



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, 2014. 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, 2014, or Fiscal 2014, with the twelve-month period ended November 30 2013, or Fiscal 2013. 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 25, 2015 and should be read in conjunction with the audited consolidated financial statements and the notes thereto. All monetary amounts set forth in this MD&A are expressed in Canadian dollars, except where otherwise indicated. References to \$ and C\$ are to Canadian dollars and references to US\$ are to U.S. dollars.

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

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 it is used in that country 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 belief and assumptions and on information currently available to our management. You can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "outlook", "believe", "plan", "envisage", "anticipate", "expect" and "estimate", or the negatives of these terms, or variations of them. The forward-looking statements contained in this MD&A include, but are not limited to, statements regarding the successful commercialization of *EGRIFTA*[™] in the United States, the launch of *EGRIFTA*[™] in Canada, the finding of a commercial partner and the entering into an agreement with such commercial partner to distribute *EGRIFTA*[™] in Europe and the issuance of a decision of the Mexican regulatory authority regarding *EGRIFTA*[™].

Forward-looking statements are based upon a number of assumptions and include, but are not limited to, the following: *EGRIFTA*[™] will receive approvals in various territories outside of the United States, no additional clinical studies will be required by regulatory authorities outside of the United States to obtain these regulatory approvals, *EGRIFTA*[™] will be accepted by the marketplace in territories outside of the United States and will be on the list of reimbursed drugs by third-party payors in these territories, the relationships with our commercial partner 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, our marketing campaign in the United States will allow us to increase the patient base for *EGRIFTA*[™] and to thereby build a profitable base of operations, we will have continuous supply of *EGRIFTA*[™], and we will be able to find and enter into an agreement with a commercial partner to distribute *EGRIFTA*[™] in Europe.

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 is, to date, the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

The primary focus of our 2015 business plan is the successful commercialization of *EGRIFTA*[™] in the United States and to thereby build a profitable base of operations for the Company. Other objectives include launching *EGRIFTA*[™] in the Canadian market and securing a commercial partner to distribute *EGRIFTA*[™] in Europe. We also expect to receive a regulatory decision concerning the approval of *EGRIFTA*[™] in Mexico.

The following paragraphs describe the key developments in our business in 2014 and provide a context for the business plan objectives listed above.

United States Market

From January 10, 2011 until April 30, 2014, *EGRIFTA*[™] was marketed in the United States by EMD Serono, Inc., or EMD Serono, pursuant to a collaboration and licensing agreement dated October 28, 2008, as amended, or EMD Serono Agreement. On December 13, 2013, we entered into an agreement with EMD Serono, or EMD Serono Termination Agreement, in order to regain the commercialization rights to *EGRIFTA*[™] in the United States. The transaction closed on May 1, 2014 and from that date on we are solely responsible for the commercialization of *EGRIFTA*[™] in the United States.

The EMD Serono Termination Agreement paved the way for a fundamental shift in our business plan. We are moving forward in the US market under a specialty pharmaceutical business model that is solely focused on our own product. New messaging is aimed directly at elevating the importance of treating excess abdominal fat in HIV-infected patients with lipodystrophy, for patients, health-care providers and third-party payors. We have also revised pricing and we are actively seeking broader reimbursement coverage. Our ultimate goal is to increase the patient base, revenues and cash flows in the United States in order to establish a profitable base of operations for the Company.

Our exclusive distributor in the United States is Rx Acquisition Company, or RxCrossroads. Rx Crossroads, which is licensed to distribute drug products in all of the American states, re-sells *EGRIFTA*[™] to our authorized wholesalers and ships the product directly to specialty pharmacies that belong to our network of approved specialty pharmacies throughout the United States. In addition to filling orders, RxCrossroads provides warehousing and logistical support services including inventory control, account management, customer support and product return management.

Our marketing partner in the US is Ventiv Commercial Services, LLC, or inVentiv Health, a recognized provider of commercial, clinical and consulting services around the globe. We have entered into a master service agreement with inVentiv Health, or inVentiv Agreement, pursuant to which inVentiv Health is

providing us with various services in connection with the commercialization of *EGRIFTA*[™] in the United States. Initially, inVentiv Health helped us to establish the infrastructure needed to effectively market *EGRIFTA*[™] including negotiation support with wholesalers, specialty pharmacies and other entities involved in the commercialization and distribution activities. They also helped us early on to develop an appropriate series of *EGRIFTA*[™] marketing tools. With the commercial foundation now in place, the ongoing services provided by inVentiv Health include provision of a sales force fully dedicated to *EGRIFTA*[™], as well as other staff solely assigned to our business in reimbursement and communications with patients and health-care professionals. The communications aspect includes a call center, *EGRIFTA Assist*[™], which guides physicians and patients through the process of initiating treatment under reimbursement. This process, which can be complex and time-consuming, begins with a statement of medical necessity and concludes with the final reimbursement decision. inVentiv Health also assists us with pharmacovigilance activities and with other regulatory matters that may arise.

Regaining the US commercialization rights to *EGRIFTA*[™] on May 1, 2014 also had a significant impact on our financial reporting. Our revenues now include the full proceeds of sales of *EGRIFTA*[™] to RxCrossroads and our expenses encompass all of the related marketing and distribution expenses, which were previously incurred by EMD Serono. We also have new financial obligations in the form of a long-term obligation and royalties payable to EMD Serono.

Technical issues and other disruptive events at our third-party manufacturer caused us to suspend manufacturing of *EGRIFTA*[™] in its 2 mg/vial presentation on February 14, 2014 and there was no inventory of finished goods available at that time. In order to replenish inventory and resume shipping as soon as possible, we reverted to the initial presentation of *EGRIFTA*[™] (1 mg/vial), which was supplied to us without any commercial delays during the first two years of marketing the product. We began re-filling the supply chain in early September 2014 and supplied our first patient in mid-September. By late October *EGRIFTA*[™] was again widely available to patients. With approximately four months' supply as of the date of this MD&A, we are producing sufficient quantities of *EGRIFTA*[™] to meet both current and anticipated market demand and maintain adequate inventory levels.

From when *EGRIFTA*[™] was reintroduced to the market in mid-September, until the end of Fiscal 2014, sales met expectations by growing to reach \$2.7 million. We experienced a high recapture rate of previous patients and broad acceptance by third-party payors. Our sales force, which started with two representatives in September 2014, was increased to a full complement of ten representatives in early February 2015. Because of the time-consuming process that must be followed in order to initiate treatment under reimbursement, the impact of the additional sales representatives on revenue will only begin to be felt in our second quarter. Even without the benefit of our full sales force and based on the sales data currently available, we expect that our sales for the first quarter of fiscal 2015 will be approximately 70% higher than in the fourth quarter of Fiscal 2014.

Canadian Market

On April 30, 2014, we announced that we received a notice of compliance (regulatory approval) for *EGRIFTA*[™] in the 2 mg/vial presentation from Health Canada. We also announced that as of the same date, we entered into a termination agreement with Actelion Pharmaceuticals Canada Inc. (our former commercial partner for the Canadian market), pursuant to which we regained all of the rights to *EGRIFTA*[™] in Canada. We have filed a Supplemental New Drug Submission seeking approval to commercialize *EGRIFTA*[™] in its 1 mg/vial presentation in Canada and we are awaiting a response from Health Canada. In the meantime we have applied for a license required to operate in Canada and are preparing for the market launch, which will initially focus on reimbursement by private drug plans, as opposed to public payors. We also will be 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.

European Market

In Europe we are actively seeking a commercial partner to distribute *EGRIFTA*[™], through Named Patient Sales Programs in the short term and by pursuing marketing authorizations on a country-by-country basis in the longer term.

Latin America and Middle East

There were few significant developments in Fiscal 2014 with respect to the markets served by sanofi, our commercial partner in Latin America, Africa and the Middle East. Within the sanofi territory, the largest potential markets for *EGRIFTA*[™] are Mexico and Brazil, and sanofi is focusing its efforts on these two markets.

In Mexico, sanofi is currently responding to a series of administrative questions raised by the Mexican regulatory authority and sanofi has informed us that a decision could be reached around mid-year.

In Brazil, the regulatory process had slowed in 2013 due to technical deficiencies identified by the Brazilian National Health Surveillance Agency, or ANVISA. These issues were resolved in Fiscal 2014, which allowed the marketing authorization process to resume. However, based on the information presently available, we are not able to predict timelines for a decision from the Brazilian authorities.

It should also be noted that in both Mexico and Brazil, regulators have been asked to assess the 2 mg/vial presentation of *EGRIFTA*[™], which is no longer being supplied. As such, in the event that approvals are granted by the authorities in these countries, sanofi will need to take the necessary steps to seek approval of the then-current presentation of the product.

In Israel the Minister of Health cancelled the approval for registration of *EGRIFTA*[™] after a review of the data on file and after considering that the registration process was halted in Europe. sanofi has advised us that it is assessing the opportunity to appeal the Israeli decision.

Previous applications for *EGRIFTA*[™] approval in Argentina, Colombia and Venezuela have been abandoned by sanofi.

Research and Development

We are currently conducting two Phase 4 clinical trials with *EGRIFTA*[™] in the United States in order to fulfil post approval commitments made to the FDA. The first trial is a long-term observational safety study, or Observational Study, and the second 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, or Retinopathy Study. With the closing of the EMD Serono Termination Agreement on May 1, 2014, we assumed responsibility for all of the costs associated with these two studies. Prior to May 1, 2014, we were responsible for 50% of the cost of the Observational Study and all of the direct costs of the Retinopathy Study. Further information on the expenses related to the conduct of these two studies can be found under "R&D Expenses" below.

Our other research and development activities in Fiscal 2014 were largely related to resolving the manufacturing problems experienced by our third-party supplier with *EGRIFTA*[™] in its 2 mg/vial presentation. As described above, we resumed manufacturing in June using the initial presentation of *EGRIFTA*[™] (1 mg/vial), which had proven to be a reliable source of supply in the past. We remain committed to reverting to a 2 mg/vial presentation for *EGRIFTA*[™] and have made a proposal in this regard to the FDA. As of the date of this MD&A, we are waiting for feedback from the FDA on our proposal.

Liquidity

With the resumption of *EGRIFTA*[™] shipments in the fourth quarter of Fiscal 2014, we expect our revenue stream to grow in Fiscal 2015. In addition, in light of the delay in the commercialization of *EGRIFTA*[™] caused by the supply problems we incurred in 2014, we restructured the amount and payment terms of the initial US \$4,000,000 payment due May 1, 2015 for the long-term obligation. Under the new terms, the payment will total US \$4,167,808 and will be paid in three unequal installments with the final payment due on November 30, 2015. Given these more favorable conditions, we believe that we will be able to adequately fund our operations and meet our cash flow requirements for the next twelve months.

However, in the future this determination could be impacted if we encounter a significant shortfall in expected revenues. See “Liquidity and Capital Resources” below.

Other Developments

On February 3, 2015 we announced the filing of a Form 15 with the Securities and Exchange Commission, or SEC, under the *Securities Exchange Act of 1934*, as amended, or the Exchange Act, to suspend our reporting obligations under Section 15(d) of the Exchange Act. The Company expects that the termination of its duty to file reports will become effective 90 days after the filing of this Form 15 with the SEC. However, as a result of the filing, our reporting obligations with the SEC, including our obligation to file annual reports on Form 20-F and reports on Form 6-K were suspended immediately.

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. All of the Company’s filings can be found under the Company’s profile on SEDAR at www.sedar.com.

On February 24, 2012, the Superior Court of Québec authorized 121851 Canada Inc. to institute a class action against the Company, a director and a former executive officer and on March 20, 2012, we filed a motion seeking permission to appeal this judgement with the Court of Appeal of Québec. The hearing took place on January 24, 2013 and our motion was dismissed by the Court on July 17, 2013. An application for leave to appeal the decision issued by the Court of Appeal was filed in November 2013 with the Supreme Court of Canada. Such application was approved by the Supreme Court of Canada and the hearing occurred on December 1, 2014. As of the date of this MD&A, no decision has been rendered by the Supreme Court. Further information on the class action can be found below under “Contingent Liability”.

On June 9, 2014, the United States Patent and Trademark Office issued a patent term extension certificate for tesamorelin. As a result, the term of U.S. patent 5,861,379 was extended by five years and is now set to expire in May 2020.

Selected Annual Information

Years ended November 30 (in thousands of Canadian dollars, except per share amounts)	2014	2013	2012
Revenue	\$6,732	\$7,553	\$13,567
Selling and market development expenses	\$6,963	\$250	\$858
Restructuring costs	\$--	\$(3,111)	\$10,702
Net loss	\$(10,541)	\$(4,055)	\$(13,940)
Basic and diluted loss per share	\$(0.17)	\$(0.07)	\$(0.23)
Total assets	\$32,654	\$24,844	\$36,332
Long-term obligation	\$17,152	\$--	\$--

The variation in revenue from 2012 to 2013 was due to declines in net sales, upfront and milestone payments, and royalties. The decline in net sales was due to lower shipments to EMD Serono and a lower

selling price following the transition from supplying *EGRIFTA*[™] in the 1 mg/vial presentation to the 2mg/vial presentation. Revenue from upfront and milestone payments was lower due to an adjustment made in 2013 to the amortization rate used to take the EMD Serono upfront payment into revenue. Revenue from royalties was lower principally because the 2012 royalties were for a 14-month period compared to a 12-month period in 2013. The supply shortage experienced in the fourth quarter of 2013 also had a negative effect on royalties in that period.

The variation in revenue from 2013 to 2014 is attributable to changes in our business model as a result of the EMD Serono Termination Agreement and the supply shortage experienced in 2014. For more detail on these factors, see the discussion on operating results below.

The variation in net loss from 2012 to 2013 was principally due to restructuring costs and the revenue decline described above. The net loss in 2012 was impacted by \$10,702,000 of restructuring costs while the net loss in 2013 benefitted from a partial recovery of restructuring costs in the amount of \$3,111,000.

The increase in net loss from 2013 to 2014 was principally due to significantly higher selling and market development expenses in 2014 as well as the revenue decline described above, partially offset by an increase in net finance income resulting from a Federal investment tax credit refund. For more detail on these factors, see the discussion on operating results below.

The decrease in total assets from 2012 to 2013 is principally due to cash flows used in operations. The increase in total assets from 2013 to 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 in 2014 is in relation to the early termination fee included in the EMD Serono Termination Agreement. See Contractual Obligations below.

Operating Results - twelve months ended November 30, 2014 compared to twelve months ended November 30, 2013

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. From May 1, 2014, our revenues are essentially net sales of *EGRIFTA*[™] to our exclusive distributor, RxCrossroads, which were nil from May 1 to August 31, 2014 due to the supply shortage we experienced. Consolidated revenue for the twelve months ended November 30, 2014 was \$6,732,000 compared to \$7,553,000 Fiscal 2013.

(in thousands of Canadian dollars)	2014	2013
Net sales	\$3,332	\$2,544
Upfront and milestone payments	\$2,770	\$1,710
Royalties and license fees	\$630	\$3,299
Revenue	\$6,732	\$7,553

Revenue generated from net sales in Fiscal 2014 included \$2,657,000 of sales to RxCrossroads (all of which occurred in the fourth quarter of the fiscal year) and \$675,000 of sales to EMD Serono. In Fiscal 2013, net sales amounted to \$2,544,000, which were solely sales to EMD Serono.

Amortization of an upfront payment in Fiscal 2014 was \$2,770,000 compared to \$1,710,000 Fiscal 2013. 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.

Royalties in Fiscal 2014 were \$630,000 compared to \$3,299,000 in Fiscal 2013. Prior to May 1, 2014, royalties from EMD Serono were adversely affected by the previously described *EGRIFTA*[™] supply shortage and, with the closing of the EMD Serono Termination Agreement on that date, Rx Crossroads is now our exclusive distributor of *EGRIFTA*[™] in the United States and we no longer receive royalties from EMD Serono.

Cost of Sales

For the twelve months ended November 30, 2014, the cost of sales was \$2,455,000 compared to \$3,711,000 in Fiscal 2013. The cost of sales is made up of cost of goods sold and unallocated production costs. The cost of goods sold component in 2014 amounted to \$991,000 compared to \$2,262,000 in the prior year, reflecting lower volumes. Unallocated production costs were \$1,464,000 in Fiscal 2014 compared to \$1,449,000 in the prior year. In Fiscal 2014, unallocated production costs were essentially due to inventory write-downs of \$1,071,000, unabsorbed fixed costs and costs associated with changing over from the 2 mg/vial to the 1 mg/vial presentation of *EGRIFTA*[™]. In Fiscal 2013, the unallocated manufacturing costs were principally inventory write downs and other costs associated with the manufacturing problems experienced by our third-party manufacturer.

R&D Expenses

R&D expenses, net of tax credits, amounted to \$5,617,000 in the twelve months ended November 30, 2014 compared to \$7,371,000 in Fiscal 2013. R&D expenses are principally expenses for the two Phase 4 clinical trials currently being conducted. The first trial is the Observational Study and the second study is the Retinopathy Study. With the closing of the EMD Serono Termination Agreement on May 1, 2014, we assumed responsibility for all of the costs associated with these two studies. Prior to May 1, 2014, we were responsible for 50% of the cost of the Observational Study and all of the direct costs of the Retinopathy Study.

Our costs associated with the Retinopathy Study amounted to \$2,686,000 in Fiscal 2014 compared to \$3,005,000 in the prior year; while the costs associated with the Observational Study were \$1,018,000 in Fiscal 2014 compared to \$654,000 in the prior year.

R&D expenses in 2013 also included approximately \$1,500,000 of costs related to our efforts to improve the lyophilization cycle used in the manufacture of *EGRIFTA*[™]. In both Fiscal 2014 and Fiscal 2013, the remaining R&D expenses were essentially staffing, regulatory expenses and patent fees.

Selling and Market Development Expenses

Selling and market development expenses amounted to \$6,963,000 for the twelve months ended November 30, 2014, compared to \$250,000 in Fiscal 2013. The significant increase in expenses in Fiscal 2014 is due to our regaining the commercialization rights for *EGRIFTA*[™] in the United States market and the resulting changes to our business model. 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, representing seven months, amounted to \$1,009,000 in Fiscal 2014. Initial organization building and marketing initiatives in 2014 amounted to \$1,823,000 while ongoing commercialization expenses were \$4,131,000.

General and Administrative Expenses

General and administrative expenses amounted to \$4,566,000 in the twelve months ended November 30, 2014 compared to \$3,815,000 in Fiscal 2013. The increase in expenses in Fiscal 2014 is largely temporary in nature and is principally due to professional fees.

Restructuring Costs

There were no restructuring costs in Fiscal 2014. In Fiscal 2013, we reversed previously accrued restructuring costs resulting in a gain of \$3,111,000. This was largely as a result of the lease amendment agreement entered into in April 2013, which eliminated the remaining \$3,133,000 of an onerous lease provision.

Net Financial Income

Finance income for the twelve months ended November 30, 2014 was \$329,000 compared to \$541,000 in Fiscal 2013. Interest revenue has decreased due to a gradual decline in the portfolio size as investments were liquidated to fund operations.

Finance costs for the twelve months ended November 30, 2014 were \$2,080,000 compared to \$87,000 in Fiscal 2013. Finance costs in Fiscal 2014 included \$1,203,000 of accretion expense on the \$15,900,000 long-term obligation owed to EMD Serono under the terms of the EMD Serono Termination Agreement, as well as an unrealized foreign currency loss on the long-term obligation of \$714,000 (note 19 of our consolidated financial statements).

Federal Investment Tax Credits

In the second quarter of fiscal 2014, the Company settled a dispute with the Canada Revenue Agency in respect of an investment tax credit refund claim related to its 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 in interest less associated fees).

Net Loss

Taking into account the revenue and expense variations described above, we recorded a net loss of \$10,541,000 or \$0.17 per share in the twelve months ended November 30, 2014 compared to a net loss of \$4,055,000 or \$0.07 per share in Fiscal 2013.

Fourth Quarter Comparison

Consolidated revenue for the three months ended November 30, 2014 amounted to \$2,663,000 compared to \$1,246,000 for the comparable period of 2013.

(in thousands of Canadian dollars)	2014	2013
Net sales	\$2,657	\$311
Upfront and milestone payments	\$--	\$320
Royalties and license fees	\$6	\$615
Revenue	\$2,663	\$1,246

Revenue generated from net sales for the three months ended November 30, 2014 was \$2,657,000 compared to \$311,000 in the comparable period in Fiscal 2013. With the closing of the EMD Serono Termination Agreement on May 1, 2014, the U.S. commercialization rights for *EGRIFTA*[™] reverted to us

and the \$2,657,000 of net sales in the fourth quarter of Fiscal 2014 represented sales to RxCrossroads, our exclusive distributor in the United States. The \$311,000 recorded as sale of goods in the fourth quarter of Fiscal 2013 represented sales to EMD Serono for re-sale.

Revenue related to the amortization of the initial payment received upon the closing of the EMD Serono Agreement was nil for the three-month period ended November 30, 2014, compared to \$320,000 in the comparable period of Fiscal 2013. 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.

Royalties were \$6,000 in the three months ended November 30, 2014, compared to \$615,000 in the comparable period of Fiscal 2013, which came largely from EMD Serono. With the closing of the EMD Serono Termination Agreement on May 1, 2014, EMD Serono is no longer selling *EGRIFTA*[™] and is therefore no longer obligated to pay royalties to the Company.

The cost of sales for the three months ended November 30, 2014 was \$604,000 compared to \$1,155,000 in the comparable period of Fiscal 2013. The cost of sales is made up of cost of goods sold and unallocated production costs. The cost of goods sold component for the three months ended November 30, 2014 was \$391,000 compared to \$322,000 in the comparable period of Fiscal 2013. Unallocated production costs were \$213,000 in the three months ended November 30, 2014 compared to \$833,000 in the comparable period of 2013. The higher unallocated production costs in 2013 were mainly due to inventory write downs and other costs associated with the manufacturing problems experienced at that time.

R&D expenses, net of tax credits, amounted to \$1,164,000 in the three months ended November 30, 2014 compared to \$1,547,000 in the comparable period of Fiscal 2013. R&D expenses are principally expenses for the two Phase 4 clinical trials currently being conducted. The first trial is the Observational Study and the second study is the Retinopathy Study. With the closing of the EMD Serono Termination Agreement on May 1, 2014, we assumed responsibility for all of the costs associated with these two studies. Prior to May 1, 2014, we were responsible for 50% of the cost of the Observational Study and all of the direct costs of the Retinopathy Study.

Our costs associated with the Retinopathy Study amounted to \$480,000 in the three months ended November 30, 2014 compared to \$893,000 in the comparable period of Fiscal 2013; while the costs associated with the Observational Study were \$310,000 in the three months ended November 30, 2014 compared to \$133,000 in the comparable period of Fiscal 2013.

Selling and market development expenses amounted to \$1,716,000 for the three months ended November 30, 2014, compared to \$60,000 for the comparable period of Fiscal 2013. The significant increase in expenses in 2014 is due to our regaining the commercialization rights for *EGRIFTA*[™] in the United States market and the resulting changes to our business model. 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 \$433,000 in the three months ended November 30, 2014.

General and administrative expenses amounted to \$1,312,000 in the three months ended November 30, 2014 compared to \$1,201,000 in the comparable period of Fiscal 2013. The increase in expenses in 2014 is largely temporary in nature and is principally due to professional fees.

There were no restructuring costs incurred in the three months ended November 30, 2014. In the comparable period of Fiscal 2013, there was a recovery of previously expensed restructuring costs amounting to \$18,000.

The loss from operating activities for the three months ended November 30, 2014 was \$2,133,000 compared to \$2,699,000 in the comparable period of Fiscal 2013.

Finance income for the three months ended November 30, 2014 was \$35,000 compared to \$108,000 in the comparable period of Fiscal 2013. 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, 2014 were \$1,519,000 compared to \$8,000 in the comparable period of Fiscal 2013. Finance costs in Fiscal 2014 included \$525,000 of accretion expense on the long-term obligation as well as an unrealized foreign currency loss on the long-term obligation of \$835,000.

Net financial income for the three months ended November 30, 2014 was a loss of 1,484,000 compared to income of \$100,000 in the comparable period of Fiscal 2013.

Taking into account the revenue and expense variations described above, we recorded a net loss of \$3,620,000 or \$0.06 per share in the three months ended November 30, 2014 compared to a net loss of \$2,598,000 or \$0.04 per share in the comparable period of Fiscal 2013.

In the three months ended November 30, 2014, the use of cash in operating activities amounted to \$2,416,000 compared to \$1,404,000 in the comparable period of Fiscal 2013.

Quarterly Financial Information

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

(In thousands of dollars, except per share amounts)

	2014				2013			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Net sales	\$2,657	\$--	\$--	\$675	\$311	\$786	\$996	\$451
Upfront and milestone payments	\$--	\$--	\$2,450	\$320	\$320	\$463	\$463	\$464
Royalties and license fees	\$6	\$4	\$(57)	\$677	\$615	\$928	\$872	\$884
Revenue	\$2,663	\$4	\$2,393	\$1,672	\$1,246	\$2,177	\$2,331	\$1,799
Net (loss) profit	\$(3,620)	\$(4,394)	\$1,007	\$(3,534)	\$(2,598)	\$(1,935)	\$(1,382)	\$1,860
Basic and diluted (loss) profit per share	\$(0.06)	\$(0.07)	\$0.02	\$(0.06)	\$(0.04)	\$(0.03)	\$(0.02)	\$0.03

Revenue from net sales in the second and third quarters of 2014 was nil due to a lack of inventory following the suspension of *EGRIFTA*[™] manufacturing on February 14, 2014. With the closing of the EMD Serono Termination Agreement on May 1, 2014, the U.S. commercialization rights for *EGRIFTA*[™] reverted to us and the \$2,657,000 of net sales in the fourth quarter of Fiscal 2014 represented sales to RxCrossroads. Net sales in the prior quarters represented lower margin sales to EMD Serono for re-sale.

Revenue generated from net sales declined in Fiscal 2013, reflecting lower shipments to EMD Serono and a lower selling price. The lower level of shipments was largely due to reductions in EMD Serono's inventory as well as to a supply shortage, which occurred in the fourth quarter as a result of the

manufacturing problems encountered earlier in the year. The lower selling price in 2013 was the result of the introduction of the 2 mg/vial presentation of *EGRIFTA*[™] in October 2012.

With the closing of the EMD Serono Termination Agreement on May 1, 2014, all of the \$2,238,000 unamortized balance of the initial payment was recognized as revenue in the second quarter of 2014.

The lack of *EGRIFTA*[™] shipments in the second quarter of 2014 had a direct impact on royalties, which were almost entirely derived from the sales of *EGRIFTA*[™] by EMD Serono at the time.

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.

The net profit in the first quarter of 2013 resulted from the elimination of an onerous lease provision in the amount of \$3,093,000, which was no longer required following the signing of an amended lease agreement with our landlord.

Liquidity and Capital Resources

Our objective in managing capital is to ensure a sufficient liquidity position to finance our business activities. Prior to Fiscal 2011, we funded our activities by relying primarily on public offerings of common shares in Canada and private placements of our common shares as well as on up-front payments and milestone payments primarily associated with the EMD Serono Agreement. 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 (note 19 of our consolidated financial statements). In light of the delay in the commercialization of *EGRIFTA*[™] caused by the supply problems discussed above, 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 will total US \$4,167,808 (previously US \$4,000,000) and will be 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. (See “Contractual Obligations” below and note 32 of our consolidated financial statements).

Since the repatriation of *EGRIFTA*[™] on May 1, 2014, the Company’s ability to generate revenue is solely based on the commercialization of *EGRIFTA*[™] in the United States.

During the last fiscal year, the Company experienced manufacturing difficulties at its third-party manufacturer, which led to shortages of *EGRIFTA*[™] and negatively impacted sales and operating results. The Company ceased manufacturing and there was no inventory of finished goods available. A plan was developed based on reverting to the initial presentation of *EGRIFTA*[™] (1 mg/ vial), which was supplied without any commercial delays during the first two years of marketing the product. In early September 2014, shipments of *EGRIFTA*[™] began using the 1 mg/vial presentation, allowing the Company to resume revenue generation and replenish its inventories.

The Company believes that it will be able to adequately fund its operations and meet its cash flow requirements for the next twelve months. However, in the future this determination could be impacted if it encounters a significant shortfall in expected revenues.

For the twelve months ended November 30, 2014, the use of cash in operating activities was \$8,039,000 compared to \$7,744,000 in Fiscal 2013. The impact of the higher net loss on the use of cash in Fiscal 2014 was largely offset by changes in operating assets and liabilities. Trade and other receivables at November 30, 2014 were \$1,870,000 higher than they were at the end of Fiscal 2013; while accounts payable and accrued liabilities in 2014 were \$3,842,000 higher than they were in 2013. These working

capital fluctuations occurred in the ordinary course of business and reflect the changes in the Company's business model following the closing of the EMD Serono Termination agreement on May 1, 2014.

As a result of the EMD Serono Termination Agreement, as at November 30, 2014 the Company had a long-term obligation in the amount of \$17,152,000 (See "Contractual Obligations – EMD Serono Termination Agreement" below).

The Company's share purchase plan, or Plan, was discontinued in March 2012 and consequently no common share subscriptions were received in connection with the Plan in Fiscal 2014 and Fiscal 2013.

No stock options were exercised in Fiscal 2014 or Fiscal 2013.

As at November 30, 2014, cash and bonds amounted to \$3,178,000 compared to cash and bonds of \$12,353,000 at the end of Fiscal 2013. We invest our available cash in highly liquid fixed income instruments from governmental, municipal and paragonovernmental bodies (\$2,484,000 November 30, 2014).

In the second quarter of Fiscal 2014, the Company terminated its \$1,800,000 revolving credit facility.

Contractual Obligations

Commitments

The following table lists as at November 30, 2014 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	\$22,880	\$4,576	\$18,304	\$--
Operating Lease Obligations	\$1,227	\$170	\$917	\$140
Total	\$24,107	\$4,746	\$19,221	\$140

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, 2014, we had outstanding purchase orders and minimum payments required under these agreements amounting to \$3,782,000 (\$3,128,000 in 2013) 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 will total US \$4,167,808 (previously US

\$4,000,000) and will be 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, bringing the early termination fee to US \$20,167,808.

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 of the Company within eighteen (18) months of May 1, 2014, EMD Serono has the option to accelerate the full payment of the early termination fee and to seek the payment of an amount intended to equal the net present value of the maximum future undisclosed royalties. If such change of control occurs 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 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, we are waiting for feedback from the FDA on our proposal.

The Observational Study is to evaluate the safety of long-term administration of *EGRIFTA*[™] and is in the recruitment phase. With the closing of the EMD Serono Termination Agreement, we are now responsible for all of the cost of this study and estimate that this will amount to an average of US \$2,600,000 per year, over a fifteen-year period. Expenditures to date amounted to \$2,997,000.

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

FDA-approved protocol for the trial calls for patients to inject themselves daily with either *EGRIFTA*[™] or placebo over a three-year treatment period. We estimate that the trial could cost approximately US \$20,000,000. Expenditures to date amounted to \$7,192,000.

Contingent Liability

A motion to authorize the institution of a class action was originally filed in July 2010 in the Superior Court of Québec, District of Montreal, entitled 121851 Canada Inc. v. Theratechnologies Inc. et al., Number 500-06-000515-102. The complaint alleged that the Company, a director and a former executive officer violated the secondary market liability provisions of the *Securities Act* (Québec) by failing to disclose a material change relating to the administration of *EGRIFTA*[™]. The plaintiff sought damages on behalf of a class of persons who were shareholders at May 21, 2010 and who sold their common shares on May 25 or 26, 2010. On February 24, 2012, the Superior Court of Québec authorized 121851 Canada Inc. to institute a class action against the Company, a director and a former executive officer. On March 20, 2012, we filed a motion seeking permission to appeal this judgement with the Court of Appeal of Québec, District of Montreal, Number 500-09-022519-128, and the hearing took place on January 24, 2013. Our motion was dismissed by the Court on July 17, 2013. An application for leave to appeal the decision issued by the Court of Appeal was filed in November 2013 with the Supreme Court of Canada. Such application was approved by the Supreme Court of Canada and the hearing occurred on December 1, 2014. As of the date of this MD&A, no decision has been rendered by the Supreme Court.

In addition, 121851 Canada Inc. filed a new motion in the Superior Court of Québec, district of Montréal, in May 2013, to institute a class action against the Company, a director and a former executive officer. The second motion is based on the same facts and seeks the same conclusion as the first motion except that damages are sought under the *Civil Code of Québec* instead of the *Securities Act* (Québec). The parties have agreed to stay this motion until a final decision is issued under the first motion.

We intend to contest these class actions and consider them to be without merit. The Company has subscribed to insurance covering its potential liability and the potential liability of its directors and officers in the performance of all their duties for the Company.

Off-Balance Sheet Arrangements

We were not involved in any off-balance sheet arrangements for the year ended November 30, 2014, with the exception of the lease of our headquarters as described above.

Subsequent Events

Long term obligation

Under the terms of the EMD Serono Termination Agreement, the Company agreed to pay an early termination fee of US \$20,000,000 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 will total US \$4,167,808 (previously US \$4,000,000) and will be 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, bringing the early termination fee to US \$20,167,808.

Deferred stock unit plan

In December 2014, the two cash-settled forward stock contracts (note 21(a) of our Consolidated Financial Statements) were amended to expire in December 2015.

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. We regularly monitor credit risk exposure and take steps to mitigate the likelihood of this exposure resulting in losses. Our exposure to credit risk currently relates to accounts receivable with only one customer (see note 5 of the audited consolidated financial statements) and derivative financial assets which we manage by dealing only with highly-rated Canadian financial institutions.

Included in the consolidated statement of financial position are trade receivables of \$2,291,000 (2013 - \$445,000), all of which were aged under 60 days. There was no amount recorded as bad debt expense for the year ended November 30, 2014 (2013 -- nil). Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds. We invest our available cash in highly liquid fixed income instruments from governmental, paragonovernmental and municipal bodies (November 30, 2014 - \$2,484,000; November 30, 2013 - \$11,386,000). As at November 30, 2014, we believe we were not exposed to any significant credit risk for the carrying amount of the bonds.

Liquidity Risk

Liquidity risk is the risk that we will not be able to meet our financial obligations as they become due. We manage 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, 2014, are presented in notes 19, 23, 26 and 29 of the audited consolidated financial statements.

Currency Risk

We are exposed to financial risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. Currency risk is limited to the portion of our business transactions denominated in currencies other than the Canadian dollar, primarily long-term obligation, sale of goods and expenses incurred in U.S. dollars.

From time to time, we enter into forward foreign exchange contracts. No forward foreign exchange contract was outstanding on November 30, 2014 or November 30, 2013.

Exchange rate fluctuations for foreign currency transactions can cause cash flows as well as amounts recorded in the consolidated statement of comprehensive 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 Canadian dollar at the rates of exchange at each consolidated statement of financial position date, the impact of which is reported as foreign exchange gain or loss in the consolidated statement of comprehensive loss. We do not believe a sudden change in foreign exchange rates would impair or enhance our ability to pay our U.S. dollar denominated obligations.

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

(In thousands)

	November 30, 2014	November 30, 2013
	\$US	\$US
Cash	557	858
Trade and other receivables	1,997	408
Accounts payable and accrued liabilities	(4,159)	(1,356)
Provisions	(372)	-
Long-term obligation	(14,993)	-
Total exposure	(16,970)	(90)

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

	November 30, 2014		November 30, 2013	
	Average rate	Reporting date rate	Average rate	Reporting date rate
\$ US – CA \$	1.0971	1.1440	1.0239	1.0620

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, 2014	November 30, 2013
	\$US	\$US
Positive impact	849	5

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

Interest Rate Risk

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

Our short-term bonds are invested at fixed interest rates and/or mature in the short-term. Long-term bonds are also instruments that bear interest at fixed rates. The risk that we will realize a loss as a result of a decline in the fair value of our bonds is limited because these investments, although they are

classified as available for sale, are generally held until close to maturity. The unrealized gains or losses on bonds are recorded in accumulated other comprehensive income.

Based on the value of our short and long-term bonds at November 30, 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 (2013 - \$125,000); 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, 2014 which was \$966,000 (\$540,000 in 2013), 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 \$5,000 (\$3,000 in 2013); 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%.

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 and deferred 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.

Estimation uncertainties

- Revenue

Management uses judgment in estimating provisions for sales of goods deductions such as cash discounts, allowances, returns, rebates, chargebacks and distribution fees. 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 discounts, rebates, chargebacks and allowances.

- Contingent liability:

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

Other areas of judgment and uncertainty relate to the estimation of accruals for clinical trial expenses, the recoverability of inventories, the measurement of the amount and assessment of the recoverability of tax credits and grants receivable and the measurement of intangible asset and long-term obligation.

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

On July 24, 2014, the IASB issued the final version of IFRS 9, bringing together the classification and measurement, impairment and hedge accounting phases of the IASB's project to replace IAS 39. The final version of IFRS 9 supersedes all previous versions of IFRS 9 and is effective for periods beginning on or after January 1, 2018; however an entity may elect to apply earlier versions of IFRS 9 if the entity's relevant date of initial application is before February 1, 2015.

b) IFRS 15, Revenue from Contracts with Customers

In May 2014, the IASB issued IFRS 15 which establishes principles for reporting the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. It provides a single model in order to depict the transfer of promised goods or services to customers.

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, 2017 with earlier adoption permitted, the Company has not yet assessed the impact of the adoption of this standard on its consolidated financial statements.

Standard adopted

IFRS 10, Consolidated Financial Statements

In May 2011, the IASB issued IFRS 10, Consolidated Financial Statements, which replaces SIC-12, Consolidation – Special Purpose Entities, and parts of IAS 27, Consolidated and Separate Financial Statements. IFRS 10 builds on existing principles by identifying the concept of control as the determining factor in whether an entity should be included within the consolidated statements of an entity. The standard provides additional guidance to assist in the determination of control where this is difficult to assess. IFRS 10 became effective December 1, 2013. The adoption of this standard had no impact on the Company's consolidated financial statements.

IFRS 13, Fair Value Measurement

In May 2011, the IASB issued IFRS 13, Fair Value Measurement. IFRS 13 improves consistency and reduces complexity by providing a precise definition of fair value and a single source of fair value measurement and disclosure requirements for use across IFRS. IFRS 13 became effective December 1, 2013. The adoption of this standard had no impact on the Company's consolidated financial statements.

Amendments to IAS 19, Employee Benefits

In June 2011, the IASB published an amended version of IAS 19, Employee Benefits. The amendments impact termination benefits, which would now be recognized at the earlier of when the entity recognizes costs for a restructuring within the scope of IAS 37, Provisions, Contingent Liabilities and Contingent Assets, and when the entity can no longer withdraw the offer of the termination benefits. The adoption of this standard had no impact on the Company's consolidated financial statements.

Outstanding Share Data

On February 25, 2015, the number of common shares issued and outstanding was 61,010,603 while outstanding options granted under our stock option plan were 1,842,669.

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, 2014. Based upon that evaluation, our President and Chief Executive Officer and Vice President, Finance, have concluded that, as of November 30, 2014, 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 2014 based on the criteria established in the "*Internal Control - Integrated Framework (1992)*" 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, 2014, 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, 2014 to November 30, 2014 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Risks and Uncertainties

Before you invest in our common shares, you should understand the high degree of risk involved. You should consider carefully the following risks and uncertainties described below before you decide to purchase our common shares. The following risks may adversely impact our business, financial condition, operating results and prospects. Additional risks and uncertainties, including those that we do not know

about or that we currently believe are immaterial, may also adversely affect our business, financial condition, operating results or prospects. As a result, the trading price of our common shares could decline and you could lose all or part of your investment.

Risks Related to the Commercialization of EGRIFTA™

Our commercial success and revenue growth depend solely 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 solely 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 represents 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, sanofi is responsible for seeking reimbursement of *EGRIFTA*[™] in each country where marketing authorization will be obtained and, as a result, we have no control over whether, or what level of, reimbursement is 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, revenue that we generate from its sales may be limited.*

Sales of *EGRIFTA*[™] or any future products for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of such product by the medical community, including physicians, patients and 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 become 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 or any other potential 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, 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.

Sanofi, our commercial partner in Latin America, Africa and the Middle East, has filed marketing authorization applications for *EGRIFTA*[™] in Brazil and Mexico and those are still pending. In those two most important markets in Latin America, marketing authorization applications have been filed for more than three (3) years. The regulatory authority in Israel has rejected the marketing authorization application filed by sanofi and sanofi is currently assessing whether it will appeal the decision or not.

The marketing authorization application filed by sanofi in Brazil and Mexico are based on the commercialization of *EGRIFTA*[™] in a 2 mg/vial presentation. As of this date, 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 and Mexico, sanofi will need to resubmit a new marketing authorization application in each of those countries for the commercialization of *EGRIFTA*[™] in the then current 1 mg/vial presentation. Resubmitting a revised marketing authorization application could be the equivalent of submitting an initial marketing authorization application 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 are awaiting a decision from Health Canada following the filing of a SNDS in August 2014 to commercialize *EGRIFTA*[™] in a 1 mg/vial presentation. There can be no assurance that Health Canada will approve our SNDS. If Health Canada does not approve our SNDS, we will not be able to commercialize *EGRIFTA*[™] in Canada and our capacity to grow our revenues will be affected. Revenue growth may also be affected if we are unable to obtain reimbursement coverage for *EGRIFTA*[™] in Canada.

In Europe, we have consulted with key physicians, patient groups, and regulatory experts and subsequently met with regulators in certain jurisdictions to evaluate our prospects for acceptance should we decide to re-file for approval. The result of these consultations and meetings led us to believe that we do not have a reasonable likelihood of being approved in Europe without including additional clinical data on *EGRIFTA*[™]. Therefore, we are actively seeking a commercial partner to distribute *EGRIFTA*[™] through named patient sales programs and to pursue marketing authorizations on a country-by-country basis. There is no assurance that we will be able to find a qualified commercial partner and, if we do, that the negotiation that will take place between us and such potential commercial partner will result in an agreement between us. If we are unable to find a commercial partner, we may forego the opportunity to distribute *EGRIFTA*[™] in Europe and 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 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 a collaboration and licensing agreement for the commercialization of EGRIFTA[™] in Latin America, Africa and the Middle East. This agreement places the commercialization of EGRIFTA[™] in

these markets outside of our control.

Although our collaboration and licensing agreement with sanofi contains provisions governing its responsibilities as a partner for the commercialization of *EGRIFTA*[™] in these territories, our dependence on sanofi to commercialize *EGRIFTA*[™] is subject to a number of risks, including:

- our limited control of the amount and timing of resources that it 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 sanofi, which could adversely affect the commercialization of *EGRIFTA*[™], all of which would divert our management's attention and our resources;
- sanofi 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, which could adversely affect its willingness or ability to fulfill its obligations under its agreement; and
- sanofi being found in breach of local laws.

Our collaboration and licensing agreement may be terminated by sanofi 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 sanofi 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 sanofi 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 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 particularly in light of our past restructurings 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.

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.

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 is currently set to expire in 2019, we became aware that the validity of all Brazilian pharmaceutical-related patents having a term in excess of 20 years from the filing date are judicially challenged in the Brazilian courts by the *Instituto Nacional da Propriedade Industrial*, or INPI, the Brazilian patent office. INPI alleges 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 are either invalid or that their terms should be reduced to 20 years from the filing date. The Brazilian courts ruled against the arguments of INPI and INPI has appealed the case. The case was scheduled to be heard in October 2014 but the hearing was suspended following the filing of a brief by an association of generic pharmaceutical companies seeking to support the arguments of INPI. There has been no development since the suspension of the hearing. If INPI succeeds in its arguments, we may lose our patent protection on tesamorelin, or we may have a reduction of our patent term from 2019 to 2016.

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

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

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

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

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

Our capacity to commercialize 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.

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.

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 payer. 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 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 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*[™], 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. Federal or state regulatory authorities might challenge our current or 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

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

A motion to authorize the institution of a class action was originally filed in July 2010 in the Superior Court of Québec, District of Montreal, entitled 121851 Canada Inc. v. Theratechnologies Inc. et al., Number 500-06-000-515-102. The complaint alleged that the Company, a director and a former executive officer violated the secondary market liability provisions of the *Securities Act* (Québec) by failing to disclose a material change relating to the administration of *EGRIFTA*[™]. The plaintiff sought damages on behalf of a class of persons who were shareholders at May 21, 2010 and who sold their common shares on May 25 or 26, 2010. On February 24, 2012, the Superior Court of Québec authorized 121851 Canada Inc. to institute a class action against us, a director and a former executive officer. On March 20, 2012, we filed a motion seeking permission to appeal this judgment with the Court of Appeal of Québec, District of Montreal, Number 500-09-022519-128, and the hearing took place on January 24, 2013. On July 17, 2013, the Court of Appeal of Québec dismissed our motion to dismiss the authorization to institute such class action and confirmed the decision of the Superior Court of Québec. On November 6, 2013, we filed a motion with the Supreme Court of Canada seeking permission to appeal the decision issued by the Court of Appeal of Québec. Such motion was granted by the Supreme Court of Canada on February 20, 2014 and the hearing occurred on December 1, 2014. No decision has been issued yet.

In May 2013, the same plaintiff instituted a second class action based on the same facts and seeking the same conclusion as the first motion except that damages are sought under the *Civil Code of Québec* instead of the *Securities Act* (Québec). The differences between the claim made under the *Securities Act* (Québec) and the *Civil Code of Québec* rest on the type of evidence the plaintiff will need to show the court to prove its claim and the value of the damages that may be awarded to the plaintiff if it is successful in its allegations against the Company, a director and a former executive officer. Under the *Securities Act* (Québec), the plaintiff does not have to demonstrate causation between an alleged breach of the provisions of the *Securities Act* (Québec) and the damages incurred, if any, but the amount of damages that may be sought is limited by laws. Damages that may be claimed under the *Civil Code of Québec* are not limited, but the plaintiff has to demonstrate that there is causation between the alleged breach of an obligation and the damages sought. The parties have agreed to stay this motion until a final decision is issued under the first motion.

Whether or not the plaintiff's claims are successful, this type of litigation is often expensive and diverts management's attention and resources, which could adversely affect our business, financial condition and operating results. We may also be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition. We maintain liability insurance. However, if any costs or expenses (including the award of damages, if any) associated with this or any other litigation exceed our insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial and could have a material adverse effect on our available funds and operating results.

*If we fail to comply with our contractual obligations, undertakings and covenants under our agreements with our commercial partner 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 to commercialize and to obtain and maintain regulatory approvals of *EGRIFTA*[™] in the territories covered under our distribution and licensing agreement with it. 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 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 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 sanofi 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 sanofi 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 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 is payable as to 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 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 have a history of net losses and we may never achieve consistent profitability.

We have been reporting losses since our inception (except for the financial years ended November 30, 2010, 2001 and 2000) and, as at November 30, 2014, we had an accumulated deficit of \$281.4 million.

Our profitability will 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 reimbursement coverage for *EGRIFTA*[™] under U.S. Medicare and Medicaid programs and under private-health insurers programs.

There is no guarantee that we or sanofi 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. 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 do not presently generate significant recurrent revenues and may need financing in order to fund all or part of our capital requirements to sustain our growth, to resume research and development of new and current 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. In the past, we have been financed through public equity offerings in Canada and private placements of our equity securities, as well as through tax credits. Since the launch of *EGRIFTA*[™], we have also been financing our activities through upfront payments, milestone payments and royalties received from EMD Serono. We may need to undertake additional equity offerings to raise capital, the size of which cannot be predicted. However, the market conditions or our business performance may prevent us from having access to the public market in the future at the times or in the amounts necessary. Therefore, there can be no guarantee that we will be able to continue to raise additional equity capital by way of public or private equity offerings in the future. In such a case, we would have to use other means of financing, such as issuing debt instruments or entering into private financing or credit agreements, the terms and conditions of which may not be favorable to us. 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 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;
- the approval of *EGRIFTA*[™] in Canada, Mexico and Brazil, or the non-approval thereof in those 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;
- changes in foreign currency fluctuations;
- the timing of achievement and the receipt of milestone or royalty payments from future third parties;
- failure to enter into new or the expiration or termination of current agreements with third parties; and
- failure to introduce our product candidates to the market in a manner that generates anticipated revenues.

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 also that in the event there occurs a change of control of the Corporation within eighteen (18) months of May 1, 2014,, EMD Serono has the option to accelerate the full payment of the Early Termination Fee and to seek the payment of an amount intended to equal the net present value of the maximum future confidential Royalties. If such change of control occurs 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.