

MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE YEAR ENDED NOVEMBER 30, 2019

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, 2019. It also provides a review of our performance by comparing the Company's results of operations, on a consolidated basis, for the year ended November 30, 2019, or Fiscal 2019, with the year ended November 30, 2018, or Fiscal 2018. Unless otherwise indicated or unless the context requires otherwise, all references in this MD&A to "Theratechnologies", the "Company", the "Corporation", "we", "our", "us" or similar terms refer to Theratechnologies Inc. and its subsidiaries on a consolidated basis. This MD&A is dated February 24, 2020 and should be read in conjunction with the audited consolidated financial statements, or Audited Financial Statements, and the notes thereto.

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

The Company's functional and presentation currency is the United States dollar, or USD. All monetary amounts set forth in this MD&A and the Audited Financial Statements are expressed in USD, unless otherwise noted. In 2019, management decided to change the presentation currency from the Canadian dollar (CAD) to the USD in its Audited Financial Statements to better reflect the market the Company operates in, and this change was applied retrospectively, resulting in the recast of the comparative information. As such, the consolidated financial statements are now presented in USD, together with the comparative numbers at November 30, 2018. The Company has also presented an opening consolidated statement of financial position as at December 1, 2017 in USD, which has been derived from the consolidated financial statements as at and for the year ended November 30, 2017.

In this MD&A, the use of *EGRIFTA*[®] (tesamorelin for injection) and *EGRIFTA SV*[™] refer to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and the use of Trogarzo[®] (ibalizumab-uiyk) injection refers to ibalizumab for the treatment of multidrug resistant HIV-1 infected patients. The use of tesamorelin refers to the use of our tesamorelin compound for the potential treatment of non-alcoholic steatohepatitis, or NASH, in HIV-infected patients and for other diseases.

Forward-Looking Information

This MD&A contains forward-looking statements and forward-looking information, or, collectively, forward-looking statements, within the meaning of applicable securities laws, that are based on our management's beliefs and assumptions and on information currently available to our management. You can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "outlook", "believe", "plan", "envisage", "anticipate", "expect" and "estimate", or the negatives of these terms, or variations of them. The forward-looking statements contained in this MD&A include, but are not limited to, statements regarding the growth of our revenues from sales of *EGRIFTA*[®], *EGRIFTA*

SV™ and Trogarzo® our guidance related to our 2020 revenues, our research and development activities related to the development of a new formulation of tesamorelin, the development of tesamorelin for the potential treatment of NASH in people living with HIV, the initiation of a phase I clinical trial with a peptide-conjugate derived from our oncology platform, as well as the obtaining of reimbursement for Trogarzo® in key European countries, the launch of Trogarzo® in Europe and our capacity to acquire or in-license new products complementary to our infrastructure.

Forward-looking statements are based upon a number of assumptions and include, but are not limited to, the following: sales of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® will continue to grow in the United States, our research and development activities will yield positive results, both with respect to the development of tesamorelin for the potential treatment of NASH in HIV-infected patients and with respect to the development of our peptide-conjugates in oncology, no delay will occur in our planned and announced timelines to begin clinical trials, to enroll patients therein, to hear from regulatory agencies or to execute material commercial agreements, no untoward side effects will be discovered through the long-term use of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo®, our third-party suppliers will be able to manufacture our drug products to meet demand, and we will succeed in finding products and entering into agreements to acquire or in-license products upon terms and conditions satisfactory to us.

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 commercial-stage biopharmaceutical company addressing unmet medical needs by bringing to market specialized therapies for people with orphan medical conditions, including those living with HIV.

Our business strategy is to grow revenues from our existing and future assets in North America and Europe and to develop our portfolio of complementary products, compatible with our expertise in drug development and our commercialisation know-how.

The Company has a sales and marketing infrastructure to commercialize its products in the United States, Canada and Europe.

Our Products

Developed in-house, *EGRIFTA*[®] (tesamorelin for injection) is approved by the United States Food and Drug Administration, or FDA, and by Health Canada for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

EGRIFTA SV[™] is a new formulation of *EGRIFTA*[®] approved by the FDA and launched in the United States in November 2019. Unlike *EGRIFTA*[®], *EGRIFTA SV*[™] can be kept at room temperature, comes in a single vial and has a higher concentration resulting in a smaller volume of administration.

In March 2016, we entered into an agreement with TaiMed Biologics, Inc., or TaiMed, to acquire the commercial rights to Trogarzo[®] for the United States and Canada, or TaiMed Agreement. In March 2017, the TaiMed Agreement was amended to include the commercial rights to ibalizumab in the European Union countries and in other countries such as Israel, Norway, Russia and Switzerland.

Trogarzo[®] was approved by the FDA in March 2018 for the treatment of human immunodeficiency virus type 1, or HIV-1, infection in heavily treatment-experienced adults with multidrug resistant, or MDR, HIV-1 infection failing their current antiretroviral regimen.

Trogarzo[®] was also approved in Europe by the European Medicines Agency, or EMA, in September 2019 for the treatment of adults infected with MDR HIV-1 for whom it is otherwise not possible to construct a suppressive antiviral regimen. Trogarzo[®] will be launched sequentially on a country-by-country basis across Europe as it gains public reimbursement in each such country. A number of patients are already being treated with Trogarzo[®] in some European countries through early access programs.

An intravenous slow push formulation of Trogarzo[®] is currently under study by TaiMed. Under the terms of the TaiMed Agreement, we are entitled to commercialize such new formulation of Trogarzo[®] if, and when, approved.

Our Pipeline

Since the beginning of 2019, the Company has been working on rebuilding its research and development, or R&D, pipeline.

Our pipeline rests on a variety of research and development activities.

In Fiscal 2019, we announced that we would pursue the development of tesamorelin for the treatment of NAFLD/NASH in people living with HIV. This decision is largely based on positive data from a study conducted by Dr. Steven Grinspoon of the Massachusetts General Hospital, or MGH, which were published on October 11, 2019 in *The Lancet HIV Journal*. Preliminary market research indicates that NASH affects over 100,000 people living with HIV. At the end of Fiscal 2019, we submitted a Type C meeting request with the FDA to ascertain some aspects of a phase III clinical trial. The FDA advised us that they would reply to our questions in writing. We expect to receive a response from the FDA in the second quarter of 2020. If the FDA's position is favorable, we will then complete our protocol for a phase III clinical trial in order to initiate the trial by the end of 2020, using

a new formulation of tesamorelin, or F8 Formulation. The F8 Formulation is currently being evaluated for bioequivalence.

To support the clinical development of tesamorelin for the treatment of NAFLD/NASH in people living with HIV, we announced on February 4, 2020, that we had signed agreements with the MGH and Dr. Steven Grinspoon. The MGH, through Dr. Steven Grinspoon, who is chief of the hospital's Metabolism Unit, has agreed to assist us in connection with a phase III clinical trial design, selection of optimal patient population, dosing, study duration and other safety matters and to participate, if need be, in regulatory meetings with the FDA or the EMA.

In 2019, we also acquired a unique targeted oncology platform. This platform is aimed at treating various types of cancers where sortilin receptors are overexpressed. *In vivo* and *in vitro* models have yielded promising results. Based on the positive feedback received from the FDA, we aim to initiate a phase I clinical trial using one of our peptide-conjugates before the end of 2020.

Fiscal 2019 Highlights

For the year ended November 30, 2019, consolidated revenue was \$63,216,000 compared to \$45,217,000 for the same period last year, representing an increase of 39.8%.

***EGRIFTA*[®] and *EGRIFTA SV*[™]**

For the year ended November 30, 2019, sales of *EGRIFTA*[®] were \$35,520,000 compared to \$36,329,000 for the same period last year, representing a decrease of 2.2%.

Net sales in 2019 were negatively impacted by an unexpected charge related to government rebates not previously recorded by one of our distributing pharmacies. A portion of units sold to this pharmacy were previously incorrectly identified by the pharmacy as commercial patients, when they were actually government reimbursed patients, who are eligible to rebates.

At the end of November 2019, *EGRIFTA SV*[™] became available in the United States. We expect *EGRIFTA SV*[™] to help supporting sales growth of tesamorelin for the treatment of HIV-associated lipodystrophy in the United States. Earlier, during Fiscal 2019, we announced the entering into of an agreement with the Aids Drug Assistance Program in the United States for the coverage of *EGRIFTA SV*[™] for uninsured and underinsured patients.

In Fiscal 2019, we also regained all of our worldwide distribution rights to *EGRIFTA*[®].

Trogarzo[®]

Net sales of Trogarzo[®] reached \$27,696,000 for the year ended November 30, 2019 compared to \$8,888,000 for the same period last year, representing an increase of 212%.

In the United States, Trogarzo[®] sales are growing steadily as more efforts are put behind marketing, medical education and patient engagement such as a direct-to-consumer campaigns and increased social media presence.

In Fiscal 2019, we started building our European infrastructure to prepare for the anticipated marketing authorization of Trogarzo[®], which was received on September 26, 2019. Since then, the Company has filled key strategic positions in distribution, medical and marketing and has focused its efforts on obtaining reimbursement in key European countries. Trogarzo[®] will be launched sequentially in European countries as public reimbursement is obtained in individual countries. Already, some patients are being treated with Trogarzo[®] in Europe through early access programs.

Research and Development Activities

In Fiscal 2019, we made significant progress on its research and development activities to help fuel its growth.

As part of its strategy to rebuild its pipeline, Theratechnologies announced the development of tesamorelin for the potential treatment of NASH in people living with HIV. The development of tesamorelin in NASH for people living with HIV is intended to be made using the F8 Formulation which is patent protected until 2033 in the United States and in key European countries until 2034. The F8 Formulation could also be introduced for the treatment of lipodystrophy.

Theratechnologies has requested a meeting with the FDA and the EMA to discuss the design of the phase III clinical trial required to obtain approval for the new indication. Provided discussions are conclusive, Theratechnologies should be in a position to initiate the phase III clinical trial by the end of 2020. In the future, the Company may also consider the feasibility and viability of developing tesamorelin for the treatment of NASH in non-HIV patients.

As we continue to support the development of tesamorelin and work towards a new indication for the treatment of NASH in people living with HIV, we announced on August 8, 2019 that we had regained full control over the distribution rights of *EGRIFTA*[®] worldwide.

Furthermore, we announced in early Fiscal 2019 the acquisition of a unique and promising technology for the treatment of several types of cancers overexpressing sortilin receptors. TH-1902 is the first peptide-conjugate originating from this technology. Docetaxel, a commonly used treatment in breast cancer, attaches to our proprietary peptide-conjugate targeting sortilin receptors. TH-1902, an investigational drug-peptide conjugate, is currently being studied for the treatment of Triple-Negative Breast Cancer, or TNBC. In late December 2019, new *in vivo* and *in vitro* data, presented at the San Antonio Breast Cancer Symposium, showed greater efficacy and tolerability of TH-1902 over docetaxel used alone. Based on positive feedback received from the FDA regarding our clinical trial design, we intend to initiate a phase I clinical trial using TH-1902 by the end of 2020.

An investigational new drug application for TH-1904 will also be filed once manufacturing scale-up is completed which will occur following the initiation of the phase I clinical trial with TH-1902.

Corporate Developments

On October 10, 2019, our common shares started trading on the U.S. NASDAQ stock market, or NASDAQ. The Company believes that being listed on NASDAQ will diversify its shareholder base, increase the liquidity of its common shares, and support greater awareness of the Company.

In conjunction with the NASDAQ listing, the Company filed a preliminary short form base shelf prospectus, or Shelf Prospectus, with the securities regulators in each of the provinces of Canada and a corresponding shelf registration statement on Form F-10, or Registration Statement, with the United States Securities and Exchange Commission, or SEC.

The Shelf Prospectus and Registration Statement will allow the Company to make offerings of common shares, preferred shares, subscription receipts, warrants, debt securities and units comprised of one or more of the foregoing securities for gross proceeds of up to \$150 million during a 25-month period beginning on November 15, 2019. Should the Company decide to distribute securities during this period, the specific terms, including the use of proceeds from any offering, would be set forth in a related prospectus supplement to the Shelf Prospectus, which would be filed with the applicable Canadian securities regulatory authorities and the SEC.

Outlook

Our strategy for the current fiscal year, or Fiscal 2020, remains to generate revenue growth through increased sales of our products in the United States while working on securing an appropriate pricing and widespread reimbursement for Trogarzo® in key European countries. We also plan on advancing with the development of the F8 Formulation and on pursuing the clinical development of tesamorelin for the treatment of NASH in people living with HIV. We intend to initiate a human clinical trial in oncology by the end of Fiscal 2020. Finally, we will remain open to potential product acquisitions or in-licensing transactions that would be complementary to our infrastructure.

2020 Revenue Guidance

On December 19, 2019, Theratechnologies issued revenue guidance for Fiscal 2020. The Company expects Fiscal 2020 revenues between \$83,000,000 and \$87,000,000 representing an increase of 31 to 37 percent from Fiscal 2019. In addition, the Company expects to maintain a solid cash position as the expected revenue growth will generate enough cash to fund its operations and its clinical research programs in Fiscal 2020.

Selected Annual Information

| Years ended November 30 (in thousands of U.S. dollars, except per share amounts) | 2019 | 2018 | 2017 |
|--|----------|---------|----------|
| Revenue | 63,216 | 45,217 | 33,021 |
| Selling expenses | 26,482 | 21,693 | 20,047 |
| Research and development expenses | 10,841 | 7,994 | 9,104 |
| General and administrative expenses | 8,330 | 5,828 | 4,468 |
| Adjusted EBITDA ¹ | 323 | 1,664 | (5,323) |
| Net loss | (12,496) | (4,700) | (14,061) |
| Loss per share: Basic and diluted | (0.16) | (0.06) | (0.19) |
| Cash, bonds and money market funds | 41,244 | 53,888 | 25,542 |
| Total assets | 117,555 | 111,116 | 59,180 |
| Long-term obligations (including current portion) | 7,987 | -- | 7,151 |
| Convertible unsecured senior notes | 50,741 | 49,233 | -- |

1. See "Non-IFRS Financial Measures" below.

Operating results – Year ended November 30, 2019 compared to Year ended November 30, 2018

| (in thousands of dollars) | 2019 | 2018 |
|---------------------------------------|---------------|-------------|
| <i>EGRIFTA</i> [®] net sales | 35,520 | 36,329 |
| Trogarzo [®] net sales | 27,696 | 8,888 |
| Revenue | 63,216 | 45,217 |

Consolidated revenue for the year ended November 30, 2019 was \$63,216,000 compared to \$45,217,000 for the same period ended November 30, 2018, an increase of 39.8%. Revenue growth reflects the added contribution of Trogarzo[®]. This was the first full year of commercialization for Trogarzo[®] in the United States where sales reached \$27,696,000 as at November 30, 2019. Trogarzo[®] was approved in the United States on March 6, 2018 and has been commercially available since April 30, 2018.

The contribution of *EGRIFTA*[®] remains significant. For the year ended November 30, 2019, sales of *EGRIFTA*[®] were \$35,520,000 compared to \$36,329,000 for the same period last year, representing a decrease of 2.2%. Net sales in 2019 were negatively impacted by an unexpected charge related to government rebates not previously recorded by one of our distributing pharmacies. A portion of units sold to this pharmacy were previously incorrectly identified by the pharmacy as commercial patients, when they were actually government reimbursed patients, who are eligible to rebates.

Cost of Sales

For the year ended November 30, 2019, cost of sales was \$26,076,000 compared to \$13,263,000 in the comparable period of Fiscal 2018. Cost of sales includes the cost of goods sold which amounted to \$21,125,000 in Fiscal 2019 compared to \$9,376,000 in Fiscal 2018. The increase in cost of goods sold is mainly due to the growth of Trogarzo[®] net sales.

Prior to the third quarter of 2018, cost of sales included royalties due under the terms of an agreement terminating our collaboration and licensing agreement with EMD Serono Inc., or EMD Serono. In June 2018, we made a full and final payment of \$23,850,000 to EMD Serono which enabled Theratechnologies to realize savings from a reduction of future payment obligations including royalty payments.

The payment in connection with the settlement of the future royalty obligation has been accounted as “Other asset” on the consolidated statement of financial position. Consequently, an amortization of \$4,884,000 has been recorded in relation to this transaction in Fiscal 2019 compared to \$2,442,000 during Fiscal 2018 and is included in cost of sales.

R&D Expenses

R&D expenses amounted to \$10,841,000 for Fiscal 2019 compared to \$7,994,000 in Fiscal 2018.

The increase in R&D expenses is largely due to regulatory and medical activities in Europe, on tesamorelin and investments in the oncology platform.

R&D expenses also included medical affairs initiatives aimed at raising awareness among physicians and nurses who interact with patients living with MDR HIV-1 and lipodystrophy, in addition to regulatory affairs activities, such as handling of the European filing of Trogarzo[®] and quality assurance activities.

This was partially offset by the decision of the FDA to release Theratechnologies from its last post-approval commitments relating to *EGRIFTA*[®].

Selling Expenses

Selling expenses for the year ended November 30, 2019 amounted to \$26,482,000 compared to \$21,693,000 for the same period last year.

The increase in selling expenses is largely associated with preparation work related to the approval and launch of Trogarzo[®] in Europe as well as the launch of *EGRIFTA SV*[™] and the direct-to-consumer campaign in the United States.

The amortization of the intangible asset value established for the *EGRIFTA*[®] and Trogarzo[®] commercialization rights in North America is also included in selling expenses. We recorded an expense of \$2,412,000 for Fiscal 2019 compared to \$1,767,000 in Fiscal 2018.

General and Administrative Expenses

General and administrative expenses for the year ended November 30, 2019 amounted to \$8,330,000 compared to \$5,828,000 for the same period in Fiscal 2018.

The increase in general and administrative expenses is mainly associated with business growth, increased activity in Europe, the listing on NASDAQ and additional investor relations initiatives.

Finance Income

Finance income, consisting of interest income, for the year ended November 30, 2019 amounted to \$1,097,000 compared to \$608,000 in Fiscal 2018. Higher finance income is mostly related to a higher average liquidity position.

Finance Costs

Finance costs for the year ended November 30, 2019 were \$5,080,000 compared to \$3,016,000 in Fiscal 2018. Finance costs in Fiscal 2019 mostly represent interest of \$3,317,000 on the convertible senior unsecured notes, or Notes, issued on June 18, 2018, or the Offering, compared to \$1,486,000 last year.

Finance costs also included accretion expense, which amounted to \$1,673,000 during Fiscal 2019 compared to \$1,041,000 during Fiscal 2018.

Adjusted EBITDA

Adjusted EBITDA for Fiscal 2019 was \$323,000 compared to \$1,664,000 in Fiscal 2018, reflecting increased investments towards building our infrastructure in Europe, the development of our oncology platform and the listing of our common shares on the NASDAQ. These higher expenses were partially offset by higher revenues related to growing Trogarzo[®] sales. See “Non-IFRS Financial Measures” below.

Net loss

Taking into account the revenue and expense variations described above, we recorded a net loss of \$12,496,000 or \$0.16 per share in Fiscal 2019 compared to a net loss of \$4,700,000 or \$0.06 in Fiscal 2018.

Fourth quarter comparison

| (in thousands of dollars) | Q4 2019 | Q4 2018 |
|---------------------------------------|---------------|---------|
| <i>EGRIFTA</i> [®] net sales | 8,731 | 9,732 |
| Trogarzo [®] net sales | 7,669 | 4,251 |
| Revenue | 16,400 | 13,983 |

Consolidated revenue for the three months ended November 30, 2019 amounted to \$16,400,000 compared to \$13,983,000 for the same period last year, representing an increase of 17.3%.

For the fourth quarter of Fiscal 2019, sales of *EGRIFTA*[®] reached \$8,731,000 compared to \$9,732,000 in the fourth quarter of the prior year. While unit sales to our US distributor were up 5.3% compared to Q4 of 2018, net sales decreased for two main reasons: (i) net sales for Q4 2019 were impacted by an unexpected charge related to government rebates not previously recorded by one of our distributing pharmacies. A portion of units sold to this pharmacy were previously incorrectly identified by the pharmacy as commercial patients, when they were actually government reimbursed patients, who are eligible to rebates, and (ii) net sales for Q4 2018 were positively impacted by the reversal of a provision related to chargebacks and rebates.

In the fourth quarter of 2019, Trogarzo[®] sales amounted to \$7,669,000 compared to \$4,251,000 for the same quarter of 2018, representing an increase of 80.4%.

Cost of Sales

For the three-month period ended November 30, 2019, cost of sales was \$6,989,000 compared to \$4,751,000 in the comparable period of Fiscal 2018. Cost of goods sold was \$5,754,000 compared to \$3,516,000 for the same period last year. The increase in cost of goods sold is mainly due to higher sales of Trogarzo[®]. Cost of sales include an amortization of \$1,221,000 in the fourth quarter of 2019 and of 2018 in connection with the settlement of the future royalty obligation which has been accounted as “Other asset” on the consolidated statement of the financial position.

R&D Expenses

R&D expenses in the three-month period ended November 30, 2019 amounted to \$3,877,000 compared to \$2,063,000 in the comparable period of Fiscal 2018. As previously explained, this increase is largely due to investments made towards the approval of Trogarzo® in Europe, the development of our oncology platform and of tesamorelin for the treatment of NASH in people living with HIV as well as medical activities related to Trogarzo®.

Selling Expenses

Selling expenses in the three-month period ended November 30, 2019 amounted to \$7,673,000 compared to \$5,233,000 in the comparable period of Fiscal 2018.

The increase in selling expenses is largely associated with preparation work related to the approval and launch of Trogarzo® in Europe as well as to the launch of *EGRIFTA SV*TM and to the direct-to-consumer campaign in the United States.

The amortization of the intangible asset value established for the *EGRIFTA*® and Trogarzo® commercialization rights in North America is also included in selling expenses. We recorded an expense of \$642,000 for the fourth quarter of Fiscal 2019 compared to \$487,000 for the same quarter the previous year.

General and Administrative Expenses

General and administrative expenses in the fourth quarter of Fiscal 2019 amounted to \$3,258,000 compared to \$1,865,000 reported in the same period of Fiscal 2018. The increase is mainly associated with business growth, the expansion in Europe and the listing of our common shares on NASDAQ.

Finance Income

Finance income, consisting of interest income, for the three-month period ended November 30, 2019 was \$217,000 compared to \$276,000 in the comparable quarter of Fiscal 2018. Lower finance income is a reflection of our slightly lower liquidity position during the fourth quarter of Fiscal 2019 compared to the same period of 2018.

Finance Costs

Finance costs for the fourth quarter of Fiscal 2019 were \$1,275,000 compared to \$1,330,000 for the same quarter of Fiscal 2018. As previously stated, finance costs are mostly comprised of interest on the Notes.

Finance costs also include accretion expense, which was \$440,000 for the fourth quarter of 2019 compared to \$357,000 for the same period last year. Accretion expense was is mainly associated with the Notes issued in June 2018.

Adjusted EBITDA

Adjusted EBITDA for the fourth quarter of 2019 was \$(3,217,000) compared to \$1,996,000 in same period of Fiscal 2018. See “Non-IFRS Financial Measures” below.

The variation from Q4 2018 to Q4 2019 is mainly due to the increased activity in Europe, our investment in new research and development activities and the previously described charges related to government rebates. Our Q4 2018 Adjusted EBITDA was also positively impacted by the reversal of chargebacks and provisions, as previously mentioned.

Net loss

Taking into account the revenue and expense variations described above, we recorded a net loss of \$6,445,000 or \$0.08 per share in the fourth quarter of Fiscal 2019 in comparison to a net loss of \$983,000 or \$0.01 per share in the fourth quarter of 2018.

Financial Position

We ended the fourth quarter of 2019 with \$41,244,000 in cash, bonds and money market funds.

For the three-month period ended November 30, 2019, operating activities used \$2,760,000 compared to generating \$2,622,000 in the comparable period of Fiscal 2018.

In the fourth quarter of Fiscal 2019, changes in operating assets and liabilities had a positive impact on cash flow of \$488,000. These changes include an increase of \$9,096,000 in accounts payable and accrued liabilities and a decrease in accounts receivable of \$1,258,000, which were mainly offset by a \$8,082,000 increase in inventories. These changes are related to an increase in our commercial activities.

Quarterly Financial Information

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

(In thousands of dollars, except per share amounts)

| | 2019 | | | | 2018 | | | |
|--|---------|---------|---------|---------|---------|---------|---------|---------|
| | Q4 | Q3 | Q2 | Q1 | Q4 | Q3 | Q2 | Q1 |
| Revenue | 16,400 | 16,111 | 15,609 | 15,096 | 13,983 | 13,523 | 9,598 | 8,113 |
| Operating expenses | | | | | | | | |
| Cost of sales | | | | | | | | |
| Cost of goods sold | 5,754 | 5,215 | 5,346 | 4,810 | 3,516 | 3,325 | 1,594 | 941 |
| Other production-related costs | 14 | 1 | 18 | 34 | 14 | 91 | 127 | (127) |
| Royalties | - | - | - | - | - | - | 450 | 890 |
| Amortization of other asset | 1,221 | 1,221 | 1,221 | 1,221 | 1,221 | 1,221 | - | - |
| R&D | 3,877 | 2,152 | 2,285 | 2,527 | 2,063 | 2,130 | 1,897 | 1,904 |
| Selling | 7,673 | 6,389 | 6,972 | 5,448 | 5,233 | 5,189 | 5,957 | 5,314 |
| General and administrative | 3,258 | 1,772 | 1,784 | 1,516 | 1,865 | 1,482 | 1,279 | 1,202 |
| Total operating expenses | 21,797 | 16,750 | 17,626 | 15,556 | 13,912 | 13,438 | 11,304 | 10,124 |
| Finance income | 217 | 253 | 292 | 335 | 276 | 175 | 77 | 80 |
| Finance costs | (1,275) | (1,253) | (1,449) | (1,103) | (1,330) | (1,247) | (283) | (156) |
| Net (loss) profit | (6,455) | (1,639) | (3,174) | (1,228) | (983) | 282 | (1,912) | (2,087) |
| Basic and diluted (loss) earnings per share | (0.08) | (0.02) | (0.04) | (0.02) | (0.01) | 0.00 | (0.03) | (0.03) |

Factors Affecting the Variability of Quarterly Results

Results for Fiscal 2019 reflect the increased contribution of Trogarzo®.

There are quarter-over-quarter variations in net sales revenue, principally due to changes in distributor inventory levels with some additional impact from time to time related to average net selling price, which is affected by changes in the mix of private payors versus government drug reimbursement plans.

Higher expenses in 2019 are associated with business growth and the development of our product pipeline.

Liquidity and Capital Resources

Our objective in managing capital is to ensure a sufficient liquidity position to finance our business activities. We depend primarily on revenue generated by sales of *EGRIFTA*® and Trogarzo® in the United States and, from time to time, on public offerings of securities in North America. Currently, our general policy on dividends is to retain cash to keep funds available to finance our growth.

For Fiscal 2019, cash flow used in operating activities was \$3,391,000 compared to cash flow generated of \$92,000 in Fiscal 2018.

In Fiscal 2019, changes in operating assets and liabilities negatively affected cash flow by \$3,662,000 compared to \$1,637,000 in Fiscal 2018. Those changes are directly related to an increase in our commercial activities.

During Fiscal 2019, we paid \$3,417,000 in interest on the convertible unsecured notes. In addition, under the terms of the TaiMed Agreement, a commercial milestone of \$7,000,000 is payable in two equal annual installments of \$3,500,000 after achieving aggregate net sales of \$20,000,000 over four consecutive quarters of the Company's financial year. The Company accrued the discounted value of the obligation during the quarter ended February 28, 2019 because it was probable of being achieved. The milestone was achieved during the quarter ended May 31, 2019. The first payment of \$3,500,000 was made in July 2019 and the second payment will be made in June 2020.

On June 19, 2018, Theratechnologies closed the Offering. The Notes issued as a result of the Offering are direct, senior, unsecured obligations of Theratechnologies and bear interest at a rate of 5.75% per annum, payable semi-annually on June 30 and December 31 of each year, commencing on December 31, 2018. The notes are convertible into common shares of the Company. (See note 17 to the Audited Financial Statements).

Theratechnologies used a portion of the net proceeds of the Offering to fund payments totaling US\$23,850,000 due under an amendment to our termination and transfer agreement entered into on May 29, 2018 with EMD Serono.

As at November 30, 2019, cash, bonds and money market funds amounted to \$41,244,000 compared to \$53,888,000 in November 30, 2018. Available cash is invested in highly liquid fixed income instruments including governmental, municipal and paragonovernmental organizations, high-grade corporate bonds and money market funds.

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

Subsequent Event

On February 4, 2020, we entered into an amended and restated licence agreement with the MGH in order to benefit from the assistance and knowledge of the MGH for the development of tesamorelin for the potential treatment of NASH in the HIV population. Under the terms of the agreement, the MGH, through Dr. Steven Grinspoon, will provide services related to the study design, selection of optimal patient population, dosing, study duration and other safety matters and to participate, if need be, in regulatory meetings with the FDA or the EMA. In consideration, we agreed to make certain milestone payments to the MGH related to the development of tesamorelin and a low single-digit royalty payment on all sales of *EGRIFTA*[®] above a certain threshold amount. The payment of the royalty will begin upon approval by the FDA or the EMA (the first to occur) of an expanded label of tesamorelin for the treatment of NAFLD or NASH in the HIV population.

In addition, on that same date, we entered into a consulting agreement with the MGH pursuant to which Dr. Grinspoon became one of our scientific advisors. In such a role, Dr. Grinspoon will provide guidance about current developments in the HIV patient population, potential treatments, and the possible development of tesamorelin for treatment of additional diseases.

Commitments

Off Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Contractual obligations

The following table lists as of November 30, 2019 information with respect to the Corporation's known contractual obligations.

| Contractual Obligations | Total | Less than 1 | | | More than |
|-----------------------------|-----------------------|----------------------|----------------------|----------------------|---------------------|
| | | Year | 1 to 3 Years | 3 to 5 Years | 5 years |
| Long Term Debt Obligations | — | — | — | — | — |
| Capital Lease Obligations | — | — | — | — | — |
| Operating Lease Obligations | \$ 4,777,563 | \$ 679,871 | \$ 1,449,693 | \$ 1,494,669 | \$ 1,153,330 |
| Purchase Obligations | 21,356,000 | 21,356,000 | — | — | — |
| Other Long-Term Liabilities | 79,225,000 | 6,806,000 | 11,613,000 | 60,806,000 | — |
| Total | \$ 105,358,563 | \$ 28,841,871 | \$ 13,062,693 | \$ 62,300,669 | \$ 1,153,330 |

Other Long-Term Liabilities comprise the convertible unsecured senior notes issued in June 2018, including interest thereon, and long-term obligations.

Credit facility:

The Corporation has a CA\$1,500,000 credit facility for its ongoing operations, bearing interest at the bank's Canadian prime rate, plus 1.0%, and a \$1,000,000 revolving credit facility bearing interest at the Bank's U.S. prime rate plus 1.0%. Under the terms of the credit facility, the bank has a first rank movable hypothec on all of the assets of the Corporation.

As at November 30, 2019 and 2018, the Corporation did not have any borrowings outstanding under this credit facility.

Reference should be made to Note 12 (Intangible Assets) to the Audited Financial Statements for the year ended November 30, 2019 for a description of all potential commercial milestones payable by the Corporation.

Financial Risk Management

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

Credit Risk

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

The Company's exposure to credit risk currently relates to accounts receivable with one major customer (see Note 26 to the Audited Financial Statements) and derivative financial assets which it manages by dealing only with highly rated Canadian financial institutions. Included in the consolidated statements of financial position are trade receivables of \$9,538,000 (2018 – \$10,720,000), all of which were aged under 60 days. There was nil recorded as bad debt expense for the years ended November 30, 2019 and 2018. Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds and money market funds. The Company invests its available cash in highly liquid fixed income instruments from governmental, paragonovernmental, municipal and high-grade corporate bodies and money market funds (2019 – \$12,583,000; 2018 – \$14,891,000). As at November 30, 2019, the Company believes it was not exposed to any significant credit risk. The Company's maximum credit exposure corresponded to the carrying amount of these financial assets.

Liquidity Risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they become due. As indicated in Note 23, the Company manages this risk through the management of its capital structure. It also manages liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors and/or the Audit Committee reviews and approves the Company's operating and capital budgets, as well as any material transactions out of the ordinary course of business.

The Company has adopted an investment policy in respect of the safety and preservation of its capital designed to ensure that the Company's liquidity needs are met. The instruments are selected with regard to the expected timing of expenditures and prevailing interest rates.

Currency Risk

The Company is 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 the Company's business transactions denominated in currencies other than USD, primarily cash, sale of goods and expenses incurred in CAD and Euro.

Exchange rate fluctuations for foreign currency transactions can cause cash flows as well as amounts recorded in the consolidated statements of comprehensive income to vary from period to period and not necessarily correspond to those forecasted in operating budgets and projections. Additional earnings variability arises from the translation of monetary assets and liabilities denominated in currencies other than the USD 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 statements of comprehensive income. The Company does not believe a sudden change in foreign exchange rates would impair or enhance its ability to pay its CAD or Euro denominated obligations.

The following table presents the significant items in the original currencies exposed to currency risk as at November 30, 2019 and 2018:

| | 2019 | | 2018 |
|---|---------|-------|---------|
| | CAD | EURO | CAD |
| Cash | 740 | 662 | 1,869 |
| Bonds and money market funds | 6,982 | - | 9,754 |
| Trade and other receivables | 328 | 447 | 470 |
| Accounts payables and accrued liabilities | (5,101) | (793) | (6,437) |
| Total exposure | 2,949 | 316 | 5,656 |

The following exchange rates are those applicable as at November 30, 2019 and 2018 to:

| | 2019 | | 2018 | |
|------------|--------------|---------------------|--------------|---------------------|
| | Average rate | Reporting date rate | Average rate | Reporting date rate |
| CAD – USD | 0.7524 | 0.7530 | 0.7752 | 0.7522 |
| Euro – USD | 1.1217 | 1.1018 | - | - |

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

| | 2019 | | 2018 |
|-----------------|------|------|------|
| | CAD | EURO | CAD |
| Positive impact | 147 | 16 | 283 |

An assumed 5% weakening of the CAD 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.

Short-term bonds held by the Company 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 the Company will realize a loss as a result of a decline in the fair value of its 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 the Company's short- and long-term bonds as at November 30, 2019, 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 \$14,000 (2018 – \$46,000); an assumed increase in the interest rate of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

Cash and money market funds bear 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 and money market funds during the year ended November 30, 2019 of \$39,032,000 (2018 – \$24,810,000), an assumed 0.5% increase in interest rates during such year would have increased future cash flows and net profit by approximately \$195,000 (2018 – \$124,000); an assumed decrease of 0.5% would have had an equal but opposite effect.

As the Company's convertible unsecured senior notes bear interest at a fixed rate of 5.75%, the Company does not face cash flow interest rate risk but is subject to market price interest rate risk. The Company's long-term obligations do not bear interest.

Fair Values of Financial Instruments

Certain of the Company's accounting policies and disclosures require the determination of fair value, for both financial and non-financial assets and liabilities. Fair values have been determined for measurement and/or disclosure purposes based on the following methods. When applicable, further information about the assumptions made in determining fair values is disclosed in the notes specific to that asset or liability.

The Company has determined that the carrying values of its short-term financial assets and financial liabilities, including cash, trade and other receivables, derivative financial assets, accounts payable and accrued liabilities, long-term obligation approximate their fair value because of the relatively short period to maturity of the instruments.

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

The fair value of the convertible unsecured notes, including the equity portion, as at November 30, 2019 were approximately \$44,275,000 based on market quotes.

Share-based payment transactions

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

The DSU liability is recognized at fair value and considered Level 2 in the fair value hierarchy for financial instruments. The fair value is determined using the quoted price of the common shares of the Company.

Related party transactions

Refer to Note 27 of the Audited Financial Statements

Critical Accounting Estimates

Use of estimates and judgments

The preparation of the Company's 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 consolidated financial statements and the reported amounts of revenues and expenses during the reporting year.

Judgments in applying accounting policies

Information about critical judgments in applying accounting policies and assumptions that have the most significant effect on the amounts recognized in the consolidated financial statements is noted below.

Milestones payments related to Trogarzo®

The commercialization rights related to Trogarzo® are subject to additional cash-based milestone payments based on the attainment of commercial milestones, including development, launch and sales milestones. Milestones payments will be accrued and recorded in the cost of intangible assets when it is probable that they will be achieved. The determination of probability to pay the milestones is subject to judgment. In order to demonstrate that the commercial milestone payment is probable, the following will be taken into consideration: product approval, product launch and approved development plan. In addition, there should be a sufficient history of sales to have reasonable expectation that the commercial milestone payments related to sales milestone will be reached.

Contingent consideration related to oncology platform

The purchase consideration for the oncology platform (note 12) includes additional milestone payments based on the attainment of commercial milestones that will be settled through the issuance of the company's shares, which represents a transaction in the scope of IFRS 2, Share-based Payments. Accordingly, the fair value of the *oncology platform* at date of acquisition incorporates management's judgement as to the probability of attaining the shares-based milestones as well as the expected timing of the attainment of the milestones.

Convertible senior unsecured notes

The determination of the fair value of the liability component of a convertible instrument was at time of issuance based on the estimated interest rate that the Company could obtain for a similar debt instrument without a conversion option.

Key sources of estimation uncertainty

Key sources of estimation uncertainty that have a significant risk of resulting in a material adjustment to the carrying amount of assets and liabilities within the next financial year are as follows:

Sales promotional programs

Management uses judgment in estimating provisions for sale deductions such as cash discounts, allowances, returns, rebates, chargebacks and distribution fees (see Notes 2 (Revenue recognition, Net sales) and 4 to the Audited Financial Statements for additional information).

Other

Other areas of judgment and uncertainty related to the estimation of accruals for clinical trial expenses, the recoverability of inventories, the measurement and recoverability of intangible assets, the measurement of derivative financial assets, and the measurement of share-based arrangements.

Reported amounts and note disclosures 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 year in which the estimates are revised and in any future years affected.

Recent Changes in Accounting Standards

Amendments to IFRS 3, Business Combinations (Definition of a Business)

On October 22, 2018, the IASB issued amendments to IFRS 3, Business Combinations that seek to clarify whether a transaction results in an asset or a business acquisition. The amendments apply to businesses acquired in annual reporting periods beginning on or after January 1st, 2020. Early application is permitted. The amended definition emphasizes that the output of a business is to provide goods and services to customers, whereas the previous definition focused on returns in the form of dividends, lower costs or other economic benefits to investors and others.

The amendments include an election to use a concentration test. This is a simplified assessment that results in an asset acquisition if substantially all of the fair value of the gross assets is concentrated in a single identifiable asset or a group of similar identifiable assets. If a preparer chooses not to apply the concentration test, or the test is failed, then the assessment focuses on the existence of a substantive process. The Company early adopted the amendments with a date of initial application of December 1st, 2018 and applied the amendment in connection with the acquisition of oncology platform (Note 12).

IFRS 9, Financial Instruments

The Company adopted all of the requirements of IFRS 9, Financial Instruments ("IFRS 9") with a date of initial application of December 1st, 2018. IFRS 9 does not require restatement of comparative periods. This standard establishes principles for the financial reporting classification and measurement of financial assets and financial liabilities. This standard also incorporates a new hedging model which increases the scope of hedged items eligible for hedge accounting and aligns hedge accounting more closely with risk

management. This standard also amends the impairment model by introducing a new "expected credit loss" model for calculating impairment. This new standard increases required disclosures about an entity's risk management strategy, cash flows from hedging activities and the impact of hedge accounting on the consolidated financial statements.

IFRS 9 uses a single approach to determine whether a financial asset is measured at amortized cost or fair value, replacing the multiple rules in IAS 39, Financial Instruments Recognition and Measurement ("IAS 39"). The approach in IFRS 9 is based on how an entity manages its financial instruments and the contractual cash flow characteristics of the financial assets. Most of the requirements in IAS 39 for classification and measurement of financial liabilities were carried forward in IFRS 9.

IFRS 15, Revenue from Contracts with Customers

IFRS 15 establishes a comprehensive framework for determining whether, how much and when revenue is recognized. It replaces IAS 18, Revenue, IAS 11, Construction Contracts and related interpretations. Under IFRS 15, revenue is recognized when a customer obtains control of the goods or services. The Company has adopted IFRS 15 using the modified retrospective method without practical expedients, with the effect on initially applying this standard recognized at the date of initial application of December 1, 2018. Accordingly, the information presented for 2018 has not been restated. The adoption of the standard did not have a material impact on the financial statements.

IFRS 16, Leases

On January 13, 2016, the IASB issued IFRS 16, Leases.

The new standard is effective for annual periods beginning on or after January 1st, 2019. IFRS 16 will replace IAS 17, Leases.

This standard introduces a single lessee accounting model and requires a lessee to recognize assets and liabilities for all leases with a term of more than 12 months, unless the underlying asset is of low value. A lessee is required to recognize a right-of-use asset representing its right to use the underlying asset and a lease liability representing its obligation to make lease payments.

This standard substantially carries forward the lessor accounting requirements of IAS 17, while requiring enhanced disclosures to be provided by lessors.

The Company intends to adopt IFRS 16 in its consolidated financial statements for the annual period beginning on December 1st, 2019 using the modified retrospective transition method. The extent of the impact of adoption of the standard has not yet been determined, but the Company expects the majority of its operating leases will need to be recognized in the consolidated statement of financial position on initial adoption. At December 1st, 2019, the Company expects to record right-of-use assets and lease liabilities of approximately \$3,000,000. The Company also expects decrease of its operating lease costs, offset by an increase of its depreciation and amortization and financial expenses resulting from the changes in the recognition, measurement and presentation requirements. However, no significant impact on net earnings is expected at this time. The Company is completing the assessment of the overall impact on the Company's disclosures and is addressing any system and process changes necessary to

compile the information to meet the recognition and disclosure requirements of the new guidance starting in the first quarter of Fiscal 2020.

Outstanding Securities Data

As at February 24, 2020, the number of common shares issued and outstanding was 76,953,411 while outstanding options granted under our stock option plans were 2,410,118. We also had \$57,500,000 aggregate principal amount of 5.75% convertible unsecured senior notes due June 30, 2023 issued and outstanding as a result of the Offering. These notes are convertible into common shares at the option of the holder at a conversion price of \$14.85, representing a conversion rate of approximately 67.3401 common share per \$1,000 principal amount of notes. The conversion of all of the outstanding notes would result in the issuance of 3,872,055 common shares.

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 our Senior Vice President and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, 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, 2019. Based upon that evaluation, our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, have concluded that, as of November 30, 2019, 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 our Senior Vice President and Chief Financial Officer, 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 controls 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 our Senior Vice President and Chief Financial Officer, assessed the design and operating effectiveness of our internal controls over financial reporting as of the end of Fiscal 2019 based on the criteria established in the “*Internal Control - Integrated Framework*” (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Management’s assessment included an evaluation of the design of our internal controls over financial reporting and testing of the operating effectiveness of our internal control over financial reporting. Based on that assessment, our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, concluded that as of November 30, 2019, 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 1st, 2019 to November 30, 2019 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Non-IFRS Financial Measures

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

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

We obtain our Adjusted EBITDA measurement by adding to net profit or loss, finance income and costs, depreciation and amortization, and income taxes. We also exclude the effects of certain non-monetary transactions recorded, such as share-based compensation for the stock option plan, lease inducements, and write-downs (or related reversals) of inventories, for our Adjusted EBITDA calculation. We believe it is useful to exclude these items as they are either non-cash expenses, items that cannot be

influenced by management in the short term, or items that do not impact core operating performance. Excluding these items does not imply they are necessarily nonrecurring. Share-based compensation costs are a component of employee remuneration and can vary significantly with changes in the market price of the Company's shares. In addition, other items that do not impact core operating performance of the Company may vary significantly from one period to another. As such, Adjusted EBITDA provides improved continuity with respect to the comparison of our operating results over a period of time. Our method for calculating Adjusted EBITDA may differ from that used by other companies.

Adjusted EBITDA
(In thousands of dollars)

| | Three-month periods ended November 30 | | Year-ended November 30 | | |
|--|---------------------------------------|--------------|------------------------|--------------|----------------|
| | 2019 | 2018 | 2019 | 2018 | 2017 |
| Net loss | (6,455) | (983) | (12,496) | (4,700) | (14,061) |
| Add (deduct) | | | | | |
| Depreciation and amortization | 1,930 | 1,714 | 7,495 | 4,230 | 1,528 |
| Lease inducement | 5 | - | 238 | - | - |
| Finance costs | 1,275 | 1,330 | 5,080 | 3,016 | 5,784 |
| Finance income | (217) | (276) | (1,097) | (608) | (260) |
| Income tax recovery | - | - | - | (1,269) | - |
| Share-based compensation for stock option plan | 232 | 173 | 1,087 | 851 | 773 |
| Write-down of inventories | 13 | 38 | 16 | 144 | 913 |
| Adjusted EBITDA | (3,217) | 1,996 | 323 | 1,664 | (5,323) |

Risks and Uncertainties

Before you invest in our securities, you should understand the high degree of risk involved and consider carefully the risks and uncertainties described below. The following risks may adversely impact our business, financial condition, operating results and prospects. Additional risks and uncertainties, including those that we do not know about or that we currently believe are immaterial, may also develop as our operations evolve and,

therefore, may adversely affect our business, financial condition, operating results or prospects. As a result, the trading price of our securities, including our common shares, could decline and you could lose all or part of your investment.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS

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

Our ability to generate revenue and sustain growth is currently based on the commercialization of EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®] in the United States.

Our success in generating sales revenue from EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®] in the United States and in the European Union will depend on our capacity:

- to pursue the deployment of a commercialization strategy that will be accepted by patients, healthcare professionals and third-party payors;
- to maintain reimbursement coverage for EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®] by third-party payors;
- to obtain reimbursement coverage for EGRIFTA SV[™] in the United States;
- to obtain reimbursement coverage for Trogarzo[®] in major European countries;
- to maintain the registration of EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®] on U.S. governmental forms as drugs available for purchase in the United States;
- to ensure that adequate supplies of EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®] are available;
- to maintain conflict-free relationships with our principal third-party suppliers of services, namely our agent in the United States and in the European Union (inVentiv Commercial Services, or Syneos), our manufacturers, (TaiMed and Jubilant HolliesterStier, or Jubilant), our distributor in the United States (RxC Acquisition Company, or RxCrossroads), as well as other specialized third parties; and
- to defend our intellectual property rights regarding EGRIFTA[®] and EGRIFTA SV[™] against third parties.

Our success in commercializing our products in the United States and in the European territory will also depend on:

- the capacity of Syneos, in collaboration with us, to retain qualified, motivated and talented sales representatives and other key individuals instrumental in the commercialization of our products; 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 our products to customers in the United States and in the European territory will increase in the future or that we will generate sales at a profitable level. If sales of our products 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*[®], *EGRIFTA SV*[™] and Trogarzo[®] for the foreseeable future, any negative developments relating to these products, 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 successfully manage any of the abovementioned factors, will have a material adverse effect on our business and our future business prospects.

RxCrossroads is our only client in the United States in connection with the sale of EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®] and a default or a dispute under our agreement, or its termination or non-renewal at term, would materially adversely affect our revenues, business and operating results.

More than 95% of our revenues are derived from the sale of our products to RxCrossroads that acts as our exclusive distributor in the United States. If our agreement with RxCrossroads is terminated, or is not renewed at term and we are unable to find another distributor prior to its term, or if we are in default or engaged in a dispute with RxCrossroads, our sales may be materially adversely impacted and our revenues could decrease substantially.

In addition, under the terms of our agreement with RxCrossroads, we agreed to reimburse RxCrossroads for chargebacks and other discounts that RxCrossroads may offer to its clients. If RxCrossroads' clients omit to timely claim from RxCrossroads any discount they are entitled to, or if they make a mistake in assessing the types of discounts they are entitled to claim and they claim those discounts later in a year, we will have to refund RxCrossroads for such discounts to which RxCrossroads' clients are entitled to and this may materially adversely affect our level of revenues and operating results for the year.

We rely on third parties for the manufacture, distribution and commercialization of our products 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 our products, namely their manufacturing, distribution and 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 or rapidly replaced.

We do not own or operate manufacturing facilities for the production of *EGRIFTA*[®], *EGRIFTA SV*[™] and tesamorelin, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on Bachem Americas Inc., or Bachem, and Jubilant to manufacture and supply all of our required raw materials, drug substance and drug product for sales of *EGRIFTA*[®] and *EGRIFTA SV*[™]. Our agreement

with Bachem will expire in May 2020 and our agreement with Jubilant will expire in December 2020. Although we are in discussions with Bachem and Jubilant to extend the term of these agreements, our inventory of drug product is high and potential alternative suppliers and manufacturers have been identified, but we have not entered into any agreements with them. Also, we have not qualified these alternative manufacturers to date and no assurance can be given that such manufacturers 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.

TaiMed is our sole supplier of Trogarzo[®]. TaiMed does not currently own or operate any manufacturing facilities for the production of Trogarzo[®] and must rely on its sole supplier, WuXi AppTec Biopharmaceuticals, or WuXi. We are not in a contractual relationship with WuXi and, therefore, we may not be able to interact with Wuxi in the event they encounter issues which could adversely affect the supply of Trogarzo[®]. In such circumstances, we will need to rely on TaiMed to address any of those issues. We have no control over the time and efforts that TaiMed will devote in finding solutions to supply issues if such were to occur, or any say on the solution itself. Any delay in addressing manufacturing issues or any solution to address a manufacturing problem that is not to our liking could have a material adverse effect on the supply and sale of Trogarzo[®] and, accordingly, materially adversely affect our revenues.

We do not have state licensure in the United States to distribute *EGRIFTA*[®], *EGRIFTA SV*[™], Trogarzo[®] or any other product we may acquire or in-licence and we do not currently intend to pursue applications to obtain the licenses required in order to distribute a drug product in the United States. Our supply chain model is based upon that fact and the distribution of *EGRIFTA*[®], *EGRIFTA SV*[™] and Trogarzo[®] in the United States is done through RxCrossroads which currently holds all state licensure required to distribute a drug product in every American state. Although potential alternative third-party service providers have been identified to replace RxCrossroads in the event that it becomes unable to distribute *EGRIFTA*[®], *EGRIFTA SV*[™] and Trogarzo[®], we have not entered into any agreements with them and no assurance can be given that such providers would enter into any agreement with us on terms satisfactory to us.

We do not have country licensure in the European territory to distribute Trogarzo[®] and do not currently intend to pursue applications to obtain such licenses. We will be relying on single third-party suppliers for various supply functions, such as packaging and labeling, storage and distribution. Although we have identified and are in discussions with third-party suppliers to perform these functions, we have not entered into long-term commercial agreements with any of them. There can be no assurance that we will enter into agreements with those third-party suppliers and, if we do, that the terms of those agreements will be on terms satisfactory to us. Our failure to enter into long-term commercial agreements with those third-party suppliers would disrupt our supply and distribution chain and would delay the commercialization of Trogarzo[®] in the European

territory. All such events could result in a material adverse effect on our business, revenues and financial conditions.

We do not employ sales, medical service liaison and reimbursement personnel in the United States and in the European territory in connection with the commercialization of our products in these territories. We rely on Syneos to provide us with all of the services related to the commercialization of our products, namely sales personnel, medical science liaison personnel, reimbursement specialists and other individuals whose roles and functions pertain to the commercialization of our products. Although we are aware that there exists other third-party services providers that could provide the same services as Syneos, 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 Syneos, 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*[®], *EGRIFTA SV*[™] and Trogarzo[®] if a third-party manufacturer:

- becomes unavailable to us, or to TaiMed, 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*[®], *EGRIFTA SV*[™] and Trogarzo[®] 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 our products in the United States or in the European territory or we may face reimbursement challenges if Syneos:

- 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*[®], *EGRIFTA SV*[™] and/or Trogarzo[®];
- experiences compliance issues with the FDA or the EMA; or
- fails to perform its contractual obligations under our agreement.

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

New safety issues may arise as EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®] are 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 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. For instance, under U.S. laws, the FDA has broad authority over drug manufacturers to compel any number of actions if safety 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 problems could also result in product recalls, restrictions on the products' permissible uses, or withdrawal of the products from the territory(ies) where they are approved for commercialization. If new safety issues are discovered, sales of EGRIFTA[®], EGRIFTA SV[™] and/or Trogarzo[®] may decrease and result in a material adverse effect on our business, financial condition and operating results.

Our levels of revenues are highly dependent on obtaining and maintaining patient reimbursement for EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®].

Market acceptance and sales of EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®] 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[®], EGRIFTA SV[™] and Trogarzo[®].

Sales of EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®] to patients benefitting from U.S. funded reimbursement programs represent the most important part of all sales of our products. EGRIFTA SV[™] is currently not as covered as EGRIFTA[®] and Trogarzo[®] in the United States since it was recently launched. Denial of coverage for any of those products under any of the current programs would materially adversely affect our revenues.

In the European territory, sales of Trogarzo[®] will be highly dependent on obtaining reimbursement. The process of seeking reimbursement for a new drug is complex and varies from one EU Member State to another. In many EU Member States, pricing plays

an important role in the evaluation of prescription drugs for reimbursement. There can be no assurance that Trogarzo® will be reimbursed by all or any EU Member State.

Even if Trogarzo® is reimbursed, in EU Member States, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment in the European Union. Certain of these changes could impose limitations on the prices we will be able to charge for Trogarzo® or the amounts of reimbursement available for Trogarzo® from governmental agencies or third-party payors. Further, an increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our potential revenues and profitability from Trogarzo®. Moreover, in order to obtain reimbursement for Trogarzo® in some EU Member States, we may be required to conduct clinical trials that compare the cost-effectiveness of Trogarzo® to other available therapies. There can be no assurance that Trogarzo® will obtain favorable reimbursement status in any EU Member States.

Even though EGRIFTA®, EGRIFTA SV™ and Trogarzo® are approved for sale in one or more territories, revenue that we generate from their sales may be limited.

Sales of EGRIFTA®, EGRIFTA SV™ and Trogarzo® will depend upon the acceptance of such products 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;
- the product price; and
- the effectiveness of sales and marketing efforts.

If our products do not achieve adequate sales, we may not generate sufficient revenue in order to become profitable.

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. We believe there is currently no approved drug product competing directly with our approved products. However, with respect to *EGRIFTA*[®] and *EGRIFTA SV*[™], we face competition from companies selling human growth hormone, testosterone, insulin sensitizing agents, GLP-1 receptor agonists and sermorelin as those products may be prescribed by physicians. In addition, other approaches to reduce visceral adipose tissue in the abdominal area include coping mechanisms such as lifestyle modification (diet and exercise), switching antiretrovirals, or ARTs, or liposuction. With respect to Trogarzo[®], we are aware that dolutegravir and darunavir are being used in regimens to treat MDR HIV-1 and that attachment inhibitors, long-acting ARTs and broadly working antibody products are under development. We are also aware that the manufacturer of fostemsavir has filed a new drug application with the FDA and a marketing authorization application with the EMA.

RISKS RELATED TO RESEARCH AND DEVELOPMENT ACTIVITIES

The conduct of research and development activities is risky and results obtained therefrom may not be those anticipated. As a result, there can be no assurance that any research and development plan on a product candidate will result in an approved drug.

Research and development activities are highly risky and the results obtained therefrom may not yield any of the anticipated benefits. The development of a product candidate into a new drug requires the conduct of many tests on animals and humans, all of which must comply with stringent regulation and require substantial investments. There can be no assurance that any research and development program designed to develop a new formulation, a new drug, or provide a new treatment, such as the development of the F8 Formulation, the development of tesamorelin for the potential treatment of NASH in patients living with HIV and the development of our proprietary peptides resulting from our oncology platform, will end up generating positive results leading up to an approved formulation, label expansion or a new product by a regulatory authority. The failure to develop a new formulation, a new method of treatment or a drug product could hamper the future growth of our business and have long-term adverse effects on our potential revenues 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.

In connection with the development of a new treatment or a new drug, such as the development of tesamorelin for the potential treatment of NASH in patients living with HIV and the development of our proprietary peptides resulting from our oncology platform, we must conduct clinical trials. Clinical trials require the enrolment of patients and we may have difficulties enrolling patients for those clinical trials. These difficulties may arise 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 in connection with the conduct of clinical trials could result in their cancellation 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 also result in the clinical trial being cancelled. The cancellation of clinical trials for the foregoing reasons could lead to our forfeiting the development of the product candidate tested in those clinical trials and have a material adverse effect on our long-term growth and revenue prospect.

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.

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 *EGRIFTA*[®], *EGRIFTA SV*[™] and Trogarzo[®] 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*[®] and *EGRIFTA SV*[™] 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*[®] and *EGRIFTA SV*[™] in the United States for the treatment of lipodystrophy. To counter that risk, we have obtained a non-exclusive licence from EMD Serono's affiliate under the EMD Serono Termination Agreement in order to continue selling *EGRIFTA*[®] and *EGRIFTA SV*[™] in the United States. The termination of that licence could prevent us from selling *EGRIFTA*[®] and *EGRIFTA SV*[™] in the United States for the treatment of lipodystrophy 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 willful infringement) and/or cease the development and commercialization of our product candidates. Even if we were able to obtain a licence, 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[®], EGRIFTA SV[™] or Trogarzo[®].

Our promotional materials and training methods must comply with the *Federal Food, Drug and Cosmetic Act*, as amended, of the United States, or FFDC, as well as with laws in the European Union, including EU Member States laws, and other applicable laws and regulations, including restraints and prohibitions on the promotion of off-label, or unapproved, use. Physicians may prescribe our products for off-label use without regard

to these prohibitions, as the FDCA 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 our products, the FDA or other regulatory agencies, such as Health Canada and the EMA, could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products 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.

We are not allowed to conduct promotional activities related to Trogarzo® in Canada since it has not been approved in this territory. Promotional activities may begin once a drug is approved by Health Canada, in Canada.

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 payors 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 FDCA and similar laws regulating advertisement and labeling; and
- European Union's, EU Member States' and U.S. States' 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 payor, including commercial insurers.

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

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

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to certain healthcare professionals. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply

with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

If our activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our activities with regard to the commercialization of our products in the United States, which could harm the commercial sales of our products 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*[®], *EGRIFTA SV*[™], Trogarzo[®] or their respective manufacturing processes, withdrawal of *EGRIFTA*[®], *EGRIFTA SV*[™] or Trogarzo[®] from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material adverse effect on our product sales, business and results of operations.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. U.S. federal or state regulatory authorities might challenge our current 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

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

We rely on third-party service providers for sales, marketing, distribution and manufacturing activities related to *EGRIFTA*[®], *EGRIFTA SV*[™] and Trogarzo[®] in the United States. Under our agreements with our third-party service providers, 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 TaiMed as well as with 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 single third-party service providers, each of whom performing key services for the success of our business plan.

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

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

The development of a vaccine against HIV or of any cure against HIV would have a material adverse effect on our business, operating results and financial conditions.

Although there exists no known vaccine and cure for HIV, we are aware that there are research and development activities carried out in order to eradicate this disease. If a vaccine or a cure was found to prevent or cure HIV, sales of our products would be materially adversely impacted and our revenue growth would be hampered. The discovery of any vaccine or cure against HIV would have a material adverse effect on our business, operating results and 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, Europe, China, Taiwan and elsewhere subject us to additional risks, including:

- disruptions of important government services;
- 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 labor 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 labor 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, or epidemic such as the one related to the coronavirus.

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

The effects of Brexit are still unknown to us and it is difficult to assess how it will affect our commercialization plan for Trogarzo® in the United Kingdom, the cost associated with such commercialization and the potential conduct of clinical trials in this country.

As of January 31, 2020, the United Kingdom left the European Union, or Brexit. There is a transition period until December 31, 2020, during which the European Union's pharmaceutical laws will continue to apply in the United Kingdom. However, as of February 1st, 2020, the United Kingdom will no longer be able to participate in European Union's institutions and their decision making. Base on publicly available information, the European Union and the United Kingdom are set to begin discussions on their future relationship in March 2020. As a result, the effects of Brexit are currently unknown to us and will depend on the agreement the United Kingdom, or UK, will enter into with the European Union. The Medicines and Healthcare Products Regulatory Agency, or MHRA, published guidelines on how it would treat drugs having been issued a marketing authorization prior to Brexit, but we are unable to confirm how these guidelines will apply. We may have to incur various costs to keep Trogarzo®'s marketing authorization valid in the UK through the filings of various documents with the MHRA. In addition, various requirements regarding the UK residency of individuals and entities carrying out pharmacovigilance activities, batch analysis, release of batches, and other similar functions may force us to contract with additional suppliers. We may not be able to negotiate the terms and conditions of such contracts to our advantage or enter into any

contract at all. Under both circumstances, our management team will have to spend time not otherwise spent on other projects. Overall, we may incur additional costs that may adversely impact our business, operating results and financial condition.

In addition, there exists uncertainty regarding the acceptability by the MHRA of results obtained from the conduct of clinical trials in European Union's countries if no UK patients are included in those clinical trials. We are not certain whether clinical trials will need to include patients residing in the UK in order to seek the approval of a product in the UK. If we need to enroll UK patients in our clinical trials in order to be able to present our results to the MHRA, if we decide to seek approval in the UK, this may delay the conduct of our clinical trials and require more financial resources both of which could have a material adverse effect on our business, operating results and financial condition.

OTHER RISKS RELATED TO OUR BUSINESS

We rely extensively on the information technology systems of third-party service providers to store data, such as personal identifiable information, regarding our commercial activities for EGRIFTA[®], EGRIFTA SV[™] and Trogarzo[®]. Security breaches and other disruptions to those information technology systems could cause a violation of privacy laws, exposing us to liability which could cause our business and reputation to suffer.

In the ordinary course of business, we rely upon information technology and networks, most of which are managed by third parties, to process, transmit and store electronic information to manage and support our business decisions and strategy. We have no control and access over the information technology systems of third-party service providers where most of this information is stored and we are unable to assess whether appropriate measures have been implemented to prevent or limit a security breach of their information technology systems.

We also use our information technology systems to collect and store proprietary data, such as those related to our intellectual property, customers, employees and suppliers.

In connection with the conduct of activities in Europe, we have to comply with the European Union General Data Protection Regulation, or GDPR. The GDPR introduced data protection requirements in the European Union relating to the consent of individuals to whom the personnel data relates, the information provided to the individuals, the security we must retain, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR has increased the responsibility of all parties collecting personal data. As we build our infrastructure in Europe, we will have to put in place mechanisms to ensure compliance with the GDPR. However, our efforts to comply with the GDPR may not be successful and could increase our costs of doing business. In addition, data protection authorities of the various EU Member States may interpret the GDPR differently adding a layer of complexity in implementing adequate compliance measures.

The secure and uninterrupted operation of third-party information technology systems and of ours is material to our business operations and strategy. Unauthorized access to data files held in our information technology systems or those of third parties could result in inappropriate use, change or disclosure of sensitive and/or personal data of our

customers, employees, suppliers and patients. Any such access, disclosure or other loss of information could subject us to litigation, regulatory fines, penalties or reputational damages, any of which could have a material adverse effect on our competitive position, reputation, business, financial condition and operating results.

We did not generate a profit from our operation in the last fiscal year and there can be no guarantee that we will achieve consistent profitability.

We did not generate a profit in the fiscal year ended November 30, 2019. Our profitability will mainly depend on our capacity to maintain the commercialization of *EGRIFTA*[®], *EGRIFTA SV*[™] and Trogarzo[®] successfully in the United States through a low-cost and effective distribution network, the recruitment and retention of talented personnel by Syneos, the deployment of an effective marketing campaign and through continued reimbursement coverage for *EGRIFTA*[®], *EGRIFTA SV*[™] and Trogarzo[®] under U.S. Medicare and Medicaid programs and under private-health insurers programs.

There is no guarantee that we will continue succeeding in growing sales of *EGRIFTA*[®], *EGRIFTA SV*[™] and Trogarzo[®] in the United States. In addition, there is no guarantee that we will be able to successfully launch and commercialize Trogarzo[®] in the European territory. 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 not be able to generate sufficient cash from our operating activities to service our debt obligations.

Our ability to make payment on the Notes and our overall indebtedness will depend on future financial and operating performance, which is subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We may be unable to maintain a level of positive cash flows from operating activities sufficient to pay the principal and interest on our Notes.

As at November 30, 2019, we had negative operating cash flow of US\$3,391,000. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay investments and capital expenditures, seek additional capital or restructure or refinance our debt. These measures may not be successful and may not permit us to meet our scheduled debt service obligations. In the absence of such cash flows and resources, we could face substantial liquidity problems and we could have to resort to insolvency laws to seek protection from our creditors.

We may require additional funding and may not be able to raise the capital necessary to fund all or part of our capital requirements.

We may need financing in order to fund all or part of our capital requirements to sustain our growth, to develop our marketing and commercial capabilities, to meet our compliance obligations with various rules and regulations to which we are subject, to conduct our research and development activities, and to in-licence or acquire new molecules or approved products. However, our business performance may prevent us from generating enough cash-flow to meet our obligations and the market conditions may also 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 capital by way of public or private offerings in the future. In such a case, we would have to use other means of financing, such as 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 provided them with long-term incentives as a retention mechanism, but such agreements and incentives do not guarantee that our executive officers 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, Syneos, has hired sales representatives and other qualified individuals to assist us with the commercialization of *EGRIFTA*[®], *EGRIFTA SV*[™] and Trogarzo[®] in the United States. Syneos has also hired medical science liaison personnel in the European territory. Although these individuals are not our employees, the loss of any of those individuals and the inability of Syneos to attract and retain these individuals could have a material adverse effect on the commercialization of *EGRIFTA*[®], *EGRIFTA SV*[™] and Trogarzo[®], 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 beginning of commercialization of a product, levels of sales, revenues and other financial metrics may vary from what is publicly disclosed. These variations may occur as a result of a series of events, including problems with a supplier or a commercial partner, change in the procurement policy of a commercial partner or any other event having the effect of

delaying the publicly announced timeline or reducing the publicly announced commercial objective. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of certain events having the effect of postponing such events or any variation in the occurrence of certain events having the effect of altering publicly announced commercial objectives could have a material adverse effect on our business, financial condition and operating results. In addition, it could adversely affect the market price of our common shares.

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

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

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

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

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

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

RISKS RELATED TO OUR COMMON SHARES

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

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

Our revenues and expenses may fluctuate significantly and any failure to meet financial expectations and/or our own financial guidance, if any, 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*® and *EGRIFTA SV*™ in the United States;
- the level of sales of Trogarzo® in the United States;
- the level of sales of Trogarzo® in the European territory;
- supply issues with *EGRIFTA*®, *EGRIFTA SV*™ or Trogarzo®;
- default under the terms of our Notes;
- 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 and willingness of any current or future collaborators to invest the resources necessary to commercialize our product candidates;
- the outcome of any litigation;
- payment of fines or penalties for violations of laws;
- foreign currency fluctuations;
- the timing of achievement and the receipt of milestone or royalty payments from future third parties; and
- failure to enter into new or the expiration or termination of current agreements with third parties.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, or if we need to reduce our financial guidance, if any, 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.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, the price of our common shares and trading volume may decline.

The trading market for our common shares will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common shares, the lack of research coverage may adversely affect the market price of our common shares. Furthermore, if one or more of the analysts who do cover us downgrade our common shares or if those analysts issue other unfavorable commentary about us or our business, the price of our common shares would likely decline. If one or more of these analyst cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our common shares could decrease, which in turn could cause our share price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

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 and certain Canadian laws could delay or deter a change of control.

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

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

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