related to our 1994 and 1995 taxation years.

Liquidity and Capital Resources

Our objective in managing capital is to ensure a sufficient liquidity position to finance our business activities. Prior to fiscal 2011, we funded our activities by relying primarily on public offerings of common shares in Canada and on private placements of our common shares as well as on upfront payments and milestone payments primarily associated with the EMD Serono Agreement. With the market launch of *EGRIFTA*® in Fiscal 2011, we began to receive revenues in the form of product sales and royalties.

On December 13, 2013, the Company entered into the EMD Serono Termination Agreement in order to regain commercialization rights for *EGRIFTA*® in the United States. The closing of the transaction occurred on May 1, 2014. Operations of the Company have significantly changed upon the completion of this transaction which may impact the risk profile of its cash flows and its contractual obligations with respect to the early termination fee (see "Contractual Obligations – EMD Serono Termination Agreement" below and note 18 of our consolidated financial statements).

For the twelve months ended November 30, 2015, cash flow from operating activities was $7,086,000 compared to a use of cash of $8,039,000 in Fiscal 2014. The greatly improved cash flow was largely due to the Company earning a profit of $1,571,000 in Fiscal 2015 compared to a loss of $10,541,000 in the prior year. Non-cash expenses, particularly amortization of intangible assets and accretion expense, were significantly higher in Fiscal 2015. Changes in operating assets and liabilities, in keeping with the growth in the scale of our business, contributed a further $1,126,000 to cash flow from operating activities in Fiscal 2015. The principal components were an increase in accounts payable and accrued liabilities of $3,635,000, partly offset by an increase in trade and other receivables of $1,665,000.

The Company believes that it will be able to adequately fund its operations and meet its cash flow requirements for the next twelve months.

The Company made payments totaling $5,398,000 to EMD Serono during Fiscal 2015, in partial settlement of its long-term obligation (see "Contractual Obligations – EMD Serono Termination Agreement" below).

On August 6, 2015, the Company closed a public offering of 4,600,000 units for gross proceeds of $11,040,000. Each unit consisted of one common share and one-half of a common share purchase warrant of the Company, with each whole warrant, or Warrant, exercisable for a period of 24 months from the date of the closing of the offering at an exercise price of $3.00 per share. Under IFRS, the prescribed treatment for Warrants issued with an exercise price denominated in a foreign currency, in this case CAD, is to classify these Warrants as a liability measured at fair value. Share issue costs paid during the year totalled $1,126,000, resulting in net proceeds of $9,914,000.

In the twelve months ended November 30, 2015, the Company issued 5,000 common shares following the exercise of stock options for cash proceeds of $9,000. No stock options were exercised in Fiscal 2014.

As at November 30, 2015, cash amounted to $15,350,000 compared to cash and bonds of $3,178,000 at the end of Fiscal 2014. When we invest our available cash, we do so in highly liquid fixed income instruments from governmental, municipal and paragovernmental bodies (nil November 30, 2015, $2,484,000 November 30, 2014).

Having terminated its $1,800,000 revolving credit facility in Fiscal 2014, the Company established a $2,000,000 revolving credit facility to support future growth in the fourth quarter of Fiscal 2015. The new facility, which is secured by inventories and accounts receivable, bears interest at prime rate plus 1%. As at November 30, 2015, there were no borrowings outstanding under this credit facility. The terms of the revolving credit facility require the Company to comply with certain covenants including maintenance of financial ratios. We are in compliance with all covenants as at February 24, 2016.

Contractual Obligations

Commitments

The following table lists as at November 30, 2015 information with respect to the Company's known contractual obligations.

(In thousands of Canadian dollars)

Contractual Obligations	Total	Less than 1 Year	Between 1 and 5 Years	More than 5 Years
Long Term Debt Obligations	$21,365	$5,341	$16,024	$--
Operating Lease Obligations	$1,057	$221	$836	$--
Total	**$22,422**	**$5,562**	**$16,860**	**$--**

Long-Term Procurement Agreements

We have long-term procurement agreements with third-party suppliers in connection with the commercialization of *EGRIFTA®*. As at November 30, 2015, we had outstanding purchase orders and minimum payments required under these agreements amounting to $3,099,000 ($3,782,000 in 2014) for the manufacture of *EGRIFTA®* and various services.

EMD Serono Termination Agreement

On December 13, 2013, the Company announced that it reached an agreement with EMD Serono to regain all rights under the EMD Serono Agreement, including commercialization rights for *EGRIFTA®* in the United States. The transaction closed on May 1, 2014.

Under the terms of the EMD Serono Termination Agreement, the Company agreed to pay an early termination fee of US $20,000,000 in equal tranches over a five-year period starting on May 1, 2015. In light of the delay in the commercialization of *EGRIFTA®* caused by the supply problems incurred in 2014, the Company restructured the amount and payment terms of the initial long-term obligation payment, which was due May 1, 2015. Under the new terms, the payment amounted to US $4,167,808 (previously US $4,000,000) and was paid in three unequal installments in Fiscal 2015. The Company also agreed to pay EMD Serono a confidential increasing royalty based on annual net sales. Starting on January 1, 2016, the royalties will be paid until a confidential cumulative aggregate amount is reached or until January 1, 2024, the first of these events to occur.

In order to secure the payment of the early termination fee, the Company agreed to grant EMD Serono a security interest on its present and future corporeal and incorporeal movable property related to *EGRIFTA®* until such time as the long-term obligation has been reimbursed in full to EMD Serono. Thereafter, the Company and EMD Serono agreed to reduce the security interest to all present and future corporeal and incorporeal movable property related to *EGRIFTA®* in the United States only to secure the payment of the royalties.

The EMD Serono Termination Agreement provides that as of May 1, 2014, the Company is responsible for the conduct of all regulatory and commercialization activities in the United States, including the conduct of the post-approval studies mandated by the FDA upon approval of *EGRIFTA®*.

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

In connection with regaining the commercialization rights for *EGRIFTA®* in the United States, the Company retained the services of Ventiv Commercial Services, LLC, or inVentiv Health, to establish and

manage its U.S. operations. The services provided by inVentiv Health include sales force, marketing support, patient communications, regulatory compliance, pharmacovigilance activities, reimbursement and market access. All decisions regarding the commercialization of *EGRIFTA*® are made by the Company.

Post-Approval Commitments

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

- to develop a single vial formulation of *EGRIFTA*® (the development of a new presentation of the same formulation);
- to conduct the Observational Study using *EGRIFTA*®; and
- to conduct the Retinopathy Study using *EGRIFTA*®.

We developed a new presentation of *EGRIFTA*® which complied with the first of the FDA's post-approval requirements and was launched by EMD Serono in October 2012. However manufacturing difficulties caused us to suspend production of new (2 mg/vial) presentation and revert to the original presentation (1 mg/vial) in 2014. We remain committed to supplying a 2 mg/vial presentation of *EGRIFTA*® and have made a proposal in this regard to the FDA. As of the date of this MD&A, our proposal has been approved by the FDA and we are proceeding with the first step, which is to produce R&D batches of the new presentation.

The Observational Study is to evaluate the safety of long-term administration of *EGRIFTA*®, while the Retinopathy Study is to assess whether *EGRIFTA*® increases the incidence or progression of diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat. The Company estimates that completing the Observational Study will cost US$14,000,000 over the next 10 years; whereas the estimated cost of completing the Retinopathy Study is US$13,000,000 over the next 8 years.

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

Credit risk is the risk of a loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations. The Company regularly monitors credit risk exposure and takes steps to mitigate the likelihood of this exposure resulting in losses.

The Company's exposure to credit risk currently relates to accounts receivable with only one customer and derivative financial assets which it manages by dealing only with highly rated Canadian financial institutions. Included in the consolidated statements of financial position are trade receivables of $4,479,000 (2014 - $2,291,000), all of which were aged under 60 days. There was no amount recorded as bad debt expense for the year ended November 30, 2015 (2014 - nil). Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds. The Company invests its available cash in highly liquid fixed income instruments from governmental, paragovernmental and municipal bodies (2015 - nil; 2014 - $2,484,000). As at November 30, 2015, the Company believes it was not exposed to any significant credit risk.

Liquidity Risk

Liquidity risk is the risk that we will not be able to meet our financial obligations as they become due. We manage this 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 designed 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 and the long-term obligation, as at November 30, 2015, are presented in Notes 18, 22, 25 and 28 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. Since the change of functional currency effective December 1, 2015, currency risk is limited to the portion of the Company's business transactions denominated in currencies other than US dollars (2014 - Canadian dollars), primarily cash, sale of goods and expenses incurred in Canadian dollars.

From time to time, we enter into forward foreign exchange contracts. No forward foreign exchange contract was outstanding on November 30, 2015 or November 30, 2014.

Exchange rate fluctuations for foreign currency transactions can cause cash flows as well as amounts recorded in the consolidated statement of comprehensive income (loss) 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 U.S. 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 (loss). We do not believe a sudden change in foreign exchange rates would impair or enhance our ability to pay our Canadian dollar denominated obligations.

The following table presents the significant items in the original currencies exposed to currency risk at the following dates:

-- In thousands

		2015
Cash	CDN$	7,189
Accounts payable and accrued liabilities		(2,312)
Warrant liability		(702)
Total exposure	CDN$	4,175

-- In thousands

		2014
Cash	US$	557
Trade and other receivables		1,997
Accounts payable and accrued liabilities		(4,159)
Provisions		(372)
Long-term obligation		(14,993)
Total exposure	US$	(16,970)

The following exchange rates are those applicable to the following periods and dates:

	November 30, 2015		November 30, 2014	
	Average rate	**Reporting date rate**	**Average rate**	**Reporting date rate**
$ US – CA $	1.2606	1.3353	1.0971	1.1440

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

(In thousands)

	November 30, 2015	November 30, 2014
	$CA	**$US**
(Negative) positive impact	(209)	849

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

Interest Rate Risk

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

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

As at November 30, 2015, we held no short- and long-term bonds. Based on the value of our short- and long-term bonds at November 30, 2014, 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 $20,000; 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 and provisions bear no interest.

Based on the average value of variable interest-bearing cash during the year ended November 30, 2015 which was $7,124,000 ($966,000 in 2014), an assumed 0.5% increase in interest rates during such period would have increased the future cash flows and decreased the net loss by approximately $36,000 ($5,000 in 2014); an assumed decrease of 0.5% would have had an equal but opposite effect.

Fair Values of Financial Instruments

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

Bonds and derivative financial assets and liabilities are stated at estimated fair value, determined by inputs that are primarily based on broker quotes at the reporting date.

Long-term obligation

The obligation is initially recognized at fair value. The valuation model considered the present value of expected payments, discounted using a risk-adjusted discount rate. The significant unobservable input used is the risk-adjusted discount rate of 13.5%.

Share-based payment transactions

The fair value of the employee stock options is measured based on the Black-Scholes valuation model. Measurement inputs include share price on measurement date, exercise price of the instrument, expected volatility (based on weighted average historic volatility adjusted for changes expected due to publicly available information), weighted average expected life of the instruments (based on historical experience and general option holder behaviour), expected dividends, and the risk-free interest rate (based on government bonds). Service and non-market performance conditions attached to the transactions, if any, are not taken into account in determining fair value.

Warrant liability

The warrant liability is recognized at fair value determined using the quoted price or adjusted quoted price in order to consider the bid and ask price in low-market trade activities.

Critical Accounting Estimates

Use of Estimates and Judgment

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

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

Judgments in applying accounting policies

- Revenue

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

- Warrant liability

  The determination of fair value of warrant liability is subject to critical judgments, particularly in establishing the level in the fair value hierarchy for financial instruments and the method used to determine the fair value measurement.

Estimation uncertainties

- Revenue

  Management uses judgment in estimating provisions for sale of goods deductions such as cash discounts, allowances, returns, rebates, chargebacks and distribution fees. Provisions are estimated by management using estimates of revenues by states and by governmental and commercial rebate programs. Management uses judgment in estimating the amount of royalties earned. The amount earned is calculated as a percentage of net sales of its products realized by the Company's licensees. Net sales are provided by licensees or estimated by management using estimates of revenues from product sales of the licensees less estimates for cash discounts, allowances, rebates and chargebacks.

Other areas of judgment and uncertainty relate to the estimation of accruals for clinical trial expenses, the recoverability of inventories, the measurement of intangible assets, long-term obligation and warrant liability.

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

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

Recent changes in accounting standards

New or revised standards and interpretations issued but not yet adopted

The following revised standards and interpretations have been issued but are not yet effective for the Company:

a) IFRS 9, Financial Instruments

   In July, 2014, the IASB issued the complete IFRS 9 (2014), *Financial Instruments*. IFRS 9 (2014) introduces new requirements for the classification and measurement of financial assets. Under IFRS 9 (2014), financial assets are classified and measured based on the business model in which they are held and the characteristics of their contractual cash flows.

   The standard introduces additional changes relating to financial liabilities.

   It also amends the impairment model by introducing a new "expected credit loss" model for calculating impairment.

   IFRS 9 (2014) also includes a new general hedge accounting standard which aligns hedge accounting more closely with risk management. This new standard does not fundamentally change the types of hedging relationships or the requirement to measure and recognize ineffectiveness; however, it will provide more hedging strategies that are used for risk management to qualify for hedge accounting and introduce more judgment to assess the effectiveness of a hedging relationship.

   Special transitional requirements have been set for the application of the new general hedging model.

   The mandatory effective date of IFRS 9 is for annual periods beginning on or after January 1, 2018 and must be applied retrospectively with some exemptions. Early adoption is permitted.

The Company intends to adopt IFRS 9 (2014) in its financial statements for the annual period beginning on December 1, 2018. The extent of the impact of adoption of the standard has not yet been determined.

b) IFRS 15, Revenue from Contracts with Customers

In May 2014, the IASB issued IFRS 15, *Revenue from Contracts with Customers*. The standard contains a single model that applies to contracts with customers and two approaches to recognizing revenue: at a point in time or over time. The model features a contract-based five-step analysis of transactions to determine whether, how much and when revenue is recognized. New estimates and judgmental thresholds have been introduced, which may affect the amount and/or timing of revenue recognized.

The new standard applies to contracts with customers. It does not apply to insurance contracts, financial instruments or lease contracts, which fall in the scope of other IFRS.

IFRS 15 supersedes the following standards: IAS 11, *Construction Contracts*, IAS 18, *Revenue*, IFRIC 13, *Customer Loyalty Programmes*, IFRIC 15, *Agreements for the Construction of Real Estate*, IFRIC 18, *Transfers of Assets from Customers*, and SIC-31, *Revenue - Barter Transactions Involving Advertising Services*.

The core principle of IFRS 15 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services.

IFRS 15 also includes a cohesive set of disclosure requirements that would result in an entity providing comprehensive information about the nature, amount, timing and uncertainty of revenue and cash flows arising from the entity's contracts with customers.

This standard is effective for annual periods beginning on or after January 1, 2018, with earlier adoption permitted. The Company intends to adopt IFRS 15 in its financial statements for the annual period beginning on December 1, 2018. The extent of the impact of adoption of the standard has not yet been determined.

c) Amendments to IAS 1

In December 2014, the IASB issued amendments to IAS 1, *Presentation of Financial Statements*, as part of its major initiative to improve presentation and disclosure in financial reports (the "Disclosure Initiative").

These amendments will not require any significant change to current practice, but should facilitate improved financial statement disclosures.

The amendments are effective for annual periods beginning on or after January 1, 2016. Early adoption is permitted.

The Company will adopt these amendments in its financial statements for the annual period beginning on December 1, 2016. The Company does not expect the amendments to have a material impact on the financial statements.

d) Amendments to IAS 16 and IAS 38, Acceptable Clarification of Methods of Depreciation and Amortization

On May 12, 2014, the IASB issued amendments to IAS 16, *Property, Plant and Equipment*, and IAS 38, *Intangible Assets*.

The amendments made to IAS 16 explicitly state that revenue-based methods of depreciation cannot be used for property, plant and equipment. This is because such methods reflect factors other than the consumption of economic benefits embodied in the asset.

The amendments in IAS 38 introduce a rebuttable presumption that the use of revenue-based amortization methods for intangible assets is inappropriate. This presumption could be overcome only when revenue and consumption of the economic benefits of the intangible asset are highly correlated or when the intangible asset is expressed as a measure of revenue.

The amendments apply prospectively for annual periods beginning on or after January 1, 2016. Early adoption is permitted.

The Company will adopt the amendments to IAS 16 and IAS 38 in its financial statements for the annual period beginning on December 1, 2016. The Company does not expect the amendments to have a material impact on the financial statements.

e) Transfer of assets between an investor and its associate or joint venture

On September 11, 2014, the IASB issued *Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (Amendments to IFRS 10 and IAS 28)*.

The amendments address an acknowledged inconsistency between the requirements in IFRS 10 and those in IAS 28 (2011), in dealing with the sale or contribution of assets between an investor and its associate or joint venture (JV). Specifically, under the existing consolidation standard the parent recognizes the full gain on the loss of control, whereas under the existing guidance on associates and JVs the parent recognizes the gain only to the extent of unrelated investors' interests in the associate or JV.

The main consequence of the amendments is that a full gain/loss is recognized when the assets transferred meet the definition of a "business" under IFRS 3, *Business Combinations*. A partial gain/loss is recognized when the assets transferred do not meet the definition of a business, even if these assets are housed in a subsidiary.

The amendments were to be applied prospectively for annual periods beginning on or after January 1, 2016, however, on December 17, 2015 the IASB decided to defer the effective date for these amendments indefinitely. Early adoption is still permitted.

The Company does not intend to early adopt these amendments in its financial statements for the annual period beginning December 1, 2016, as the effective date for these amendments has been deferred indefinitely.

f) Annual improvements to IFRS (2012-2014) cycles

In September 2014, the IASB issued narrow-scope amendments to a total of four standards as part of its annual improvements process.

Amendments were made to clarify the following in their respective standards:

- Changes in method for disposal under IFRS 5, *Non-current Assets Held for Sale and Discontinued Operations*;
- "Continuing involvement" for servicing contracts and offsetting disclosures in condensed interim financial statements under IFRS 7, *Financial Instruments: Disclosures*;
- Discount rate in a regional market sharing the same currency under IAS 19, *Employee Benefits*;

- Disclosure of information "elsewhere in the interim financial report" under IAS 34, *Interim Financial Reporting.*

The amendments will apply for annual periods beginning on or after January 1, 2016. Early application is permitted, in which case, the related consequential amendments to other IFRS would also apply.

Each of the amendments has its own specific transition requirements.

The Company intends to adopt these amendments in its financial statements for the annual period beginning on December 1, 2016. The Company does not expect the amendments to have a material impact on the financial statements.

Outstanding Share Data

On February 23, 2016, the number of common shares issued and outstanding was 65,615,603 while outstanding options granted under our stock option plan were 2,092,835. There were also 2,300,000 common share purchase warrants and 184,000 broker warrants issued and outstanding. The broker warrants allow for the purchase of 184,000 common shares and 92,000 common share purchase warrants (see note 19) of our consolidated financial statements).

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the annual filings, interim filings or other reports filed under securities legislation is recorded, processed, summarized and reported within the time periods specified in the securities legislation and include controls and procedures designed to ensure that information required to be disclosed is accumulated and communicated to management, including our President and Chief Executive Officer and Vice President, Finance, as appropriate to allow timely decisions regarding required disclosure.

Our management, including our President and Chief Executive Officer and Vice President, Finance, have evaluated, or caused the evaluation of, under their direct supervision, the design and operating effectiveness of the Company's disclosure controls and procedures, as defined under National Instrument 52-109 – Certification of Disclosure in Issuer's Annual and Interim Filings as at November 30, 2015. Based upon that evaluation, our President and Chief Executive Officer and Vice President, Finance, have concluded that, as of November 30, 2015, our disclosure controls and procedures were designed and operating effectively.

Internal Control over Financial Reporting

Our management, including our President and Chief Executive Officer and Vice President, Finance, is responsible for establishing and maintaining adequate internal control over financial reporting, as defined under National Instrument 52-109 – Certification of Disclosure in Issuer's Annual and Interim Filings. Our internal control over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS, as issued by the IASB. Internal controls over financial reporting include those policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets, (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS, as issued by the IASB, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable

assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

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

Our management, including our President and Chief Executive Officer and Vice President, Finance, assessed the design and operating effectiveness of our internal controls over financial reporting as of the end of Fiscal 2015 based on the criteria established in the "*Internal Control - Integrated Framework*" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Management's assessment included an evaluation of the design of our internal controls over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on that assessment, our management, including our President and Chief Executive Officer and Vice President, Finance, concluded that as of November 30, 2015, our internal controls over financial reporting were appropriately designed and operating effectively.

Changes in Internal Control over Financial Reporting

There was no change in our internal controls over financial reporting that occurred during the period from September 1, 2015 to November 30, 2015 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Non-IFRS Financial Measures

Reconciliation of net profit or loss to adjusted earnings before interest, taxes, depreciation and amortization (Adjusted EBITDA)

Adjusted EBITDA is a non-IFRS financial measure. A reconciliation of the Adjusted EBITDA is presented in the table below. We use adjusted financial measures to assess our operating performance. Securities regulations require that companies caution readers that earnings and other measures adjusted to a basis other than IFRS do not have standardized meanings and are unlikely to be comparable to similar measures used by other companies. Accordingly, they should not be considered in isolation. We use Adjusted EBITDA to measure operating performance from one period to the next without the variation caused by certain adjustments that could potentially distort the analysis of trends in our business, and because we believe it provides meaningful information on our financial condition and operating results.

We obtain our Adjusted EBITDA measurement by adding to net profit or loss, finance income and costs, depreciation and amortization, income taxes, as well as federal investment CRA credits recorded in 2014. We also exclude the effects of certain non-monetary transactions recorded, such as share-based compensation for stock option plan and write down of inventories, for our Adjusted EBITDA calculation. We believe it is useful to exclude these items as they are either non-cash expenses, items that cannot be influenced by management in the short term, or items that do not impact core operating performance. Excluding these items does not imply they are necessarily nonrecurring. Share-based compensation costs are a component of employee remuneration and can vary significantly with changes in the market price of the company's shares. In addition, other items that do not impact core operating performance of the company may vary significantly from one period to another. As such, Adjusted EBITDA provides improved continuity with respect to the comparison of our operating results over a period of time. Our method for calculating Adjusted EBITDA may differ from that used by other companies.

Adjusted EBITDA

(in thousands of Canadian dollars)

	Three-month periods ended November 30,		Year ended November 30,		
	2015	2014	**2015**	2014	2013
	$	$	**$**	$	$
Net profit (loss)	**488**	(3,620)	**1,571**	(10,541)	(4,055)
Add (deduct):					
Depreciation and amortization	**502**	524	**1,917**	1,142	121
Finance costs	**399**	1,519	**2,294**	2,080	87
Finance income	**(27)**	(35)	**(289)**	(329)	(541)
Share-based compensation for stock option plan	**46**	20	**148**	81	74
Federal investment tax credits	**0**	0	**0**	(4,110)	0
Income tax expenses	**559**	3	**569**	31	26
Writedown of inventories	**218**	84	**229**	1,071	1,118
Adjusted EBITDA	**2,185**	(1,505)	**6,439**	(10,575)	(3,170)

Risks and Uncertainties

Before you invest in our common shares or Warrants, you should understand the high degree of risk involved and consider carefully the risks and uncertainties described below. The following risks may adversely impact our business, financial condition, operating results and prospects. Additional risks and uncertainties, including those that we do not know about or that we currently believe are immaterial, may also adversely affect our business, financial condition, operating results or prospects. As a result, the trading price of our common shares could decline and you could lose all or part of your investment.

Risks Related to the Commercialization of EGRIFTA®

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

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

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

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

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

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

There can be no assurance that sales of *EGRIFTA*® to customers in the United States will increase in the future. If sales of *EGRIFTA*® to customers decrease, our revenue would be adversely affected which, in turn, could materially adversely affect our business, financial condition and operating results.

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

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

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

We do not own or operate manufacturing facilities for the production of *EGRIFTA*®, tesamorelin or any of our other compounds, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on Bachem and Jubilant to manufacture and supply all of our required raw materials, drug substance and drug product for our commercial sales and for the conduct of the Observational Study and the Retinopathy Study mandated by the FDA. Although potential alternative suppliers and manufacturers have been identified, we have not entered into any agreements with them nor have we qualified these vendors to date and no assurance can be given that such suppliers will be qualified in the future or receive necessary regulatory approvals. The replacement of a third-party manufacturer is time-consuming and costly due to the required validation of their capabilities. The validation process includes an assessment of the capacity of such third-party manufacturer to produce the quantities that we may request from time to time, the manufacturing process and its compliance with current good manufacturing practice, or GMP, regulations. In addition, the third-party manufacturer would have to familiarize itself with our technology. Validation of an additional third-party manufacturer takes at least twenty-four (24) months and could take as long as thirty-six (36) months or more.

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

We do not employ sales or medical service liaison personnel in the United States in connection with the commercialization of *EGRIFTA*® in this territory. We rely on inVentiv Health to provide us with all of the services related to the commercialization of *EGRIFTA*®, namely sales personnel, medical science liaison

personnel, reimbursement specialists and other individuals whose roles and functions pertain to the commercialization of *EGRIFTA*®. In addition, we rely on inVentiv Health for the conduct of the Observational Study and the Retinopathy Study. Although we are aware that there exists other third-party services providers that could provide the same services as inVentiv Health, we have not entered into any agreements with them nor conducted any audit on them. If we need to find another third-party service provider for some or all of the services provided by inVentiv Health, it will be time-consuming and will be disruptive to our business. In addition, there can be no assurance that we will be able to find such third-party service provider if we are unable to agree on the terms and conditions of an agreement with them.

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

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

We may also be subject to distribution disruption and interrupted sales of *EGRIFTA*® in the United States if RxCrossroads:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our ability to grow our revenues from sales of EGRIFTA® *in countries outside of the United States will be limited if we, sanofi, AOP, BL&H or any other future commercial partner do not obtain market approval and reimbursement coverage or experience significant delays in the efforts to obtain market approval and reimbursement coverage for* EGRIFTA®*. Even if approval is obtained, it may take many months before the commercialization of* EGRIFTA® *occurs since amended filings will be required in certain territories to reflect the use of the then-current presentation of* EGRIFTA®*.*

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

Sanofi, has filed marketing authorization applications for *EGRIFTA*® in Brazil and Mexico. In Brazil, one of the most important markets in Latin America, the marketing authorization application has been filed for more than three (3) years. The marketing authorization applications filed by sanofi in Brazil and Mexico are based on the commercialization of *EGRIFTA*® in a 2 mg/vial presentation. We no longer commercialize *EGRIFTA*® in such presentation but rather in a 1 mg/vial presentation. Even if we obtain approval for the commercialization of *EGRIFTA*® in the 2 mg/vial presentation in Brazil, sanofi will need to resubmit a new marketing authorization application for the commercialization of *EGRIFTA*® in the current 1 mg/vial presentation. Similarly in Mexico, although sanofi obtained a decision from COFEPRIS in March 2015 approving *EGRIFTA*® for commercialization in its 2 mg/vial presentation, additional filings are being prepared in order to seek approval for *EGRIFTA*® in its current presentation of 1 mg/vial.

Resubmitting revised marketing authorization applications in Brazil and Mexico could be the equivalent of submitting initial marketing authorization applications and it may take many months before sanofi is able to commercialize *EGRIFTA*® in those countries. If we do not obtain approval of *EGRIFTA*® in Brazil and Mexico or if there are additional delays in obtaining approval, our potential revenue growth could be adversely affected. Revenue growth may also be affected if sanofi does not obtain reimbursement coverage for *EGRIFTA*® or if sanofi decides not to file a marketing authorization application in countries where they believe that it will not be commercially viable to sell *EGRIFTA*®.

In Canada, we have obtained Health Canada's approval of *EGRIFTA*® in its 1 mg/vial presentation and we began commercialization activities in June 2015. To date, *EGRIFTA*® has been added to the list of most of the major private payors and we are working on obtaining reimbursement for *EGRIFTA*® from public payors. Our revenue growth may be affected if we are unable to obtain reimbursement coverage for *EGRIFTA*® from the public payors.

In Europe, we have entered into the AOP Agreement where AOP is responsible for seeking marketing approval for *EGRIFTA*® in the countries covered by the AOP Agreement. To date, AOP is analyzing the file that we submitted to the FDA and has not made any filings with any of the regulatory authorities of those countries.

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

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

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

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

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

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

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

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

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

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

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

The biopharmaceutical and pharmaceutical industries are highly competitive and we must compete with pharmaceutical companies, biotechnology companies, academic and research institutions as well as governmental agencies for the development and commercialization of products, most of which have

substantially greater financial, technical and personnel resources than us. Although we believe that we have currently no direct competitors with an approved product indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, new competitive products could come on the market and we could face indirect competition from other companies developing and/or commercializing metabolic products and/or other products that reduce or eliminate the occurrence of excess abdominal fat. In addition, a company could file an ANDA with the FDA with the aim of selling and marketing a generic version of *EGRIFTA®*.

Risks Related to Research and Development Activities

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

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

We have suspended all significant research and development activities related to our compounds, including TH1173, and the discovery of new peptides until we have sufficient funds to invest in our research and development programs. We may never resume these activities, which could materially adversely affect our long-term growth and could cause us to rely solely on EGRIFTA® *as a revenue-generating asset indefinitely.*

Our portfolio of compounds is very limited and these compounds are at early stages of development. As a result of business plan revisions announced in October 2012, we put on hold the launch of the Phase I clinical program for TH1173 and suspended all significant long-term research and development activities on our compounds and the discovery of new peptides. There is no assurance that we will resume these activities and our long-term growth could be materially adversely affected.

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

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

We have limited human resources to conduct preclinical studies and clinical trials and will have to rely on third-party service providers to conduct our studies and trials and carry out certain data gathering and analyses in the future. inVentiv Health has been retained to conduct the Observational Study and the Retinopathy Study mandated by the FDA. The preclinical, or non-clinical, studies must be conducted in compliance with good laboratory practice, or GLP, regulations. Clinical trials must comply with good clinical practice, or GCP, requirements, which are ethical and scientific quality standards for conducting, recording and reporting clinical trials to assure the integrity of study data and that the rights, safety and wellbeing of trial participants are protected. If our third-party service providers become unavailable for any reason, including as a result of the failure to comply with the rules and regulations governing the conduct of preclinical studies and clinical trials, operational failures such as equipment failures or unplanned facility shutdowns, or damage from any event such as fire, flood, earthquake, business restructuring, labour

dispute or insolvency or, if they fail to perform their contractual obligations pursuant to the terms of our agreements with them, such as failing to perform the testing, compute the data or complete the reports further to the testing, we may incur delays which may be significant in connection with our post-approval commitments with the FDA for *EGRIFTA*® and/or the planned timing of our trials and studies which could adversely affect the timing of the development program of a compound or the filing of an application seeking marketing approval in a jurisdiction where we rely on third-party service providers to make such filing. In addition, where we rely on such third-party service provider to help in answering any questions raised by a regulatory agency during its review of one of our applications, the unavailability of such third-party service provider may adversely affect the timing of the review of an application and could ultimately delay the approval. If the damages to any of our third-party service providers are material, or, for any reason, such providers do not operate in compliance with GLP or GCP regulations or are unable or refuse to perform their contractual obligations, we would need to find alternative third-party service providers.

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

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

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

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

Risks Related to our Intellectual Property

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

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

our proprietary technologies, inventions, improvements and tradenames that are important to the development of our business.

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

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

In Brazil, where we were granted a patent covering the composition of matter for tesamorelin that was set to expire in 2019, we recently became aware that the Brazilian Court of Appeal has issued a split (2-1) decision in which it ruled in favour of the *Instituto National da Propriedade Industrial*, or INPI, the Brazilian patent office, that all pharmaceutical-related patents granted by INPI that were filed between 1995 and 1997 and that were granted a term in excess of 20 years from the filing date will have their terms reduced to 20 years from such filing date. Accordingly, our patent protection on tesamorelin has been reduced to 2016 from 2019.

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

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

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

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

access to our proprietary information and may harm our competitive position.

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

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

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

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

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

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

We have not been served with any notice alleging that we infringe a third-party patent, but there may be issued patents that we are unaware of that our products may infringe, or patents that we believe we do not infringe but ultimately could be found to infringe. If we were to challenge the validity of a competitor's

issued United States patent in a United States court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. We cannot guarantee that a court would find in our favour on questions of infringement and validity. Any finding that we infringe or violate a third-party patent or other intellectual property right could materially adversely affect our business, financial condition and operating results.

Regulatory Risks

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

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

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

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

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

- the federal healthcare program's anti-kickback law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FFDCA and similar laws regulating advertisement and labeling; and

- Non-U.S. and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

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

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

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

If our activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our activities with regard to the commercialization of *EGRIFTA*® in the United States, which could harm the commercial success of *EGRIFTA*® and materially affect our business, financial condition and results of operations. We cannot guarantee that we will be able to mitigate all operational risks. In addition, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws. Because of the far-reaching nature of these laws, we may be required to alter or discontinue

one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on *EGRIFTA®* or manufacturing processes, withdrawal of *EGRIFTA®* from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material and adverse effect on our product sales, business and results of operations.

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

Litigation Risks

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

We rely on sanofi, AOP and BL&H to commercialize and to obtain and maintain regulatory approvals of *EGRIFTA®* in the territories covered under our distribution and licensing agreements with each of them. We also rely on third-party service providers for sales, marketing and distribution activities in the United States and to manufacture *EGRIFTA®* for commercialization and tesamorelin for our clinical trials. Under those agreements, we have assumed certain obligations, undertakings and covenants which, if breached by us and not remedied within the agreed upon periods, could expose us to claims for damages and/or termination of these agreements. If we are unable to meet our obligations under any of our agreements with sanofi, AOP, BL&H and third-party service providers which results in termination of such agreements, this will materially adversely affect our business, financial condition and operating results since we rely on one commercial partner per territory and single third-party service providers, each of whom performing key services for the success of our business plan. In addition, under the terms of the EMD Serono Termination Agreement, we have granted EMD Serono a security interest over all of our tesamorelin-related assets. If we are in breach of the EMD Serono Termination Agreement by failing to meet our payment obligations to EMD Serono, EMD Serono has the right to seize all of those tesamorelin-related assets. Unless we are able to generate sufficient revenues from *EGRIFTA®* or other assets, a breach of the payment provisions under the EMD Serono Termination Agreement by us will have a material adverse effect on our business and could lead to recourses under insolvency laws.

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

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

If a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim and, if the claim is successful, damage awards may be substantial and/or may not be covered, in whole or in part, by our insurance. We may not have sufficient capital resources to pay a

judgment, in which case our creditors could levy against our assets. We may also be obligated to indemnify our commercial partners and third-party service providers as well as make payments to other parties with respect to product liability damages and claims. Defending any product liability claims, or indemnifying others against those claims, could require us to expend significant financial and managerial resources and would have a material adverse effect on our reputation and our financial condition.

Geo-political Risks

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

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

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

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

Other Risks Related to our Business

We have contracted a debt under the EMD Serono Termination Agreement and collateralized most of our assets. We may not be able to sell the collateralized assets if we need capital and our breach of the payment obligations under the EMD Serono Termination Agreement could allow EMD Serono to seize those assets, all of which would have a material adverse effect on our business.

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

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

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

We generated a profit from our operation in Fiscal 2015 but there can be no guarantee that we will achieve consistent profitability.

We generated a profit of $1.6 million in Fiscal 2015. Our profitability will mainly depend on our capacity to maintain the commercialization of *EGRIFTA*® successfully in the United States through a low-cost and effective distribution network, the recruitment and retention of talented personnel by inVentiv Health, the deployment of an effective marketing campaign and through continued reimbursement coverage for *EGRIFTA*® under U.S. Medicare and Medicaid programs and under private-health insurers programs.

There is no guarantee that we or our commercial partners will succeed in commercializing *EGRIFTA*® and that *EGRIFTA*® and our product candidates will ever receive approval for commercialization in any jurisdictions and outside of the United States and Canada. In addition, if revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, financial condition and operating results could be materially adversely affected and we may never sustain profitability.

We may require additional funding and may not be able to raise the capital necessary to fund all or part of our capital requirements, including resuming the research and development programs of our compounds and their commercialization.

We may need financing in order to fund all or part of our capital requirements to sustain our growth, to resume research and development of new and current compounds, to conduct clinical programs, to develop our marketing and commercial capabilities and to meet our compliance obligations with various rules and regulations to which we are subject. However, the market conditions or our business performance may prevent us from having access to the public market in the future at the times or in the amounts necessary. Therefore, there can be no guarantee that we will be able to continue to raise additional equity capital by way of public or private equity offerings in the future. In such a case, we would have to use other means of financing, such as issuing debt instruments or entering into private financing or credit agreements, the terms and conditions of which may not be favorable to us. In addition, the issuance and sale of substantial amounts of equity, or other securities, or the perception that such issuances and sales may occur could adversely affect the market price of our common shares.

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

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

adversely affect our business. Our third-party service provider, inVentiv Health, has hired sales representatives and other qualified individuals to assist us with the commercialization of *EGRIFTA*® in the United States. Although these individuals are not our employees, the loss of any of those individuals and the inability of inVentiv Health to attract and retain these individuals could have a material adverse effect on the commercialization of *EGRIFTA*® and, accordingly, our business, financial condition and operating results. In addition, it could adversely affect the market price of our common shares.

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

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

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

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

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

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

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

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

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

Risks Related to our Common Shares

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

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

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

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

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

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

Our shareholder rights plan, the EMD Serono Termination Agreement and certain Canadian laws could delay or deter a change of control.

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

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

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

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